

Accessories Guide

VITROS[®] 350
Chemistry Systems

VITROS[®] 250
Chemistry Systems

VITROS[®] 950
Chemistry Systems

VITROS[®] ECiQ
Immunodiagnostic Systems

VITROS[®] ECi
Immunodiagnostic Systems



Accessories Guide

VITROS[®] Systems
Chemistry

VITROS[®] Systems
Chemistry



VITROS[®] Systems
Chemistry



VITROS[®] Systems
Immunodiagnostic

VITROS[®] ECiQ

VITROS[®] Systems
Immunodiagnostic

VITROS[®] ECi



Ortho-Clinical Diagnostics
a Johnson & Johnson company

Export authorized under general license GTDA (General Technical Data Available)

IMPORTANT

The information contained herein is based on the experience and knowledge relating to the subject matter gained by Ortho-Clinical Diagnostics, Inc. prior to publication.

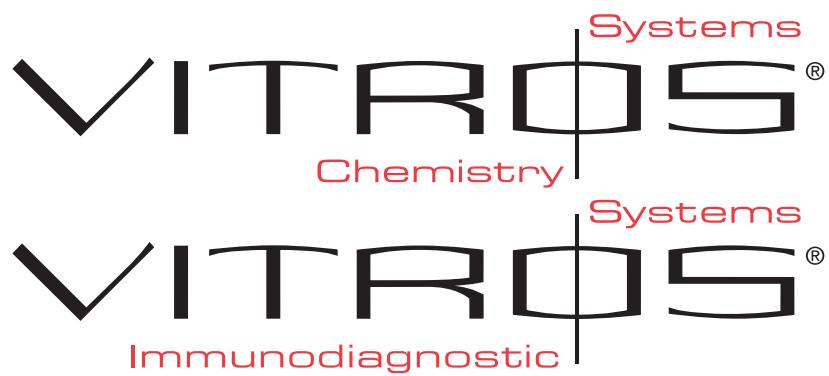
No patent license is granted by the information.

Ortho-Clinical Diagnostics, Inc. reserves the right to change this information without notice, and makes no warranty, express or implied, with respect to the information. The company shall not be liable for any loss or damage, including consequential or special damages resulting from the use of this information, even if loss or damage is caused by its negligence or other fault.

VITROS is a trademark of Ortho-Clinical Diagnostics, Inc.

© Ortho-Clinical Diagnostics, Inc., 2005. All rights reserved.

Specifications for Laboratory Computer Interface



Revision History

Revision Date	Description
2005-09-30	<p>Chapter 4 Application Interface: Upload-Only Mode</p> <ul style="list-style-type: none"> • Added 4 tests to Figure 4-6: dHDL, ALTJ, ASTJ, and CRPJ • Added 2 new tests to Figure 4-7: LDL and C/H, and modified old Test Names; LDL to LDLC, and C/H to C/HC <p>Appendix E Test Codes and Results Codes</p> <ul style="list-style-type: none"> • Modified 4 Test Names in Figure E-2 to be consistent with all the Test Names added to Figure 4-7 • Removed “O’s” in Figure E-2 for VLDL row at bottom of table • Corrected C/H Test Name in Figure E-4 to be consistent with C/H Test Name added to Figure 4-7
09/04	<p>Section 5 For VITROS ECi/ECiQ Immunodiagnostic System</p> <ul style="list-style-type: none"> • Updated data <p>Section 7 For VITROS ECi/ECiQ Immunodiagnostic System</p> <ul style="list-style-type: none"> • Updated data
07/04	<p>Incorporate updates for Direct HDL Slide, based on software release 950 v4.01 and 250 v8.0</p> <ul style="list-style-type: none"> • New LIS character for the new Direct HDL (dHDL) test • New LIS characters for the associated derived chemistry tests (LDL and C/H) • Modified test names for existing derived tests for magnetic HDL (HDLC) • Modified LIS characters for existing derived tests and Magnetic HDL (HDLC) • Added Results Decimal Positions for the new Direct HDL (dHDL)
09/02	<p>Incorporated Technical Bulletins:</p> <ul style="list-style-type: none"> • J12247 - Software Version 2.3 Updates (Codes EM, EP) • J12252 - Software Version 2.2 Update (Code ID) <p>Test Code Chart Updates</p> <p>Logo change to Ortho-Clinical Diagnostics, Inc. (Chapter 1)</p> <p>Removed references to Workstation Manager</p> <p>Remove some references for the model 700 ECi System</p> <p>Change incidences of the word “error” and “range” to “result”</p> <p>The following sections were removed:</p> <ul style="list-style-type: none"> • Checking Port Assignment on WSM (9.4.2) • VITROS Workstation Manager Configuration Troubleshooting (9.6) • Error Troubleshooting in VITROS Workstation Manager (9.9) • WSM’s Error Logs (9.9.1) • Queue Status in WSM (9.9.2) • System Diagnostics in WSM (9.11.7) <p>Ensure that the illustrations reflect current equipment configuration and procedures for all sections</p>

Revision Date	Description
12/97	<p>Title page, inside front and inside back covers pages for name, address, and logo change to Ortho-Clinical Diagnostics, Inc.</p> <p>For VITROS ECi Immunodiagnostic System</p> <ul style="list-style-type: none"> • Reflects Version 2.0 software update: <ul style="list-style-type: none"> – Updated ASCII Characters for Assays tables changed to Test Code table and to reflect new analytes – Update to support test dilution factors (TDF) in LIS transmission • Other miscellaneous updates: <ul style="list-style-type: none"> – Format of Reportable Results fields – Format of Downloaded Records – Sample Patient Record Layouts – Test Order Record table – Results Records table – Sample Results Record Layouts – Message Terminator Record table
11/96	<p>New release: Document Version 2.0</p> <p>Previous Chapter 7, “Automation Interface Using KERMIT,” deleted and subsequent chapters renumbered.</p> <p>For VITROS Analyzers:</p> <ul style="list-style-type: none"> • Addition of error flags for future implementation (250, 950) • Addition of AF error flag • Addition of new chemistry, UPRO • Addition/change of <i>Kermit</i> Protocol information <ul style="list-style-type: none"> – Table of Logical Configuration Defaults – Packet exchange diagrams – ASCII values • Changed procedures <ul style="list-style-type: none"> – Removing or replacing cables – Accessing online configuration information – Session establishment – Bidirectional diagnostics (950 only) – Entering System Diagnostics (950 only) <p>For VITROS ECi Immunodiagnostic System:</p> <ul style="list-style-type: none"> • Changed information on prediction failure error flags • Changed packet exchange diagrams • Addition of AF error flag • New information on default configuration for ASTM • Additional assays with their reporting units; list of derived tests <p>For <i>Vitros</i> Workstation Manager:</p> <ul style="list-style-type: none"> • Label for recording Laboratory Computer port settings • Table of logical configuration defaults for <i>Kermit</i> • Changes to session establishment • Changed information on prediction failure error flags • Changed procedures <ul style="list-style-type: none"> – Checking port assignment – accessing WSM configuration information online – accessing WSM error log • Additional error function keys <p>Miscellaneous minor content and format changes</p>
8/96	<p>Draft</p> <p>Temporary VITROS ECi Immunodiagnostic System trademark nomenclature.</p>

Revision Date	Description
6/96	Introduction of Johnson & Johnson VITROS Chemistry Systems, VITROS Immunodiagnostic System, and VITROS Workstation Manager trademark nomenclature.
10/14/95	<p>Draft</p> <p>For the <i>Ektimma</i> System, reflects changes consistent with released software:</p> <ul style="list-style-type: none"> • Change of length of analyte code from 1 to 3 in <i>Kermit</i> and 1, 2, or 3 in ASTM • Inclusion of codes for <i>Ektimma</i> System chemistries • Inclusion of an <i>Ektimma</i> System Result Decimal Positions chart in Appendix F • Inclusion of <i>Ektimma</i> System diagnostics for serial ports • Inclusion of <i>Ektimma</i> System sample <i>Kermit</i> upload session in Appendix C • Changes in downloaded messages • Addition of error codes: RC, RE, RR, and SC • Updates and additions to field values, lengths and defaults • Addition of <i>Ektimma</i> System support of CTS/RTS and DSR/DTR <p>For <i>Ektachem</i> analyzers:</p> <ul style="list-style-type: none"> • Changes to the error codes for <i>Kermit</i> • Inclusion of 4800 in the baud rate charts • Deletion of the Acid Phosphate Blank Test • Increase of sample program storage capacity • Addition of error code: WE <p>For <i>Ektanet</i> Workstation Manager:</p> <ul style="list-style-type: none"> • Inclusion of 4800 to the baud rate charts • Changes to baud rates available on WSM • Changes to the editing rules for downloaded sample programs • Changes to charts indicating a too-busy or delayed response in communication or indicating a down loading in batch mode from WSM <p>Miscellaneous minor content and format changes</p>
4/27/95	Title Page change

Revision Date	Description
3/1/95	<p>New release</p> <p>Reflects the addition of several new products:</p> <ul style="list-style-type: none"> • The <i>Ektanet</i> Workstation Manager • The 950IRC System • The <i>Ektimma</i> System • The use of the ASTM protocol <p>Table of Contents revised and List of Figures added</p> <p>Revision History added</p> <p>Copyright and disclaimer added</p> <p>New introduction</p> <p>New or revised general information:</p> <ul style="list-style-type: none"> • New mechanical and electrical connections for new devices • New options and default settings for character transmission for new devices • Additional test names • New diagnostic messages • Changes in the maximum number of measured and derived tests the analyzers can perform • New Configuration Reports reflecting variations based on model • Addition of LCPA diagnostic screens reflecting variations based on model <p>New feature: the Software Only Automation Interface</p> <p>New <i>Ektimma</i> System information:</p> <ul style="list-style-type: none"> • Chart of the tests the <i>Ektimma</i> System will perform • <i>Ektimma</i> System implementation of upload-only and <i>Kermit</i> data options <p>New ASTM information:</p> <ul style="list-style-type: none"> • ASTM communications protocol conventions • WSM and <i>Ektimma</i> System implementation of ASTM data options <p>New Workstation Manager information:</p> <ul style="list-style-type: none"> • WSM use of default settings in <i>Kermit</i> • WSM use of packet parameters in <i>Kermit</i> <p>New 950IRC information: List of the tests the 950IRC can perform</p>
2/1/94	<p>New release</p> <p>Change of format</p> <p>Additional ports described</p> <p>Standard voltages changed</p> <p>Parity changes</p> <p>New test names added to upload-only and bidirectional modes</p> <p>Changes in valid value for fluid in bidirectional mode</p> <p>Increase in size of results file</p> <p>Changes in error flags for measured and derived tests in bidirectional mode</p> <p>Changes in error codes for measured tests</p> <p>Addition of model 250 for list of models to check</p> <p>Model 250 system diagnostics</p> <p>Changes in download messages</p> <p>Addition of Laboratory Computer Protocol Analyzer for 250 and its procedures.</p> <p>Upload session record layout examples</p>

List of Revised Pages

Each page in your manual should be at the effective date listed below:

Release Date	Section	Page	Effective Date
2005-09-30	<ul style="list-style-type: none">• Figure 4-6, Test Results Record for VITROS Chemistry Systems• Figure 4-7, Derived Test Results Record for VITROS Chemistry Systems• Figure E-2, ASCII Characters for Derived Tests for the Vitros Chemistry Systems (from figure 6-4)• Revision History	4-4 4-6 E-2	2005-09-30 2005-09-30 2005-09-30
09/04	<ul style="list-style-type: none">• Communications Interface: Bidirectional Mode Kermit Protocol• Communications Interface: Bidirectional Mode ASTM Protocol	5-26, 5-27 7-11	09/04 09/04
12/03	<ul style="list-style-type: none">• Figure E-1, ASCII Character for Measured Tests for Vitros Chemistry Systems (from figure 6-3)• Figure E-2, ASCII Characters for Derived Tests for the Vitros Chemistry Systems (from figure 6-4)• Figures E-3 and E-4, Results Record for the VITROS Chemistry Systems (from figure 4-6 and 4-7)• Figure E-13, Results Decimal Positions for 250 and 950• Revision History	E-2 E-2 E-3 - E-5 E-16	1/04 1/04 1/04 1/04
09/02	All sections	All pages	09/02

Release Date	Section	Page	Effective Date
12/97	<ul style="list-style-type: none"> • Cover (front and back) and Title pages • Revision History • 6.3 Uploaded Results Records section and 6.4 Downloaded Sample Programs section • 8.4.5.10 Plus Sign Delimiter in the Universal Test ID Manufacturer's Code and 8.5 Record Definitions section • Figure E-6, ASCII Characters for Assays 	<ul style="list-style-type: none"> • Cover (front and back) and Title pages • iii and vi • 6-12 through 6-14 • 8-6, 8-10, 8-11,8-13, 8-14, 8-17 and 8-18 • E-8 and E-9 	1/1/98 12/97 12/97 12/97 12/97
11/96	All	All	11/96
8/15/96	All	All	8/15/96
4/27/95	Cover & Title Page	Cover>Title Page	4/27/95
3/1/95	All	All	3/1/95
2/1/94	All	All	2/1/94

Table of Contents

CHAPTER 1	INTRODUCTION	1-1
1.1	Introduction	1-1
1.2	Communications Mode Selections	1-1
1.2.1	No Communication and Upload-only	1-1
1.2.2	Bidirectional Mode using the <i>Kermit</i> File Transfer Protocol	1-1
1.2.3	Bidirectional Mode using the ASTM Protocol	1-2
1.3	Chapter Outline	1-2
1.4	Acknowledgments	1-2
CHAPTER 2	MECHANICAL AND ELECTRICAL INTERFACES	2-1
2.1	Mechanical Interface	2-1
2.1.1	Data and Transmit Control Pins	2-1
2.1.2	Cable	2-1
2.2	Electrical Interface	2-1
CHAPTER 3	COMMUNICATIONS INTERFACE: UPLOAD-ONLY MODE	3-1
3.1	Introduction	3-1
3.2	Method of the Transmission	3-1
3.3	Parity	3-1
3.4	Character Transmission/Reception (Baud Rate)	3-1
3.5	Communication Protocol	3-1
3.6	Logical (Procedural) Configuration Options	3-3
3.6.1	ACK/NAK Option Selection	3-3
3.6.2	Analyzer Response Delay Option (Pacing Timer)	3-3
3.6.3	Acknowledgment Timeout Option (Response Timer)	3-3
3.7	Data Transmission Procedure	3-4
3.7.1	Transmission with ACK/NAK	3-4
3.7.2	Transmission without ACK/NAK	3-4
3.7.3	Communication Interruption	3-4
3.7.4	Acknowledgments	3-4
CHAPTER 4	APPLICATION INTERFACE: UPLOAD-ONLY MODE	4-1
4.1	Information Transmitted	4-1
4.2	Message Records	4-1
4.3	Record Format	4-1
4.3.1	General Format for VITROS Chemistry Systems	4-1
4.3.2	Header Record for VITROS Chemistry Systems	4-2
4.3.3	Patient Description Record for VITROS Chemistry Systems	4-3
4.3.4	Doctor Description Record for VITROS Chemistry Systems	4-3
4.3.5	Miscellaneous Information Record for VITROS Chemistry Systems	4-4
4.3.6	Test Results Record for VITROS Chemistry Systems	4-4
4.3.7	Derived Test Results Record for VITROS Chemistry Systems	4-6
4.3.8	Trailer Record for VITROS Chemistry Systems	4-7

4.3.9	General Format for the VITROS ECi Immunodiagnostic System	4-7
4.3.10	Header Record for the VITROS ECi Immunodiagnostic System	4-8
4.3.11	Patient Description Record for the VITROS ECi Immunodiagnostic System	4-9
4.3.12	Doctor Description Record for the VITROS ECi Immunodiagnostic System	4-9
4.3.13	Miscellaneous Information Record for the VITROS ECi Immunodiagnostic System	4-10
4.3.14	Test Results Record for the VITROS ECi Immunodiagnostic System	4-10
4.3.15	Derived Test Results Record for the VITROS ECi Immunodiagnostic System	4-11
4.3.16	Trailer Record for the VITROS ECi Immunodiagnostic System	4-12
CHAPTER 5	COMMUNICATIONS INTERFACE: BIDIRECTIONAL MODE <i>KERMIT</i> PROTOCOL	5-1
5.1	Introduction	5-1
5.2	Method of Transmission/Reception	5-1
5.3	Parity	5-1
5.4	Character Transmission/Baud Rate	5-1
5.5	Logical (Procedural) Configuration Options	5-2
5.5.1	Flow Control Mechanism	5-2
5.5.2	Flow Control Timeout on Analyzers	5-2
5.5.3	Analyzer Response Delay (Pacing Timer)	5-2
5.5.4	Analyzer Response Timeout (Response Timer)	5-2
5.5.5	Packet Retry Limit	5-2
5.5.6	NAK ZERO (Download Solicitation)	5-2
5.5.7	Start-of-Packet Marker	5-2
5.5.8	Handshake Character	5-3
5.5.9	Checksum Method	5-3
5.6	Communication Protocol	5-4
5.6.1	Bidirectional Protocol	5-4
5.6.2	<i>Kermit</i> Protocol	5-5
5.6.3	Session Establishment	5-5
5.6.4	Session Continuation	5-5
5.6.5	Session Establishment Failure	5-5
5.6.6	Session Termination	5-5
5.6.7	Session Contention	5-5
5.6.8	Supported Packet Types	5-6
5.6.9	Packet Field Encoding	5-6
5.6.10	S/Y Session Start Packet Parameter Description	5-6
5.6.11	Packet Exchange	5-7
5.7	Considerations for System Applications	5-26
5.7.1	Download File Names	5-26
5.7.2	File Level Acknowledgment	5-26
5.7.3	Session Duration	5-26
5.7.4	Automatic Function Disabling	5-26
5.7.5	Performance Considerations	5-26
5.7.6	Error Packet Field Codes	5-26
5.7.7	Download File Capacity	5-27
5.7.8	Broadcast Sample Program Downloading (DL)	5-27

5.7.9	Editing of Downloaded Sample Programs by the Laboratory Computer	5-27
5.7.10	Sample Program Time Stamp & Deletion Feature	5-28
5.8	Summary of <i>Kermit</i> Procedures and Protocol	5-28
CHAPTER 6	APPLICATION INTERFACE: BIDIRECTIONAL MODE <i>KERMIT</i> PROTOCOL	6-1
6.1	Uploaded Results Files for VITROS Chemistry Systems	6-1
6.1.1	File Name	6-1
6.1.2	Format of Uploaded Files for VITROS Chemistry Systems	6-1
6.1.3	Format of Reportable Results Field for VITROS Chemistry Systems	6-2
6.2	Downloaded Sample Programs for VITROS Chemistry Systems	6-6
6.2.1	File Name	6-7
6.2.2	Format of Downloaded Files for VITROS Chemistry Systems	6-7
6.3	Uploaded Results Records for the VITROS ECi Immunodiagnostic System	6-9
6.3.1	Record Name	6-9
6.3.2	Format of Uploaded Records for the VITROS ECi Immunodiagnostic System	6-9
6.3.3	Format of Reportable Results Fields for the VITROS ECi Immunodiagnostic System	6-10
6.4	Downloaded Sample Programs for the VITROS ECi Immunodiagnostic System	6-13
6.4.1	Record Name	6-13
6.4.2	Format of Downloaded Records for the VITROS ECi Immunodiagnostic System	6-13
CHAPTER 7	COMMUNICATIONS INTERFACE: BIDIRECTIONAL MODE ASTM PROTOCOL	7-1
7.1	General	7-1
7.1.1	Method of Transmission/ Reception	7-1
7.1.2	Parity	7-1
7.1.3	Character Transmission and Reception	7-1
7.2	The Data Link	7-1
7.2.1	Terminology	7-2
7.2.2	Layered Structure	7-2
7.2.3	Types of Frames	7-2
7.2.4	Frame Numbering (FN)	7-2
7.2.5	Checksum	7-3
7.3	Session Establishment Phase	7-3
7.3.1	Timer for Reply	7-3
7.3.2	Timer for NAK Reply and Retries	7-3
7.3.3	Session Contention	7-3
7.3.4	Session Contention Timers	7-3
7.4	Transfer Phase	7-3
7.4.1	Receiver Timers in Transfer Phase	7-3
7.4.2	Acknowledgments	7-4
7.4.3	Timers for Acknowledgments	7-4
7.4.4	Interrupt Timers	7-4
7.5	Session Termination Phase	7-4
7.6	Error and Recovery in the Data Link	7-4
7.7	Performance Issues	7-5
7.8	Considerations in System Applications	7-11
7.8.1	Session Duration	7-11

7.8.2	Sample Program and Results Capacity	7-11
7.8.3	Transmission Errors and Condition Codes	7-11
7.8.4	Broadcasting Sample Programs.	7-11
7.8.5	Editing Downloaded Sample Programs.	7-12
7.9	Summary of Key Features	7-12
CHAPTER 8	APPLICATION INTERFACE: BIDIRECTIONAL MODE ASTM PROTOCOL	8-1
8.1	General	8-1
8.2	Terminology	8-1
8.3	Record Types	8-1
8.4	Conventions	8-2
8.4.1	The Hierarchy	8-2
8.4.2	Record Sequencing and Numbering	8-3
8.4.3	Logical Storage	8-3
8.4.4	Transmission Conditions and Recovery	8-3
8.4.5	Character Codes and Delimiters	8-4
8.4.6	Text Characters	8-6
8.5	Record Definitions	8-6
CHAPTER 9	TROUBLESHOOTING	9-1
9.1	Overview	9-1
9.2	Skills Required.	9-1
9.3	Key Troubleshooting Questions	9-1
9.4	Hardware Troubleshooting	9-1
9.4.1	Correct Ports	9-4
9.5	Configuration Troubleshooting for Analyzers	9-5
9.5.1	VITROS Chemistry System Configuration Information	9-5
9.5.2	The VITROS ECi Immunodiagnostic System Configuration Information	9-6
9.5.3	Configuration Worksheets	9-6
9.6	Checking Transmission Settings and Report Configurations on the Analyzers	9-10
9.6.1	Transmission/Report Troubleshooting for VITROS Chemistry Systems	9-10
9.6.2	The VITROS ECi Immunodiagnostic System Transmission/Report Control Troubleshooting	9-10
9.6.3	Default Report Status for the Imm. System	9-10
9.7	Troubleshooting Conditions for Chemistry Systems	9-11
9.8	Transmitting A Result to the Laboratory Computer	9-11
9.8.1	Transmitting a Result from the VITROS Chemistry Systems	9-11
9.8.2	Transmitting a Result in the VITROS ECi Immunodiagnostic System	9-12
9.9	System Diagnostics, Other Utilities and Diagnostic Tools	9-12
9.9.1	Breakout Boxes or Data Taps (circuit testers)	9-12
9.9.2	Laboratory Computer Resident Diagnostics	9-13
9.9.3	Bidirectional Diagnostics (except 950)	9-13
9.9.4	Bidirectional Diagnostics (950 Only)	9-13
9.9.5	Upload-only Diagnostics	9-14
9.9.6	Entering System Diagnostics	9-14
9.9.7	System Diagnostics in the <i>VITROS ECi Immunodiagnostic System</i>	9-15
9.9.8	The Laboratory Computer Protocol Analyzer and Monitor	9-15
9.10	Summary of Common Implementation Oversights	9-19

9.11	Downloaded Messages for All VITROS Chemistry Systems	9-20
9.12	Download Messages for the <i>VITROS ECi Immunodiagnostic System</i>	9-21
APPENDIX A	ASCII CHART	A-1
APPENDIX B	CONFIGURABLE OPTIONS	B-1
APPENDIX C	EXAMPLES OF KERMIT SESSIONS	C-1
APPENDIX D	ASTM RECORD LAYOUTS	D-1
APPENDIX E	TEST CODES AND RESULTS CODES	E-1
APPENDIX F	CONDITION CODES	F-1

List of Figures

Figure 1-1.	Communication Options	1-1
Figure 2-1.	Port Usage.....	2-1
Figure 2-2.	Null-Modem Cable Configuration Examples (DTE-DTE).	2-2
Figure 2-3.	Modem Cable Configuration Examples (DTE-DCE)....	2-3
Figure 2-4.	ASTM Wire Cable Configuration.....	2-4
Figure 3-1.	Baud Rates.	3-1
Figure 3-2.	Example of an Upload Transaction.....	3-2
Figure 3-3.	Possible Acknowledgments.	3-5
Figure 3-4.	Acknowledgment Format.	3-5
Figure 3-5.	Verification of Acknowledgments.....	3-6
Figure 4-1.	General Record Format for VITROS Chemistry Systems.....	4-1
Figure 4-2.	Header Record for VITROS Chemistry Systems.....	4-2
Figure 4-3.	Patient Description Record for VITROS Chemistry Systems.	4-3
Figure 4-4.	Doctor Description Record for VITROS Chemistry Systems.	4-3
Figure 4-5.	Miscellaneous Information Record for VITROS Chemistry Systems.	4-4
Figure 4-6.	Test Results Record for VITROS Chemistry Systems.	4-4
Figure 4-7.	Derived Test Results Record for VITROS Chemistry Systems.	4-6
Figure 4-8.	Trailer Record for VITROS Chemistry Systems.	4-7
Figure 4-9.	General Record Format for the VITROS ECi Immunodiagnostic System.....	4-7
Figure 4-10.	Header Record for the VITROS ECi Immunodiagnostic System.	4-8
Figure 4-11.	Patient Description Record for the VITROS ECi Immunodiagnostic System.....	4-9
Figure 4-12.	Doctor Description Record for the VITROS ECi Immunodiagnostic System.	4-9
Figure 4-13.	Miscellaneous Information Record for the VITROS ECi Immunodiagnostic System.....	4-10
Figure 4-14.	Test Result Record for the VITROS ECi Immunodiagnostic System.	4-10
Figure 4-15.	Derived Test Results Record for the VITROS ECi Immunodiagnostic System.....	4-11
Figure 4-16.	Trailer Record for the VITROS ECi Immunodiagnostic System.	4-12
Figure 5-1.	Baud Rates.	5-1
Figure 5-2.	Example of One-Character Checksum.....	5-4
Figure 5-3.	Packet Structure and Functionality.....	5-6
Figure 5-4.	Packet Exchange for Normal Download of Sample Programs (One File).....	5-8
Figure 5-5.	Packet Exchange for Normal Download of Sample Programs (Multiple Files).....	5-9
Figure 5-6.	Packet Exchange for Normal Download of Sample Programs (NAK ZERO Operation). .	5-10
Figure 5-7.	Packet Exchange for Download of Sample Programs (Downloading-Inhibited Situations). .	5-11
Figure 5-8.	Packet Exchange for Download of Sample Programs (Downloading-Inhibited Situations). .	5-12
Figure 5-9.	Packet Exchange for Upload of Test Results and Download of Sample Programs (NAK Zero and Upload Interaction).....	5-13
Figure 5-10.	Packet Exchange for Upload of Test Results and Download of Sample Programs (Effect of Analyzer Response Delay on Downloading). .	5-14
Figure 5-11.	Packet Exchange for Normal Upload of Test Results (One File).....	5-15
Figure 5-12.	Packet Exchange for Normal Upload of Test Results (Multiple File). .	5-16
Figure 5-13.	Packet Exchange for Upload of Test Results (Effect and Use of Analyzer Response Timer at Session Establishment and During Session). .	5-17

Figure 5-14.	Packet Exchange for Upload of Test Results (Initial Connection Behavior if Link Up But No Response).....	5-18
Figure 5-15.	Packet Exchange for Upload of Test Results (Error Situations).....	5-19
Figure 5-16.	Packet Exchange for Upload of Test Results (Line Drop Situation).....	5-20
Figure 5-17.	Packet Exchange for Upload of Test Results (Error Line—Drop Situations).....	5-21
Figure 5-18.	Packet Exchange for Upload of Test Results (Effect of Analyzer Response Delay on Uploading). 5-22	
Figure 5-19.	Packet Exchange for Upload of Test Results and Download of Sample Programs (Session Contention).....	5-23
Figure 5-20.	Packet Exchange for Upload of Test Results and Download of Sample Programs (Use of Checksum and Analyzer Response Timeout).....	5-24
Figure 5-21.	Packet Exchange for Upload of Test Results (Flow Control Mechanism).....	5-25
Figure 5-22.	Packet Data Field Errors.....	5-27
Figure 6-1.	General Format of Uploaded Files for VITROS Chemistry Systems.....	6-1
Figure 6-2.	Format of Reportable Results Fields for the VITROS Chemistry Systems.....	6-2
Figure 6-3.	ASCII Characters for Measured Tests.....	6-5
Figure 6-4.	ASCII Characters for Derived Tests for the VITROS Chemistry Systems.....	6-6
Figure 6-5.	Format of Downloaded Files for VITROS Chemistry Systems.....	6-7
Figure 6-6.	Maximum Number of Tests/Assays.....	6-9
Figure 6-7.	General Format of Uploaded Records for the VITROS ECi Immunodiagnostic System.....	6-9
Figure 6-8.	Format of Reportable Results Fields for the VITROS ECi Immunodiagnostic System.....	6-10
Figure 6-9.	Test Code Characters for Assays on the VITROS ECi Immunodiagnostic System. Availability of some of these assays are pending regulatory clearance or approval.....	6-12
Figure 6-10.	Test Code Characters for Derived Tests on the VITROS ECi Immunodiagnostic System. Availability of some of these assays are pending regulatory clearance or approval.....	6-13
Figure 6-11.	Format of Downloaded Records for the VITROS ECi Immunodiagnostic System.....	6-14
Figure 7-1.	Restricted ASCII Control Characters Used by ASTM.....	7-2
Figure 7-2.	ASTM Protocol Layers.....	7-2
Figure 7-3.	Frame Structure.....	7-2
Figure 7-4.	Checksum Calculation.....	7-3
Figure 7-5.	Summary of ASTM Timers.....	7-4
Figure 7-6.	Normal Download Session.....	7-5
Figure 7-7.	Session Contention.....	7-6
Figure 7-8.	No Response Timer.....	7-7
Figure 7-9.	Session Establishment and NAK Replies.....	7-8
Figure 7-10.	Discard Last Message.....	7-8
Figure 7-11.	Interrupt Honored During a Download Session.....	7-9
Figure 7-12.	Interrupt Not Honored.....	7-10
Figure 7-13.	Error Condition and Cancel.....	7-11
Figure 8-1.	Logical Structure of a Laboratory Computer Download Message to the VITROS ECi Immunodiagnostic System.....	8-2
Figure 8-2.	Logical Structure of a VITROS ECi Immunodiagnostic System Upload Message.....	8-3
Figure 8-3.	Recovery and Re-transmission.....	8-4
Figure 8-4.	ASCII Restricted Character Set.....	8-4
Figure 8-5.	ASTM Delimiters.....	8-5
Figure 8-6.	ASCII Allowed Characters.....	8-6
Figure 8-7.	Header Record	8-6

Figure 8-8.	Sample Header Record Layouts.	8-7
Figure 8-9.	Patient Record	8-7
Figure 8-10.	Sample Patient Record Layouts.	8-8
Figure 8-11.	Comment Record.	8-9
Figure 8-12.	Sample Comment Record Layout.	8-9
Figure 8-13.	Test Order Record	8-9
Figure 8-14.	Sample Test Order Record Layouts.	8-11
Figure 8-15.	Result Record.	8-12
Figure 8-16.	Sample Results Record Layouts.	8-14
Figure 8-17.	Message Terminator Record.	8-14
Figure 8-18.	Sample Message Terminator Record Layout.	8-14
Figure 9-1.	Wire Cabling Connections	9-2
Figure 9-2.	Port Assignment and Location.	9-4
Figure 9-3.	<i>Kermit</i> Configuration Requirements Checklist.	9-5
Figure 9-4.	ASTM Configuration Checklist.	9-5
Figure 9-5.	Upload-only Configuration Checklist.	9-5
Figure 9-6.	Configuration Worksheet for VITROS Chemistry Systems.	9-7
Figure 9-7.	Configuration Worksheet for the VITROS ECi Immunodiagnostic System.	9-8
Figure 9-8.	Transmission and Report Control Settings.	9-10
Figure 9-9.	The Imm. System Report Control Settings.	9-10
Figure 9-10.	Error Log Worksheet.	9-11
Figure 9-11.	Download File.	9-18
Figure 9-12.	Data Steam.	9-18
Figure 9-13.	Partial Download.	9-18
Figure 9-14.	Additional Example 1.	9-19
Figure 9-15.	Additional Example 2.	9-19
Figure 9-16.	Download Messages for VITROS Chemistry Systems.	9-20
Figure 9-17.	Download Messages for the VITROS ECi Immunodiagnostic System	9-21
Figure A-1.	ASCII Codes in Ascending Order.	A-1
Figure D-1.	Sample Header Record Layouts.	D-1
Figure D-2.	Sample Patient Record Layouts.	D-1
Figure D-3.	Sample Comment Record Layout.	D-1
Figure D-4.	Sample Test Order Record Layouts.	D-1
Figure D-5.	Sample Results Record Layout.	D-1
Figure D-6.	Sample Message Terminator Record Layout.	D-1
Figure E-1.	ASCII Characters for Measured Tests for VITROS Chemistry Systems (from figure 6-3)	E-1
Figure E-2.	ASCII Characters for Derived Tests for the VITROS Chemistry Systems (from figure 6-4).	E-2
Figure E-3.	(Upload-only) Results Record for the VITROS Chemistry Systems (from figure 4-6)	E-3
Figure E-4.	(Upload-only) Results Record for VITROS Chemistry Systems (from figure E-4).	E-5
Figure E-5.	(<i>Kermit</i>) Results Record for the VITROS Chemistry Systems (from figure 6-2).	E-6
Figure E-6.	Test Code for Assays on the VITROS ECi Immunodiagnostic System (from figure E-7). Availability of some of these assays are pending regulatory clearance or approval.	E-8
Figure E-7.	Test Code Characters for Derived Tests on the VITROS ECi Immunodiagnostic System (from figure 6-10). Availability of some of these assays are pending regulatory clearance or approval.	E-9

Figure E-8.	(Upload-only) Results Record for the VITROS ECi Immunodiagnostic System (from figure 4-14).	E-10
Figure E-9.	(Kermit) Results Record for the VITROS ECi Immunodiagnostic System (from figure 6-8).	E-11
Figure E-10.	(ASTM) Results Record for the VITROS ECi Immunodiagnostic System (from figure 8-15).	E-13
Figure E-11.	(ASTM) Sample Results Record Layout (from figure 8-16).	E-14
Figure E-12.	Results Decimal Positions for 500 series, 700, 700C series.	E-15
Figure E-13.	Results Decimal Positions for 250 and 950.	E-16
Figure E-14.	Results Units for the VITROS ECi Immunodiagnostic System.	E-17
Figure E-15.	Results Units for Derived Tests for the VITROS ECi Immunodiagnostic System.	E-17
Figure F-1.	(Upload-only) Test Results Conditions and Warning Codes for the VITROS Chemistry Systems <i>from Figure 4-6</i>	F-1
Figure F-2.	(Upload-only) Derived Test Results Conditions and Warning Codes for VITROS Chemistry Systems <i>from Figure 4-7</i>	F-2
Figure F-3.	(Kermit) Test Results Conditions and Warning Codes for VITROS Chemistry System <i>from Figure 6-2</i>	F-3
Figure F-4.	Download Messages for VITROS Chemistry Systems. <i>from Figure 9-16</i>).	F-5
Figure F-5.	(Upload-only) Assay Results Conditions and Warning Codes for the VITROS ECi Immunodiagnostic System <i>from Figure 4-14</i>	F-7
Figure F-6.	(Upload-only) Derived Test Results Conditions and Warning Codes for the VITROS ECi Immunodiagnostic System <i>from Figure 4-15</i>	F-7
Figure F-7.	(Kermit) Assay Results Conditions and Warning Codes for the VITROS ECi Immunodiagnostic System <i>from Figure 6-8</i>	F-8
Figure F-8.	(ASTM) Assay Results Conditions and Warning Codes <i>from Figure 9-7</i>).	F-9
Figure F-9.	Download Messages for the VITROS ECi Immunodiagnostic System <i>from Figure 9-17</i> . .	F-10

About This Manual

Purpose

The purpose of this manual is to explain the interfaces created for devices made by Ortho-Clinical Diagnostics in their communications with the laboratory computer. The devices include the VITROS Systems and the VITROS ECi Immunodiagnostic System. This guide describes the following:

- The characteristics of the communications protocols that the products use
- The options and configurable features available in the protocols
- The implementation choices reflected in the analyzers
- The data supported by these devices

This information should assist the laboratory computer specialist in writing additional interface software intended to communicate with Ortho-Clinical Diagnostics devices. It should also provide the information needed to troubleshoot these laboratory computer communications and ensure smooth operation of the interfaces.

Audience

This manual is intended for laboratory computer specialists, software engineers, LIS programmers, and laboratory coordinators. It assumes a general knowledge of software programming and computer operations like ASCII usage.

This manual also assumes a basic knowledge of the functions and features of Ortho-Clinical Diagnostics analyzers. The terms and operations of these instruments are not explained here.

How This Manual Is Organized

The first chapter of the guide provides general information about the analyzers and the protocols. The second chapter describes the mechanical connections and the electrical characteristics.

Six chapters deal with the protocols themselves. Each protocol has two chapters: one called the “Communications Interface” and the other called the “Application Interface.” The “Communications Interface” chapters contain the following information:

- The general features of the protocol
- The conventions used by the protocol
- The configurable options and the implementation choices made for the analyzers.

The “Application Interface” chapters contain descriptions of the data transferred to and from the analyzers and the laboratory computer. These chapters address the following information:

- File and record structure
- Data fields implemented
- Data values and descriptions

Chapter 9 discusses many of the common ways you can troubleshoot communications problems between the

laboratory computer and the analyzers. This chapter contains many procedures and checklists.

Finally, for your convenience, the various appendices repeat charts found in the rest of the manual.

Conventions Used in this Manual

Throughout this manual the following conventions are used:

- **Screen Title.** These appear in mixed case as a standard throughout the manual although screen titles on some analyzers are in upper case.
- **Targets and Buttons.** These appear in boldface, matching the case used on the analyzers.
- **Screen Areas.** There may be headings for areas on screens. When cited, these appear in regular type and match the case used on the screen.
- **Keys.** These appear in boldface matching the case used on the actual keys.
- **Procedures.** These usually take the form of a list of steps, each starting with a verb.
- **ASCII Characters.** Where ASCII characters appear in columns, and stand alone, double and single quotes are not used. If ASCII characters are found among other items, then they are quoted.
- **Defaults.** These appear in italics. However, when there are differences in defaults among the devices, they are pointed out in boldface as well. This occurs most often in discussing baud rates, parity options, stop bits, and data bits.
- **Test Order.** The ASTM protocol uses the term “test order” throughout its specifications. This manual generally uses the terms sample program or test request in place of test order, since these are the term used in other product documentation. However, when discussing the actual ASTM record itself, the document refers to the test order record.
- **Assay.** The VITROS ECi Immunodiagnostic System uses the term “assay” in many instances rather than “analyte” or “test.” In sections of this manual describing the Immunodiagnostic System exclusively, the term assay often replaces test or analyte.

1.1 Introduction

This publication provides information needed to establish interfaces between the laboratory computer and the family of analyzers made by Ortho-Clinical Diagnostics. Specifically, this document addresses the following aspects of the products:

- The hardware connections required for appropriate transfer
- The modes of communication used by the analyzers
- The conditions necessary to run an interface and the options available
- The data transmitted from one device to another by these protocols
- The procedures most often used in troubleshooting interfaces with the analyzers.

The VITROS Chemistry Systems and the VITROS ECi Immunodiagnostic System offer a wide range of choices and configurable options to help create the optimum processing environment for a given laboratory. This document specifies which options are available on each analyzer. It provides both summary and detailed information to support operations decisions. When you install an analyzer, you must configure it to enable communications, using features found under these menus and screens:

- For VITROS Chemistry Systems, ANALYZER CONFIG under the Options menu (screens OP22A through OP22N).
- For the Immunodiagnostic System, in the Options & Configuration function, the SYSTEM SET UP group of screens (screens OP22A through OP22N).

Before connecting systems, you must have detailed knowledge of the interface capabilities of the laboratory computer and the analyzers. There is a great deal of commonality among all the analyzers in the way they communicate with the laboratory computer. Where physical connections, protocol options, data implementation, and other options vary, you will find them clearly marked in this manual, most often in bold letters.

1.2 Communications Mode Selections

With the introduction of the VITROS ECi Immunodiagnostic System, the range of communication options continues to expand in the Ortho-Clinical Diagnostics product line. In [figure 1-1](#) we summarize the number of possible communication

modes available on each analyzer. Analyzers can be configured for only one communications mode at a time.

The communication modes themselves differ in a number of key ways, and the selection you make to use one rather than another will depend on the benefits and limitations of each and on the protocols supported by your laboratory information system.

1.2.1 No Communication and Upload-only

No communication is the default setting found on the Communication Configuration Option screen on the VITROS Chemistry Systems or on the Configure Ports screen on the VITROS ECi Immunodiagnostic System, and it must be changed to start communication. The upload-only option allows the analyzer to send patient test results to the laboratory computer. It also permits the up load of patient and doctor demographic data. The upload-only mode requires that the laboratory operator enter all sample program requests manually at the analyzer since these cannot be down loaded automatically from the laboratory computer. This manual entry involves additional staff time and offers an opportunity for additional error.

The upload-only mode provides acknowledgment of receipt of data and checksum validation from the laboratory computer. While upload-only does protect data integrity, it lacks the flow control and timers available in other protocols.

1.2.2 Bidirectional Mode using the *Kermit* File Transfer Protocol

This option is available on all analyzers. It allows the laboratory computer to down load sample programs to the analyzers. It then allows the analyzers to send test results back to the laboratory computer. Although not specifically designed for laboratory environments, it is often used by laboratory information systems. It is a robust system with significant flow control, handshaking, and data acknowledgment features that protect data integrity. *Kermit* is the protocol created by the Columbia University Center for Computing Activity. Information about this protocol can be found in the *Kermit Protocol Manual* and the *Kermit User Guide*.

Communications Protocol	Analyzer Options					
	VITROS 250	VITROS 500 series	VITROS 700 series	VITROS 700C series	VITROS 950	VITROS Imm. System
Bidirectional:						
<i>Kermit</i>	X	X	X	X	X	X
ASTM						X (future)
Upload-only	X	X	X	X	X	X

Figure 1-1. Communication Options

1.2.3 Bidirectional Mode using the ASTM Protocol

This is the communications protocol created by the American Society for Testing and Materials (ASTM). It is designed specifically for medical devices and supports the transfer of an array of medical data. It enables speedy communication while using a number of data protection mechanisms like acknowledgments, timing mechanism, and data recovery procedures. It also establishes a national standard for communication among medical facilities and may eventually become an international standard as well. The ASTM protocol promotes data integrity while handling a great volume of data.

Information about this protocol can be found in a publication produced by ASTM: *Annual Book of ASTM Standards*.

Designation: E 1394-91: "Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems" and Designation: 1381-91: "Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems."

1.3 Chapter Outline

For more information about the analyzer implementation of these communication modes and features, their transmission and the data they transfer, please refer to the following chapters:

Chapter 2 Mechanical and Electrical Interfaces

Chapter 3	Communications Interface: Upload-only Mode
Chapter 4	Application Interface: Upload-Only Mode
Chapter 5	Communication Interface: Bidirectional Mode using <i>Kermit</i>
Chapter 6	Application Interface: Bidirectional Mode using <i>Kermit</i>
Chapter 7	Communication Interface: Bidirectional Mode using ASTM
Chapter 8	Application Interface: Bidirectional Mode using ASTM
Chapter 9	Interface Troubleshooting

1.4 Acknowledgments

Ortho-Clinical Diagnostics acknowledges the Columbia University Center for Computing Activity as the developer of the *Kermit* protocol and the American Society for Testing and Material as the developer for the ASTM protocol. Refer to the following for further protocol information:

da Cruz F. *Kermit, A File Transfer Protocol*. Bedford, MA: Digital Press; 1987.

American Society for Testing and Materials
1916 Race Street
Philadelphia, Pennsylvania 19103

2.1 Mechanical Interface

An EIA RS-232 (or CCIT V.24) compatible serial communications port, with a standard DB25F female connector (AMP Inc., Part No. 2066 53-1), is used to connect the *Vitros* Chemistry Systems and VITROS ECi Immunodiagnostic System to the laboratory computer. The Immunodiagnostic System uses chassis mounted connectors rather than cable mounted connectors. If the laboratory computer being connected to the analyzers is EIA RS-449 (or other standard interface) compatible, you must install an interface adapter. The correct analyzer ports used for connection with the laboratory computer are shown in [figure 2-1](#).

Analyzer	Analyzer Port to the Laboratory Computer
250	J3
500 series	J5
700 C series	J5
950	J5
Immunodiagnostic System	J3

Figure 2-1. Port Usage.

2.1.1 Data and Transmit Control Pins*

The analyzer is configured as DTE.

- Pin 1 *Protective ground (AA)*.
- Pin 2 *Analyzer-transmitted data (BA)*—Serial data from the analyzer to the laboratory computer.
- Pin 3 *Analyzer-received data (BB)*—Serial data from the laboratory computer to the analyzer.
- Pin 4 *Request to send (CA)*—Control signal from the analyzer that indicates the analyzer is ready to transmit data.
- Pin 5 *Clear to send (CB)*—Control signal to the analyzer that indicates the laboratory computer is ready to receive data.

* All unused pins must be left unconnected or damage may result to the analyzer or laboratory computer. Ortho-Clinical Diagnostics will not be responsible for damage caused due to improper connections.

- Pin 6 *Data set ready (CC)*—Control signal to the analyzer that indicates the laboratory computer is on-line.
- Pin 7 *Signal ground (AB)*—Common ground reference point for all circuits except AA.
- Pin 8 *Carrier Detect (CF)*—Optional.
- Pin 20 *Data terminal ready (CD)*—Control signal from the analyzer to the laboratory computer that indicates the analyzer is on-line.

2.1.2 Cable

The interface cable is supplied by the user. Cable configurations are determined by the interface to the laboratory computer. Most computer systems have an RS232C-compatible serial port, and emulate DTE or DCE. Several cable/connector configurations are illustrated in [figure 2-2](#) through [figure 2-4](#).

A null-modem cable is used if the laboratory computer is a DTE emulator. A straight-through cable is needed if the laboratory computer is a DCE emulator. For hardware flow control, the laboratory computer output signal is connected to the analyzer's CTS input.

On an analyzer a cable length of no more than 50 feet (5.24 meters) is recommended to maintain electrical signal characteristics defined by standard EIA RS-232C.

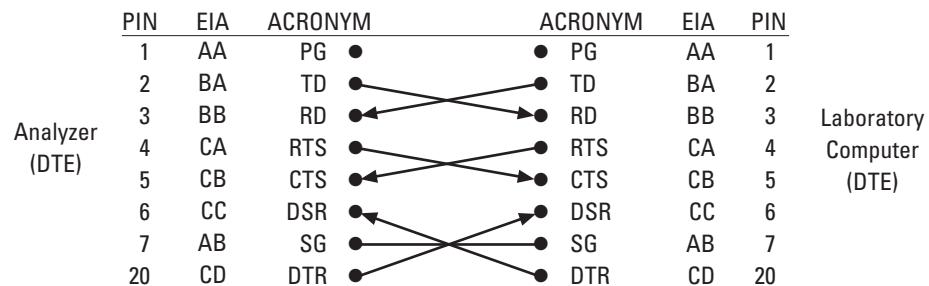
2.2 Electrical Interface

The analyzers operate interface signals according to the voltage levels and electrical characteristics defined by EIA Standard RS-232C (August 1969), which are +5 V to +25 V for a SPACE (logic 0) and -5 V to -25 V for a MARK (logic 1). The analyzers use the NRZ encoding technique with signal transitions between +12 V (logic 0) and -12 V (logic 1).

The DSR signal is used as the on-line indicator from the laboratory computer. If the DSR goes off during transmission, an error is reported. No further communication will be attempted until the DSR signal is active. If DSR goes on, the communication will resume with the Header Record (see also [figure 4-2](#), [figure 4-10](#), and [figure 9-9](#)). When DSR switches to off during communication, a single ATTENTION level condition will be reported.

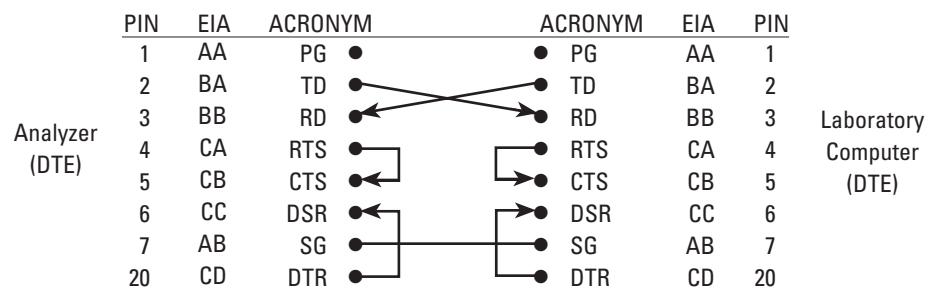
CTS Hardware Flow Control (DTS/DSR and CTS/RTS Handshake)

Applicable for systems where CTS hardware flow control is required. Half duplex transmission is allowed. On-line control is required by the laboratory computer (that is, the laboratory computer can go off-line or on-line, and it will be noticed by the analyzer).



Existing 3-Wire Cable (DTS/DSR and CTS/RTS Loopback)

Applicable for installations with 3-wire cable already installed. Hardware CTS flow control is not possible. Each system interprets the other as being on-line when the system itself is on-line.



CTS Hardware Flow Not Functional (DTS/DSR Handshake and CTS/RTS Loopback)

Either system can sense when the other goes on-line or off-line.

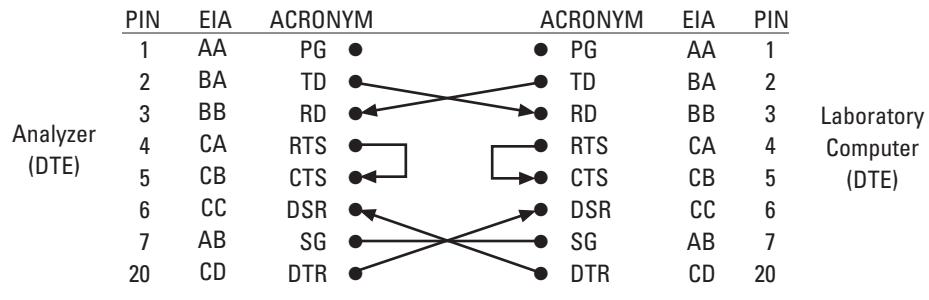
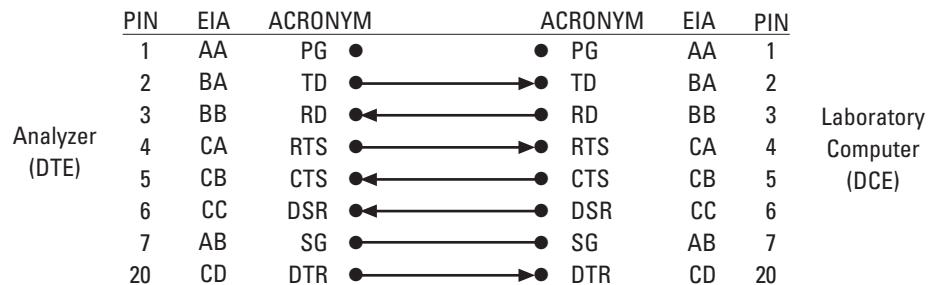


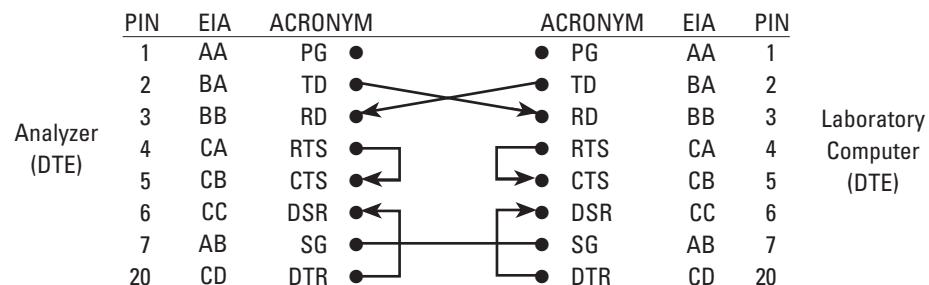
Figure 2-2. Null-Modem Cable Configuration Examples (DTE-DTE).

Hardware Flow Control Functional (DTS/DSR and CTS/RTS Handshake)



3-Wire Capability (DTS/DSR and CTS/RTS Loopback)

Hardware CTS flow control is not possible. Each system interprets the other as being on-line when the system itself is on-line.



Hardware CTS Flow Control Not Functional (DTS/DSR Handshake and CTS/RTS Loopback)

Either system can sense when the other goes on-line or off-line.

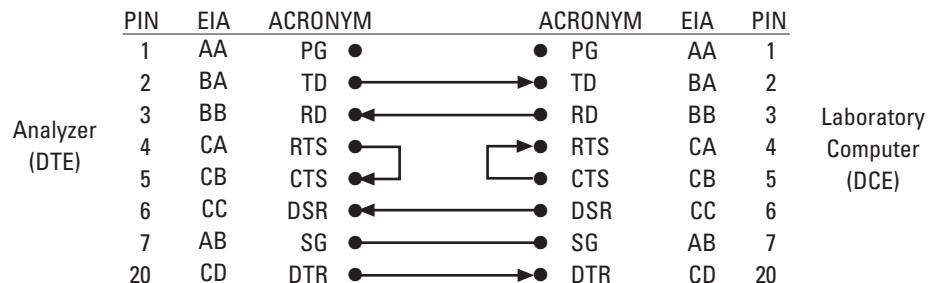
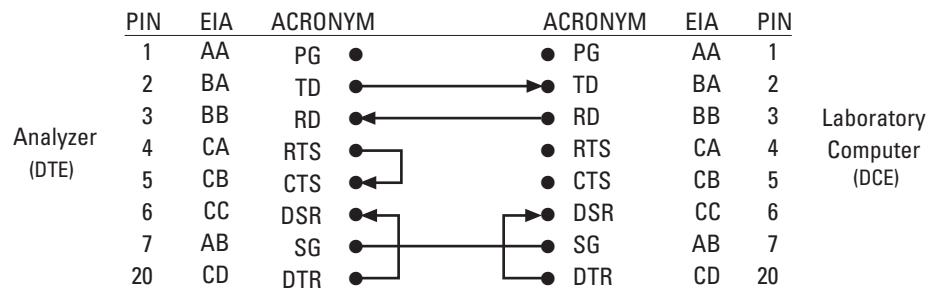


Figure 2-3. Modem Cable Configuration Examples (DTE-DCE).

MODEM



NULL MODEM

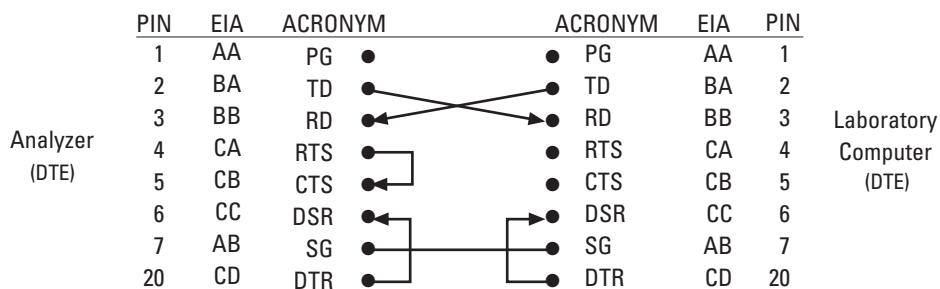


Figure 2-4. ASTM Wire Cable Configuration.

3.1 Introduction

In this chapter we will discuss the configurable options for the upload-only mode of communication available on the analyzers. The laboratory coordinator can set these options using the Options dialog of the Communication Configuration Option screen in the VITROS Chemistry Systems or using the Configure Ports screen from the Options & Configuration function in the VITROS ECI Immunodiagnostic System. The current or initial settings for the analyzer will display when the operator first enters these screens. Any changes to these settings will only become active upon exiting these screens. However, if communication is in progress, it will be cancelled upon exiting and the new settings will apply when that session restarts.

All configuration information is stored on hard disk and will be reported in the Configuration Report. All backup and restore functions are part of the Disk File Services Subsystem.

3.2 Method of the Transmission

All analyzers support the upload-only mode of communication. In upload-only mode, the asynchronous method of data transmission (serial-by-bit) with start/stop and parity character encoding (NRZ electrical encoding) is used. All information is encoded according to the ASCII character code. ASCII control characters such as NUL and DLE will be ignored in the received data stream as long as they are not within a record.

3.3 Parity

Character parity is user-defined. The following parity selections are available:

- ODD for odd parity
- EVEN for even parity
- MARK if the parity bit is to be binary 1 Not used by Imm. System
- SPACE if the parity bit is to be binary 0 Imm. System
- NONE if parity is not desired (8 bits are sent per character; the parity or eighth bit is ignored)

Default Configuration: ODD parity. NONE for the Imm. System

3.4 Character Transmission/Reception (Baud Rate)

Each character is transmitted in 10-bit format. Stop bits and data bits are user-defined:

- 1 start bit
- 7 data bits*
- 1 parity bit
- 1 stop bit

If parity is set to NONE:

- 1 start bit
- 8 data bits
- 1 stop bit

Default Configuration: 1 stop bit, 7 data bits for Chemistry Systems; 1 stop bit, 8 data bits for the Imm. System

*8 data bits can be selected in the 250 analyzers version 3.0 or higher.

The transmission fields are user-defined. The following baud rates are available on various analyzers.

Device	Baud Rate							
	300*	600*	1200	2400	4800	9600	19,200	38,400
250	X	X	X	X	X	X		
500 series	X	X	X	X	X	X		
700 series	X	X	X	X	X	X		
950		X	X	X	X	X		
Imm. System			X	X	X	X	X	X

Figure 3-1. Baud Rates.

Default Configuration: 1200 for 250 through 950; 9600 for the Imm. System

* no longer recommended

3.5 Communication Protocol

Communication between the analyzer and the laboratory computer consists of a sequence of records passing one way, record by record, and an optional acknowledgment for each record sent in the opposite direction. These individual records combine to form a message. The half-duplex mode of operation is used; that is, the communication between the sender and the receiver is in one direction at a time. In figure 3-2 there is an example of an upload transaction.

Header Record

0	10	20	30	40	50	60	70	80	90	100	110
!000a020005**700**112410850710309721 1096 1 1 2b301 FF01.000 62[]											(77 Bytes)
!000 + 0581[]											(13 Bytes)

Patient Description Record

0	10	20	30	40	50	60	70	80	90	100	110	
!001c7209464				John Doe		Any Street		Any City, NY		10000M31 b-30225[]		(103 Bytes)
!001 + 0582[]											(13 Bytes)	

Doctor Description Record

0	10	20	30	40	50	60	70	80	90	100	110
!002d301			Dr. William Smith		Any Hospital		Any City, NY		1000054[]		(85 Bytes)
!002 + 0583[]											(13 Bytes)

Miscellaneous Information Record

0	10	20	30	40	50	60	70	80	90	100	110	
!003e Physical Exam.					2F[]							(39 Bytes)
!003 + 0584[]											(13 Bytes)	

Test Result Record

0	10	20	30	40	50	60	70	80	90	100	110		
!004fGLU				80. mg/dL		02CE[]							(31 Bytes)
!004 + 0585[]											(13 Bytes)		

0	10	20	30	40	50	60	70	80	90	100	110		
!005f BUN				21. mg/dL		02C7[]							(31 Bytes)
!005 + 0586[]											(13 Bytes)		

0	10	20	30	40	50	60	70	80	90	100	110		
!006f CREA				.5 mg/dL		02D0[]							(31 Bytes)
!006 + 0587[]											(13 Bytes)		

The lines shown in boldface type indicate the information sent from the analyzer to the laboratory computer. The lines shown in lightface type indicate the information sent from the laboratory computer to the analyzer.

Note: [= a carriage return character (ASCII 0Dh) in this example.

] = a line feed character (ASCII 0Ah) in this example.

Figure 3-2. Example of an Upload Transaction.

0	10	20	30	40	50	60	70	80	90	100	110
!007f NH3	60.	umol/L	727c[]								
<hr/>											
!007 +	0588[]										
<hr/>											
Derived Test Result Record											
0	10	20	30	40	50	60	70	80	90	100	110
!008g B/CR	38.4	OC3[]									
!008 +	0589[]										
<hr/>											
Trailer Record											
0	10	20	30	40	50	60	70	80	90	100	110
!009h0005E7[]											
!009 +	058A[]										
<hr/>											

The lines shown in boldface type indicate the information sent from the analyzer to the laboratory computer. The lines shown in lightface type indicate the information sent from the laboratory computer to the analyzer.

Note: [= a carriage return character (ASCII 0Dh) in this example.
] = a line feed character (ASCII 0Ah) in this example.

Figure 3-2. Example of an Upload Transaction (Continued).

3.6 Logical (Procedural) Configuration Options

3.6.1 ACK/NAK Option Selection

This is a user-selected option. If you select ACK/NAK = **YES**, the analyzer will expect acknowledgment messages. If you select ACK/NAK = **NO**, the analyzer will not expect these messages. Otherwise, communications operate exactly alike for either selection.

You can enable the Analyzer Response Delay option (Section 3.6.2) for either ACK/NAK configuration (**YES or NO**). The Acknowledgment Timeout option (Section 3.6.3) applies only if ACK/NAK is selected (**YES**).

Default Configuration: ACK/NAK YES.

3.6.2 Analyzer Response Delay Option (Pacing Timer)

You can increase the length of the delay between analyzer record transmissions beyond that normally required for the analyzer to ready the next record for transmission; that is, analyzer software time is not included in this delay value. This option is available to accommodate laboratory computers that

require additional time for message preparation. The default setting (0.00 seconds) is recommended for laboratory computers that do not require any additional delay.

You can enter delay values within the range of 0.00 to 9.99 seconds (or 0 to 10 seconds on the Immunodiagnostic System).

Default Configuration: 0.00 seconds (or 0 for the Imm. System).

3.6.3 Acknowledgment Timeout Option (Response Timer)

When ACK/NAK has been selected (refer to Section 3.6.1), you can specify the length of time the analyzer must wait for an acknowledgment record before retransmission. The timer begins when an analyzer record expecting a response sends its last character. If the time expires before an acknowledgment is received, the analyzer invokes the retry logic. Refer to Section 3.7.1.

You can enter values within the range of 0 to 99 seconds.

Note: The analyzer will wait indefinitely for a response from the laboratory computer if you enter the value of zero for this option.

Default Configuration: 15 seconds.

3.7 Data Transmission Procedure

3.7.1 Transmission with ACK/NAK

To begin transmission, place the analyzer in the sampling mode (analyzer must also be in the upload-only communications mode). This activates data terminal ready (DTR) and request to send (RTS) signals. The laboratory computer must then activate the analyzer's data set ready (DSR) and clear to send (CTS) signals. The analyzer will start or restart transmission with a header record.

When a record is transmitted to the laboratory computer, the analyzer starts a timer. If transmission time between the first and last characters of a record exceeds 10 seconds, communication is stopped. A minimum 12-second delay will occur before communication will begin again, starting with the header record of a message. However, the message transmitted may not be the same message that was interrupted.

If a record is transmitted within the 10-second time limit, a response timer is started (Acknowledgment Timeout). If the last character of an acknowledgment record is not received within this timeout interval, the analyzer assumes the acknowledgment is negative and the record is retransmitted. This same action occurs in the event of a corrupted record, a negative acknowledgment (NAK), or a canceled acknowledgment (CAN). If an acknowledgment record is received within the timeout interval, the acknowledgment is verified, communications continue, and the next record is sent.

When the analyzer is ready to transmit a record after receiving a response message from the laboratory computer, it will delay for the time configured by the Analyzer Response Delay option (refer to Section 3.6.2) before initiating transmission of that record.

3.7.2 Transmission without ACK/NAK

Transmission without ACK/NAK follows the rules defined in Section 3.7.1, "Transmission with ACK/NAK" with the following exceptions.

If a record is transmitted within the 10-second time limit, the analyzer will delay for the time configured by the Analyzer Response Delay option (refer to Section 3.6.2) before initiating transmission of the next record. The analyzer will ignore all characters received from the laboratory computer, including positive and negative acknowledgments and flow control characters. Each record will be considered by the analyzer to

have been successfully transmitted when all characters of the record have been transmitted within the allowable 10-second interval.

3.7.3 Communication Interruption

Communication is interrupted if CTS or DSR go off. Special considerations apply to hardware flow control.

CTS Goes Off

- Transmission stops after the current character is transmitted.
- If CTS goes back on and the record is transmitted within the 10-second time limit, communication is not affected.
- If CTS goes back on after the 10-second time limit is exceeded, communication is affected. Transmission will resume again after the minimum 12-second delay, beginning once again with a header record of a message, which may or may not be the same message that was interrupted.

DSR Goes Off

- If transmission or reception is in progress, it stops immediately and an error is reported. No error is reported if either transmission or reception is not in progress and if upload records or acknowledgments are not expected by either station according to the protocol. No further communications will be attempted until the DSR signal is active.
- If DSR becomes active again, communication will resume beginning with a header record of a message, which may or may not be the same as any that were in progress when DSR went off.

Hardware Flow Control Notes

- The analyzer's RS-232C interface port is configured to emulate DTE. If the laboratory computer employs hardware flow control, the flow control signal output by the laboratory computer must be connected to the analyzer CTS input signal (Pin 5). DSR analyzer input signal (Pin 6) must not be used for character level flow; this is the on-line indicator from the laboratory computer.
- An error is generated if DSR is deactivated during a message. The analyzer will wait for DSR to become active again before attempting transmission of results data. The analyzer will not transmit unless both CTS and DSR are active.

3.7.4 Acknowledgments

When the ACK/NAK option has been selected, three

Acknowledgment	Acknowledgment Character	Hexadecimal Equivalents	Description
Positive (ACK)	+	2B	Indicates to the analyzer that the previous transmission record was accepted.
Negative (NAK)	-	2D	Indicates to the analyzer that the previous transmission record was in error and that the laboratory computer requests retransmission of that record.
Cancel (CAN)	?	3F	Requests the analyzer terminate transmission of the current message, but indicates that the laboratory computer is ready to accept retransmission. The current message must be retransmitted, starting once again with record 0, the header record.

Figure 3-3. Possible Acknowledgments.

The format for acknowledgments are shown in [figure 3-4](#).

Starting Location	Number of Characters	Description
1	1	Start Character: ! (21h).
2	3	Record Sequence Number (within message): 000 to 999. This field identifies the record sequence number within the message. Refer to section 4.3.1, “General Format for VITROS Chemistry Systems.”
5	1	Acknowledgment Character: +, -, or ?. Refer to definitions of acknowledgments in figure 3-3
6	1	Undefined Field.
7	1	Undefined Field.
8	2	Message Sequence Number: 00 to 99. This field identifies the sequence number of the message being acknowledged.
10	2	Checksum: 00 to FF (ASCII). The two-character checksum is computed on bytes 1 through 9. Refer to Section 4.3.1, “General Format for VITROS Chemistry Systems.” The resulting sum is expressed in its hexadecimal equivalent.
12	2	End Characters: CR-LF (CR=0Dh; LF=0Ah). Refer to Section 4.3.1.

Figure 3-4. Acknowledgment Format.

Verification for acknowledgments takes place in the order shown in [figure 3-5](#) with the corresponding analyzer action.

Order of Verification	Information Verified	Analyzer Action
1	Time out (No Acknowledgment)	Increment NAK count and retransmit data record.
2	Data Error	Reset internal status of USART, increment NAK count, and retransmit data record (data errors include receive errors; for example, overrun).
3	Start Character Error	Increment NAK count and retransmit data record.
4	End Character Error	Increment NAK count and retransmit data record.
5	Checksum Error	Increment NAK count and retransmit data record.
6	Message Sequence Number Error	Increment NAK count and retransmit data record.
7	Record Sequence Number Error	Increment NAK count and retransmit data record.
8	Positive Acknowledgment (ACK)	Reset NAK count, format next data record, and transmit.
9	Negative Acknowledgment (NAK)	Increment NAK count and retransmit data record.
10	Cancel Acknowledgment (CAN)	Increment CAN count and retransmit the entire message beginning with the header record.
11	Undefined Acknowledgment	Increment NAK count and retransmit data record.

Figure 3-5. Verification of Acknowledgments.

If a single record receives five of the errors described above in any combination (that is, NAK count equals five), or a single message receives five cancel errors, the analyzer assumes that an uncorrectable error condition has occurred and data transmission is terminated.

4

Application Interface: Upload-Only Mode

4.1 Information Transmitted

The results message sent from the analyzer to the laboratory computer contains all of the test results information for a single specimen.

4.2 Message Records

The results message contains the following records:

- Header record (1)
- Patient description record (0 to 1)*
- Doctor description record (0 to 1)*

*Records are not transmitted when all fields in the record contain ASCII space characters (20 hexadecimal).

- Miscellaneous record (0 to 1)*
- Test results records (0 to 30 for *VITROS Chemistry Systems* and 0 to 50 for the *VITROS ECi Immunodiagnostic System*)
- Derived test results records (0 to 16 for Chemistry Systems and 0 to 30 for the Immunodiagnostic System)
- Trailer record (1)

4.3 Record Format

A message consists of a variable number of fixed-length records.

4.3.1 General Format for VITROS Chemistry Systems

The general format for each record is shown in figure 4-1.

Starting Location	Number of Characters	Description
1	1	Start Character: !.
2	3	Record Sequence Number (within message): 000 to 999. The first record of any message always has record number 000. Records that follow in that message continue in sequence, 001, 002, etc., through 999. If a message consists of more than 1,000 records, the sequence number wraps around and continues with 000.
5	1	Record Type: This field contains one of the following ASCII characters as identifying the record type: a,c,d,e, f, g, and h.
6	Variable	Record Body: This field contains the information to be transmitted. Length varies according to record type. All records of the same type are equal in length. The maximum length for all records is 103 bytes. Note: All fields are spaced filled.
Variable	2	Checksum: The two-digit characters in this field represent an eight-bit checksum of the record, which includes the start character through the last data character. The end characters are not included. It is produced by taking the arithmetic sum, modulo 256, of the seven-bit representation of each character. The result is then expressed as an ASCII hexadecimal number (11010110 binary becomes D6 hexadecimal, which is then displayed as D6 ASCII characters).
Variable	2	End Characters: This field contains the last two characters of each record transmitted. These characters are always CR-LF (carriage return-line feed).

Figure 4-1. General Record Format for VITROS Chemistry Systems.

4.3.2 Header Record for VITROS Chemistry Systems

The record layout in figure 4-2 identifies the data in the header record.

Starting Location	Number of Characters	Description
1	1	Start Character: !
2	3	Record Sequence Number (within message): 000.
5	1	Record Type: a. This character identifies the record as a result message header record.
6	2	Message Format Version Number: 02.
8	1	Undefined Field.
9	1	Undefined Field.
10	2	Message Sequence Number: 00 to 99.
12	6	Analyzer ID: This field contains the analyzer ID defined using the Analyzer Configuration feature of the Options dialog (via screen OP00E, then OP35A). If the analyzer ID has fewer than 6 characters, the field is left-justified and blank-filled. If no analyzer ID has been defined, the default, **700*, is used. This feature is useful to identify individual analyzers in situations where more than one is present.
18	6	Time of Metering: (HHMMSS).
24	6	Date of Metering: (YYMMDD).
30	15	Sample ID.
45	1	Fluid Type: 1 to 3 (in ASCII characters): 1 Serum 2 Cerebrospinal fluid (CSF) 3 Urine
46	1	Quadrant.
47	2	Cup (in ASCII characters): 1 to 10.
49	15	Tray Name.
64	1	Stat Flag: T Stat sample F Non-stat sample
65	1	Control Flag: T Control sample F Non-control sample
66	1	Mode (in ASCII characters): 0 Select mode 1 Batch mode
67	7	Dilution Factor: (left justified). This field contains four significant digits and a floating decimal point. The last two characters will always contain blanks. If this field contains question marks (??????), an error has occurred or the data is not numeric.
74	2	Checksum: 00 to FF (ASCII). The two-character checksum is computed on bytes 1 through 73.
76	2	End Characters: CR-LF.

Figure 4-2. Header Record for VITROS Chemistry Systems.

4.3.3 Patient Description Record for VITROS Chemistry Systems

The record layout in [figure 4-3](#) identifies the data in the patient description record.

Starting Location	Number of Characters	Description
1	1	Start Character: !
2	3	Record Sequence Number (within message): 001 to 999
5	1	Record Type: c*. This character identifies the record as a patient description record.
6	15	Patient ID.
21	15	Patient's Last Name: left-justified and space-filled.
36	9	Patient's First Name: left-justified and space-filled.
45	1	Patient's Middle Initial.
46	25	Patient Location (Line 1).
71	20	Patient Location (Line 2).
91	1	Patient Sex.
92	3	Patient Age: right-justified with leading zeros.
95	5	Patient Room.
100	2	Checksum: 00 to FF (ASCII). The two-character checksum is computed on bytes 1 through 99.
102	2	End Characters: CR-LF.

*Record type b is undefined

Figure 4-3. Patient Description Record for VITROS Chemistry Systems.

4.3.4 Doctor Description Record for VITROS Chemistry Systems

The record layout in [figure 4-4](#) identifies the data in the doctor description record.

Starting Location	Number of Characters	Description
1	1	Start Character: !
2	3	Record Sequence Number (within message): 001 to 999.
5	1	Record Type: d. This character identifies the record as a doctor description record.
6	5	Doctor ID.
11	15	Doctor's Last Name: left-justified and space-filled.
26	9	Doctor's First Name: left-justified and space-filled.
35	1	Doctor's Middle Initial.
36	25	Doctor Location (Line 1).
61	21	Doctor Location (Line 2).
82	2	Checksum: 00 to FF (ASCII). The two-character checksum is computed on bytes 1 through 81.
84	2	End Characters: CR-LF.

Figure 4-4. Doctor Description Record for VITROS Chemistry Systems.

4.3.5 Miscellaneous Information Record for VITROS Chemistry Systems

The record layout in figure 4-5 identifies the data in the miscellaneous information record.

Starting Location	Number of Characters	Description
1	1	Start Character: !
2	3	Record Sequence Number (within message): 001 to 999.
5	1	Record Type: e. This character identifies the record as a miscellaneous information record.
6	10	Miscellaneous Field 1.
16	10	Miscellaneous Field 2.
26	10	Miscellaneous Field 3.
36	2	Checksum: 00 to FF (ASCII). The two-character checksum is computed on bytes 1 through 35.
38	2	End Characters: CR-LF.

Figure 4-5. Miscellaneous Information Record for VITROS Chemistry Systems.

4.3.6 Test Results Record for VITROS Chemistry Systems

The record layout in figure 4-6 identifies the data in the test results record.

Starting Location	Number of Characters	Description				
1	1	Start Character: !				
2	3	Record Sequence Number (within message): 001 to 999.				
5	1	Record Type: f. This character identifies the record as a test results record.				
6	4	Test Name (left-justified): This field identifies the test for which the result is being reported. The test name is abbreviated as in the laboratory report format (maximum of four characters):	<i>Test Name</i>	<i>Report Name</i>	<i>Test Name</i>	<i>Report Name</i>
		Glucose	GLU	Total Protein	TP	
		Urea Nitrogen	BUN (UREA if SI)	Albumin	ALB	
		Creatinine	CREA	Aspartate Aminotransferase	AST	
		Sodium	Na+	Alanine Aminotransferase	ALT	
		Potassium	K+	Lactate Dehydrogenase	LDH	
		Chloride	Cl	Creatine Kinase	CK	
		Amylase	AMYL	Alkaline Phosphatase	ALKP	
		Lipase	LIPA	Gamma Glutamyltransferase	GGT	
		Calcium	Ca	Total Bilirubin	TBIL	
		Phosphorus	PHOS	Bilirubin, Unconjugated	Bu	
		Cholesterol	CHOL	Bilirubin, Conjugated	Bc	
		Triglycerides	TRIG	Magnesium	Mg	
		HDL Cholesterol	HDLC	Iron	Fe	
		Direct HDLC	dHDL	Total Iron Binding Capacity	TIBC	
		CK-MB	CKMB	CSF Protein	PROT	
		Theophylline	THEO	Lactate	LAC	
		Enzymatic CO2	ECO2	Cholinesterase	CHE	
		Alcohol	ALC	Digoxin	DGXN	
		Salicylate	SALI	Phenobarbital	PHBR	
		Ammonia	AMON	Phenytoin	PHYT	
		Lithium	Li	C Reactive Protein	CRP	
		Acid Phosphatase	ACP	Acetaminophen	ACET	
		Uric Acid	URIC	Carbamazepine	CRBM	
				Urine Protein	UPRO	
		Japanese Only:				
		Alanine Aminotransferase	ALTJ	C Reactive Protein	CRPJ	
		Aspartate Aminotransferase	ASTJ			

Figure 4-6. Test Results Record for VITROS Chemistry Systems.

Starting Location	Number of Characters	Description
10	9	<p>Test Result: The test result is a 8-character floating-point field that includes the decimal point and a negative sign when applicable. The number of precision point digits will vary by test and is configurable on the analyzer. If the test result is less than 8 characters, this field will be padded with blanks preceding the result. Significant digits displayed are the same as in the laboratory report. Derived test results have a maximum of eight character spaces.</p> <p>Note: If the field contains question marks (?), an error has occurred. If the field contains 99999.99, a prediction failure has occurred.</p>
19	8	Reporting Units (left-justified).
27	1	<p>Error Flags (in ASCII characters):</p> <ul style="list-style-type: none"> 0 No error 1 Above laboratory's range 2 Below laboratory's range 3 Outside dynamic range 4 Above analyzer's range (the value reported is the maximum limit of the range) 5 Below analyzer's range (the value reported is the minimum limit of the range) 6 Prediction failure (floating point test result, starting location 10, becomes 99999.99) 7 Outside Supplementary Range A Control result is more than 2 SDI from baseline interval mean, but no more than 3 SDI B Result is more than 3 SDI from baseline interval mean C No baseline interval mean and SDI, or test is not supported in QC database D Control result below QC range # E Control result above QC range # <p><i>For future implementation on VITROS 250 and 950 Systems:</i></p> <ul style="list-style-type: none"> F Above dynamic range G Below dynamic range H Above Supplementary Range I Below Supplementary Range
28	1	<p>Warning Flags (in ASCII characters):</p> <ul style="list-style-type: none"> 0 No warning 1 Analyzer-generated warning. The causes of this warning are: <ul style="list-style-type: none"> • Result outside dynamic range • Result above or below analyzer range • High concentration of blank analyte detected for blank-corrected test • Rate is drifting out and in trim window, or the kinetic curve exhibits excessive noise or lack of fit • Component flagged 2 Operator-induced warning. The causes of this warning are the following states: <ul style="list-style-type: none"> • Result above or below hospital range • Result above or below supplementary range • User calibrated • Adjusted result • Edited result 3 Both analyzer and operator warning
29	2	Checksum: 00 to FF (ASCII). The two-character checksum is computed on bytes 1 through 27.
31	2	End Characters: CR-LF.

Figure 4-6. Test Results Record for VITROS Chemistry Systems.

4.3.7 Derived Test Results Record for VITROS Chemistry Systems

The record layout in figure 4-7 identifies the data in the derived test result record.

Starting Location	Number of Characters	Description																																		
1	1	Start Character: !.																																		
2	3	Record Sequence Number (within message): 001 to 999.																																		
5	1	Record Type: g. This character identifies the record as a derived test result record.																																		
6	4	Derived Test Name (left-justified): This field identifies the derived test for which the result is being reported. The derived test name is abbreviated as in the laboratory report format (maximum of four characters): <table> <thead> <tr> <th>Test Name</th> <th>Report Name</th> </tr> </thead> <tbody> <tr><td>BUN/Creatinine Ratio</td><td>B/CR (U/CR if SI)</td></tr> <tr><td>Anion Gap with K+</td><td>AGPK</td></tr> <tr><td>Anion Gap without K+</td><td>AGP</td></tr> <tr><td>A/G Ratio</td><td>A/G</td></tr> <tr><td>Neonatal Bilirubin</td><td>NBIL</td></tr> <tr><td>Direct Bilirubin</td><td>DBIL</td></tr> <tr><td>Delta Bilirubin</td><td>DeLB</td></tr> <tr><td>% CK-MB</td><td>% MB</td></tr> <tr><td>Osmolality</td><td>OSMO</td></tr> <tr><td>Globulin</td><td>GLOB</td></tr> <tr><td>VLDL</td><td>VLDL</td></tr> <tr><td>CHOL/HDLC</td><td>C/HC</td></tr> <tr><td>CHOL/dHDL</td><td>C/H</td></tr> <tr><td>LDLC</td><td>LDLC</td></tr> <tr><td>LDL</td><td>LDL</td></tr> <tr><td>% Saturation</td><td>% SAT</td></tr> </tbody> </table>	Test Name	Report Name	BUN/Creatinine Ratio	B/CR (U/CR if SI)	Anion Gap with K+	AGPK	Anion Gap without K+	AGP	A/G Ratio	A/G	Neonatal Bilirubin	NBIL	Direct Bilirubin	DBIL	Delta Bilirubin	DeLB	% CK-MB	% MB	Osmolality	OSMO	Globulin	GLOB	VLDL	VLDL	CHOL/HDLC	C/HC	CHOL/dHDL	C/H	LDLC	LDLC	LDL	LDL	% Saturation	% SAT
Test Name	Report Name																																			
BUN/Creatinine Ratio	B/CR (U/CR if SI)																																			
Anion Gap with K+	AGPK																																			
Anion Gap without K+	AGP																																			
A/G Ratio	A/G																																			
Neonatal Bilirubin	NBIL																																			
Direct Bilirubin	DBIL																																			
Delta Bilirubin	DeLB																																			
% CK-MB	% MB																																			
Osmolality	OSMO																																			
Globulin	GLOB																																			
VLDL	VLDL																																			
CHOL/HDLC	C/HC																																			
CHOL/dHDL	C/H																																			
LDLC	LDLC																																			
LDL	LDL																																			
% Saturation	% SAT																																			
10	9	Derived Test Result: The test result is a 8-character floating-point field that includes the decimal point and a negative sign when applicable. The number of precision point digits will vary by test and is configurable on the analyzer. If the test result is less than 8 characters, this field will be padded with blanks preceding the result. Significant digits displayed are the same as in the laboratory report. Derived test results have a maximum of eight character spaces. Note: If the field contains question marks (?), an error has occurred. If the field contains 99999.99, a prediction failure has occurred.*																																		
19	8	Reporting Units (left justified).																																		
27	1	Error Flags (in ASCII characters): <ul style="list-style-type: none"> 0 No error 1 Above laboratory's range 2 Below laboratory's range 3 Edited test result 4 Unusable component for derived test result 5 Prediction failure (floating point test result, starting location 10, becomes 99999.99) 7 Outside Supplementary Range 8 Pre-treated Multiple Sample Derived Test (MSDT) A Control result is more than 2 SDI from baseline interval mean, but no more than 3 SDI B Result is more than 3 SDI from baseline interval mean C No baseline interval mean and SDI, or test is not supported in QC database D Control result below QC range # E Control result above QC range # 																																		
28	2	Checksum: 00 to FF (ASCII). The two-character checksum is computed on bytes 1 through 27.																																		
30	2	End Characters: CR-LF.																																		

*The characters PS are transmitted when the neat (untreated) sample result is available, but the pretreated sample result is unavailable. When the pretreated sample result is available, the calculated value for the Derived Test Result is then retransmitted.

Figure 4-7. Derived Test Results Record for VITROS Chemistry Systems.

4.3.8 Trailer Record for VITROS Chemistry Systems

The record layout in [figure 4-8](#) identifies the data in the trailer record.

Starting Location	Number of Characters	Description
1	1	Start Character: !.
2	3	Record Sequence Number (within message): 001 to 999.
5	1	Record Type: h. This character identifies the record as a trailer record.
6	1	Undefined Field.
7	1	Undefined Field.
8	2	Message Sequence Number: 00 to 99.
10	2	Checksum: 00 to FF (ASCII). The two-character checksum is computed on bytes 1 through 9.
12	2	End Characters: CR-LF.

Figure 4-8. Trailer Record for VITROS Chemistry Systems.

4.3.9 General Format for the VITROS ECi Immunodiagnostic System

The general format for each VITROS ECi Immunodiagnostic System record is shown in [figure 4-9](#).

Starting Location	Number of Characters	Description
1	1	Start Character: !.
2	3	Record Sequence Number (within message): 000 to 999. The first record of any message always has record number 000. Records that follow in that message continue in sequence, 001, 002, etc., through 999. If a message consists of more than 1,000 records, the sequence number wraps around and continues with 000.
5	1	Record Type: This field contains any one of the 95 printable ASCII characters that identifies the record type.
6	Variable	Record Body: This field contains the information to be transmitted. Length varies according to record type. All records of the same type are equal in length. The maximum length for all records is 103 bytes. Note: All fields are space-filled.
Variable	2	Checksum: The two-digit characters in this field represent an eight-bit checksum of the record, which includes the start character through the last data character. The end characters are not included. It is produced by taking the arithmetic sum, modulo 256, of the seven-bit representation of each character. The result is then expressed as an ASCII hexadecimal number (11010110 binary becomes D6 hexadecimal, which is then displayed as D6 ASCII characters).
Variable	2	End Characters: This field contains the last two characters of each record transmitted. These characters are always CR-LF (carriage return-line feed).

Figure 4-9. General Record Format for the VITROS ECi Immunodiagnostic System.

4.3.10 Header Record for the VITROS ECi Immunodiagnostic System

The record layout in figure 4-10 identifies the data in the header record for the VITROS ECi Immunodiagnostic System.

Starting Location	Number of Characters	Description
1	1	Start Character: !
2	3	Record Sequence Number (within message): 000.
5	1	Record Type: a. This character identifies the record as a result message header record.
6	2	Message Format Version Number: 02.
8	1	Undefined Field.
9	1	Undefined Field.
10	2	Message Sequence Number: 00 to 99.
12	6	System Name: This field contains the system name defined using the Configure System screen. If the system name has fewer than 6 characters, the field is left-justified and blank-filled. The Immunodiagnostic System allows for 7 characters but will truncate to 6. If no system name has been defined, the default, blank, is used. This feature is useful to identify individual analyzers in situations where more than one is present.
18	6	Time of Metering: (HHMMSS).
24	6	Date of Metering: (YYMMDD).
30	15	Sample ID.
45	1	Fluid Type (in ASCII characters): In the Imm. System, this range of numbers and characters is used: 4 Serum 5 Plasma 6 Urine 7 Blood 8 Amnio 9 Reserved 1 : Reserved 2 ; Reserved 3 < Reserved 4 These will be stored as ASCII values 52–60, respectively
46	1*	Quadrant: This field is ignored by the Imm. System.
47	2	Cup (in ASCII characters): 1 to 10.
49	15	Tray Name: In the ECi System the tray name has up to two characters. The remainder of the field will be blank filled.
64	1	Stat Flag: T Stat sample F Non-stat sample
65	1	Control Flag: T Control sample F Non-control sample
66	1	Mode: In the Imm. System this field is ignored and select mode is assumed.
67	7	Dilution Factor: (left justified). This field contains four significant digits and a floating decimal point. The last two characters will always contain blanks. If this field contains question marks (??????), an error has occurred or the data is not numeric.
74	2	Checksum: 00 to FF (ASCII). The two-character checksum is computed on bytes 1 through 73.
76	2	End Characters: CR-LF.

Figure 4-10. Header Record for the VITROS ECi Immunodiagnostic System.

4.3.11 Patient Description Record for the VITROS ECi Immunodiagnostic System

The record layout in [figure 4-11](#) identifies the data in the patient description record for the VITROS ECi Immunodiagnostic System.

Starting Location	Number of Characters	Description
1	1	Start Character: !
2	3	Record Sequence Number (within message): 001 to 999
5	1	Record Type: c*. This character identifies the record as a patient description record.
6	15	Patient ID.
21	15	Patient's Last Name: left-justified and space-filled, if required. The Imm. System database holds 20 characters so truncation may occur.
36	9	Patient's First Name: left-justified and space-filled, if required. The Imm. System database holds 15 characters so truncation may occur.
45	1	Patient's Middle Initial.
46	25	Patient Location (Line 1): The Imm. System database holds 20 characters so padding, left-justified, may occur.
71	20	Patient Location (Line 2).
91	1	Patient Sex.
92	3	Patient Age.
95	5	Patient Room.
100	2	Checksum: 00 to FF (ASCII). The two-character checksum is computed on bytes 1 through 99.
102	2	End Characters: CR-LF.

*Record type b is undefined

Figure 4-11. Patient Description Record for the VITROS ECi Immunodiagnostic System.

4.3.12 Doctor Description Record for the VITROS ECi Immunodiagnostic System

The record layout in [figure 4-12](#) identifies the data in the doctor description record in the VITROS ECi Immunodiagnostic System.

Starting Location	Number of Characters	Description
1	1	Start Character: !
2	3	Record Sequence Number (within message): 001 to 999.
5	1	Record Type: d. This character identifies the record as a doctor description record.
6	5	Doctor ID: The Immunodiagnostic System database holds 15 characters so truncation may occur.
11	15	Doctor's Last Name: left-justified and space-filled, if required. The Imm. System database holds 20 characters so truncation may occur.
26	9	Doctor's First Name : (left-justified and space-filled, if required) The Imm. System database holds 15 characters so truncation may occur.
35	1	Doctor's Middle Initial.
36	25	Doctor Location (Line 1): The Imm. System database holds 25 characters so padding may occur, left justified.
61	21	Doctor Location (Line 2): The Imm. System database holds 20 characters so padding may occur, left justified.
82	2	Checksum: 00 to FF (ASCII). The two-character checksum is computed on bytes 1 through 81.
84	2	End Characters: CR-LF.

Figure 4-12. Doctor Description Record for the VITROS ECi Immunodiagnostic System.

4.3.13 Miscellaneous Information Record for the VITROS ECi Immunodiagnostic System

The record layout in figure 4-13 identifies the data in the miscellaneous information record in the VITROS ECi Immunodiagnostic System.

Starting Location	Number of Characters	Description
1	1	Start Character: !
2	3	Record Sequence Number (within message): 001 to 999.
5	1	Record Type: e. This character identifies the record as a miscellaneous information record.
6	10	Miscellaneous Field 1.
16	10	Miscellaneous Field 2.
26	10	Miscellaneous Field 3.
36	2	Checksum: 00 to FF (ASCII). The two-character checksum is computed on bytes 1 through 35.
38	2	End Characters: CR-LF.

Figure 4-13. Miscellaneous Information Record for the VITROS ECi Immunodiagnostic System.

4.3.14 Test Results Record for the VITROS ECi Immunodiagnostic System

The record layout in figure 4-14 identifies the data in the assay results record in the VITROS ECi Immunodiagnostic System.

Starting Location	Number of Characters	Description
1	1	Start Character: !
2	3	Record Sequence Number (within message): 001 to 999.
5	1	Record Type: f. This character identifies the record as a assay result record.
6	5	Test Name (left-justified): This field identifies the assay for which the result is being reported. The assay name is abbreviated as in the laboratory report format (maximum of five characters) Refer to Appendix E for the names of Imm. System assays.
11	9	Test Results: The assay result is a 9-character floating-point field that includes the decimal point and a negative sign when applicable. The number of precision point digits varies by assay and the magnitude of the result. If the assay result is less than 9 characters, this field will be padded with blanks preceding the result. The string NO RESULT is reported in this field if one of a number of conditions exist, like a numerical processing error.
20	12	Reporting Units (left-justified): Blank if not applicable; for qualitative results see "Q"- "R" below in Error Flags.
32	1	Result Flags (in ASCII characters): 0 No flag 1 Above reference range 2 Below reference range 4 Above dynamic range (the value reported is the maximum limit of the range) 5 Below dynamic range (the value reported is the minimum limit of the range) 6 Prediction failure (floating-point assay result, starting location 10, becomes 99999.99) 7 Above supplementary range 8 Below supplementary range A Control result is more than 2 SDI from baseline interval mean, but no more than 3 SDI B Result is more than 3 SDI from baseline interval mean C No baseline interval mean and SDI, or assay is not supported in QC database Q Result limit 1 ← R Result limit 2 ← S Result limit 3 ← T Result limit 4 ← U Result limit 5 ←

These are classified for qualitative results.

Figure 4-14. Test Result Record for the VITROS ECi Immunodiagnostic System.

Starting Location	Number of Characters	Description
33	1	Warning Flags (in ASCII characters): 0 No warning 1 Analyzer-generated warning. The causes of this warning are: • Result outside dynamic range • Component flagged 2 Operator-induced warning. The causes of this warning are: • Result above or below lab normal range • Result above or below supplementary range • User calibrated • Adjusted result • Edited result 3 Both analyzer and operator warning
34	2	Checksum: 00 to FF (ASCII). The two-character checksum is computed on bytes 1–33
36	2	End Characters: CR-LF.

Figure 4-14. Test Result Record for the VITROS ECi Immunodiagnostic System.

4.3.15 Derived Test Results Record for the VITROS ECi Immunodiagnostic System

The record layout in [figure 4-15](#) identifies the data in the derived test results record in the VITROS ECi Immunodiagnostic System.

Starting Location	Number of Characters	Description
1	1	Start Character: !
2	3	Record Sequence Number (within message): 001 to 999.
5	1	Record Type: g. This character identifies the derived test for which the result is being reported. The derived test name is abbreviated as in the laboratory report format (maximum of four characters).
6	5	Derived Test Name (left-justified): This field identifies the derived test for which the result is being reported. The derived test name is abbreviated as in the laboratory report format (maximum of four characters): Refer to Appendix E for Immunodiagnostic System assay names.
11	9	Derived Test Result: The test result is a 9-character floating-point field that includes the decimal point and a negative sign when applicable. The number of precision point digits will vary by test and is configurable on the analyzer. If the test result is less than 9 characters, this field will be padded with blanks preceding the result. NO RESULT is reported in this field if one of a number of conditions exist, like a numerical processing error.
20	12	Reporting Units (left-justified): Blank if not applicable; for qualitative results see “Q”–“R” below in Error Flags.
32	1	Result Flags (in ASCII characters): 0 No flag 1 Above reference range 2 Below reference range 4 Above dynamic range (the value reported is the maximum limit of the range) 5 Below dynamic range (the value reported is the minimum limit of the range) 6 Prediction failure (floating point test result, starting location 10, becomes 99999.99) 7 Above supplementary range 8 Below supplementary range A Control result is more than 2 SDI from baseline interval mean, but no more than 3 SDI B Result is more than 3 SDI from baseline interval mean C No baseline interval mean and SDI, or assay is not supported in QC database

Figure 4-15. Derived Test Results Record for the VITROS ECi Immunodiagnostic System.

Starting Location	Number of Characters	Description
33	2	Checksum: 00 to FF (ASCII). The two-character checksum is computed on bytes 1–33
35	2	End Characters: CR-LF.

Figure 4-15. Derived Test Results Record for the VITROS ECi Immunodiagnostic System.

4.3.16 Trailer Record for the VITROS ECi Immunodiagnostic System

The record layout in figure 4-16 identifies the data in the trailer record.

Starting Location	Number of Characters	Description
1	1	Start Character: !.
2	3	Record Sequence Number (within message): 001 to 999.
5	1	Record Type: h. This character identifies the record as a trailer record.
6	1	Undefined Field.
7	1	Undefined Field.
8	2	Message Sequence Number: 00 to 99.
10	2	Checksum: 00 to FF (ASCII). The two-character checksum is computed on bytes 1 through 9.
12	2	End Characters: CR-LF.

Figure 4-16. Trailer Record for the VITROS ECi Immunodiagnostic System.

5.1 Introduction

In this chapter we will discuss the configurable options for the bidirectional mode of communication using the *Kermit* File Transfer Protocol. Details of this protocol may be found in the source documents referenced in [Section 1.4](#). This chapter contains a summary of the rules pertinent to the analyzers' implementation of the *Kermit* protocol. Any differences in implementation choices among devices is clearly marked.

The laboratory coordinator can set configuration options using these features:

- For VITROS Chemistry Systems, the Options dialog of the Communication Configuration Option screen.
- For the VITROS ECi Immunodiagnostic System, the CONFIGURE PORTS group of screens under the Options & Configuration function.

The current settings or default settings for the analyzers will display when the laboratory coordinator first views these screens. Any changes to these settings will only become active upon exiting the dialog or screen. However, if communication is in progress, it will be cancelled upon exiting and the new settings will apply when the session restarts.

All configuration information is stored on hard disk and will be reported in the Configuration Report. All backup and restore functions are part of the Disk File Services SubSystem.

The bidirectional mode, unlike the upload-only mode, supports the down loading of sample programming criteria as well as the up loading of test results. The bidirectional mode includes configurable capabilities not available in upload-only mode. These configurable features increase the flexibility of the protocol, allowing accommodation of the wider range of user systems and easier adaptation to unique system environments. Users who have not previously installed a laboratory computer interface, who plan to use downloading capability, or who are considering bidirectional transmission at some future time should select the bidirectional mode at system set up time.

5.2 Method of Transmission/Reception

For *Kermit*, the asynchronous method of data transmission and reception (that is, serial by bit) with NRZ encoding is used. All information is encoded using the ASCII character code in accordance with ANSI Standard X3.4, 1968, with logical character transformation as defined by the *Kermit* Protocol. Bit transmission sequence is performed in accordance with ANSI Standard X3.15, 1976.

5.3 Parity

Character parity is user-defined. The following parity selections are available:

ODD	for odd parity
EVEN	for even parity
MARK	if the parity bit is to be binary 1 (not used by the VITROS ECi Immunodiagnostic System)
SPACE	if the parity bit is to be binary 0 (not used by VITROS ECi Immunodiagnostic System)
NONE	if parity is not desired (8 bits are sent per character; the parity or eighth bit is ignored)

Default Configuration: ODD for Chemistry Systems ; NONE for the ECi System and the Japanese.

5.4 Character Transmission/Baud Rate

Each character is transmitted in 10-bit or 11-bit format. Stop bits, data bits, and baud rates are user-defined. See [figure 5-1](#).

If parity is used:

1 start bit
7 data bits (8 data bits in the 250 analyzers version 3.0 or higher)
1 parity bit
1 or 2 stop bits

If parity is set to NONE:

1 start bit
7 or 8 data bits
1 or 2 stop bits

Default Configuration: 1 stop bit, 7 data bits for Chemistry Systems; 1 stop bit, 8 data bits for the Imm. System

Japanese Configuration: 1 stop bit, 8 data bits.

Device	Baud Rate							
	300*	600*	1200	2400	4800	9600	19,200	38,400
250	X	X	X	X	X	X		
500 series	X	X	X	X	X	X		
750 series	X	X	X	X	X	X		
950		X	X	X	X	X		
Imm. System			X	X	X	X	X	X

Figure 5-1. Baud Rates.

Default Configuration: 1200 for Chemistry Systems and 9600 for the ECi System

*no longer recommended.

5.5 Logical (Procedural) Configuration Options

This section explains the logical or procedural configuration options available on the analyzers using the *Kermit* Protocol for bidirectional communication.

5.5.1 Flow Control Mechanism

This selection instructs the analyzer to respond to flow control characters, ASCII DC1 and DC3 (that is, **XON** and **XOFF**). Receipt of these characters will stop or start the analyzer's transmission data stream. They allow character level "pacing" control at the laboratory computer when it has a small receiver buffer space in which to receive analyzer data. This feature has an associated timer ([refer to Section 5.5.2](#)).

You can configure flow control to **NONE** or **XON/XOFF**. When configured to **XON/XOFF**, the flow control timer also applies to hardware flow control (CTS) ([refer to Section 5.5.2](#)). If configured to **NONE**, hardware flow control is not limited.

Default Configuration: XON/XOFF (that is, feature is enabled).

5.5.2 Flow Control Timeout on Analyzers

You can set the maximum time the analyzer will wait for XON after receiving XOFF, or for CTS ON after detecting CTS OFF. If the flow control mechanism was set to **NONE** rather than to **XON/XOFF** ([refer to Section 5.5.1](#)), this parameter has no effect on either analyzer operation or hardware flow control.

Valid entries range from 1 second to 9 minutes, 59 seconds (or 1 to 599 seconds on the Imm. System).

Default Configuration: 30 seconds.

(Flow Control Pilot is set at 30 seconds and not configurable)

5.5.3 Analyzer Response Delay (Pacing Timer)

You can increase the length of the delay between analyzer record transmissions beyond that normally required for the analyzer to ready the next record for transmission; that is, analyzer software time is not included in this delay value. This option is available to accommodate laboratory computers that require additional time for message preparation. The default setting (0.00 seconds) is recommended for laboratory computers that do not require any additional delay.

Delay values within the range of 0.00 to 9.99 seconds (or 0 to 10 seconds on the Imm. System) may be entered.

Default Configuration: 0.00 seconds or 0 for Imm. System

5.5.4 Analyzer Response Timeout (Response Timer)

This parameter is sent to the laboratory computer during session initialization. It is inserted in the TIME field of the session-initiating exchange packet (for example, S or Y) to specify the time the laboratory computer should wait for an expected

packet from the analyzer. If this timer is used with a laboratory computer that also uses a timer (that is, TIME field in the exchanged session parameters), the two timers should be significantly different in value by at least a few seconds. This will prevent duplication, which would result if both stations timed out simultaneously.

Timeout values within the range of 0 to 99 may be entered.

Note: The laboratory computer will wait indefinitely for a response from the analyzer if the value zero is entered for this option.

Default Configuration: 25 seconds.

5.5.5 Packet Retry Limit

This limit defines the maximum number of times the analyzer will resend a packet in response to receiving a NAK or achieving the Analyzer Response Timeout. When this limit is reached, the analyzer will terminate this session and will initiate a new session start packet.

Limit values in the range of 0 to 99 may be entered.

Default Configuration: 5 retries

5.5.6 NAK ZERO (Download Solicitation)

This feature allows the analyzer to solicit downloading of sample programs whenever it is capable of receiving them. This technique is usually performed by *Kermit* servers as a form of polling. However, the analyzer has no other server capabilities (that is, R packets, etc., are neither sent nor received by the analyzer).

If this feature is enabled, the analyzer will transmit an N packet, with SEQ field equal to 0, at 20-second intervals (60 seconds for the Imm. System) whenever sample programs can be accepted from the laboratory computer. The solicitation stops when either a download or upload session begins, and resumes one minute after the session terminates as long as the analyzer remains receptive to downloading.

Default Configuration: NO (that is, disabled).

5.5.7 Start-of-Packet Marker

You can specify the control character needed to begin each analyzer-transmitted packet. All valid entries are in the ASCII control character range. The analyzer will always expect the Control A character (01) as the start-of-packet marker in each laboratory computer transmitted packet.

The laboratory computer and analyzer are not required to use the same character for the start-of-packet marker, but each must be able to recognize the other's marker. The character specified must not be the same as that selected for the handshake character ([refer to Section 5.5.8](#)) or the EOL character exchanged at session initialization.

Decimal values in the range of 0 to 31 may be entered.

Default Configuration: 01 (Control A).

5.5.8 Handshake Character

This parameter allows you to specify a special character that will be appended to every packet the analyzer transmits. Some systems (for example, the IBM half-duplex system) require a special control character to trigger communications hardware/link level with line turnaround or with a special character indicating the end of the message. This character is not the same as the EOL field exchanged at session initialization. This handshake character, if other than 0, will be appended to each packet sent by the analyzer. It is not considered part of a packet and is not included in checksum calculations. It follows the specified EOL character.

If this character is other than zero (0), the analyzer will not transmit to the laboratory computer until the specified character is received (line turnaround use). No character transformation [that is, CTL() or CHAR()] is performed on this packet-trailer character.

Do not specify the XOFF (ASCII DC3) character for this parameter because it may cause communications hardware at the laboratory computer to inhibit subsequent transmission. The character specified must not be the same as that selected for the start of packet character ([refer to Section 5.5.8](#)) or the EOL character exchanged at session initialization.

Decimal values in the range of 0 to 31 may be entered. Zero (0) indicates that no handshake character is transmitted.

Default Configuration: 0 (that is, no handshake).

5.5.9 Checksum Method

The analyzer may be configured for either a one- or two-character checksum method. Unless the communications line is extremely noisy, the one-character method should be used because it is more efficient. The *Kermit Protocol* specifies that the station with the lesser capabilities prevails when establishing a session.

If the laboratory computer's session exchange parameter (CHKT) is one character and the analyzer has been configured for the two-character method, the laboratory computer will prevail (the one-character checksum method will be used for that session). This is useful because you can configure the analyzer for the two-character method and allow the laboratory computer to dynamically decide between the one- or two-character method based on its determination of line quality. (If the laboratory computer detects an inordinate number of checksum failures or if retransmissions occur frequently, it can automatically enable the two-character method during the session initialization packet exchange.)

The CHECK field of each packet, regardless of method, is encoded via the CHAR () function. The analyzer does not support the 3-character CCITT polynomial checksum method.

The one-character checksum method is used for all 'S' packets and the 'Y' packets that respond to them.

Values of 1 or 2 may be selected.

Default Configuration: One-character checksum.

One-Character Checksum Method

The arithmetic sum of all characters between but not including the MARK and CHECK field of a packet is contained in SUM. The value of the single-character CHECK field is obtained by:

$$\text{CHECK} = \text{CHAR}((\text{SUM} + ((\text{SUM AND C0})/40)) \text{ AND } 3F) \quad [\text{Hex Notation}]$$

or

$$\text{CHECK} = \text{CHAR}((\text{SUM} + ((\text{SUM AND } 192)/64)) \text{ AND } 63) \quad [\text{Decimal Notation}]$$

Two-Character Checksum Method

The arithmetic (16 bit) sum of all characters between but not including the MARK and CHECK is contained in SUM. The two CHECK field characters are obtained by:

$$\text{CHECK1} = \text{CHAR}((\text{SUM AND } 0FC0)/40) \quad [\text{Hex Notation}]$$

$$\text{CHECK2} = \text{CHAR}(\text{SUM AND } 003F)$$

or

$$\text{CHECK1} = \text{CHAR}((\text{SUM AND } 4032)/64) \quad [\text{Decimal Notation}]$$

$$\text{CHECK2} = \text{CHAR}(\text{SUM AND } 63)$$

Example of One-Character Checksum

If the packet is $S_h \# Y A_r^c$:

$$\text{SUM} = 35d + 35d + 89d = 159d$$

$$\text{SUM AND } 192d = 10011111$$

$$\begin{array}{r} 11000000 \\ \hline 10000000 = 128d \end{array}$$

$$(\text{SUM AND } 192d)/64d = 2d$$

$$(\text{SUM} + 2d) = 161d$$

$$161d \text{ AND } 63d = 10100001$$

$$\begin{array}{r} 111111 \\ \hline 100001 = 33d \end{array}$$

$$\text{CHAR}(33) = 33d + 32d = 65d = A \text{ ASCII}$$

Note: The CHAR() function adds 32 decimals to the value to assure that the checksum is transmitted as a printable ASCII character.

Figure 5-2. Example of One-Character Checksum.

5.6 Communication Protocol

5.6.1 Bidirectional Protocol

The bidirectional protocol is similar to other popular “layered” protocols in that it employs packets of various types to control the link and to exchange information. The package structure supports layering of functionality, as shown in figure 5-3. It exhibits major differences from other layered protocols, however, in that it employs serial start/stop asynchronous ASCII character encoding, is half-duplex by definition, and requires no special frame-structure devices or sophisticated packet routing methods (point-to-point only).

The protocol is “session” oriented in one direction at a time. This means that a session in one direction (for example, download) must be completed before a session in the other direction is initiated (up loading). Once a session is established in a given direction, neither station should begin a session in the opposite direction until the first is completed. The analyzer will initiate upload sessions only when not in a downloading session, and vice versa.

When the laboratory computer attempts a download session and the analyzer starts an upload session, the download is given priority.

The bidirectional protocol can be used for up loading of results even if the laboratory computer is unable to download sample programs.

5.6.2 Kermit Protocol

The full implementation of *Kermit* Protocol is not required for the analyzer application.

5.6.3 Session Establishment

A session consists of the transfer of one or more files from one station to another. The analyzer may send results (an upload session), or the laboratory computer may send sample programs (a download session). The data field of an S packet (or responding Y packet) contains pertinent station characteristics. A station's capabilities/limitations can, therefore, be accommodated on a session-by-session basis.

A session is considered to be established successfully when the initiating station sends an S packet and receives a proper Y packet in return.

When the analyzer is the initiator of the session to the laboratory computer (that is, up loading), it will wait for the responding Y packet for 13 seconds before retransmitting the S packet. The Chemistry Systems will continue to retransmit the S packet at 13-second intervals and the Immunodiagnostic System at 12-second intervals until they receive a proper response. After the start of a session, a packet can be retransmitted a total of 3 times the value configured in the Packet Retry Limit before giving up on the session in progress. This will result in a Laboratory Computer Communications error. The session will be restarted.

If the laboratory computer is the initiator of a session to the analyzer (that is, downloading), the analyzer will respond immediately to the S packet unless it is off-line (for example, in a no communications mode, in Standby Mode, or powered off). The laboratory computer should implement logic to handle the situation when no response is made to its S packet (as the analyzer does when it is the initiator) and initiate proper retransmission procedures.

If the session cannot be established, and the reason is not described above, it is considered to be a fatal error and indicative of a mismatch in baud rate settings, parity method, cable problems, stop bit setting, or other discrepancy.

5.6.4 Session Continuation

Once a session has been established, files may be transferred between stations in the established direction. Should more than one file (that is, a result file or downloaded file) be available for transmission, the session may be extended for as long as necessary. Session extension is encouraged, as it improves link efficiency through elimination of the session initialization packets. An example of the packet sequence for a continued session is provided in [figure 5-5](#). Sessions are mutually exclusive; that is, extending download sessions prevents the analyzer from up loading results, and vice versa.

5.6.5 Session Establishment Failure

When the laboratory computer is down loading or in another non-uploading mode, it cannot receive results files from the analyzer. The laboratory computer should respond with an E (error) packet with a data field whose first four characters are 0000 when it cannot receive results. Additional characters may accompany the 0000 and will be displayed on the analyzer's troubleshooting Help screen.

The total data field of the E packet should not exceed 29 characters (including the 0000 code). The receipt of the E packet would be interpreted by the analyzer as a busy condition at the laboratory computer and cause the analyzer to attempt the session again after 13 seconds. When this E packet is received, the limitation on number of retransmissions of the S packet is ignored. The analyzer will continue to attempt to establish a session indefinitely as long as this response is received. Any response other than described here, or the normal Y packet, will cause the analyzer to cancel the attempted session.

When the laboratory computer attempts a download session with the S packet, and the analyzer is in a busy condition, the analyzer will respond with an E packet containing the 0000 data field code. This code indicates that the condition is temporary and that the laboratory computer should attempt the session again after a minute or longer has elapsed. Data field codes other than 0000 are possible from the analyzer and indicate that operator intervention is necessary before down loading can occur ([refer to Section 5.7.6](#)).

5.6.6 Session Termination

Normal Termination. A session is normally terminated by the transmission of a B packet from the session initiator (file source) to the session responder (file receiver). The B packet should then be acknowledged by the receiving station.

Abnormal Termination (Cancel). If a problem is encountered during a session (e.g., protocol violations), the detecting station should cancel the session by transmitting an E packet with a data field to indicate the nature of the problem.

A similar procedure must be implemented in the laboratory computer. [Refer to Section 5.7.6](#) for additional information.

5.6.7 Session Contention

If the analyzer and the laboratory computer initiate a session at the same time (with simultaneous S packet transmission), the analyzer will cancel its session attempt and respond to the laboratory computer's download request. This will occur when the analyzer decodes an S packet while waiting for a response to its own S packet. The receipt of an S packet at any time in an established session will be considered to be a fatal error by the analyzer and will cause the current session to be canceled.

5.6.8 Supported Packet Types

The analyzer sends, and is capable of responding to, all of the following packets required by the *Kermit* protocol:

- D Data packet
- Y Acknowledgment packet (positive)
- N Acknowledgment packet (negative)

- S Send initiate packet (session start, exchange parameters)
- B Break transmission packet (EOT—end session)
- F File header packet
- Z End of file packet (EOF)
- E Error packet (session cancel)

Packet Structure	Basic Packet Structure								
Packet	MARK (Start char)	LEN (Packet length)	SEQ (Sequence number)	TYPE (Packet type)	DATA (Optional data)	CHECK (Check char[s])	PACKET TERMINATOR (Required by analyzer; optional for laboratory computer)	HANDSHAKE CHARACTER (Optional for analyzer and laboratory computer)	
Packet			-----Applications-----		-----Related-----				
Functionality			-----Session Control-----		-----Data Link Control-----				

Figure 5-3. Packet Structure and Functionality.

5.6.9 Packet Field Encoding

Some of the packet fields are encoded via the CHAR() function (which adds 32 decimal to the value to assure it is transmitted as a printable ASCII character). Section 6.0 of the *Kermit* Protocol Manual describes the encoding technique for the packet fields. The following illustrates the encoding:

- MARK Sent as is, **not** encoded via CHAR() or CTL() functions
- LEN Encoded via CHAR() function
- SEQ Encoded via CHAR() function
- TYPE Sent as is (that is, already is a printable ASCII character)
- DATA Sent as is except for control characters that are prefixed and not classified by the CTL() function

CHECK Encoded via the CHAR() function

Note: The packet terminator is not considered to be part of the packet and is sent without any encoding.

5.6.10 S/Y Session Start Packet Parameter Description

The parameters within an S-Packet provide a method for the laboratory computer to limit analyzer, specify how long the analyzer is to wait for laboratory computer packets, cause the analyzer to terminate each packet with a laboratory computer-specified character, cause the analyzer to preface each of its packets with a specified number of the pad character the laboratory computer may need, and to use the checksum method specified by the laboratory computer. The analyzer uses

MAXL	This parameter indicates the maximum packet length than can be received by the receiving device. The analyzer will always be capable of receiving the maximum packet size (96 decimal). Therefore, it sets MAXL to 94 decimal which, when CHAR() encoded, is represented by the tilde (~) character (7E hex). (The MAXL and LEN do not include the MARK or LEN characters in their counts.) The analyzer will honor the laboratory computer's buffering ability and limit the size of its transmit packets to the size indicated by the laboratory computer. The <i>Kermit</i> default value for this field is 80, which results in 82-byte packets, and is indicated by a "space" (20 hex) in this field. If the laboratory computer requires the analyzer to send smaller-than-default-size packets, then, using the CHAR() encoding function, this field should contain a value of two less than the maximum packet size the analyzer should transmit.	Therefore, this field is zero. But they will honor any laboratory computer needs specified in this and the PADC field. This field is CHAR() encoded and will be transmitted as an ASCII space character by the analyzer.
PADC	Since the analyzer has no need for pad characters to precede incoming packets, this field should be ignored from the analyzer. If the laboratory computer requires pad characters, this field should contain the pad character to be used. This field is CTL() encoded (that is, 40 hex is exclusively ORed to it instead of 20 hex added to it, as in the CHAR() function).	
EOL	The analyzer will always have a CR (carriage return) value in this field. If the laboratory computer requires a special character to terminate incoming packets, it should specify it in this field (field is CHAR() encoded). The analyzer encode this field as an ASCII character. This value is not the same as the handshake character described in Section 5.5.8.	
QCTL	The analyzer always uses the # character to quote control characters in the data stream (currently none are expected in the data). The laboratory computer must convey the character it will use for this purpose; the character is sent literally and is not encoded. The quote character itself must be quoted in the data stream; that is, if a # character is found in the data, it must be preceded by a # character in the packet.	
QBIN	This field is used to specify the special character that will be used to quote binary data. The analyzer does not send or receive binary data, so this field is always set to ASCII N. For Katakana and European languages the recommended prefix "&" is used.	
CHKT	The analyzer will use the value configured for checksum method (see Section 5.5.9) for this field. The station with the lesser capability prevails as far as the type of checksum technique used; that is, if the analyzer is configured for the two-character checksum technique, and the laboratory computer specifies a 1 in this field, then the one-character method will be used for that session. This character is sent literally. The analyzer will send either an ASCII 1 or 2 (that is, 31 or 32 hex) depending on the configuration.	
TIME	The analyzer will use the configured Analyzer Response Timeout value for this field (refer to Section 5.5.4). The laboratory computer should use this field to instruct the analyzer how long to wait for a laboratory computer packet when the analyzer is expecting a packet, before retransmitting. This field is encoded via the CHAR() function.	
	<i>The default is 25 seconds.</i>	
	Example: 5 seconds would be encoded as the % ASCII character.	
	The ASCII space character (20 hex) indicates that no timer value has been configured in the analyzer:	
	20 hex – 20 hex = 0	
NPAD	The analyzer has no pad character requirements.	

5.6.11 Packet Exchange

In figure 5-4 through figure 5-21 of this section we illustrate the sequence of packet exchanges for many uploading and downloading conditions. Included is an example of session contention.

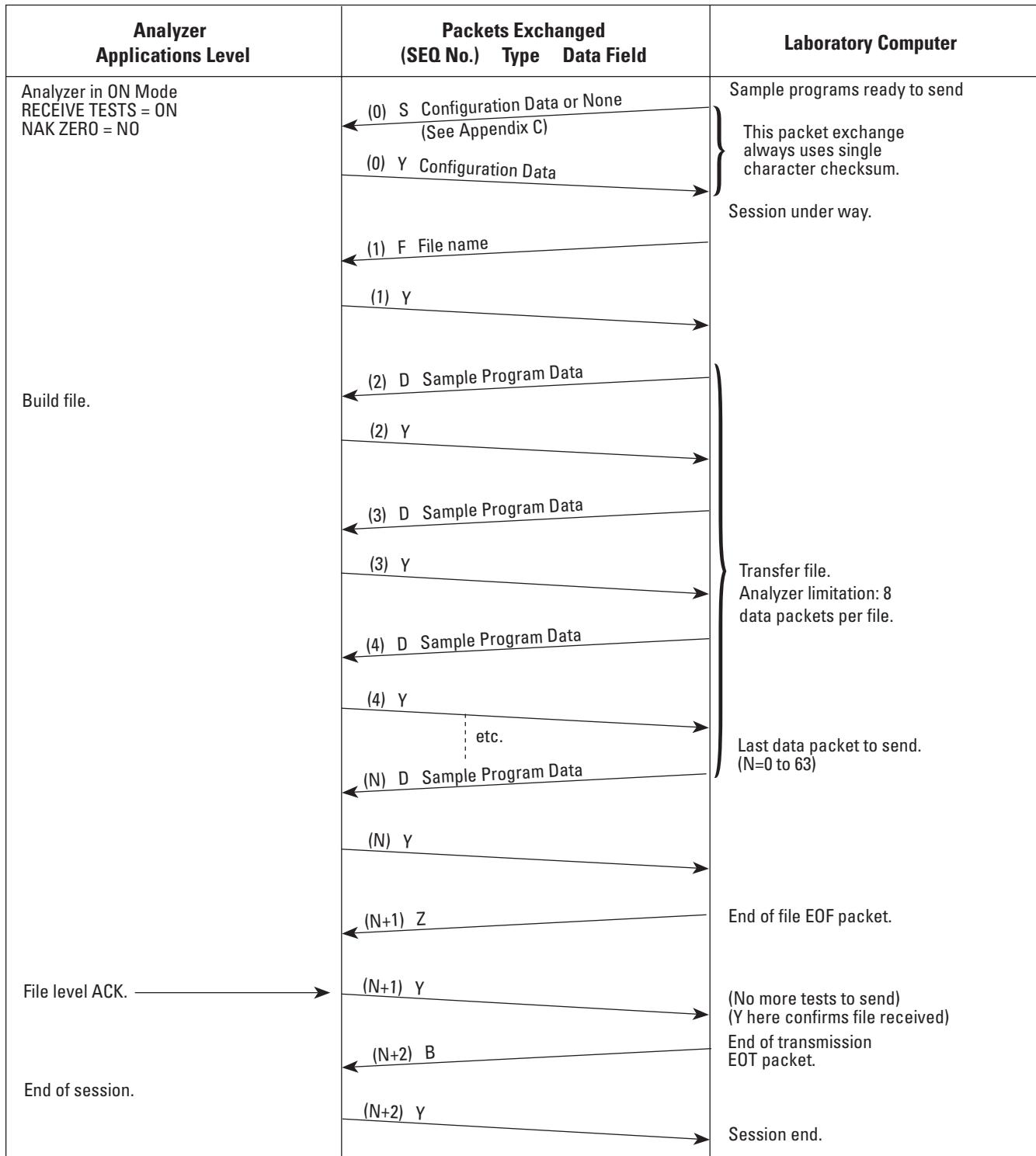


Figure 5-4. Packet Exchange for Normal Download of Sample Programs (One File).

Analyzer Applications Level	Packets Exchanged (SEQ No.) Type Data Field	Laboratory Computer
Analyzer in ON Mode RECEIVE TESTS = ON NAK ZERO = NO	(0) S Configuration Data or None (0) Y Configuration Data	1st sample file ready to send.
Build 1st file.	(1) F 1st File Name (1) Y	Session under way.
	(2) D 1st File Data (2) Y	
	etc. (N) D Last Data of 1st File Data (N) Y	End of 1st file.
Process 1st file.	(N+1) Z (N+1) Y	EOF packet.
	(N+2) F 2nd File Name (N+2) Y	Confirmed delivery. 2nd file start.
Build 2nd file.	(N+3) D 2nd File Data (N+3) D	Analyzer receptive.
	(N+4) D 2nd file Data (N+4) Y	
	etc. (X) D 2nd File Data (X) Y	X = Subsequent SEQ No. (Modulo 64).
	(X+1) D Last Data in 2nd File (X+1) Y	
	(X+2) Z (X+2) Y	EOF Packet.
Process 2nd file.	(X+3) F 3rd File Name (X+3) Y	2nd file delivery confirmed.
	(X+3) D 3rd File Data (X+3) Y	Analyzer still receptive.
Build 3rd file.	Z.	Analyzer Limitation 8 data packets per file.

Figure 5-5. Packet Exchange for Normal Download of Sample Programs (Multiple Files).

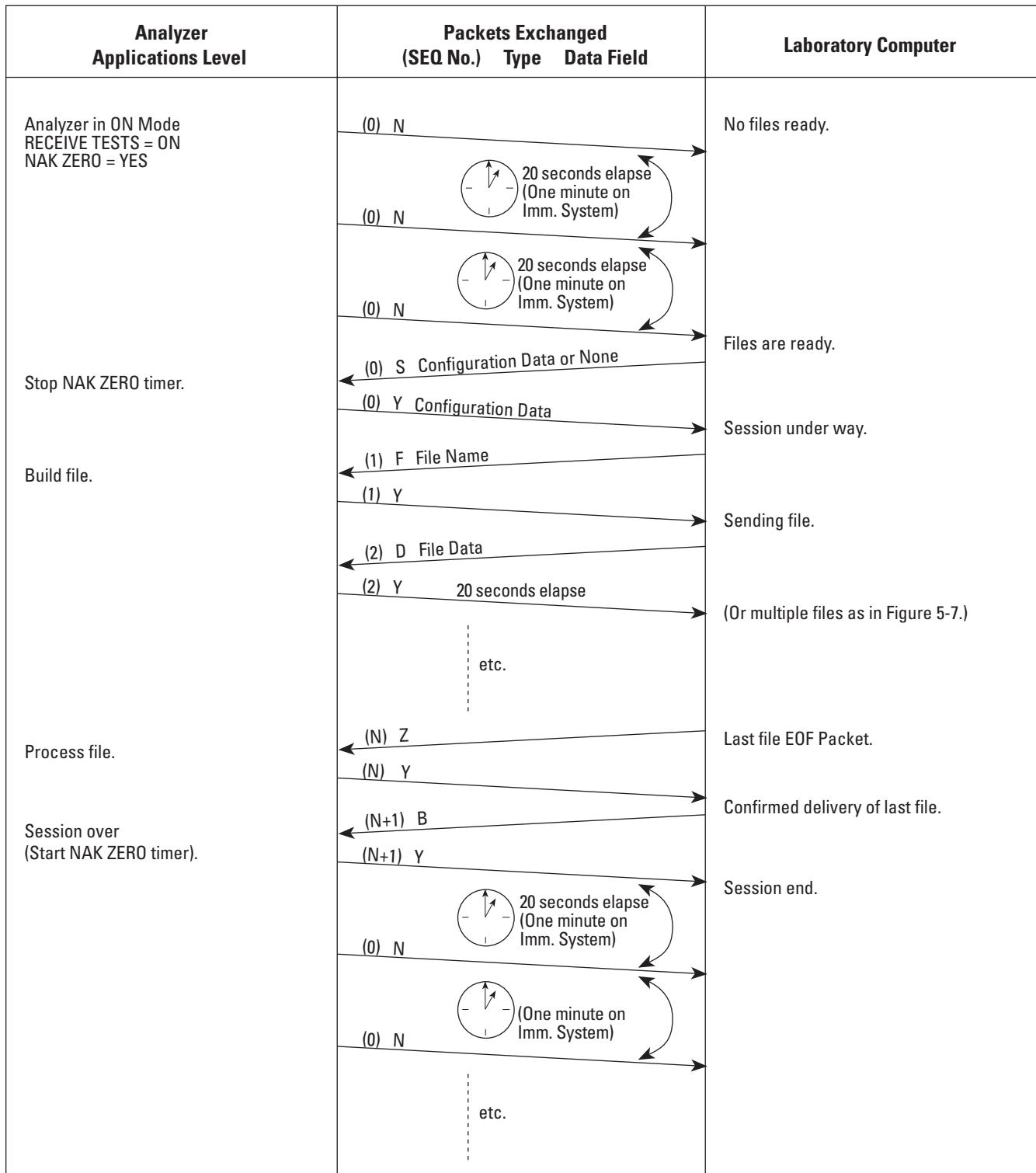


Figure 5-6. Packet Exchange for Normal Download of Sample Programs (NAK ZERO Operation).

Analyzer Applications Level	Packets Exchanged (SEQ No.) Type Data Field	Laboratory Computer
Analyzer in ON Mode RECEIVE TESTS = OFF	(0) S Configuration Data or None (0) E 0002 RECEIVER DISABLED	Operator must turn RECEIVE TESTS = ON Sample programs ready to send. Download is disabled (session not started).
Analyzer in ON Mode RECEIVE TEST = ON Receiver is "busy."	(0) S Configuration Data or None (0) E 0000 RECEIVER BUSY	(Temporary Condition) Analyzer is "busy" or "full" (session not started).
Analyzer in STANDBY Mode (RS-232) DTR = OFF	(0) S Configuration Data or None	No response. (Analyzer is offline; operator must turn analyzer on).
(Session Ongoing) Operator selects OPTIONS CONFIGURATION Mode. (Screens OP22A thru OP22N) (Download function ordered to disable at next file boundary.)	(Session Ongoing) (N) D File Data (N) Y (N+1) D File Data (N+1) Y (N+2) D File Data (N+2) Y (N+3) Z (N+3) Y (N+4) F File Name (N+4) E 0002 RECEIVER DISABLED	(Sending File To Analyzer) Last data packet to send. EOF Packet. Downloading Disabled.
(Session Ongoing) Operator selects OPTIONS CONFIGURATION Mode (as above). Download function ordered disabled (as above). Current file continuing. Operator returns (exits) Options (before file boundary reached). DTR signal set off. New configuration applied (DTR back on unless in NO COMMUN Mode).	(Session Ongoing) (N) D File Data (N) Y (N+1) D File Data (N+1) Y (N+2) D File Data (N+2) Y (N+3) D File Data (N+3) E 0001 OPERATOR RESET	(Sending file To Analyzer) Operator Reset.

Figure 5-7. Packet Exchange for Download of Sample Programs (Downloading-Inhibited Situations).

Analyzer Applications Level	Packets Exchanged (SEQ No.) Type Data Field	Laboratory Computer
(Building file, ongoing session) Analyzer in ON Mode RECEIVE TESTS = ON NAK ZERO = NO or YES	(Ongoing Session) (60) D File Data (60) Y (61) D File Data (61) Y (62) Z (62) Y (63) F File Name (63) Y (0) D File Data (0) Y (1) D File Data (1) Y (N) Z etc. (N) Y (N+1) F File Name (N+1) E 0000 RECEIVER BUSY (0) N Indefinite time period	(Sending File) Last data packet to send. EOF Packet. Next file ready. Analyzer still receptive (note SEQ No. rollover). Sending next file. EOF Packet. Confirmed delivery. Next file ready. Analyzer "busy" or "full" (implied temporary condition).
Process file. (Analyzer getting full; room for one more maximum size file.)		
Building next file. Processing last one.		
Process file. (Disk capacity reached)		
NOTE: If NAK ZERO = YES analyzer will solicit downloading again when no longer "busy" or "full."		
(Same initial conditions as above)	(On going Session) (5) D File Data (5) Y (6) D File Data (6) Y (7) D File Data (7) Y (8) Z (8) Y (9) F File Name (9) E 0002 RECEIVER DISABLED	(Sending File) Download disabled.
Operator selects screen OP04C. (RECEIVE TESTS = OFF)		
Current file transfer allowed to continue until complete.		
(File boundary)		
Operator selection takes effect.		

Figure 5-8. Packet Exchange for Download of Sample Programs (Downloading-Inhibited Situations).

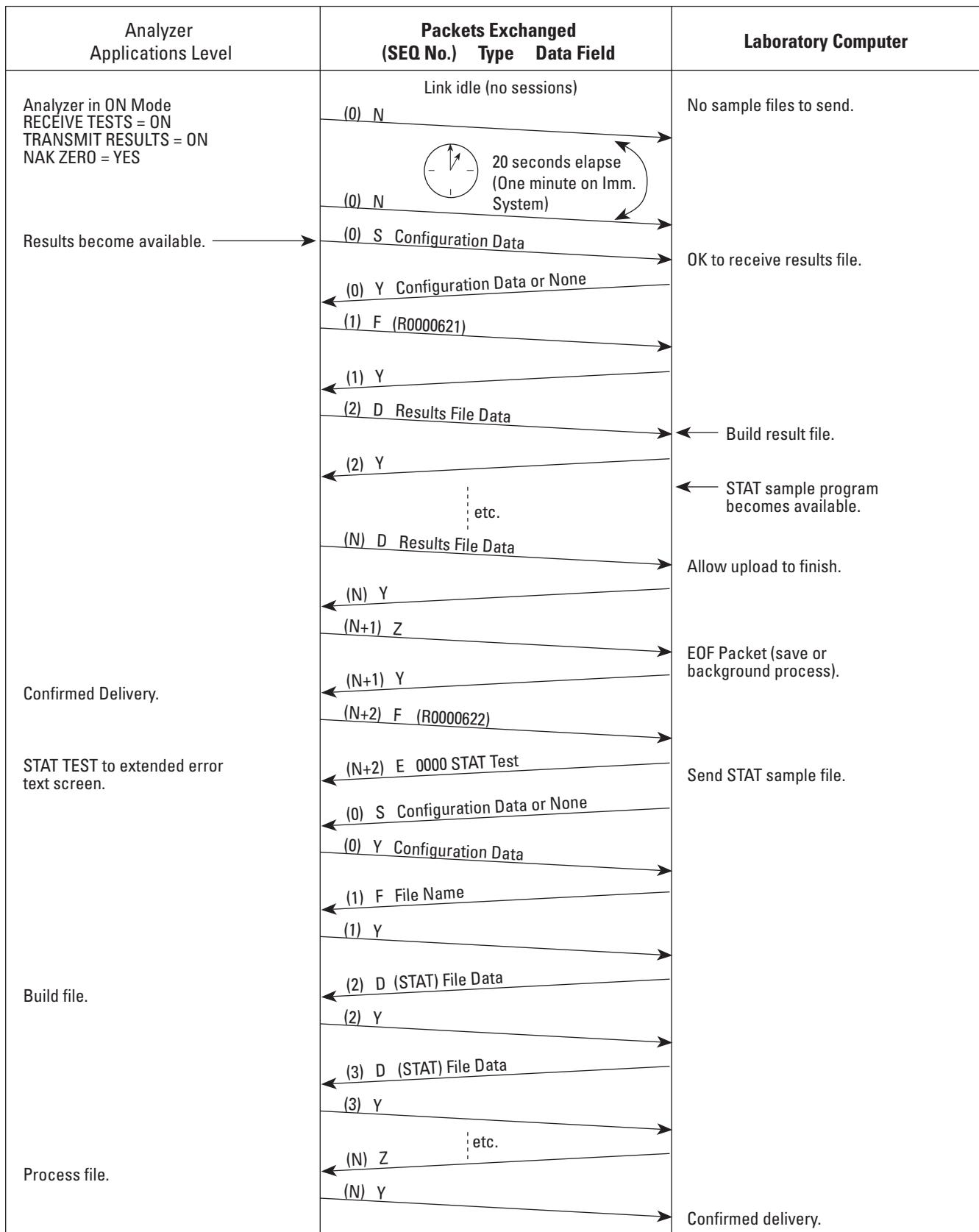


Figure 5-9. Packet Exchange for Upload of Test Results and Download of Sample Programs (NAK Zero and Upload Interaction).

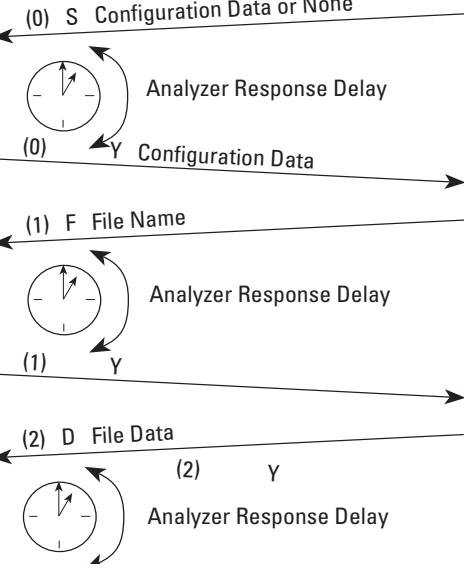
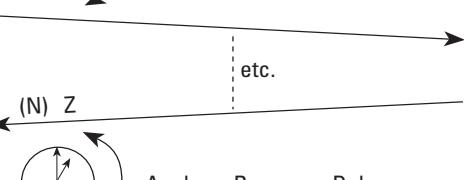
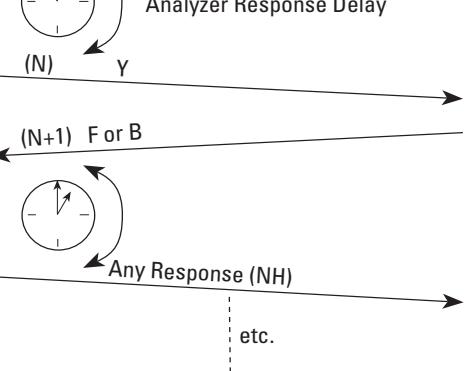
Analyzer Applications Level	Packets Exchanged (SEQ No.) Type Data Field	Laboratory Computer
Analyzer in ON Mode RECEIVE TESTS = ON TRANSMIT RESULTS = ON Not "busy" or "full"	 <p>(0) S Configuration Data or None</p> <p>(0) Configuration Data</p> <p>(1) F File Name</p> <p>(1) Y</p> <p>(2) D File Data</p> <p>(2) Y</p>	Sample file ready to send.
Build file.	 <p>etc.</p>	
Process file.	 <p>(N) Z</p> <p>(N) Y</p> <p>(N+1) For B</p> <p>Any Response (NH)</p> <p>etc.</p>	Confirmed delivery.

Figure 5-10. Packet Exchange for Upload of Test Results and Download of Sample Programs (Effect of Analyzer Response Delay on Downloading).

Analyzer Applications Level	Packets Exchanged (SEQ No.) Type Data Field	Laboratory Computer
Analyzer in ON Mode TRANSMIT RESULTS = ON RECEIVE TESTS = ON or OFF	NOTE: After power is turned ON analyzer starts with oldest result file. The same procedure is used if analyzer goes from ON to STANDBY and back to ON.	
	(0) S Configuration Data	
Session established.	(0) Y Configuration Data or None (Defaults)	Analyzer requests upload session start.
	(1) F (R0000476)	
Send file.	(1) Y	
	(2) D File Data	Build result file from D packet data.
NOTE: Packet size for D data packets is determined by received configuration data MAXL or is default 96 if no configuration data received. Packet size determined for each session.	(2) Y	
	(3) D File Data	
	(3) Y	
	(4) D File Data	
	(4) Y	
	(N) D File Data	etc.
	(N) Y	
	(N+1) Z	EOF Packet.
Confirmation that laboratory computer received file. Analyzer stores data.	(N+) Y	← Confirm file received Process file.
	(N+2) B	EOT Packet.
Link idle.	(N+2) Y	Link now idle.

Figure 5-11. Packet Exchange for Normal Upload of Test Results (One File).

Analyzer Applications Level	Packets Exchanged (SEQ No.) Type Data Field	Laboratory Computer
Analyzer in ON Mode TRANSMIT RESULTS = ON RECEIVE TESTS = ON or OFF Multiple results ready to send.	(0) S Configuration Data	Receptive to upload.
Session established.	(0) Y Configuration Data or None (Defaults)	
Sequential file name.	(1) F (R0000098)	
	(1) Y	
	(2) D File Data	Build result file.
Send result file.	(2) Y	
	(3) D File Data	
	(3) Y	
	(N) D File Data	
	(N) Y	
	(N+1) Z	
Delivery confirmed.	(N+1) Y	EOF Packet.
Send next result file.	(N+2) F (R0000099)	Another file being sent.
	(N+2) Y	
	(N+3) D File Data	Build next result (1st file can also be processed).
	(N+3) Y	
	(N+4) D File Data	
	(N+4) Y	
	(X) D File Data	
	(X) Y	
	(X+1) Z	
Delivery confirmed.	(X+1) Y	EOF Packet.
Send next result file.	(X+2) F (R00000100)	Another file coming.
	(X+2) Y	
	(X+3) D File Data	Build next result file.
	etc.	

Figure 5-12. Packet Exchange for Normal Upload of Test Results (Multiple File).

Analyzer Applications Level	Packets Exchanged (SEQ No.) Type Data Field	Laboratory Computer
<p>Analyzer in ON Mode TRANSMIT RESULTS = ON</p> <p>Results are ready. Start link level response timer: duration = 13 seconds (within a session, will retry for 3 times the packet retry limit) before giving up in error.</p> <p>After response received, use configuration data to wait for laboratory computer packets when expected.</p>	<pre> sequenceDiagram participant Analyzer participant LabComputer Analyzer->>LabComputer: (0) S Configuration Data Note over Analyzer: duration = 13 seconds (within a session, will retry for 3 times the packet retry limit) before giving up in error. Note over Analyzer: After response received, use configuration data to wait for laboratory computer packets when expected. LabComputer->>Analyzer: (0) Y Configuration Data or None Analyzer->>LabComputer: (1) F (R0000823) Note over Analyzer: the TIME element in the received Use received configuration data timer for response timer (if other than 0) LabComputer->>Analyzer: (1) Y </pre>	<p>NOTE: Use analyzer response timer included in "configuration data" when timing expected analyzer packets.</p> <p>NOTE: If "None", analyzer uses "Defaults" (TIME = Wait Forever).</p> <p>Analyzer uses "time" sent by laboratory computer (in configuration data) for remainder of session. If time = 0, analyzer will wait forever.</p>

■ **Figure 5-13. Packet Exchange for Upload of Test Results (Effect and Use of Analyzer Response Timer at Session Establishment and During Session).**

Analyzer Applications Level	Packets Exchanged (SEQ No.) Type Data Field	Laboratory Computer
<p>Analyzer in ON Mode RECEIVE TESTS = ON TRANSMIT RESULTS = ON</p> <p>Results become ready.</p> <p>Analyzer uses fixed 15-second time-out.</p> <p>Analyzer will retry continuously.</p> <p>Return result to applications and (12 seconds).</p> <p>This could be same or different result file.</p> <p>The timeout error will report in this fashion as long as DSR = ON, until operator sets TRANSMIT RESULTS = OFF, or until a session starts (upload or download).</p>	<pre> sequenceDiagram participant Analyzer participant LabComputer Analyzer->>LabComputer: (0) S Configuration Data LabComputer-->>Analyzer: ACK activate Analyzer 15 seconds elapse Analyzer->>LabComputer: (0) S Configuration Data LabComputer-->>Analyzer: ACK activate Analyzer 15 seconds elapse Analyzer->>LabComputer: (0) S Configuration Data LabComputer-->>Analyzer: ACK activate Analyzer Analyzer->>LabComputer: report timeout error etc. deactivate Analyzer deactivate Analyzer deactivate Analyzer activate Analyzer Analyzer->>LabComputer: (0) S Configuration Data LabComputer-->>Analyzer: ACK activate Analyzer 15 seconds elapse Analyzer->>LabComputer: (0) S Configuration Data LabComputer-->>Analyzer: ACK deactivate Analyzer deactivate Analyzer deactivate Analyzer </pre>	<p>Laboratory system is online (that is, asserting analyzer DSR ON) but does not respond.</p> <p>Laboratory computer does not respond.</p>

Figure 5-14. Packet Exchange for Upload of Test Results (Initial Connection Behavior if Link Up But No Response).

Analyzer Applications Level	Packets Exchanged (SEQ No.) Type Data Field	Laboratory Computer
Analyzer in ON Mode RECEIVE TESTS = ON NAK ZERO = NO Build file.	<p>(0) S Configuration Data or None</p> <p>(0) Y Configuration Data</p> <p>(1) F File Name</p> <p>(1) Y</p> <p>(2) D File Data</p> <p>etc.</p> <p>(N) D File Data</p> <p>(N) E 0003 MESSAGE TOO LARGE</p>	<p>send is too large.</p> <p>Session under way.</p>
Analyzer detects that file is too large.		Session cancels.
Analyzer in ON Mode RECEIVE TESTS = ON NAK ZERO = NO Build file.	<p>(0) S Configuration Data or None</p> <p>(0) Y Configuration Data</p> <p>(1) F File Name</p> <p>(1) Y Sample program and file ready to</p> <p>(2) D File Data</p> <p>(2) Y</p> <p>(4) D File Data</p>	<p>File ready to send.</p> <p>Session under way.</p>
Discard partial file.	(4) E 0008 INVALID SEQUENCE USE	Erroneous SEQ field. Session cancels.
(Building file) Discard partial file.	<p>(Session Ongoing)</p> <p>(N) D (Bad LEN Field)</p> <p>(N) E 0006 INVALID LENGTH FIELD</p>	<p>(Session Ongoing)</p> <p>Packet has LEN field <3 or >94.</p> <p>Session cancels.</p>
(Building file) Discard partial file.	<p>(Session Ongoing)</p> <p>(N) D File Data</p> <p>(N) Y</p> <p>(N+1) F (or S, Y, N, etc.)</p> <p>(X+3) E 0005 INVALID PACKET USAGE</p>	<p>(Sending File)</p> <p>Valid packet but wrong place.</p> <p>Session cancels. (Need not acknowledge E packets)</p>

Figure 5-15. Packet Exchange for Upload of Test Results (Error Situations).

Analyzer Applications Level	Packets Exchanged (SEQ No.) Type Data Field	Laboratory Computer
<p>Analyzer in ON Mode TRANSMIT RESULTS = ON RECEIVE TESTS = ON or OFF (Multiple results ready)</p> <p>Last data packet to send.</p> <p>EOF Packet</p> <p>Confirmed delivery send next file.</p> <p>(Session over) (DSR sensed OFF) — (Uploading not inhibited) No further attempts performed until DSR sensed ON.</p> <p>IF RECEIVE TESTS = ON and analyzer not "full" or "busy" when laboratory computer send packet immediately.</p> <p>(DSR sensed ON) — (Upload informed that line is back up) Result file could be same or different from previous.</p> <p>NOTE: No correlation between file name and results file content. File name is unique for each uploaded result to allow unique disk file name.</p>	<p>(Ongoing Upload Session)</p> <p>(42) D Data File (R0000545)</p> <p>(42) Y</p> <p>(43) D Data File</p> <p>(43) Y</p> <p>(44) Z</p> <p>(44) Y</p> <p>(45) F (R0000546) comes online (DSR = ON), the analyzer will</p> <p>(45) E 0000</p> <p>No errors generated since line dropped between sessions.</p> <p>(0) S Configuration Data Could be 0 to 12 seconds</p> <p>(0) Y Configuration Data or None (Defaults)</p> <p>(1) F (R0000546)</p>	<p>Receiving test file.</p> <p>EOF Packet received Process or save file.</p> <p>Laboratory computer wants to go offline; sends the "busy" code (session now over); operator must turn DSR = OFF.</p> <p>Laboratory computer causes analyzer DSR to go ON.</p>

Figure 5-16. Packet Exchange for Upload of Test Results (Line Drop Situation).

Analyzer Applications Level	Packets Exchanged (SEQ No.) Type Data Field	Laboratory Computer
Analyzer in ON Mode RECEIVE TESTS = ON TRANSMIT RESULTS = ON <p style="text-align: right;">DSR sensed OFF; report error to operator. No further attempts to communicate until DSR sensed ON. Only 1 error sent to operator. NOTE: The entire file being transferred must be retransmitted.</p>	<p>(Ongoing Upload Session)</p> <p>(14) D Data File → ← (14) Y</p> <p>(15) D Data File → ← (15) Y</p> <p>(16) D Data File → ← (16) Y</p> <p>(17) D Data File → Analyzer will wait indefinitely for line to come back up.</p>	Receiving file. Laboratory computer inadvertently turned off or cable disconnected. Discard incomplete file transfer.

Figure 5-17. Packet Exchange for Upload of Test Results (Error Line—Drop Situations).

Analyzer Applications Level	Packets Exchanged (SEQ No.) Type Data Field	Laboratory Computer
<p>Analyzer in ON Mode RECEIVE TESTS = ON TRANSMIT RESULTS = ON</p> <p>Send result file.</p>	<p>If analyzer response delay is other than 0, it affects all analyzer packet transmissions where a packet has been received by the analyzer prior to the transmission.</p> <pre> sequenceDiagram participant Analyzer participant Lab Analyzer->>Lab: (0) S Configuration Data Note over Analyzer: Analyzer Response Delay Lab-->>Analyzer: (1) Y Configuration Data or None Analyzer->>Lab: (1) F (R0000627) Note over Analyzer: Analyzer Response Delay Lab-->>Analyzer: (1) Y Analyzer->>Lab: (2) D etc. (every packet is Data File) Note over Analyzer: Analyzer Response Delay Lab-->>Analyzer: (2) Y Analyzer->>Lab: (N) Z Note over Analyzer: (N) Z affected Lab-->>Analyzer: (N) Y Note over Analyzer: Analyzer Response Delay Analyzer->>Lab: (N+1) F R00628 or B Note over Analyzer: etc. </pre> <p>Analyzer response delay is provided for laboratory systems needing a large time delay between transmit and ability-to-receive.</p>	<p>Receive results file.</p>

Figure 5-18. Packet Exchange for Upload of Test Results (Effect of Analyzer Response Delay on Uploading).

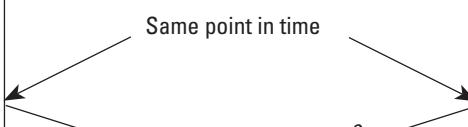
Analyzer Applications Level	Packets Exchanged (SEQ No.) Type Data Field	Laboratory Computer
Analyzer in ON Mode RECEIVE TESTS = ON TRANSMIT RESULTS = ON Results are available.	Same point in time 	Sample tests available. (Note: In <i>Kermit</i> session contention, precedence is given in this order: 1.) LIS 2.) Analyzer
Analyzer is not "busy" or "full."	(0) S Configuration (0) Y Configuration Data (1) F File Name (1) Y (2) D Data File (2) Y etc.	Send download file.
Analyzer gets "full" and has results to send.	(N) Z (N) Y (N+1) F File Name (N+1) E 0000 RECEIVER BUSY (0) S Configuration Data (0) Y Configuration Data or None (1) F (R0000081) (1) Y (1) D Data file etc.	EOF Packet. Confirmed delivery. Analyzer is "busy." Analyzer wants to upload.

Figure 5-19. Packet Exchange for Upload of Test Results and Download of Sample Programs (Session Contention).

Analyzer Applications Level	Packets Exchanged (SEQ No.) Type Data Field	Laboratory Computer
Analyzer in ON Mode RECEIVE TESTS = ON TRANSMIT RESULTS = ON	(Ongoing Upload Session)	
Start timer*. →	→ (60) D Data File	(No timer used at lab computer) Analyzer response timeout configured at 0, but analyzer received non-0 time in configuration data at session start.
Stop timer. ←	← (60) Y	
Start timer*. →	→ (61) D Data File	Packet not received.
Timer expires Start timer*. →	→ (61) D Data File	Packet received.
Packet not received. 	← (61) Y	
Timer expires. →	→ (61) D Data File	Packet received.
Packet received. 	← (61) Y → (62) D Data File	
(Retry count incremented with each retransmit)	(Ongoing Download Session)	
Start timer*. →	→ (8) D Data File → (8) Y	Sending download file.
Packet not received. 	← (9) D	Packet garbled.
Timer expires. →	→ (9) N or (8) Y	Resend if (9) N or (8) Y.
Packet received Start timer*. →	← (9) D → (9) Y	
	(Ongoing Upload) Checksum Error → (42) D	
Checksum error; don't wait for timeout. →	→ (42) Y (Bad Checksum) → (42) D → (42) Y	
	(Ongoing Upload) Checksum Error → (16) D Data File (Bad Checksum)	
Checksum error; NAK immediately.	→ (16) N	NAK Packet.

* Timer starts after the last character is transmitted.

Figure 5-20. Packet Exchange for Upload of Test Results and Download of Sample Programs (Use of Checksum and Analyzer Response Timeout).

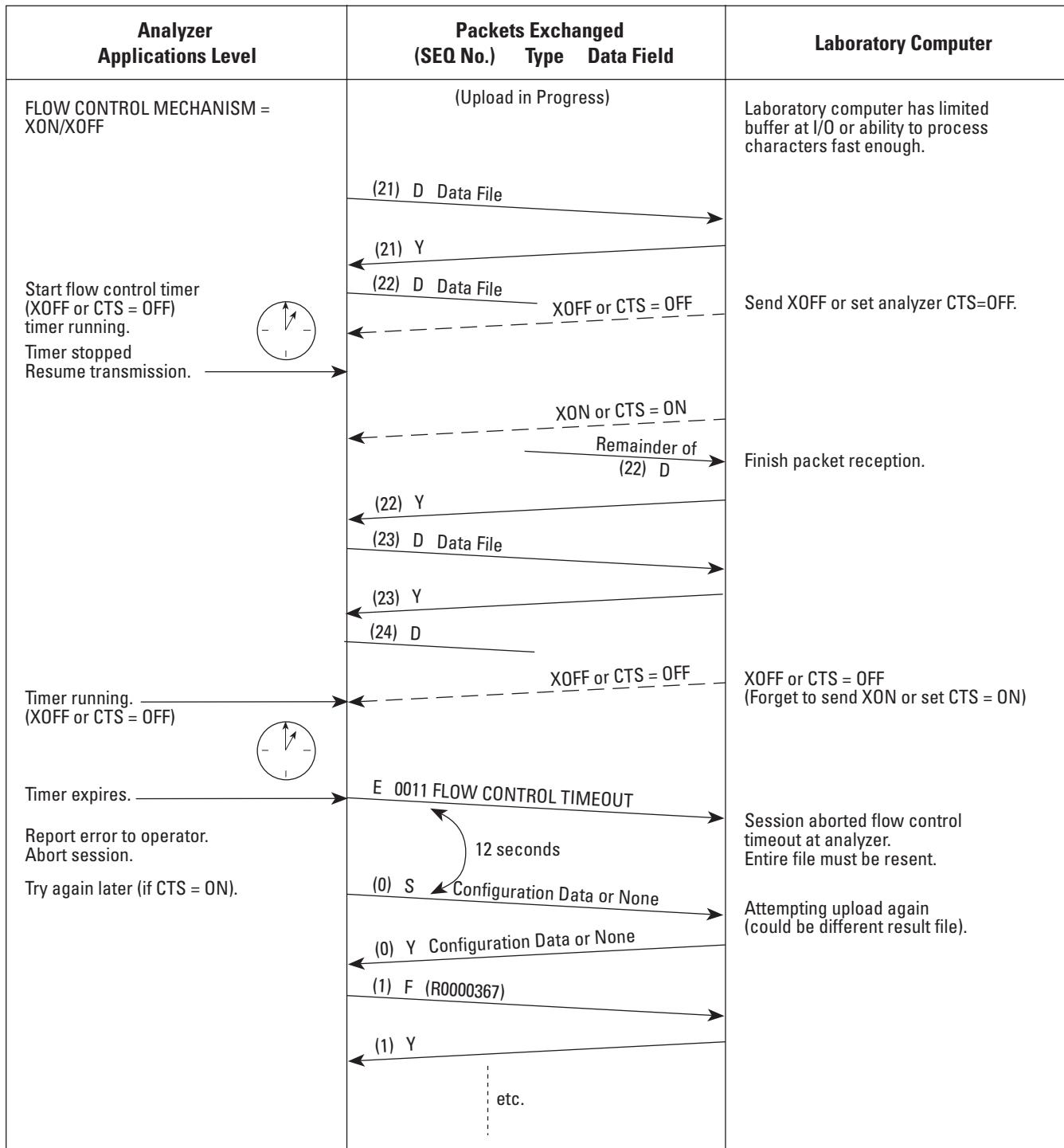


Figure 5-21. Packet Exchange for Upload of Test Results (Flow Control Mechanism).

5.7 Considerations for System Applications

This section provides information and suggestions to the laboratory computer's coordinator.

5.7.1 Download File Names

The laboratory computer is required by the *Kermit* Protocol to provide a download file name. The file name, sent as the data field of a download session's F packet, must have a capital S in the first position, and may be any valid length. The analyzer will check for the S to ensure that the downloaded file contains sample programs. If other than the S is found, an error packet will be sent to the laboratory computer.

5.7.2 File Level Acknowledgment

A file is not considered successfully delivered to the receiving station until the Z packet (EOF) has been sent and acknowledged with a Y packet. In the analyzer, the receipt of a valid Y packet to a transmitted Z packet causes the file to be marked internally as "confirmed reception at laboratory computer."

When the analyzer send a Y packet to a received Z packet, it is confirmation of a valid reception. Termination of a session prior to this packet exchange invalidates the file transfer and will cause it to be sent again in a subsequent session. Partially received files must be discarded at the receiving station. The transmitting station should not discard any part of a file until the Z/Y packet exchange has been completed.

5.7.3 Session Duration

No limit is placed on the duration of either a downloading or an uploading session. The total number of files transmitted is dependent upon how many are available and how many might become available during the session.

The laboratory computer should also be aware that the results file in the Chemistry Systems have a range of storage limits from 800 samples to 10,000 based on analyzer model. The Immunodiagnostic System has a storage limit of 10,000 samples. While performing lengthy download session file transfers, the analyzer may accumulate results that it cannot up

load until the download session is terminated. A "near full" message will be reported on the analyzer's screen. If the analyzer reaches capacity before up loading occurs, it will stop metering samples and stop generating new results until the situation is rectified. Session duration is largely dependent on whether the laboratory computer transfer method is batch-oriented or interactive.

5.7.4 Automatic Function Disabling

If an error is detected by the analyzer during a file transfer, it is reported to control software in the analyzer. If the error was caused by a received error packet during an upload session, the control software automatically disables the upload function. Further uploading is inhibited until the operator re-enables uploading in the analyzer's Options dialog on the Chemistry Systems or the Configure Report Control screen on the Immunodiagnostic System. You can also inhibit uploading by disabling the laboratory computer's DSR input.

5.7.5 Performance Considerations

The performance of the communications interface is dependent on a variety of factors, including transmission speed, cable length, signal voltage, packet size, and other applications-related criteria. The arrival rate of results files from the analyzer may be at regular 12-second intervals or in bursts of several hundred at once and will depend on the laboratory's operating environment (for example, whether test results are deferred in the analyzer).

5.7.6 Error Packet Field Codes

The analyzer will generate an error packet when a protocol error or other condition prevents communication. The transmission or reception of an E packet (error) always terminates an existing session. The laboratory computer is required to generate at least one E packet to indicate that its receiver is busy (code 0000).

The data field of the error packet is an ASCII code, followed by a number of characters (up to maximum packet length). The 4-digit code and the following 25 characters will be displayed on the analyzer's troubleshooting Help screen. Errors can occur in either the upload or download session.

Code	Error Description
0000	RECEIVER BUSY—The analyzer receive function does not have enough sample file space or tray name space and is not ready to receive another download file. If sent by the laboratory computer, it indicates either insufficient memory to receive another upload file or another temporary reason.
0001	OPERATOR RESET—The link is being reset by the operator.
0002	RECEIVER DISABLED—The receive function has been disabled by the operator.
0003	MESSAGE TOO LARGE—The received file exceeded the maximum size.
0004	UNSUPPORTED PACKET TYPE—The last packet received was not in the repertoire for received packets.
0005	INVALID PACKET USAGE—The last packet received was improperly used per protocol.
0006	INVALID LENGTH FIELD—The last received packet length field was less than 3 or greater than 94.
0007	INVALID SEQUENCE FIELD—The last received packet contained a SEQ field greater than 63.
0008	INVALID SEQUENCE USE—The last received packet contained a SEQ field that was not the expected next in sequence, nor the equal to the last received.
0009	INVALID CONSTRUCTION—The last received packet contained an invalid field for packet type (for example, NAK packet with a data field).
0010	MISSING PREFIX CHARACTER—The last received valid packet contained a nonprintable character (for example, control character) that was not prefixed.
0011	FLOW CONTROL TIMEOUT—The receiving station exercised flow control (sent XOFF character or set CTS OFF) to the sending station for a time period exceeding the flow control timeout limit.
0012	LINE ERROR—The receiving station is canceling the session because the retry limit has been exceeded.
0013	I/O BUFFER OVERFLOW—The packet received was larger than the buffer used to receive it.
0014	BUFFER SIZE ERROR—Some other buffer size internal to the receiver has been exceeded.
0015	UNSUPPORTED FILE TYPE—The file name received indicates that the file is not in the repertoire of receivable file types.

Figure 5-22. Packet Data Field Errors.

5.7.7 Download File Capacity

Downloaded sample programs can be broadcasted to multiple analyzers. The download file capacity for Chemistry Systems ranges from 800 sample programs to 10,000 samples. For the Immunodiagnostic System it is 10,000 sample programs.

An analyzer provides no warning messages to the laboratory computer as it approaches its downloaded file capacity. When the analyzer's downloaded capacity is reached, it will send an E packet (with a 0000 Data Field) in response to further attempts to download sample programs.

5.7.8 Broadcast Sample Program Downloading (DL)

Laboratories operating multiple analyzers can operate with a PSID protocol (for bar coded samples) that does not preassign samples to a specific analyzer, but rather permits personnel to load trays on the analyzer having the smallest current workload. This means each analyzer must be provided with the same sample programming. Later, after the sample has been processed by one of the analyzers, a means of eventually deleting the sample programming from the analyzer (or

analyzers) that did not process the sample must be provided. The analyzer software has features that permit batch deletion of sample programming on the basis of sample age, accommodating LIS Broadcast Download (duplicate programming of multiple analyzers).

Retransmitting an identical sample program with no tests will delete a previously broadcasted sample via the laboratory computer.

5.7.9 Editing of Downloaded Sample Programs by the Laboratory Computer

The laboratory computer can edit a previously downloaded sample program, as long as that sample is not being used and the sample program has not been edited manually. To edit the sample, both Sample ID and Patient Name (if defined) must match. Editing is done by retransmitting the sample. All data fields (except Sample ID) will be redefined to the newly-transmitted values and test requests.

A previously downloaded sample can be deleted by retransmitting the sample program with no tests.

5.7.10 Sample Program Time Stamp & Deletion Feature

The Chemistry System software incorporates a means to delete samples from the Sample Programming queue based upon sample age. Each programmed sample will be time-stamped when an original download, edited download, or manual entry to sample programming is made. When the sample program queue limit, which varies by model and device, is reached, the analyzer will not accept further downloads until the queue is reduced by processing samples on the analyzer, or samples of an age greater than a defined value are deleted via the analyzer control unit. This function must be carried out on each individual analyzer, as the queue will vary from analyzer to analyzer.

5.8 Summary of *Kermit* Procedures and Protocol

This section is derived from the *Kermit* Protocol Manual and *Kermit* User Guide ([refer to Section 1.4](#)). Only topics related to the analyzer are described here. This summary is a set of basic rules adhered to by all *Kermit* stations.

1. Communications take place over ordinary terminal connections. This precludes the need for specialized cable/wiring and keeps the protocol general purpose.
2. Stations must wait for a response (or timeout indication) to a previously transmitted packet before sending the next packet. This prevents buffer overflows and permits half-duplex systems to participate. It also preserves the integrity of the sequence number field.
3. Packet communications are half-duplex, regardless of connection medium attributes. This allows full and half-duplex systems to participate. (If a duplex connection exists and **XON/XOFF** flow control is agreed to by both stations, normal duplexity exists for the purposes of transmitting the **XON/XOFF** characters.)
4. Packet length is variable, but is restricted to 96 characters maximum (including check characters). This accommodates older host systems with limited I/O buffering capability.
5. All transmission is in ASCII. Any non-ASCII stations are responsible for conversion. This facilitates portability of the protocol.
6. All ASCII control characters are prefixed with a special character. The control character is converted to a printable character during transmission, and converted back to its original value during reception. This ensures that ASCII control characters (or information with values in control character range) are delivered to applications. This facilitates the inclusion of carriage return /linefeed control characters, necessary for some systems to delimit records.
7. Only a file's name and content are transmitted, no attributes. It is the responsibility of the receiving system to see that files are stored correctly. This is because different systems employ different file attribute schemes. Not sending attributes prevents the confusion that would arise

if a system were to receive attributes not compatible to that system.

8. Negative acknowledgments, with a packet sequence number one greater than that transmitted, imply a positive acknowledgment for the current outstanding packet, and invite the transmission of the next packet.
9. Configurable prefix (quoting) characters must be unique and single purpose. They must be printable ASCII characters of infrequent usage to avoid the additional overhead associated with prefixing when in the data stream. Making them unique with one purpose avoids confusion and complexity as to the function of the quoting characters in the receiver logic. (See number 14 below.)
10. Each station must clear its input buffer at the beginning of each transfer (session). Also, each station should clear its input buffer after reading a complete packet. This prevents the adverse effect that accumulated NAK packets (sometimes sent after timeout during an attempt to initiate a session) could cause once the accumulating station is enabled to receive.
11. Each station must disregard redundant acknowledgment packets. This relates to number 10 above.
12. If response timers are used by both stations, they must be of different durations. This prevents contention for a possible half-duplex medium if both sides were to time out simultaneously.
13. Neither station may, after agreeing to session parameters via the S packet/acknowledgment exchange, alter these parameters during the session. (Parameters are re-established at the beginning of each session.)
14. Control character prefixing (number 9 above) is not performed on S packet data fields or on their acknowledgment packet data fields because prefixing characteristics, for example, are not known prior to their exchange in session initialization.
15. All inter-session packets (for example, S packet or its acknowledgment) are transmitted with the type 1 (single character) block check for the reason described in number 14 above. This includes periodic NAK (N) packets sent by either station to solicit a session start.
16. All stations must be prepared to receive an E packet at any time during a session.
17. Only packets that conform to the structure may be exchanged.
18. Characters occurring between packets, other than those defined for flow control and for packet termination/handshaking protocol, are to be ignored and discarded.
19. Prefixed control characters must not be split over multiple packets.
20. All packets must include the sequence number field (SEQ).
21. If one station receives information about the lesser receiving station's capabilities during session establishment, those restrictions must be honored.
22. Either station must be capable of sending and receiving

- characters using 7-bit ASCII encoding (8 bits including parity) over an EIA RS-232C physical interface. If the extended ASCII set is used, either station must be capable of 8-bit ASCII coding.
- 23. All printable ASCII characters are acceptable as input to either station, and will not be transformed in any way by the communications facility.
 - 24. A single ASCII control character can pass from one system to the other without transformation.
 - 25. If a host requires a line terminator for input, that terminator must be a single ASCII control character (for example, CR, LF) that is distinct from the MARK character.
 - 26. Both stations must be capable of receiving a single burst of the defined packet size characters at the configured transmission speed.
 - 27. Both stations must be capable of performing the conversion functions.

6.1 Uploaded Results Files for VITROS Chemistry Systems

The format of uploaded result files prior to packetization for transmission is described in this chapter. The uploaded *Kermit* file will consist of a file name and all results for one specimen.

6.1.1 File Name

The analyzer assigns a unique file name to each transmitted results file. This name is 8 bytes long and contains an R followed by a 7 alphanumeric characters. The number is incremented each time a file is successfully transmitted. When the analyzer is in Standby Mode, the number is reset to 0.

File names without the R should result in transmission of an error packet by the laboratory computer.

Note: To facilitate future expansion of file types, the user may want to configure the laboratory computer to check for the R in the first position.

6.1.2 Format of Uploaded Files for VITROS Chemistry Systems

The general format for each results file is shown in figure 6-1.

Field Description	Number of Characters	Beginning Position		Ending Position		ASCII Values (in decimals)											
		Min	Max	Min	Max												
Time: The time will be in the form hhmmss (for hours, minutes, and seconds).	6	1	1	6	6	48-57											
Date: The date will be in the form mmdd (for month and day).	4	7	7	10	10	48-57											
Tray Name: All printable ASCII characters.*	15	11	11	25	25	32-126											
Sample ID: All printable ASCII characters.*	15	26	26	40	40	32-126											
Fluid: This field identifies the fluid.	1	41	41	41	41	48-52											
<table> <thead> <tr> <th>Fluid</th> <th>ASCII Char</th> <th>ASCII Dec Value</th> </tr> </thead> <tbody> <tr> <td>Serum</td> <td>1</td> <td>49</td> </tr> <tr> <td>CSF</td> <td>2</td> <td>50</td> </tr> <tr> <td>Urine</td> <td>3</td> <td>51</td> </tr> </tbody> </table>	Fluid	ASCII Char	ASCII Dec Value	Serum	1	49	CSF	2	50	Urine	3	51					
Fluid	ASCII Char	ASCII Dec Value															
Serum	1	49															
CSF	2	50															
Urine	3	51															
Stat Flag: <table> <thead> <tr> <th></th> <th>ASCII Char</th> <th>ASCII Dec Value</th> </tr> </thead> <tbody> <tr> <td>Non-stat</td> <td>0</td> <td>48</td> </tr> <tr> <td>Stat</td> <td>1</td> <td>49</td> </tr> </tbody> </table>		ASCII Char	ASCII Dec Value	Non-stat	0	48	Stat	1	49	1	42	42	42	48-49			
	ASCII Char	ASCII Dec Value															
Non-stat	0	48															
Stat	1	49															
Cup Position: Add 32 (decimal) to actual cup position (1 to 10) to shift cup number beyond range of ASCII control characters.	1	43	43	43	43	33-42											

* Characters from the ASCII extended character set can be entered by the customer into the Tray Name or Sample ID fields. These characters will be transmitted to the LIS.

Figure 6-1. General Format of Uploaded Files for VITROS Chemistry Systems.

Field Description	Number of Characters	Beginning Position		Ending Position		ASCII Values (in decimals)
		Min	Max	Min	Max	
Mode:	1	44	44	44	44	48,49,52,53
Mode	ASCII Char	ASCII Dec Value				
Select	0	48				
Batch	1	49				
Down loaded	4	52				
Down loaded and manually edited	5	53				
Dilution Factor:	5	45	45	49	49	46,48-57
An off-analyzer dilution factor; a number between .0001 to 9999. in ASCII printable characters. The 5-character dilution factor will be in one of these formats—.xxxx, x.xxx, xx.xx, xxx.x, xxxx.—where x is a number 0-9. No leading, trailing, or embedded blanks are allowed.						
Measured and Derived Tests:	0-1012	50	50	50	1061	32-126
The number of measured and derived test results reported in one sample request report will vary by analyzer. But each result will require 14 to 22 bytes, as described in Section 6.1.3 .						
Field Separator and Analyzer ID:	0 or 11 (including the field separator)	50	1062	50	1072	124, character; 32-126
The analyzer ID can be user-defined with up to 6 characters, or it can be the default and will be the model number of the analyzer. If the analyzer ID is user-defined, the field is left justified and blank filled. If the analyzer ID is defined as blanks, neither the Field Separator nor the analyzer ID field are transmitted. (User-defined unique analyzer ID is input via the ANALYZER CONFIGURATION screen OP00E, then OP35A.) Any printable characters can be used in the analyzer ID field.						
End of Sample	1	50	1073	50	1073	93,] character

Figure 6-1. General Format of Uploaded Files for VITROS Chemistry Systems. (Continued)

6.1.3 Format of Reportable Results Field for VITROS Chemistry Systems

Field Description	Number of Characters	Beginning Position		Ending Position		ASCII Values (in decimals)
		Min	Max	Min	Max	
Test ID:	1	1	1	1	1	32-79, 96-109
Test identification expressed as an ASCII value. (See figure 6-10 for specific ASCII values for measured tests; see figure 6-4 for ASCII values for derived tests.)						
Test Result:	9	2	2	10	10	32,45,46, 48-57 80, 83
Result is reported exactly as it appears on the laboratory report.* The test result is a 9-character floating-point field that includes the decimal point and a negative sign when applicable. The number of precision point digits will vary by test and is configurable on the analyzer. If the test result is less than 9 characters, this field will be padded with blanks preceding and trailing the result as needed to fill the field. Significant digits displayed are the same as in the laboratory report. Derived test results have a maximum of nine character spaces. NO RESULT is reported in this field if there is a numerical processing error or if the test is not supported.						

*The characters PS are transmitted when the neat (untreated) sample result is available, but the pretreated sample result is unavailable. When the pretreated sample result is available, the calculated value for the Derived Test Result is then retransmitted.

Figure 6-2. Format of Reportable Results Fields for the VITROS Chemistry Systems.

Field Description	Number of Characters	Beginning Position		Ending Position		ASCII Values (in decimals)
		Min	Max	Min	Max	
Reporting Units: 0 Conventional Units 1 SI Units 2 Alternate Conventional Units	1	11	11	11	11	48-50
Error Flags for Measured Tests (in ASCII characters): ASCII characters 0-7, A, B, and C are used as follows: 0 No error 1 Above laboratory's range 2 Below laboratory's range 3 Outside dynamic range 4 Above analyzer's range (the value reported is the maximum limit of the range) 5 Below analyzer's range (the value reported is the minimum limit of the range) 6 Prediction failure (reported as NO RESULT) 7 Outside Supplementary Range A Control result is more than 2 SDI from baseline interval mean but no more than 3 SDI B Result is more than 3 SDI from baseline interval mean C No baseline interval mean and SDI; or test is not supported in QC database D Control result below QC range E Control result above QC range <i>The following flags are for future implementation on VITROS 250 and VITROS 950 Systems. They are optional flags; if configured, they replace Error Flags 3 and 7.</i> F Above dynamic range G Below dynamic range H Above Supplementary Range I Below Supplementary Range	1	12	12	12	48-56, 65-73	
Error Flags for Derived Tests (in ASCII characters): 0 No error 1 Above derived test hospital range 2 Below derived test hospital range 3 Edited derived test result 4 Bad derived test component 5 No derived test result 7 Outside derived test Supplementary Range 8 Pre-treated Multiple Sample Derived Test (MSDT) A Above 2 SD from mean B Above 3 SD from mean C Not supported in QC database D Below QC range E Above QC range <i>The following flags are for future implementation on VITROS 250 and VITROS 950 Systems. They are optional flags; if configured, they replace Error Flag 7.</i> H Above Supplementary Range I Below Supplementary Range						

Figure 6-2. Format of Reportable Results Fields for the VITROS Chemistry Systems. (Continued)

Field Description	Number of Characters	Beginning Position		Ending Position		ASCII Values (in decimals)
		Min	Max	Min	Max	
Warning Flags: ASCII characters 0-3 are used as follows: 0 No warning 1 Analyzer-generated warning. The causes of this warning are: <ul style="list-style-type: none">• Result outside dynamic range• Result above or below analyzer range• High concentration of blank analyte detected for blank-corrected test• Rate is drifting out and in trim window or the kinetic curve exhibits excessive noise or lack of fit• Component flagged 2 Operator-induced warning. The causes of this warning are: <ul style="list-style-type: none">• Result above or below hospital range• Result above or below supplementary range• User calibrated• Adjusted result• Edited result 3 Both analyzer and operator warning	1	13	13	13	13	48-51
Error Codes: (Optional Field; that is, only transmitted if an error has occurred)	0-8	14	14	14	21	48-57, 65-90
For Measured Tests: AR Adjusted Results DD Drop Detection Disabled DP Sub Depletion Error ED Edited Result EM Expired Maintenance EP Edit Patient Data ER Math Error FC Derived test includes a component which is flagged HB High Blank HN High Noise in Kinetic (multiple windows, SDR dot t (error) IC Blank Prediction Failed ID Invalid Dilution IR Slide Read Error IS Insufficient Sample IT Incubator Temperature Warning KE Kinetic Error LS Lot Switch ME Mechanical Error Failure M1 Category 1 modified values M2 Category 2 modified values	NC Not Calibrated ND No Drop NF No Fluid NQ Not in QC Data Base NS Slide Not Available NT No Tip OD Out-of-Range Dilution OR Range Error (outside dynamic range, above analyzer range, below analyzer range, outside supplementary range) OS Outside Spline Range PD Pressure Detector Disabled PF Prediction Failure PI Potential Interferent SD Standard Dilution SP Multiple Spike ST Slide Time-Out TR Trim Error UC User Calibrated UD Unconfigured Diluent WD Wetness Detector Disabled WE IR Wash Error					
For Derived Tests: ED Edited Result EM Expired Maintenance EP Edit Patient Data ER No Test Result	FC Flagged Component IC Invalid Component NQ Not in QC Data Base OR Range Error (outside supplementary range)					
For a more detailed description of the error codes, see your operator's manual.	1	14	22	14	22	125, } character

Figure 6-2. Format of Reportable Results Fields for the VITROS Chemistry Systems. (Continued)

ASCII DECIMAL VALUE	ASCII CHARACTER	REPORT NAME	TEST NAME	700‡	700XR‡	700P‡	700S‡	500	250	950
32	space	GLU	Glucose	X	X	X	X	X	X	X
33	!	TP	Total Protein	X	X	X	X	X	X	X
34	"	URIC	Uric Acid	X	X	X	X	X	X	X
35	# (##)	ALB	Albumin	X	X	X	X	X	X	X
36	\$	TRIG	Triglycerides	X	X	X	X	X	X	X
37	%	CHOL	Cholesterol	X	X	X	X	X	X	X
38	& (ampersand)	AMYL	Amylase	X	X	X	X	X	X	X
39	' (apostrophe)	Cl	Chloride	X	X		X	X	X	X
40	(K+	Potassium	X	X		X	X	X	X
41)	Na+	Sodium	X	X		X	X	X	X
42	*	ECO2	Enzymatic CO2	X	X	X	X	X	X	X
43	+	PHOS	Phosphorus	X	X	X	X	X	X	X
44	, (comma)	LAC	Lactate	X	X	X	X	X	X	X
45	- (dash, hyphen, minus) (no longer used)	NH3	Ammonia	X	X	X	X	X	X	X
46	. (period, dot)	CREA	Creatinine	X	X	X	X	X	X	X
47	/ (slash)	BUN†	Urea Nitrogen	X	X	X	X	X	X	X
48	0	HDLC	HDL Cholesterol	X	X	X	X	X	X	X
49	1	Bu	Unconjugated Bilirubin	X	X	X	X	X	X	X
50	2	Ca	Calcium	X	X	X	X	X	X	X
51	3	TBIL	Total Bilirubin	X	X	X	X	X	X	X
52	4	AST	Aspartate Aminotransferase	X	X	X		X	X	X
53	5	ALKP	Alkaline Phosphatase	X	X	X		X	X	X
54	6	ALT	Alanine Aminotransferase	X	X	X		X	X	X
55	7	LDH	Lactate Dehydrogenase	X	X	X		X	X	X
56	8	CK	Creatinine Kinase	X	X	X		X	X	X
57	9	LIPA	Lipase	X	X	X	X	X	X	X
58	: (colon)	GGT	Gamma Glutamyltransferase	X	X	X		X	X	X
59	; (semicolon)	Bc	Conjugated Bilirubin	X	X	X	X	X	X	X
60	<	THEO	Theophylline	X	X	X	X	X	X	X
61	=	CKMB	CKMB	X	X	X		X	X	X
62	>	Mg	Magnesium	X	X	X	X	X	X	X
63	?	Fe	Iron	X	X	X	X	X	X	X
64	@	TIBC	Total Iron Binding Capacity	X	X	X	X	X	X	X
65	A	PROT	CSF Protein	X	X	X	X	X	X	X
66	B	SALI	Salicylate	X	X	X	X	X	X	X
67	C	ALC	Alcohol	X	X	X		X	X	X
68	D	AMON	Ammonia	X	X	X	X	X	X	X
69	E	CHE	Cholinesterase	X	X	X		X	X	X
70	F	ACP	Acid Phosphatase	X	X	X	X	X	X	X
71	G (no longer used)	ACPB	Acid Phosphatase Blank	X	X	X	X	X	X	X
72	H	Li	Lithium	X	X	X	X	X	X	X
73	I	DGXN	Digoxin						X	X
74	J	PHBR	Phenobarbital						X	X
75	K	PHYT	Phenytoin						X	X
76	L	CRP	C Reactive Protein						X	X
77	M	CRBM	Carbamazepine						X	X
79	O	ACET	Acetaminophen	X	X	X		X	X	X
80	P	UPRO	Urine Protein	X	X	X	X	X	X	X

Figure 6-3. ASCII Characters for Measured Tests.

ASCII DECIMAL VALUE	ASCII CHARACTER	REPORT NAME	TEST NAME	700‡	700XR‡	700P‡	700S‡	500	250	950
86	V	CRPJ	C Reactive Protein						X	X
87	W	ALTJ	Alanine Aminotransferase						X	X
88	X	ASTJ	Aspartate Aminotransferase						X	X

Note: The # character is used as the quote symbol for control characters. In a data field, the # character must be repeated; for example, ## = cup position 3. Refer to section 5.6.10 "QCTL."

* U/CR if Standard International.

† UREA/Creatinine Ratio if Standard International.

‡ VITROS 700 and 700 C Chemistry Systems .

O = VITROS Chemistry Systems with VITROS Data Enhancement Package / (DEP) accessory option only.
X = standard chemistry.

Figure 6-3. ASCII Characters for Measured Tests. (Continued)

ASCII DECIMAL VALUE	ASCII CHARACTER	REPORT NAME	TEST NAME	700‡	700XR‡	700P‡	700S‡	500	250	950
96	' (left apostrophe)	B/CR	Bun/Creatinine	X	X	X	X	X	X	X
97	a (lower case)	AGPK	Anion Gap (K+)	X	X	X	X	X	X	X
98	b	AGP	Anion Gap	X	X	X	X	X	X	X
99	c	A/G	A/G Ratio	X	X	X	X	X	X	X
100	d	NBIL	Neonatal Bilirubin	X	X	X	X	X	X	X
101	e	DBIL	Direct Bilirubin	X	X	X	X	X	X	X
102	f	DELB	Delta Bilirubin	X	X	X	X	X	X	X
103	g	%MB	% CK-MB	X	X	X	X	X	X	X
104	h	OSMO	Osmolality	O	O	O	O	O	X	X
105	i	%SATU	% Saturation	O	O	O	O	O	X	X
106	j	GLOB	Globulin	O	O	O	O	O	X	X
107	k	LDL	LDL	O	O	O	O	O	X	X
108	l	VLDL	VLDL	O	O	O	O	O	X	X
109	m	C/H	Chol/HDL ratio	O	O	O	O	O	X	X
110	n									
111	o									

O = VITROS Chemistry Systems with VITROS Data Enhancement Package / (DEP) accessory option only.
X = standard chemistry.

Figure 6-4. ASCII Characters for Derived Tests for the VITROS Chemistry Systems.

6.2 Downloaded Sample Programs for VITROS Chemistry Systems

The format of a downloaded sample program file is described below as it appears at the application level. The analyzer processes the file according to this structure.

Note: The downloaded *Kermit* file will consist of a file name and one to ten sample programs. If samples are identified by tray, all samples in the file must be on the same tray.

Note: When an analyzer is not configured for a specific test that is down loaded, only the affected test is deleted from the sample program by the analyzer. The download message "Invalid test received" will be posted in the message screen. Refer to figure 6-10, figure 6-4, and figure 6-8.

6.2.1 File Name

ASCII values 32-126 (decimal) are allowed for the file name. The file name will not be used by the analyzer's control software.

6.2.2 Format of Downloaded Files for VITROS Chemistry Systems

The format of downloaded files is shown in [figure 6-5](#).

Field Description	Number of Characters	Beginning Position		Ending Position		ASCII Values (in decimals)															
		Min	Max	Min	Max																
Field Separator followed by Tray Name: Optional Fields, that is, if there is no Tray Name specified, the Field Separator and Tray Name will not be transmitted. (Otherwise, they will be transmitted with the first cup only.) All printable ASCII characters. If a Tray Name is specified, it must appear only in the first sample of the file.	0 or 16	1	1	0	16	124, character; 32-126															
PSID SAMPLES: <i>Routine samples</i> Field Separator and Tray Name should not be transmitted. Samples need only be identified by sample ID (SID) or accession number (that which was bar coded in the container label). Adding Tray Name only hinders laboratory throughput of PSID samples, requiring that the Tray Name be entered when loading a tray on the analyzer. <i>Priority samples</i> Priority samples that are bar coded can be swapped into tray positions from the scanner station. These samples will be processed in sequence after any located STAT samples have been processed. As above, Field Separator and Tray Name should not be transmitted.																					
ASSIGNED (LOCATED) SAMPLES: <i>Non-bar coded samples and located STATS</i> Field Separator and Tray Name must be transmitted or entered manually via keyboard as it is today without PSID. STAT samples take precedence over all other samples, and will be handled as soon as the analyzer completes processing the current sample.																					
Sample ID: All printable ASCII characters. The sample ID field must include at least one non-blank character (ASCII space = 32 decimal).	15	1	17	15	31	32-126															
Fluid: This field identifies the fluid. Do not use 0 as a default. This field is used to select proper calibration parameters.	1	16	32	16	32	48-52															
<table> <thead> <tr> <th>Fluid</th> <th>ASCII Char</th> <th>ASCII Dec Value</th> </tr> </thead> <tbody> <tr> <td>For future use*</td> <td>0</td> <td>48</td> </tr> <tr> <td>Serum</td> <td>1</td> <td>49</td> </tr> <tr> <td>CSF</td> <td>2</td> <td>50</td> </tr> <tr> <td>Urine</td> <td>3</td> <td>51</td> </tr> </tbody> </table>	Fluid	ASCII Char	ASCII Dec Value	For future use*	0	48	Serum	1	49	CSF	2	50	Urine	3	51						
Fluid	ASCII Char	ASCII Dec Value																			
For future use*	0	48																			
Serum	1	49																			
CSF	2	50																			
Urine	3	51																			
Stat Flag: <table> <thead> <tr> <th></th> <th>ASCII Char</th> <th>ASCII Dec Value</th> </tr> </thead> <tbody> <tr> <td>Non-stat</td> <td>0</td> <td>48</td> </tr> <tr> <td>Stat</td> <td>1</td> <td>49</td> </tr> </tbody> </table>		ASCII Char	ASCII Dec Value	Non-stat	0	48	Stat	1	49	1	17	33	17	33	48-49						
	ASCII Char	ASCII Dec Value																			
Non-stat	0	48																			
Stat	1	49																			

Figure 6-5. Format of Downloaded Files for VITROS Chemistry Systems.

Field Description	Number of Characters	Beginning Position		Ending Position		ASCII Values (in decimals)
		Min	Max	Min	Max	
Cup Position: Add 32 decimals to actual cup position (1-10) to shift cup number beyond the range of control characters. If a Tray Name was specified for a file, then all samples for that file should have non-blank cup positions. If a Tray Name was not specified, then all the samples for the file should have a blank cup position.	1	18	34	18	34	32 or 33-42
PSID SAMPLES: <i>Routine samples</i> Cup position should not be transmitted. Samples need only be identified by sample ID (SID) or accession number (that which was bar coded in the container label). Adding cup position only hinders laboratory throughput of PSID samples, requiring that cup positions be entered when loading a tray on an analyzer.						
<i>Priority samples</i> Priority samples that are bar coded can be swapped into tray positions counter-clockwise from the scanner station. These samples will be processed in sequence after any located STAT samples have been processed. As above, cup position should not be transmitted.						
ASSIGNED (LOCATED) SAMPLES: <i>Non-bar coded samples and located STATS</i> Cup position must be transmitted or entered manually via keyboard as it is today without PSID. STAT samples take precedence over all other samples, and will be handled as soon as the analyzer completes processing the current sample.						
Dilution Factor: An off-analyzer dilution factor; a number between .0001 to 9999. in ASCII printable characters. The 5-character dilution factor will be in one of these formats—.xxxx, x.xxx, xx.xx, xxx.x, xxxx.—where x is a number 0-9. No leading, trailing, or embedded blanks are allowed.	5	19	35	23	39	46, 48-57
Measured Test Requests: (Optional Field) Test request expressed as an ASCII value. Refer to figure 6-3 and figure 6-6 for specific values.	0-30 0-40 (VITROS 950)	24	40	24	69	32-90
Derived Test Requests: (Optional Field) Test identification for derived tests expressed as an ASCII value. Refer to figure 6-4 for specific values. Note: Derived tests must always follow measured tests.	0-16	24	70	24	85	96-111
Field Separator followed by Patient Name: (Optional Fields; that is, only transmitted if the Patient Name is non-blank.) Field Separator Last Name ← First Name ← Middle Initial ← All printable ASCII characters.	0 or 26 0,1 0,15 0,9 0,1 24 25 40 49 86 87 102 111 24 39 48 49 86 101 110 111 124, Character 32-126 32-126 32-126					
End of Sample	1	24	112	24	112	93,] character

Figure 6-5. Format of Downloaded Files for VITROS Chemistry Systems. (Continued)

Note: The analyzer maximums are found in [figure 6-6](#). The sample will not be processed if these values are exceeded.

Analyzer	Maximum		
	Tests/Assays	Result	Derived Results
250	30	30	16
500 series	30	30	16
700 series	30	30	16
950	40	40	16
Imm. System	20	20	30

Figure 6-6. Maximum Number of Tests/Assays

record will consist of a record name and all results for one specimen.

6.3.1 Record Name

The analyzer assigns a unique record name to each transmitted results record. This name is 8 bytes long and contains an R followed by a 7-digit number. The number is incremented each time a record is successfully transmitted. When the analyzer is in Shutdown, the number is reset to 0.

6.3 Uploaded Results Records for the VITROS ECi Immunodiagnostic System

The format of uploaded results record prior to packetization for transmission is described in this section. The uploaded *Kermit*

6.3.2 Format of Uploaded Records for the VITROS ECi Immunodiagnostic System

The general format for each result record is shown in [figure 6-7](#).

Field Description	Number of Characters	Beginning Position		Ending Position		ASCII Values (in decimals)																													
		Min	Max	Min	Max																														
Time: The time will be in the form hhmmss (for hours, minutes, and seconds).	6	1	1	6	6	48-57																													
Date: The date will be in the form mmdd (for month and day).	4	7	7	10	10	48-57																													
Tray Name: All printable ASCII characters. The Imm. System actually has a 2-character tray ID, but for compatibility, it will pad to 15, left-justified.	15	11	11	25	25	32-126																													
Sample ID: All printable ASCII characters, left-justified.	15	26	26	40	40	32-126																													
Fluid: This field identifies the fluid. In the Imm. System the range of numbers is: <table border="1"> <thead> <tr> <th>Fluid</th> <th>ASCII Char</th> <th>ASCII Dec Value</th> </tr> </thead> <tbody> <tr> <td>Serum</td> <td>4</td> <td>52</td> </tr> <tr> <td>Plasma</td> <td>5</td> <td>53</td> </tr> <tr> <td>Urine</td> <td>6</td> <td>54</td> </tr> <tr> <td>Blood</td> <td>7</td> <td>55</td> </tr> <tr> <td>Amnio</td> <td>8</td> <td>56</td> </tr> <tr> <td>Reserved 1</td> <td>9</td> <td>57</td> </tr> <tr> <td>Reserved 2</td> <td>:</td> <td>58</td> </tr> <tr> <td>Reserved 3</td> <td>:</td> <td>59</td> </tr> <tr> <td>Reserved 4</td> <td><</td> <td>60</td> </tr> </tbody> </table>	Fluid	ASCII Char	ASCII Dec Value	Serum	4	52	Plasma	5	53	Urine	6	54	Blood	7	55	Amnio	8	56	Reserved 1	9	57	Reserved 2	:	58	Reserved 3	:	59	Reserved 4	<	60	1	41	41	41	52-60
Fluid	ASCII Char	ASCII Dec Value																																	
Serum	4	52																																	
Plasma	5	53																																	
Urine	6	54																																	
Blood	7	55																																	
Amnio	8	56																																	
Reserved 1	9	57																																	
Reserved 2	:	58																																	
Reserved 3	:	59																																	
Reserved 4	<	60																																	
Stat Flag: <table border="1"> <thead> <tr> <th></th> <th>ASCII Char</th> <th>ASCII Dec Value</th> </tr> </thead> <tbody> <tr> <td>Non-stat</td> <td>0</td> <td>48</td> </tr> <tr> <td>Stat</td> <td>1</td> <td>49</td> </tr> </tbody> </table>		ASCII Char	ASCII Dec Value	Non-stat	0	48	Stat	1	49	1	42	42	42	48-49																					
	ASCII Char	ASCII Dec Value																																	
Non-stat	0	48																																	
Stat	1	49																																	
Cup Position: Add 32 (decimal) to actual cup position (1 to 10) to shift cup number beyond range of ASCII control characters.	1	43	43	43	43	33-42																													

Figure 6-7. General Format of Uploaded Records for the VITROS ECi Immunodiagnostic System.

Field Description	Number of Characters	Beginning Position		Ending Position		ASCII Values (in decimals)
		Min	Max	Min	Max	
Mode: Mode Select Down loaded Down loaded and manually edited	1	44	44	44	44	48,49,52,53
Dilution Factor: An off-analyzer dilution factor; a number between .0001 to 9999. in ASCII printable characters. The 5-character dilution factor will be in one of these formats—.xxxx, x.xxx, xx.xx, xxxx.x, xxxx.—where x is a number 0-9. No leading, trailing, or embedded blanks are allowed.	5	45	45	49	49	46,48-57
Measured and Derived Tests: Up to 20 assay results and up to 30 derived test results may be in one sample results report. Each result will require 16 to 24 bytes, as described in figure 6-8.	0-1200	50	50	50	1249	32-126
Field Separator and System Name: The ECi System name can be user-defined with up to 7 characters so truncation to 6 may occur for compatibility. If the system name is user-defined, the field is left justified and blank filled. If the system name is defined as blanks, neither the Field Separator nor the analyzer name field are transmitted. (User-defined unique analyzer name is input via the Configure System screen.)	0-11	50	1150	50	1160	124, I character; 32-126
End of Sample	1	50	1161	50	1161	93,] character

Figure 6-7. General Format of Uploaded Records for the VITROS ECi Immunodiagnostic System. (Continued)

6.3.3 Format of Reportable Results Fields for the VITROS ECi Immunodiagnostic System

The record layout in figure 6-8 identifies the data in Reportable Results Records for the VITROS ECi Immunodiagnostic System.

Field Description	Number of Characters	Beginning Position		Ending Position		ASCII Values (in decimals)
		Min	Max	Min	Max	
Test ID: Assay identification is a 3-character field with leading zeros, expressed as an ASCII value. Refer to figure 6-9 for specific assay codes for assays and figure 6-10 for ASCII values for derived tests.	3	1	3	3	3	48-57 (or 001-255 in numeric range)
Test Result: The assay result is 9-character floating-point field that includes the decimal point and a negative sign when applicable. The number of precision point digits varies by assay and the magnitude of the result. If the assay result is less than 9 characters, this field will be padded with blanks preceding the result. The string NO RESULT is reported in this field if one of a number of error conditions exist, such as a numerical processing error.	9	4	4	12	12	32,45,46, 48-57 , 80, 83
Reporting Units: 0 Conventional Units 1 Alternate	1	13	13	13	13	48-50

Figure 6-8. Format of Reportable Results Fields for the VITROS ECi Immunodiagnostic System.

Field Description	Number of Characters	Beginning Position		Ending Position		ASCII Values (in decimals)
		Min	Max	Min	Max	
Result Flags for Measured Test in ASCII characters:	1	14	14	14	14	48-57 and 65-67 and 81-85
0 No flag 1 Above reference range 2 Below reference range 4 Above dynamic range (the value reported is the maximum limit of the range) 5 Below dynamic range (the value reported is the minimum limit of the range) 6 Prediction failure (floating point assay result, starting location 10, becomes NO RESULT) 7 Above supplementary range 8 Below supplementary range A Control result is more than 2 SDI from baseline interval mean, but no more than 3 SDI B Result is more than 3 SDI from baseline interval mean C No baseline interval mean and SDI, or assay is not supported in QC database						
Q Result text 1 ← R Result text 2 ← S Result text 3 ← T Result text 4 ← U Result text 5 ←						These are classified for qualitative results.
Result Flags for Derived Tests in ASCII characters:						
0 No flag 1 Above reference range 2 Below reference range 4 Above dynamic range (the value reported is the maximum limit of the range) 5 Below dynamic range (the value reported is the minimum limit of the range) 6 Prediction failure (floating point assay result, starting location 10, becomes NO RESULT) 7 Above supplementary range 8 Below supplementary range A Control result is more than 2 SDI from baseline interval mean, but no more than 3 SDI B Result is more than 3 SDI from baseline interval mean C No baseline interval mean and SDI, or test is not supported in QC database						
Q Result text 1 ← R Result text 2 ← S Result text 3 ← T Result text 4 ← U Result text 5 ←						These are classified for qualitative results.
Warning Flags: ASCII characters 0-3 are used as follows: 0 No warning 1 Analyzer-generated warning. The causes of this warning are: <ul style="list-style-type: none">• Result outside dynamic range• Component flagged 2 Operator-induced warning. The causes of this warning are: <ul style="list-style-type: none">• Result above or below reference range• Result above or below supplementary range• User calibrated• Adjusted result• Edited result 3 Both analyzer and operator warning	1	15	15	15	15	48-51

Figure 6-8. Format of Reportable Results Fields for the VITROS ECi Immunodiagnostic System. (Continued)

Field Description	Number of Characters	Beginning Position		Ending Position		ASCII Values (in decimals)
		Min	Max	Min	Max	
Result Codes: Optional Field, that is, it is only transmitted if a code has occurred.	8	16	16	16	23	49, 50, 65-90
AR User adjusted parameters changed results	NF No fluid					
CE Calibration Expired	NI No inventory					
FR Flagged replicate	NQ Not in QC data base					
DE Drop error	NW No well					
ED Edited result	NT No tip					
EM Expired maintenance	OD Operator requested dilution					
EP Edit patient data	OR Outside range					
FC Flagged component	PF Prediction failure					
IC Invalid component	RC Reference consistency check					
ID Invalid dilution	RD Reflex dilution					
II Insufficient inventory	RE Reagent expired					
IS Insufficient sample	RP Reflex process					
IT Incubator temperature	RR Recalculated result					
LS Lot switch	SC Spread check					
LT Luminometer temperature out	UC User calibrated					
ME Mechanical error occurred	WT Well wash temperature out					
M1 Category 1 modified values	ZS Zero Set					
M2 Category 2 modified values						
NC Not calibrated						
For a more detailed description of the result codes, see your operator's guide.						
Field Separator:	1	16	24	16	24	125, } character

Figure 6-8. Format of Reportable Results Fields for the VITROS ECi Immunodiagnostic System. (Continued)

Test Code	REPORT NAME	ASSAY NAME
001	TSH	TSH
002	TT4	Total T4
003	TT3	Total T3
004	FT4	Free T4
005	FT3	Free T3
006	T3U	T3 Uptake
007	TBG	TBG
008	E2	Estradiol
009	LH	LH
010	FSH	FSH
011	Prol	Prolactin
012	Prog	Progesterone
013	B-hCG	Total B-hCG
014	Testo	Testosterone
015	AFP	AFP
016	CEA	CEA
017	HBsAg	HBsAg
018	aHBs	Anti-HBs
019	aHBC	Anti HBC
020	HBC M	Anti-HBC IgM
021	HBeAg	HBeAg
022	HAV M	Anti-HAV IgM
023	aHCV	Anti-HCV
024	aHIV	Anti-HIV 1+2
025	Rub G	Rubella IgG

Figure 6-9. Test Code Characters for Assays on the VITROS ECi Immunodiagnostic System. Availability of some of these assays are pending regulatory clearance or approval.

Test Code	REPORT NAME	ASSAY NAME
026	Rub M	Rubella IgM
027	Tox G	Toxoplasma IgG
028	Tox M	Toxoplasma IgM
029	CK-MB	CK-MB
030	Trop	Troponin I
031	Ferr	Ferritin
032	B12	Vitamin B12
033	Folat	Folate
034	Cort	Cortisol
035	FBhCG	Free B-hCG
036	PSA	PSA
037	F PSA	Free PSA
038	CA125	CA 125 II
039	CA153	CA 15-3
040	CA199	CA 19-9
041	CA724	CA 72-4
042	-	Unassigned
043	aHBe	Anti-HBe
044	NTx	N-Telopeptide
045	-	Reserved for internal use
046	TSH30	TSH30
049	HBCon	HBsAg Confirmatory
051	Myog	Myoglobin
055	FT3 II	Free T3 II
056	trak C	trak C - Total HCV Ag
058	-	Reserved for internal use
061	HAV T	Anti-HAV Total

Figure 6-9. Test Code Characters for Assays on the VITROS ECi Immunodiagnostic System. Availability of some of these assays are pending regulatory clearance or approval.

Test Code	REPORT NAME	DERIVED TEST NAME
165	T3/T4	TT3/TT4 Ratio
168	FT4I	FT4 Index
169	FT3I	FT3 Index
171	L/F	LH/FSH Ratio

Figure 6-10. Test Code Characters for Derived Tests on the VITROS ECi Immunodiagnostic System. Availability of some of these assays are pending regulatory clearance or approval.

6.4 Downloaded Sample Programs for the VITROS ECi Immunodiagnostic System

The format of a downloaded sample program record is described below as it appears at the application level. The analyzer processes the record according to this structure. If samples are identified by tray, then the downloaded *Kermit* record will consist of a record name and one to ten sample programs. If the samples are NOT identified by tray, then the *Kermit* record will consist of a record name but the number of sample programs is restricted by the database size.

6.4.1 Record Name

ASCII values 32-126 (decimal) are allowed for the record name. The first character must be capital S. The record name will not be used by the analyzer's control software.

6.4.2 Format of Downloaded Records for the VITROS ECi Immunodiagnostic System

The format of downloaded records is shown in figure 6-11.

Field Description	Number of Characters	Beginning Position		Ending Position		ASCII Values (in decimals)																													
		Min	Max	Min	Max																														
Field Separator followed by Tray Name ID: (Optional Fields) If there is no Tray Name specified, the Field Separator and Tray Name will not be transmitted. Otherwise, they will be transmitted with the first cup only. All printable ASCII characters. If a Tray Name is specified, it must appear only in the first sample of the file. In the Imm. System the Tray Name is 2 characters but for compatibility, it will pad to 15 characters, left justified.	15 Only 2 most significant digits are used. Remainder is truncated.	1	1	0	16	124, I character; 32-126																													
PSID SAMPLES: <i>Routine samples</i> Field Separator and Tray Name should not be transmitted. Samples need only be identified by sample ID (SID) or accession number (that which was bar coded in the container label). Adding Tray Name only hinders laboratory throughput of PSID samples, requiring that the Tray Name be entered when loading the tray on the Imm. System. <i>Priority samples</i> Priority samples that are bar coded can be swapped into tray positions counter-clockwise from the scanner station. These samples will be processed in sequence after any located STAT samples have been processed. As above, Field Separator and Tray Name should not be transmitted.																																			
ASSIGNED (LOCATED) SAMPLES: <i>Non-bar coded samples and located STATS</i> Field Separator and Tray Name must be transmitted or entered manually via keyboard as it is today without PSID. STAT samples take precedence over all other samples, and will be handled as soon as the Imm. System completes processing the current sample.																																			
Sample ID: All printable ASCII characters.	15	1	17	15	31	32-126																													
Fluid: This field identifies the fluid. In the Imm. System the range of numbers is: <table> <thead> <tr> <th>Fluid</th> <th>ASCII Char</th> <th>ASCII Dec Value</th> </tr> </thead> <tbody> <tr> <td>Serum</td> <td>4</td> <td>52</td> </tr> <tr> <td>Plasma</td> <td>5</td> <td>53</td> </tr> <tr> <td>Urine</td> <td>6</td> <td>54</td> </tr> <tr> <td>Blood</td> <td>7</td> <td>55</td> </tr> <tr> <td>Amnio</td> <td>8</td> <td>56</td> </tr> <tr> <td>Reserved 1</td> <td>9</td> <td>57</td> </tr> <tr> <td>Reserved 2</td> <td>:</td> <td>58</td> </tr> <tr> <td>Reserved 3</td> <td>;</td> <td>59</td> </tr> <tr> <td>Reserved 4</td> <td><</td> <td>60</td> </tr> </tbody> </table>	Fluid	ASCII Char	ASCII Dec Value	Serum	4	52	Plasma	5	53	Urine	6	54	Blood	7	55	Amnio	8	56	Reserved 1	9	57	Reserved 2	:	58	Reserved 3	;	59	Reserved 4	<	60	1	16	32	16	32
Fluid	ASCII Char	ASCII Dec Value																																	
Serum	4	52																																	
Plasma	5	53																																	
Urine	6	54																																	
Blood	7	55																																	
Amnio	8	56																																	
Reserved 1	9	57																																	
Reserved 2	:	58																																	
Reserved 3	;	59																																	
Reserved 4	<	60																																	
Stat Flag: <table> <thead> <tr> <th></th> <th>ASCII Char</th> <th>ASCII Dec Value</th> </tr> </thead> <tbody> <tr> <td>Non-stat</td> <td>0</td> <td>48</td> </tr> <tr> <td>Stat</td> <td>1</td> <td>49</td> </tr> </tbody> </table>		ASCII Char	ASCII Dec Value	Non-stat	0	48	Stat	1	49	1	17	33	17	33																					
	ASCII Char	ASCII Dec Value																																	
Non-stat	0	48																																	
Stat	1	49																																	
						48-49																													

Figure 6-11. Format of Downloaded Records for the VITROS ECi Immunodiagnostic System

Field Description	Number of Characters	Beginning Position		Ending Position		ASCII Values (in decimals)
		Min	Max	Min	Max	
Cup Position: Add 32 decimal to actual cup position (1-10) to shift cup number beyond the range of control characters. If a Tray Name ID was specified for a file, then all samples for that file should have non-blank cup positions. If a Tray Name ID was not specified, then all the samples for the file should have a blank cup position.	1	18	34	18	34	32 or 33-42
PSID SAMPLES: <i>Routine samples</i> Cup position should not be transmitted. Samples need only be identified by sample ID (SID) or accession number (that which was bar coded in the container label). Adding cup position only hinders laboratory throughput of PSID samples, requiring that cup positions be entered when loading a tray on the Imm. System. <i>Priority samples</i> Priority samples that are bar coded can be swapped into tray positions counter-clockwise from the scanner station. These samples will be processed in sequence after any located STAT samples have been processed. As above, cup position should not be transmitted.						
ASSIGNED (LOCATED) SAMPLES: <i>Non-bar coded samples and located STATS</i> Cup position must be transmitted or entered manually via keyboard as it is today without PSID. STAT samples take precedence over all other samples, and will be handled as soon as the analyzer completes processing the current sample.						
Dilution Factor: An off-analyzer dilution factor; a number between .0001 to 9999. in ASCII printable characters. The 5-character dilution factor will be in one of these formats—.xxxx, x.xxx, xx.xx, xxx.x, xxxx.—where x is a number 0-9. No leading, trailing , or embedded blanks are allowed.	5	19	35	23	39	46, 48-57
Measured Test Requests: (Optional field) Assay request expressed as an ASCII value. Refer to figure 6-9 for specific values.	0 - 60 (increments of 3)	24	40	24	99	48-57
Derived Test Requests: (Optional field) Test identification for derived tests expressed as an ASCII value. Refer to figure 6-10 for specific values.	0 - 90 (increments of 3)	24	100	24	189	48-57
Field Separator followed by Patient Name: (Optional fields) It is only transmitted if the Patient Name is non-blank. Field Separator Last Name (in the Imm. System is 20 characters, but it will truncate to 15 for compatibility) First Name (in the Imm. System is 15 characters, but it will truncate to 9 for compatibility) Middle Initial All printable ASCII characters.	0,1 0,15 0,9 0,1	24 25 40 49	190 191 206 215	24 39 48 49	190 205 214 215	124, Character 32-126 32-126 32-126
End of Sample	1	24	216	24	216	93,] character

Figure 6-11. Format of Downloaded Records for the VITROS ECi Immunodiagnostic System

Note: The analyzer maximums are found in [figure 6-6](#). The sample will not be processed if these values are exceeded.

7.1 General

The bidirectional mode of communication allows you to download patient information and sample programs from the laboratory computer and upload patient test results from your analyzer. The VITROS ECi Immunodiagnostic System can utilize two bidirectional protocols: *Kermit*, described in previous chapters, and the American Society of Testing and Materials (ASTM Protocol), described in this chapter and in Chapter 8.

This chapter focuses specifically on the rules governing the ASTM data transfer protocol and describes these aspects:

- How it can be configured
- How it establishes a session
- How it transfers information
- How it terminates a session
- How data integrity is checked and maintained

It draws largely from the information found in the ASTM protocol documents themselves. For further detail on the protocol, you may review ASTM specification documents E-1381 and E1394.

Note: Where there are differences between this specification and the E-1381-91 and E-1394-91, they will be highlighted in this document.

Service engineers can assist in setting up the optimum environment for a given laboratory. Configuration set up is a function that is protected and can only be changed with appropriate password and access codes.

7.1.1 Method of Transmission/ Reception

The ASTM protocol uses an asynchronous method of data transmission and reception (that is, serial by bit, start/stop). All bit sequencing, structure, and parity conform to ANSI standard X3.15-1976 and X3.16-1976.

The ASTM protocol specifies 1 stop bit. The setting is user configurable for 1 or 2 bits.

Default Configuration: 1 stop bit

7.1.2 Parity

In ASTM character parity can be of three types:

ODD	for odd parity
EVEN	for even parity
NONE	if parity checking is not desired

The ASTM protocol does not support MARK and SPACE. The default in the ASTM protocol is NONE.

Default Configuration in the Imm. System: NONE

7.1.3 Character Transmission and Reception

The order of bits for a given character is in this sequence:

- 1 start bit
- 8 data bits
- no parity bit
- 1 or 2 stop bits

The time between the stop bit of one character and the start bit of another character can be of any duration. While waiting, the data interchange circuit is in the marking condition.

The ASTM standard requires support for a number of different baud rates, whereas other baud rates remain optional. These are the required and optional baud rates.

Required	Optional
1200	300
2400	600
4800	19200
9600	38400

Default Configuration in the Immunodiagnostic System: 9600 baud, 8 data bits, no parity, 1 stop bit; Imm. System does not support 300 and 600 baud.

7.2 The Data Link

It is the responsibility of the data link to ensure sequential control, synchronization, error detection, and error recovery.

ASTM uses a character-oriented protocol to send messages between the analyzer and the laboratory computer. It requires a one-way transfer of information with alternate supervision. That is to say, *messages* can flow only one way at a time. Replies must occur after messages are sent, not at the same time. It is a simplex stop and wait protocol that complies with ANSI standard X3.4-1986.

7.2.1 Terminology

ASTM uses several terms to indicate the logical building blocks of the data transmission. These are called frames, messages, and sessions.

- **Frames.** The basic unit of communication for the data link layer. Based on the size of the message, there can be more than one frame. Frames are sometimes referred to as packets.
- **Messages.** The actual records containing the data on patients, sample programs and test orders, test results, comments, and other data. Messages contain one or more frames. A message contains one record at one given level in the record hierarchy.
- **Sessions.** The communication events. They contain all the control characters and messages sent, starting from the establishment phase and ending with the termination phase.

ASTM also refers to “test orders” and “test batteries” rather than “sample programs.” For consistency, the request for a series of tests on a patient sample will be referred to as a sample program in this manual. For the Immunodiagnostic System “assay” is often used rather than “test.”

In communicating from one station to another, ASTM, like other protocols, designates certain ASCII control characters as restricted characters that cannot appear in message text. You may refer to figure 7-1, that lists all the ASCII characters that ASTM uses. For further detail, please refer to the ASCII chart in Appendix A.

ASCII	Meaning	Decimal Value
ACK	Positive Acknowledgment	06
DC1	Control Q	17
DC2	Control R	18
DC3	Control S	19
DC4	Control T	20
ENQ	Inquire or Enquire	05
EOT	End of Transmission	04
ETB	End of Text Block	23
ETX	End of Text	03
LF	Line Feed	10
NAK	Negative Acknowledgment	21
SOH	Start of Header	01
STX	Start of Transmission	02
DLE	Data Link Escape	16
SYN	Sync	22

Figure 7-1. Restricted ASCII Control Characters Used by ASTM.

7.2.2 Layered Structure

For purposes of logical distinction, the ASTM protocol specification documents describe the protocol as having layers; each with a particular function. The figure 7-2 provides a generalized representation of that logical structure. The data link layer concerns itself with monitoring the actual transmission of the data.

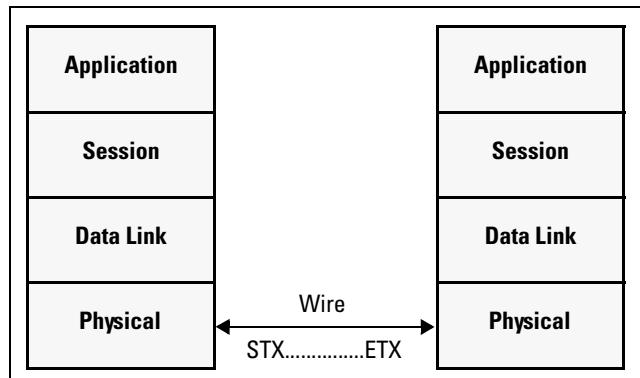


Figure 7-2. ASTM Protocol Layers.

7.2.3 Types of Frames

The maximum character limit for a frame in ASTM is **247 characters** (including overhead). If a given message is less than 240 characters, it is sent in an end frame with an <ETX>, checksum, <CR>, and <LF>. If, on the other hand, a message is greater than 240 characters, the message is sent in intermediate frames containing this structure <ETB>, checksum <CR>, <LF> with the final part of the message in an end frame. In other words, an <ETB> indicates that the message contains more than one frame. The figure 7-3 summarizes the layout for intermediate and end frames. Note that every message contains a frame number as well as two checksum characters for error checking to ensure data integrity.

An Intermediate Frame <STX> FN text <ETB> C1 C2 <CR> <LF>	
An End Frame <STX> FN text <ETX> C1 C2 <CR> <LF>	
Where:	
C1	Most significant ASCII character of checksum 0-9 and A-F
C2	Least significant ASCII character of checksum 0-9 and A-F
ETB	End of Text Block
ETX	End of Text
FN	Single digit from 0-7 for Frame Number
CR	Carriage Return
LF	Line Feed
STX	Start of Transmission
text	Data Content of Message

Figure 7-3. Frame Structure.

7.2.4 Frame Numbering (FN)

The frame number must immediately follow the <STX> character. It identifies the frame so that, in the event of a retransmission, the receiving device can distinguish it from a new frame. The FN begins with 1 and continues until 7. If more than seven frames are sent in one session, the counter rolls over to 0 and continues in the same manner.

7.2.5 Checksum

ASTM uses a two-byte checksum method. The checksum is initialized to zero with each <STX> character. The count begins with the frame number FN, and includes each character of the text ending with either the <ETB> or <ETX> characters (modulo 256). The count excludes the <STX>, <CR> <LF>, and the checksum characters themselves.

The checksum is an integer represented by eight bits having two groups of four bits each. It is provided as an ASCII representation of its hexadecimal equivalent. The two ASCII checksum characters in the ASTM frame begin with the most significant. You can observe the computations in greater detail through the examples found in figure 7-4.

Frame Structure Header Frame	<STX>FN Text <CR><ETX>Ch1Ch2<CR>LF 1 H \^ & VITROS 1995 0301154000<CR><ETX>CH1CH2<CR>LF
Sum in Hex	31+48+7C+5C+5E+26+7C+7C+7C 45+4B+54+49+4D+4D+41+7C+7C+7C+7C +7C+7C+7C+7C +31+39+39+35+30+33+30 +31+31+35+34+30+30+30+OD+03 = C83 TOTAL = 83 (modulo 256) 8= most significant 3= least significant
C1 = 38 transmitted as printable ASCII characters C2 = 33	

Figure 7-4. Checksum Calculation.

7.3 Session Establishment Phase

A session consists of the transfer of one or more frames from one station to another. It is a unit of communication between two stations or devices. A session begins with the Establishment Phase and ends with the Termination Phase and includes all the events occurring within the session.

Either station can initiate a session when it has records to send: the analyzer, for example, may wish to send results (an upload session) or the laboratory computer may wish to send a sample program (a download session).

The sender first attempts to determine if the link is in a neutral state, that is, free for use. It notifies the receiver that it is ready to send records by transmitting the <ENQ> control character.

The receiver may reply in one of two ways. If it is ready to receive records, it sends a positive acknowledgment, <ACK>, and this completes the Establishment Phase.

But if the receiver is not ready to receive, it transmits a <NAK>, indicating it is not ready.

7.3.1 Timer for Reply

If the sender transmits an enquire <ENQ>, it requires a reply within 15 seconds. If it receives no reply after 15 seconds, the sender considers the link to be in a neutral state.

7.3.2 Timer for NAK Reply and Retries

When a sender receives a <NAK>, it must wait at least 10 seconds before it tries again. In attempting to establish a session, ASTM does not specify a particular limit for number of repeated attempts.

7.3.3 Session Contention

When either the laboratory computer or the analyzer initiates a session, the session flows in one direction at a time. However, when the laboratory computer and the analyzer both wish to initiate a session at the same time, that is, when they send simultaneous <ENQ>s, they are in contention. According to the ASTM protocol, when in contention, the laboratory computer must give way to the analyzer.

7.3.4 Session Contention Timers

When contention occurs, there are two session contention timers that apply, one for the analyzer and one for the laboratory computer.

When the analyzer receives an <ENQ> in reply to its own <ENQ>, indicating a state of contention, it must wait one (1) second before retransmitting an <ENQ> to establish a session.

The laboratory computer, when in a state of contention, must wait 20 seconds for an <ENQ> from the analyzer. If it does not receive an <ENQ> in that time frame, the laboratory computer can assume that the line is in a neutral state and it can then try to establish a session itself by sending an <ENQ> again.

7.4 Transfer Phase

After a device establishes a session, it begins its transmission of message frames with supporting control information. ASTM provides a number of timers and monitoring mechanisms to ensure speed, accuracy, and completeness throughout the transfer phase. These are described in sections 7.4.1 through 7.4.4.

7.4.1 Receiver Timers in Transfer Phase

The receiver sets a timer of 30 seconds in which to receive either a frame or an <EOT>. If either of these is not received in the time limit specified, the receiver discards the frames that were received since the last successful save point and considers the line in a neutral state.

7.4.2 Acknowledgments

The ASTM protocol requires that the sender stop after each frame is sent and await an acknowledgment. The acknowledgment must occur frame by frame. Before responding, the receiver must monitor its own continuing capacity and check for error conditions. Specifically, the receiver checks the following items:

- The frame number
- The checksum value
- The receipt of an <ETB> or <ETX>

The receiver then responds with one of these three acknowledgments:

- <ACK> The last frame was successfully received. Send next frame.
- <NAK> The last frame was not successfully received. Retransmit last frame.
- <EOT> The last frame was successfully received. Please stop transmission. When the receiving station of the current session sends an <EOT> as an acknowledgment, it is urgently requesting the sending device to stop sending and put the line in a neutral state, allowing the receiver to establish its own session.

Phase	Condition	Timer/Time	Rule
Establishment	Sender issues <ENQ>	Sender <ENQ> Timer – 15 seconds	Sender must wait 15 seconds to receive any reply. If no reply, line returns to a neutral state and sender can try again.
	Sender issues <ENQ>; receiver <NAK>s	Retry Timer – 10 seconds	Sender must wait 10 seconds before it retries. No limit on number of retries.
	Session contention; sender and receiver send and receive <ENQ>s simultaneously; laboratory computer must give way	For Analyzer – 1 second For Laboratory Computer – 20 seconds	Analyzer must wait 1 second before sending new <ENQ>. Laboratory computer must wait 20 seconds to receive another <ENQ>. If not received, it can try again to establish a session.
Transfer	Beginning and continuing transfer	Frame Timer – 30 seconds	Receiver waits 30 seconds to receive frame. If it does not get one or an <EOT>, it discards last frame and terminates session.
	Acknowledgment	Response Timer – 15 seconds	Sender must wait 15 seconds for a reply. If none received, it cancels and terminates session.
	Interrupts; sender receives an <EOT> as a frame acknowledgment; sender honors interrupt	Interrupt Timer – 15 seconds	If interrupt is honored (sender responds with <EOT>), sender must wait 15 seconds to receive an <ENQ>. If it does not receive one, it can try to establish a session itself.

Figure 7-5. Summary of ASTM Timers.

7.6 Error and Recovery in the Data Link

The error checking in the ASTM protocol at the data link level occurs on a frame by frame basis to ensure that all frames are received in their entirety and exactly as sent. The protocol checks only that portion of the frame that occurs after the <STX> and before the <ETB> or <ETX>. ASTM checks for the following error conditions among others:

- Checksum (C1 and C2) does not match
- Parity errors
- Frame number (FN) is not correct, that is, either the frame number is not incremented by one (modulo 8) or is not a repeat of the last sent

7.4.3 Timers for Acknowledgments

The sender waits for an acknowledgment of receipt. If this does not occur within 15 seconds, the sender cancels the message and terminates.

7.4.4 Interrupt Timers

A receiver can request an interrupt by sending an <EOT>. The sender is not required to honor the request but may do so.

If the sender stops transmission and the receiver does not enter the establishment phase in 15 seconds, the sender may re-enter the establishment phase.

7.5 Session Termination Phase

In the ASTM protocol, termination of data transmission is straightforward. The sending station simply transmits an <EOT> to end the session and puts the data link in a neutral state. When a receiving station gets the <EOT>, it too regards the link as neutral.

In figure 7-6 through figure 7-12, we provide examples of conditions that occur in download and upload sessions.

When an error is detected, the receiving station issues a <NAK> and the sending station retransmits the last frame.

When retransmitting a single frame, the sender increases a retransmit counter by one. If the frame is sent and rejected six times, the sender must cancel the session.

After the cancel, when the line is in a neutral state, the sender tries to re-establish a session. Once the session is established, the sender transmits another header record and begins retransmission from the last record presumed saved before the cancel. Since saves occur at patient boundaries on the Immunodiagnostic System, any retransmission starts with the patient record at Level 1 of the hierarchy where the frame error was found. It is important to note here that as a result of this

error handling, frames that were already accepted are resent. The resending of frames preserves the message hierarchy and prevents corruption of any individual record. Refer to Chapter 8, "Application Interface: Bidirectional Mode ASTM Protocol" for more a more complete explanation of recovery in the ASTM protocol.

Errors in the data link and session transmission are indicated on the analyzer's status console. You can review all link errors on the Immunodiagnostic System's Condition Review screen.

10 bits per byte, then the rate becomes 3840 bytes per second. This indicates that the interface hardware and the physical layer software must be able to handle bursts of approximately 4K bytes per second.

The arrival rate of assay results on the Immunodiagnostic System can occur at regular 36 second intervals or in bursts of several hundred at once.

Performance, however, involves more than the transmission rate and depends on a variety of other factors including cable length, signal voltage, message size, and other application-related criteria.

7.7 Performance Issues

The maximum baud rate for transmission is 38,400 bits per second for the Immunodiagnostic System. If this is divided by

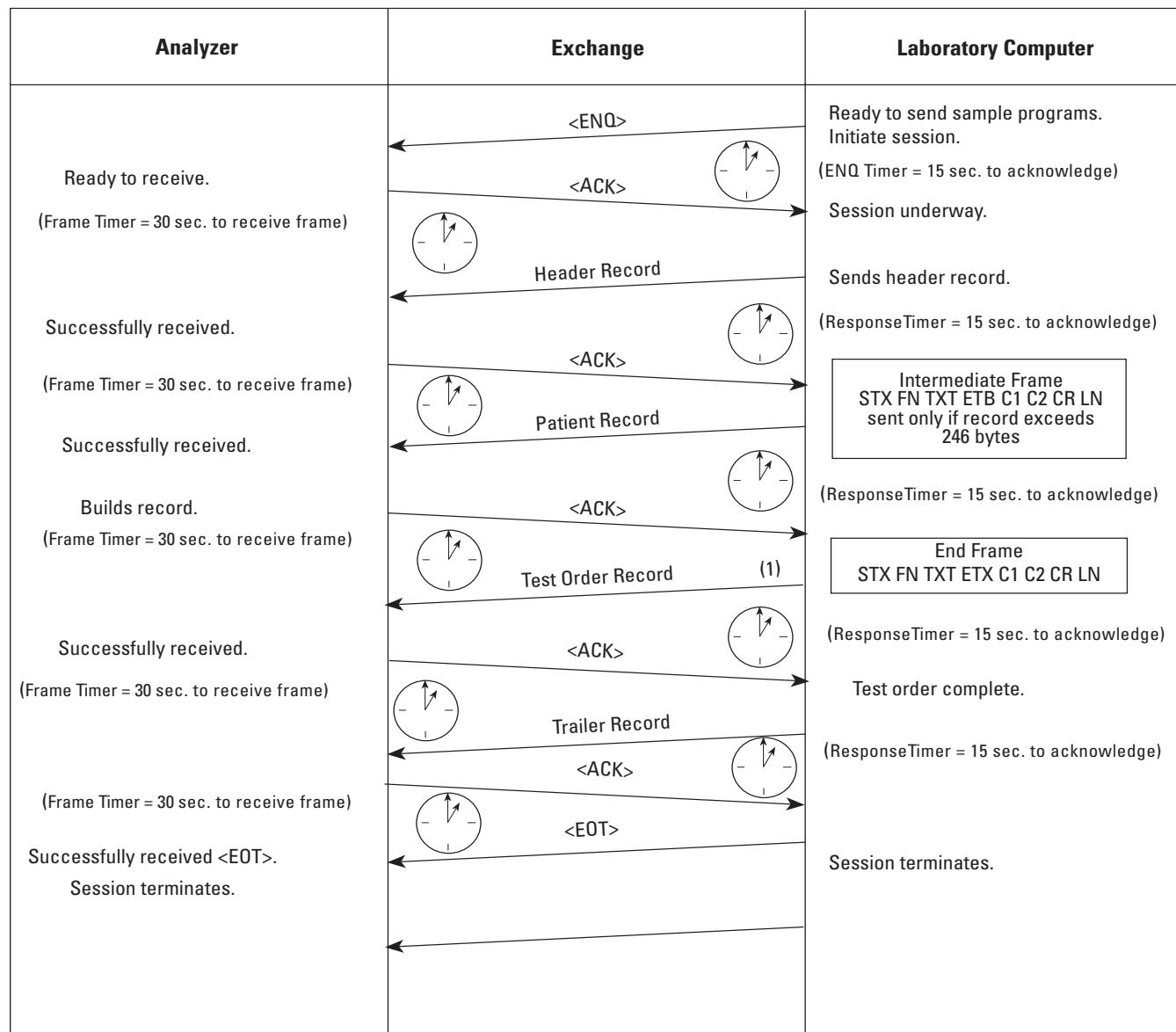


Figure 7-6. Normal Download Session.

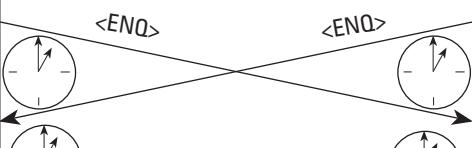
Analyzer	Exchange	Laboratory Computer
Ready to send. (ENQ timer = 15 sec. to acknowledge)		Ready to send. (ENQ timer = 15 sec. to acknowledge)
Analyzer timer = 1 second to send another <ENQ>.	<ENQ>	Laboratory computer timer gives way. (LC wait timer = 20 seconds to send another <ENQ>.)
Ready to upload. (Response timer = 15 sec. to acknowledge)	<ACK> Header Record	(FrameTimer = 30 sec. to receive frame) Session underway. Successfully received frame.
(Response timer = 15 sec. to acknowledge)	<ACK> Patient Record	Builds record.
No more records. Session terminates.	<ACK> etc. <EOT>	Session terminates.

Figure 7-7. Session Contention.

Analyzer	Exchange	Laboratory Computer
Ready to receive. (FrameTimer = 30 sec. to receive frame)	<pre> sequenceDiagram participant Analyzer participant Exchange participant LabComputer Analyzer->>Exchange: <ENQ> Exchange-->>Analyzer: <ACK> Exchange->>LabComputer: Header Record LabComputer-->>Exchange: No Reply LabComputer->>Analyzer: <EOT> </pre>	<p>Ready to send header record. (ENQ timer = 15 sec. to acknowledge)</p> <p>Session underway.</p> <p>Sends header record.</p> <p>Session underway.</p> <p>(Response timer = 15 sec. to acknowledge)</p> <p>Session terminates.</p>
	<pre> sequenceDiagram participant Analyzer participant Exchange participant LabComputer Analyzer->>Exchange: <ENQ> Exchange-->>Analyzer: <ENQ> Exchange->>LabComputer: Header Record LabComputer-->>Exchange: No Reply LabComputer->>Analyzer: <EOT> </pre>	<p>Ready to send header record. (Response timer = 15 sec. to acknowledge)</p> <p>Session terminates—Infinite retry.</p>

Figure 7-8. No Response Timer.

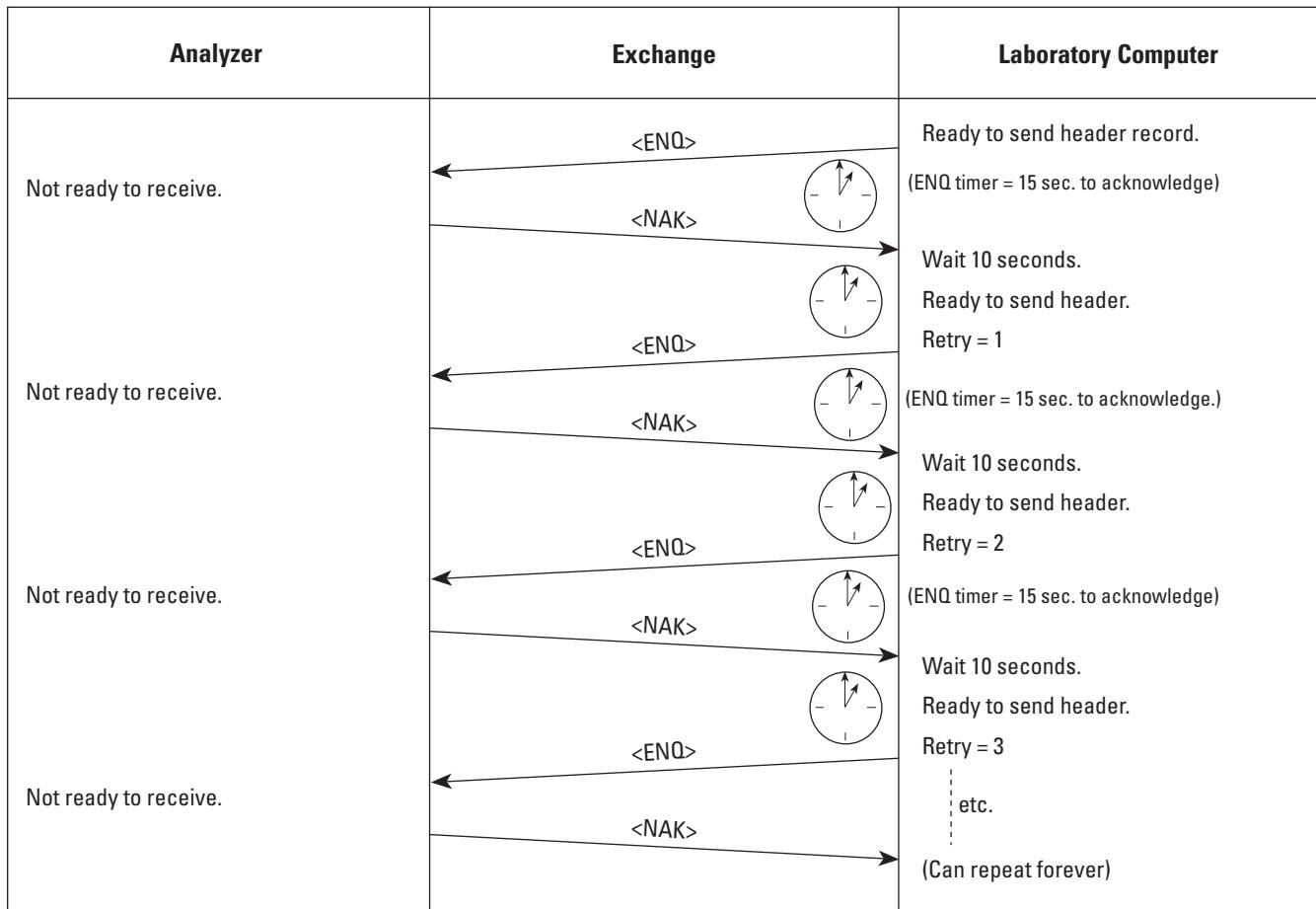


Figure 7-9. Session Establishment and NAK Replies.

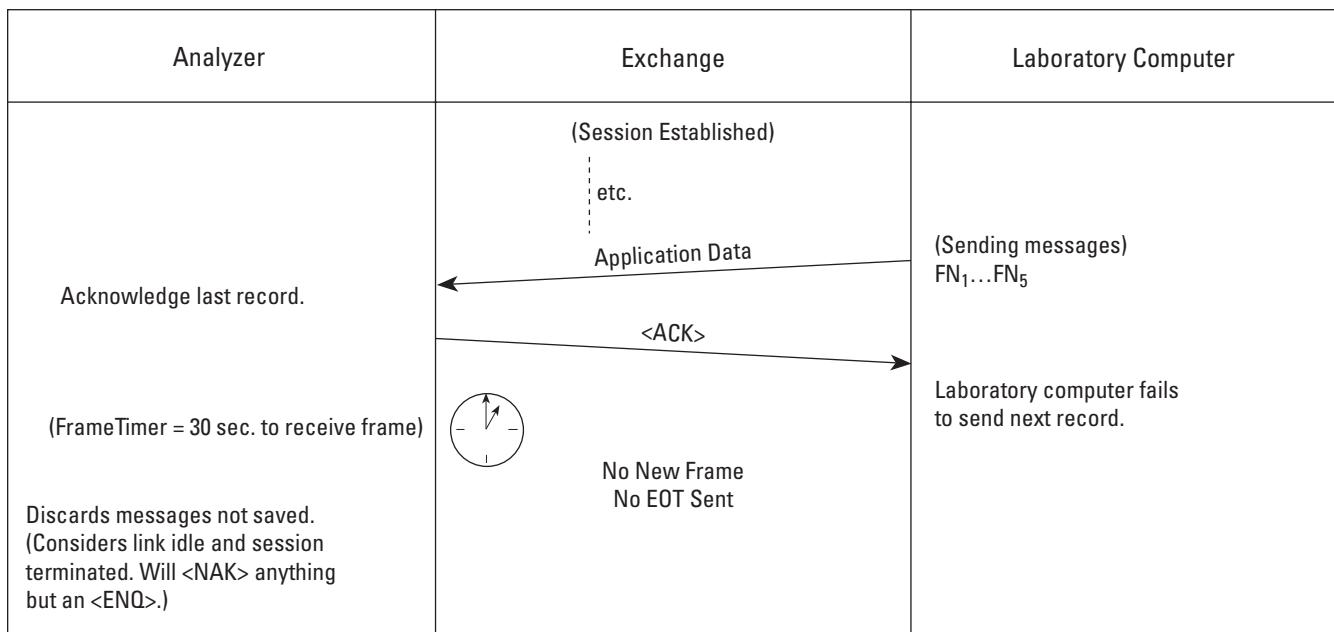


Figure 7-10. Discard Last Message.

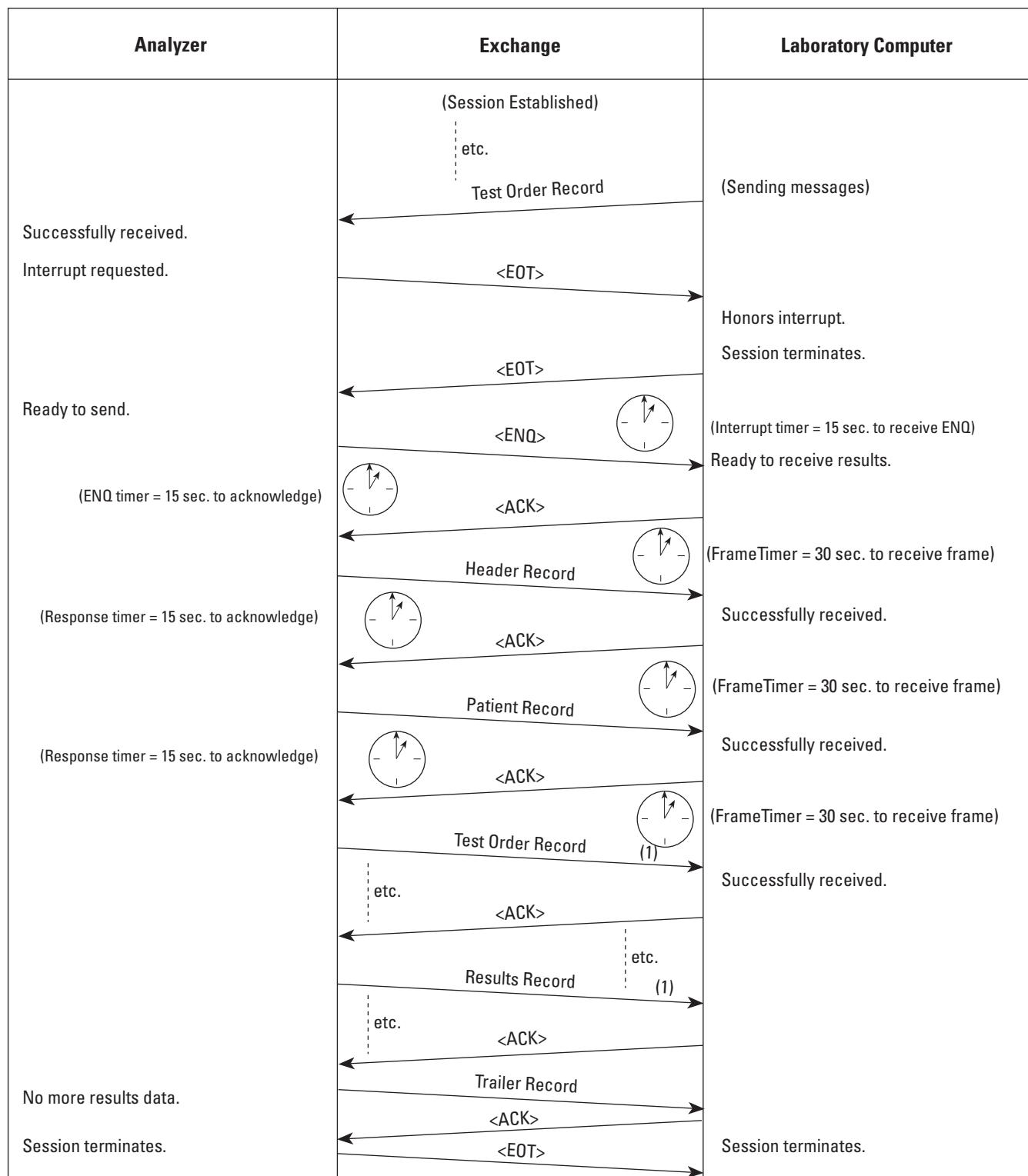


Figure 7-11. Interrupt Honored During a Download Session.

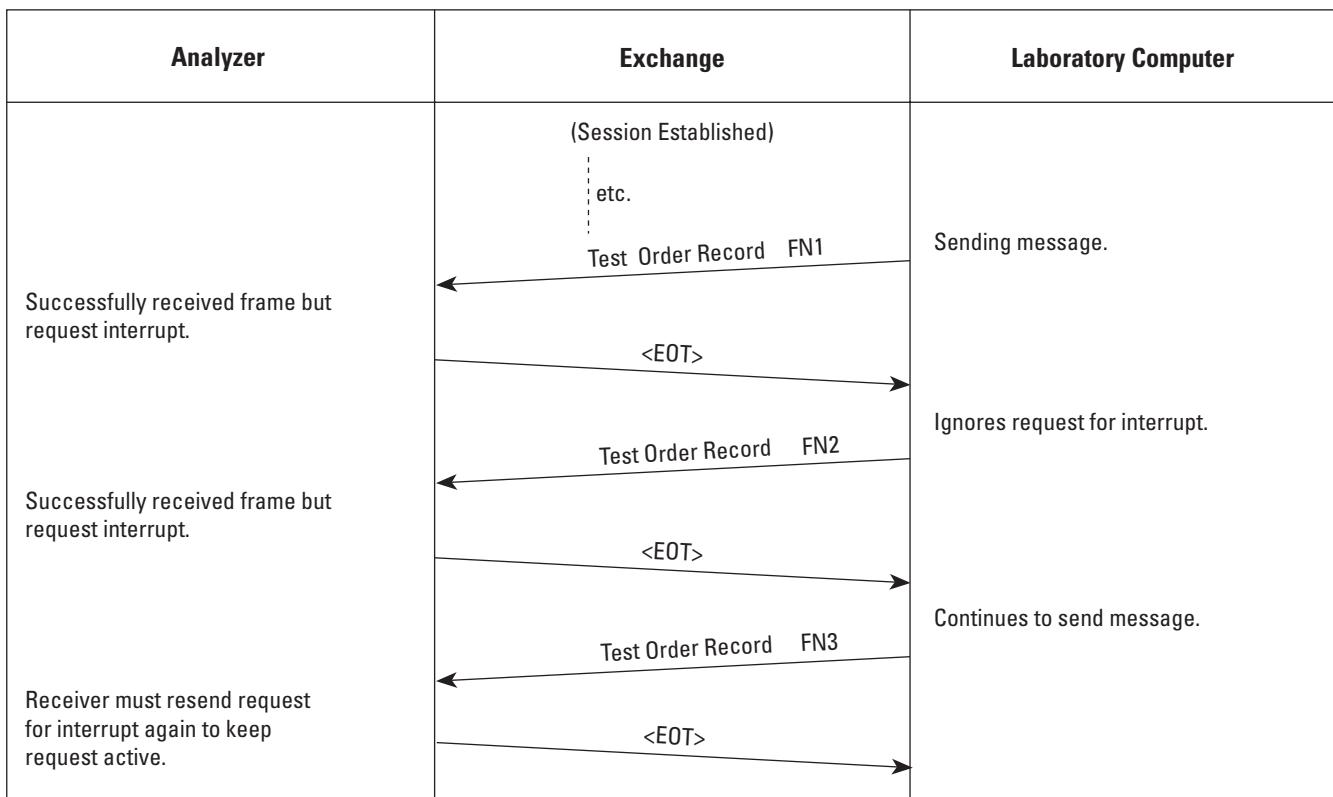


Figure 7-12. Interrupt Not Honored.

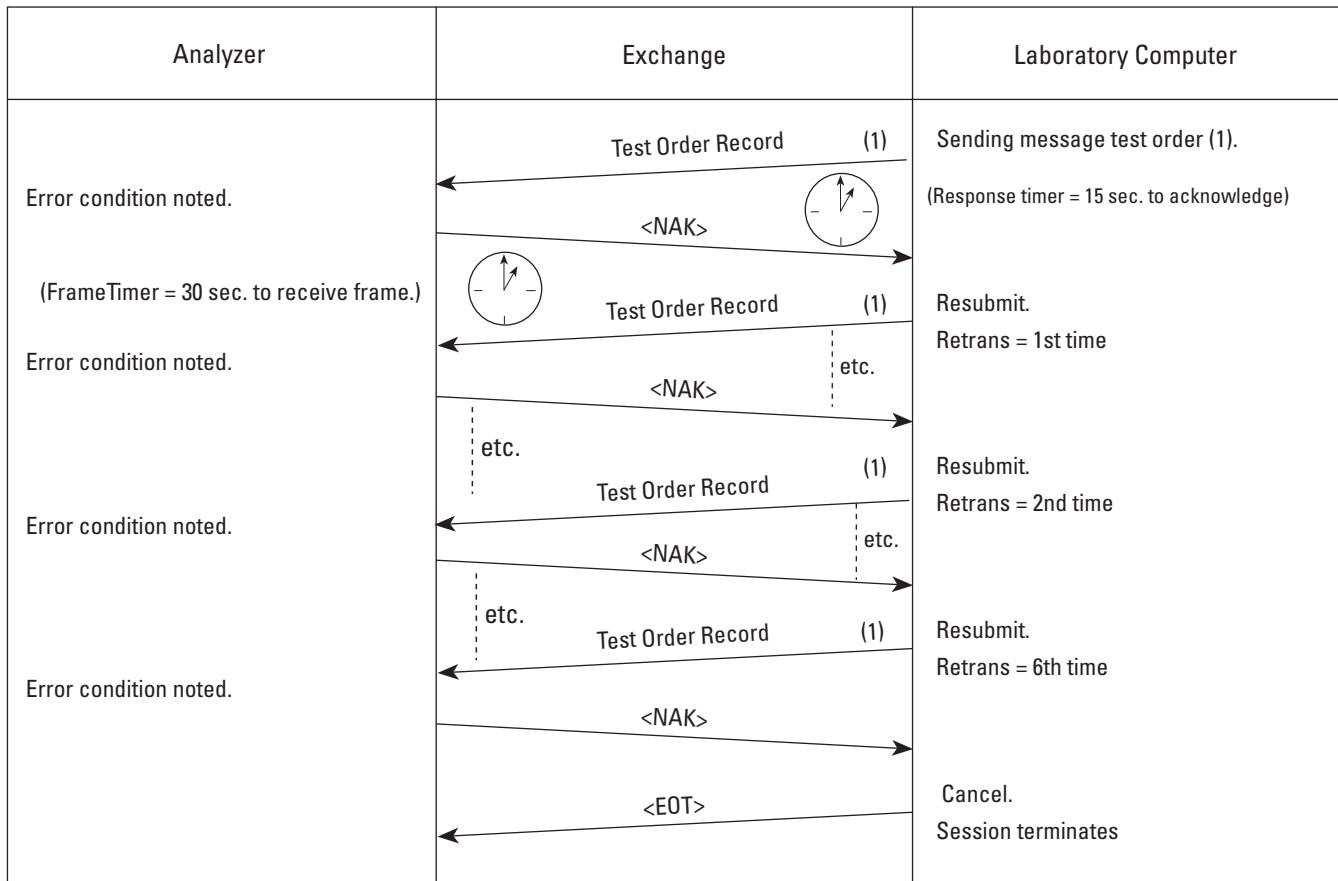


Figure 7-13. Error Condition and Cancel.

7.8 Considerations in System Applications

This section provides information that might be helpful to the laboratory computer coordinator in managing data transmission.

7.8.1 Session Duration

Sessions can extend for an unspecified amount of time. However, it is helpful to recognize that if there is an analyzer backlog in reporting results, an upload session may be quite lengthy.

7.8.2 Sample Program and Results Capacity

The Immunodiagnostic System can store up to 10,100 sample programs, 10,000 for down loading with an additional 100 for manual programs, and 5000 assay result records at any time.

In download, when the sample program database fills, the Immunodiagnostic System will respond negatively with a <NAK> to receiving more sample programs. On the other hand, as the results database fills, the analyzer sends a message to the display console at certain intervals indicating that it is near full.

This can occur, for example, as the analyzer holds results to be transmitted while accepting a download.

7.8.3 Transmission Errors and Condition Codes

If the Immunodiagnostic System detects an error during an upload session or a download session, it reports the error to the master computer software as a condition code for the operator. At the link level, if the Imm. System is up loading, it tries to resend the <NAK>ed frame six times; then it cancels and returns the line to a neutral state. When this happens, the Imm. System "remembers" the frame sent in error and later, retransmits it.

If the Immunodiagnostic System is receiving a frame with an error, it **<NAK>**s the frame. It repeats this up to six times and then, if the frame is still in error, it cancels the session, returning the line to a neutral state.

7.8.4 Broadcasting Sample Programs

If a laboratory has more than one analyzer, it can choose to implement an analyzer-supported broadcast feature. In broadcasting, the laboratory computer sends a given sample program to all analyzers simultaneously. Once the patient sample corresponding to the sample program has been loaded

onto a particular analyzer, that analyzer can then actually process the order. The broadcasted sample program will remain on the other analyzers until deleted.

On the Immunodiagnostic System, to delete a sample program manually, the operator must resubmit the sample program with the same specimen ID and universal test ID, but with the universal test ID empty or the action code equal to 'C' for cancel. The Immunodiagnostic System recognizes this string combination as a request to cancel.

Like other analyzers, the Immunodiagnostic System ignores any broadcasted sample programs with analytes that do not pertain to it. Since it has unique values for body fluid, it also ignores any sample programs with unrecognized specimen types.

7.8.5 Editing Downloaded Sample Programs

The laboratory computer can edit a previously downloaded sample program, as long as that order is not in use and has not been manually edited. In the Immunodiagnostic System, to edit

a sample program, both the specimen ID and the patient name, including all three ASTM components, must match. Editing is done by retransmitting the sample program. All data fields (except specimen ID) are redefined with the new values and assays requested.

7.9 Summary of Key Features

- ASTM is a simplex stop and wait protocol.
- Its default configuration is 9600 baud, 8 bits, with no or odd parity checking and 1 stop bit.
- All transmission is in ASCII with these restricted characters: ACK, DC1, DC2, DC3, DC4, DLE ,ENQ, EOT, ETB, ETX, LF, NAK, SOH, STX, SYN.
- ASTM transmits data records encapsulated in frames that must be acknowledged frame by frame.
- Error conditions result in <NAK> responses that require a retransmission.
- Timers exist for acknowledgments, frame reception, and replies.
- Receiver interrupts are allowed any time the receiver has a request or when capacity is reached.

8.1 General

The ASTM application layer enables the laboratory computer to automatically download patient data and sample programs to the VITROS ECI Immunodiagnostic System, and it also enables the Immunodiagnostic System to automatically upload corresponding test results. In Chapter 7 we discussed the rules by which the data is transferred between devices. In this chapter we discuss the data itself: we describe not only the data and records ASTM supports but also the conventions it uses to format that data.

One of the most important characteristics of the ASTM protocol is its flexibility. It is designed to adapt to a wide range of medical settings and to standardize laboratory communications across a variety of devices. Since the protocol has such broad-based application, each instrument manufacturer must choose among the data fields supported, implementing whatever is most appropriate for its instrument.

This chapter also describes the particular data implementation choices made for the Immunodiagnostic System.

Chapter 8 specifically addresses these topics:

- Terminology
- Record types
- Conventions used
- Condition codes and recovery
- Data field implementation, which data the Immunodiagnostic System supports

Much of the information found in this chapter draws from the ASTM specification document: *Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems (ASTM I394-91)*.

8.2 Terminology

ASTM uses a number of different terms to indicate the way it groups data. Many of the terms are already familiar to you.

- **Field.** An individual piece of data often referred to as a data field or a data element.
- **Record.** A number of logically related data fields grouped together to form one part of a complete message. Patient demographics are data fields comprising the patient record. These aggregates of related fields are often called files.
- **Repeat field.** A data field of the same type as the one immediately preceding it. A delimiter separates one instance of a repeat field from the next. Test requests are transmitted in repeat fields within their related records.

- **Component field.** Part of a data field that might contain more than one piece of data. Address is a common example of a data field that has more than one component: street number, street name, city, and other location data are all component fields of address.

8.3 Record Types

ASTM uses record types that are common and familiar to all laboratory personnel. Each of the records begins with a field identifying the record type, shown in parentheses below, and ends with a carriage return and line feed.

Later in the chapter there are charts describing the specific data fields included in each record type. The charts also show the fields and data values used by the Immunodiagnostic System. ASTM uses the following record types:

- **Header Record (H).** Contains identifying information about the sending station, conventions that the device uses for field recognition, and the date and time of send station transmission.
- **Patient Information Record (P).** Contains patient-related information like patient identification number, patient name, patient demographic information, and the name of the patient's attending physician.
- **Test Order Record (O).** Stores information about the assay or requests themselves and includes data about specimens, the time of collection, action requested, and the assay priority. **Note: In all Immunodiagnostic System and Chemistry System, “sample program” is used where ASTM would use the term “test order.” We use sample program to mean test order in this manual for consistency with other product documentation. The term test order is only used when referring to the test order record itself.**
- **Result Record (R).** Contains information about the outcome of individual tests for individual patients and always follows a sample program record. In an upload transmission, a single result for a given patient is coupled with the specific sample program it corresponds to. The result contains the actual measurements derived from the test and provides a comparison of the individual result to certain ranges specified as norms for the laboratory.
- **Comment Record (C)** Allows the laboratory to enter any information it chooses about patients, samples, or results in a free form manner. The Immunodiagnostic System, on the other hand, supports comments for patient records only and they can be a maximum of 60 characters in length.
- **Message Terminator Record (L).** Ends the session.

Although the ASTM protocol supports three additional record types, a Request for Information Record (a query record) a Scientific Record (a record used for participation in studies), and a Manufacturer's Information Record (a record used for special structures), the Immunodiagnostic System is not implementing these in the first release and will ignore them. **In fact, the Immunodiagnostic System will simply ignore any data sent that has not been implemented.**

8.4 Conventions

ASTM stipulates a number of conventions for the layout, transfer, interpretation, and recovery of data found in the records it defines. In particular, ASTM uses the following common conventions:

- A hierarchical structure
- Variable length records
- Delimiters, counters and sequence numbers to segment its data.

8.4.1 The Hierarchy

The beginning level of the hierarchy is zero (0), and ASTM reserves Level 0 for initial and terminating information about the records being sent. The header record and the message terminator record are the two record types with a Level 0 designation.

The intermediate levels form the structure of a logical hierarchy that is somewhat dynamic in nature.

- Level 1 contains the patient record.
- Level 2 contains the patient's test order record; that is, sample program.
- Level 3 contains the test result records corresponding to that patient's sample program.

The assignment of hierarchical levels ensures that the records maintain the appropriate linkages and relationships with other records while avoiding redundancy.

The Immunodiagnostic System has implemented this hierarchy in a particular way to reflect the necessary grouping of sample

programs with specific, individual patient samples. These instruments allow only one test order record per patient record. If a patient submits more than one sample for testing, for example, a urine and a blood sample, then the second sample will have its own test order record with another instance of the same patient record. If a patient record is sent with more than one order, only the last one will be kept.

The Immunodiagnostic System couples result records with their corresponding sample programs. So, in contrast to the test order record, there can be many result records related to any one test order record and patient.

To give a simple example, let us say that the laboratory takes a blood and urine sample from a patient, Mr. Jones. The laboratory creates a sample program requesting all the tests to run on Mr. Jones' blood sample as one test order record for Mr. Jones' patient record. When requesting the tests for Mr. Jones' urine sample, the laboratory staff will create another sample program using another test order record for another instance of Mr. Jones' patient record.

ASTM allows comments at any level in the hierarchy. Comments always relate to the records immediately preceding them. Wherever they occur, comments take on the same level of the next higher record in the structure. For example, if you insert comments for a particular patient record, those comments will reside at Level 2; that is, at one level deeper in the hierarchy than the patient. The patient comment is on the same level as the patient's sample program, linking the comments like the sample program with a particular patient. If comments apply to a result record at Level 3, ASTM assigns the comments to a Level 4, the next higher level. Similar to two or more order records in a row, if more than one comment record occurs, the last one will be kept and the others discarded.

The Immunodiagnostic System supports a single comment of up to 60 characters in length following patient records only.

Figure 8-1 reflects the ASTM hierarchy as implemented in the Immunodiagnostic System for any downloads to it. Notice that in **figure 8-1** comments only occur at level 2 attached to a patient record since the Immunodiagnostic System does not recognize comments at other levels in the hierarchy.

(Level 0)	HEADER
(Level 1)	PATIENT 1 (general information about the patient)
(Level 2)	COMMENT Record 1 (relates to previous patient information — up to 60 char.)
(Level 2)	ORDER 1 (Information about SAMPLE PROGRAM 1)
(Level 1)	PATIENT 2 (all of the structure repeats)
.	
.	
.	
(Level 1)	PATIENT n (all of the structure repeats)
(Level 0)	MESSAGE TERMINATOR

Adapted from the American Society of Testing and Materials. *Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems*. Designation: E1934-91

Figure 8-1. Logical Structure of a Laboratory Computer Download Message to the VITROS ECI Immunodiagnostic System.

Figure 8-2 shows the full range of the hierarchy when results are added in upload sessions from the Immunodiagnostic System.

(Level 0)	HEADER
(Level 1)	PATIENT 1 (general information about the patient)
(Level 2)	COMMENT Record 1 (relates to previous PATIENT RECORD)
(Level 2)	ORDER 1 (Information about SAMPLE PROGRAM 1)
(Level 3)	RESULT 1 (Information about the 1st result of SAMPLE PROGRAM 1)
(Level 3)	RESULT 2 (Information about the 2nd result of SAMPLE PROGRAM 1)
(Level 3)	RESULT n (information about the last result of SAMPLE PROGRAM 1)
(Level 1)	PATIENT 2 (all of the structure repeats)
	.
	.
(Level 1)	PATIENT n (all of the structure repeats)
(Level 0)	MESSAGE TERMINATOR

*Adapted from the American Society of Testing and Materials. *Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems*. Designation: E1934-91.

Figure 8-2. Logical Structure of a VITROS ECi Immunodiagnostic System Upload Message.

8.4.2 Record Sequencing and Numbering

Every record within a transmission session has a record sequence number. The number keeps incrementing for every record at the same level until a record at a lower level appears. At that point the numbering of a given record type resets to 1. This is necessary to group the data in an appropriate logical manner: sample program to patient, results to sample program, and so on.

As [figure 8-2](#) shows, a result record sequence associated with a given test order record will end when the next patient record begins. The levels are grouped such that a result belongs to a specific sample program and an order belongs to a specific patient.

8.4.3 Logical Storage

ASTM requires that as the records proceed from one level to another, any time the record level decreases (from 2 to 1 or 3 to 2), data from the previous level is saved and stored. This is a minimal requirement and the Immunodiagnostic System complies.

8.4.4 Transmission Conditions and Recovery

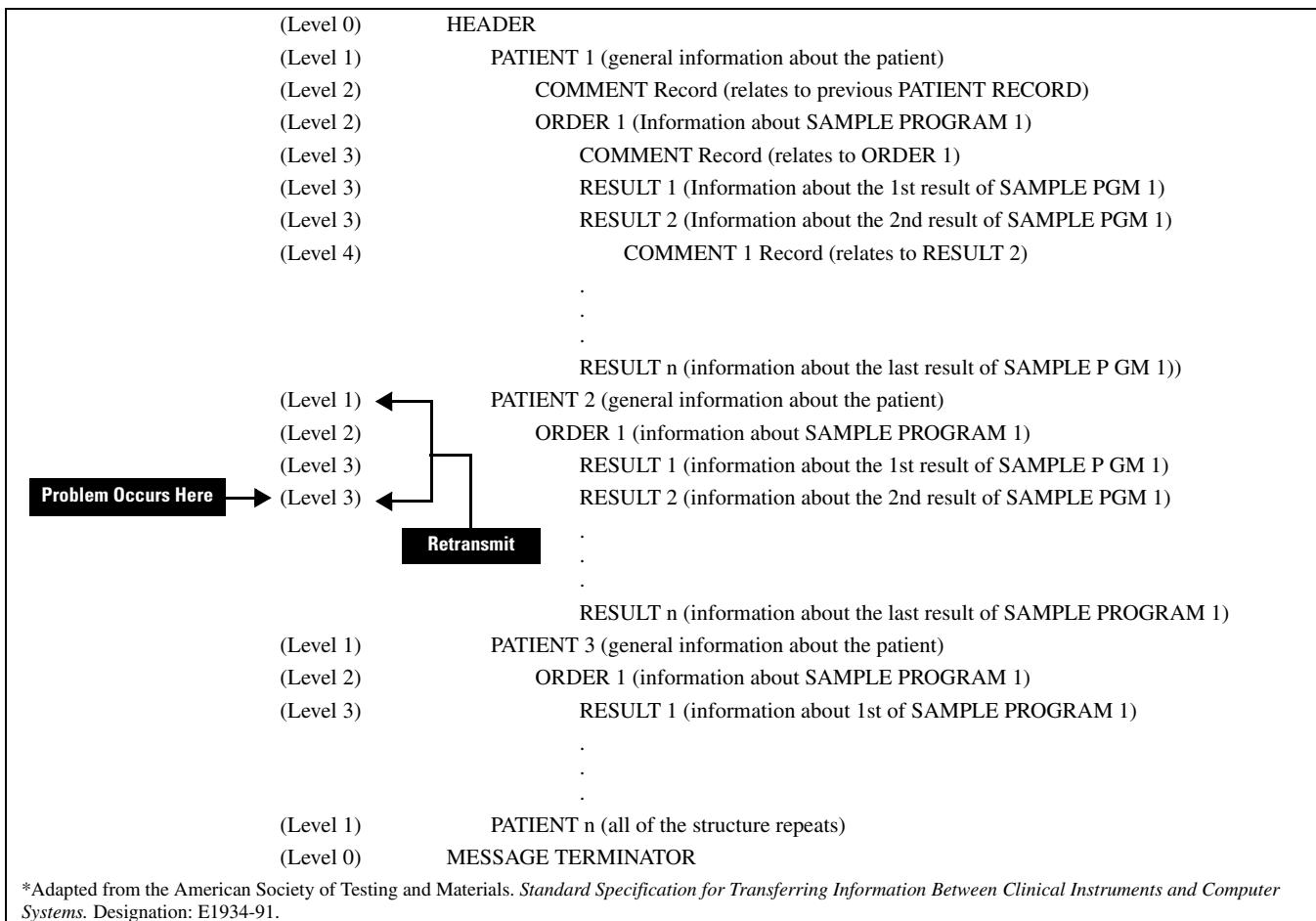
The recovery procedures in the Immunodiagnostic System relate both to the recovery at the data link level and to the method of storage just described.

If there is a problem with transmission at the data link and a frame is <NAK>ed, the protocol will retransmit a frame up to six times. If the frame is <NAK>ed six times, the message cancels and the line returns to a neutral state.

The sending station remembers the frame that was canceled. When it begins to transmit again, it recognizes the canceled frame's position in the hierarchy, and, in the case of the Immunodiagnostic System:

- Sends a header record
- Returns to the beginning of the patient record in which the cancel occurred and retransmits all records from that patient record forward

In other words, in the Immunodiagnostic System, recovery occurs at patient boundaries and begins with a new header record.



*Adapted from the American Society of Testing and Materials. *Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems*. Designation: E1934-91.

Figure 8-3. Recovery and Re-transmission.

8.4.5 Character Codes and Delimiters

Both the application and the communication layer, as implemented by the Immunodiagnostic System, use a range of ASCII character codes to do the following tasks:

- Represent transmission activity
- Define data fields by position in variable length records
- Display text

All ASCII characters used in ASTM comply with *ANSI Standard X3.4-1986*.

8.4.5.1 Restricted Characters Set

In **figure 8-4** we list all the restricted characters used in ASTM. Refer to Chapter 8, “Communications Interface, Bidirectional Mode ASTM Protocol,” which describes how the communication layer uses each character. For the full ASCII character code chart, please refer to Appendix A.

ASCII	Decimal	Hex	ASCII	Decimal	Hex
NUL	0	00	DC3	19	13

Figure 8-4. ASCII Restricted Character Set.

ASCII	Decimal	Hex	ASCII	Decimal	Hex
SOH	1	01	DC4	20	14
STX	2	02	NAK	21	15
ETX	3	03	SYN	22	16
EOT	4	04	ETB	23	17
ENQ	5	05	CAN	24	18
ACK	6	06	EM	25	19
BS	8	08	SUB	26	1A
LF	10	0A	ESC	27	1B
(record terminator)	13	0D	FS	28	1C
SO	14	0E	GS	29	1D
SI	15	0F	RS	30	1E
DLE	16	10	US	31	1F
DC1	17	11	DEL	127	7F
DC2	18	12			

Figure 8-4. ASCII Restricted Character Set.

8.4.5.2 Field Length and ASTM Delimiters

As mentioned earlier, ASTM assumes a variable length record. A blank or null value occupies no space and is only indicated by

a field delimiter to hold the field's place within the record. ASTM does not assign any maximum lengths for fields; rather, it depends on buffering capabilities and the communication layer to parse and transmit messages efficiently.

ASTM uses several printable characters as special delimiters to assist in determining record layout. Although it can accept other delimiters as defined in a download session, the Immunodiagnostic System uses only the ASTM default delimiters as displayed in [figure 8-5](#). You can find examples of record layouts using these characters at the end of each record definition in [Section 8.4](#) of this chapter; the appendix contains additional examples.

Character	Special Meaning
	Field delimiter
\	Repeat delimiter
^	Component delimiter
&	Escape delimiter

Figure 8-5. ASTM Delimiters.

You must define these delimiters in the message Header Record to indicate how to read the records that follow it. The delimiters function in the following way:

- **Field delimiters.** Define the end of a new field and the beginning of another field.
- **Repeat delimiters.** Indicate when a type of field occurs more than once in the same record. For example, if more than one test is requested for the same patient from the same sample, then a repeat delimiter will indicate where that additional test field begins.
- **Component delimiters.** Separate each part of a field having more than one part. In an address field, component delimiters may separate street from city or city from state.
- **Escape delimiters.** Optional indicators that can be used or ignored by the manufacturer. The Imm. System does not use escape delimiters and ignore them once received.

8.4.5.3 Plus Sign Delimiter in the Universal Test ID Manufacturer's Code

The Immunodiagnostic System uses the universal test ID in the test order record to specify the assays to run for a given sample. The universal test ID has four components: the test ID code, test ID name, test ID type, and the manufacturer's code. However, of the four components, the Imm. System uses only the last one, the Manufacturer's code, which ASTM allows the manufacturer to define. In the Imm. System the manufacturer's code contains these elements:

- **A Manual Dilution Factor.** Dilution for the entire sample program.
- **A plus sign (+).** Links a dilution factor with either whole series of tests or with a particular test.

- **A 1-3 character analyte or test code.** Decimal notation to represent the specific test being performed.
- **A Test Dilution Factor (TDF). Dilution** associated with a particular assay or test within a sample program.

Within a given test order record, there can be a lengthy string of manufacturer's codes, indicating the many assays to be run. Any given sample program will have this general structure:

$$N.N + d_1d_1d_1 + n\backslash d_2d_2 + n_2\dots$$

Where:

- N.N** Indicates the manual dilution factor for the sample. It appears with the first test request of the sample and can be either a whole number or fraction.
- +** Links the dilution factors to the sample program or an individual test.
- d or dd** Indicates that what follows is a decimal representation of an analyte code.
- or ddd**
- n** Indicates the test dilution factor (TDF) for the individual test (for the Immunodiagnostic System this will indicate one of the supported assay dilution factors: 1, 2, 5, 10, 15, 20, 25, 50, 100, 200, or ,400. A TDF of 1 indicates no dilution).
- ** Is a repeat delimiter; indicates that another test request follows.

The repeat delimiter (\) separates one individual assay or test from the next. For further information on the manufacturer's code, the universal test identification, and specific assay codes, please see Appendix E.

8.4.5.4 Field Delimiters and Null Values

Within a record, each field delimiter identifies a field whether or not it has a value. The protocol places field delimiters at the end of each field, but does not require a delimiter for the final field. Consequently, a record with 12 fields will have only 11 delimiters.

Since ASTM defines fields in records by position, a field with a null value is simply given a delimiter to mark its position and to maintain correct position for all subsequent fields in the record.

A field could have a null value for any number of reasons: the field is not implemented by either the laboratory computer or the particular analyzer, the field is used on one device and not the other so there is no purpose in transferring the data. **In the Immunodiagnostic System null values will overwrite, essentially erase, any existing data previously sent for a particular field. If you do not want to overwrite values on a particular record, you must resend those same values when you send a record.**

8.4.6 Text Characters

In figure 8-6 we list both the ASCII printable characters and other characters allowed as part of the record.

ASCII	Decimal	Hex
BEL	7	07
HT	9	09
VT	11	0B
FF	12	0C
All printable characters	32-126	20-7E
Mfg. defined as extended character set	128-254	extended character set

Figure 8-6. ASCII Allowed Characters..

Field	Field Title	Direction		Max Len	Description and Valid Values		
		Imm.					
		D	U				
1	Record Type ID	R	A	1	This is a required field that contains an H or h identifying it as a header record.		
2	Delimiters	R	A	4	The Imm. System will transmit only the four default values shown here. However, it will accept whatever values the laboratory computer chooses to send. Delimiters may not be duplicated. The field delimiter follows the escape character to separate the delimiter specification from subsequent fields in the header record. Using default values, the first six characters of the header record appear as the following characters: H ^& Field Delimiter Repeat Delimiter \ Component Delimiter ^ Escape Delimiter &		
3	Message Control ID	I	N				
4	Access Password	I	N				
5	Sender Name or System Name	I	A	7	This is the name of the device that is sending the data.		
6	Sender Street Address	I	N				
7	Reserved Field	I	N				
8	Sender Tel. Number	I	N				
9	Characteristics of Sender	I	N				
10	Receiver ID	I	N				
11	Comment or Special Instruction	I	N				
12	Processing ID	I	N				
13	ASTM Version No.	I	N				
14	Date and Time	I	A	14	Date and time of transmission: formatted as YYYYMMDDHHMMSS. For example, 3:35 PM on March 1, 1995 would be represented as the following characters: 19950301153500.		
Legend:							
D Down Load U Up Load							
R Required A Always							
O Optional S Sometimes							
I Ignored N Never (empty field marked by delimiter)							

Figure 8-7. Header Record.

8.5 Record Definitions

On the following pages in figure 8-8 through figure 8-18, you will find charts with record definitions for the records supported by the Immunodiagnostic System.

It is important to remember that if you choose to implement a data field that is not supported by the Immunodiagnostic System, it will ignore that data upon receipt.

Download					
Host	H ^& HOST 19950301153500<CR>				
Upload					
Imm. System	H ^& VITROS 19950301154000<CR>				

Figure 8-8. Sample Header Record Layouts.

Field	Field Title	Direction		Max Len	Description and Valid Values		
		Imm.					
		D	U				
1	Record Type ID	R	A	1	This is a required field that contains a P or p identifying it as a patient record.		
2	Sequence Number	R	A	1	This field starts with a 1 for the patient and is incremented by 1 for each additional patient within the transmission.		
3	Practice Assign Patient ID	O	S	20	This field can be assigned by the laboratory computer initially and stored in the patient ID of the sample program (Test Order Record) on the Imm. System and will be uploaded. It can also be assigned by an analyzer as part of an upload with no corresponding download.		
4	Laboratory Assigned Patient ID	I	N				
5	Patient ID No. 3	I	N				
6	Patient Name	O	S	38 or 27	<p>This field has three components:</p> <ul style="list-style-type: none"> Last Name (up to 20 characters) First Name (up to 15 characters) Middle Initial (up to 1 character) <p>With the component delimiters, the maximum length is 38.</p>		
7	Mother's Maiden Name	I	N				
8	Birth Date	O	S	8	Formatted as YYYYMMDD. For example, a birth date of December 1, 1980 would be represented as: 19801201.		
9	Patient Sex	O	S	1	Although the user can define any values here, for the Immunodiagnostic System the default values are the following codes: <ul style="list-style-type: none"> M for male F for female 		
10	Patient Race/Ethnic Origin	I	N	1	The Immunodiagnostic System will ignore this field at launch.		
11	Patient Address	O	S	41	<p>This field is free form and has two components:</p> <ul style="list-style-type: none"> Component 1 (20 characters) Component 2 (20 characters) <p>With a component delimiter included, the maximum length is 41.</p>		
12	Reserved Field	I	N				
13	Patient Tel. Number	I	N				
14	Attending Physician ID	O	S	38	<p>This field has three components:</p> <ul style="list-style-type: none"> Last Name (20 characters) First Name (15 characters) Middle Initial (1 character) <p>If information is not provided in this field, the Imm. System will take it from the "Ordering Physician" field in the test order record.</p> <p>With the component delimiters, the maximum length this field can be is 38.</p>		
15	Special Field 1	I	N				
16	Special Field 2	I	N				
17	Patient Height^Units	I	N				
18	Patient Weight^Units	I	N				

Figure 8-9. Patient Record.

Field	Field Title	Direction		Max Len	Description and Valid Values		
		Imm.					
		D	U				
19	Patient Known or Suspected Illness	I	N				
20	Patient Active Medications	I	N				
21	Patient's Diet	I	N				
22	Practice Field No. 1	I	N				
23	Practice Field No. 2	I	N				
24	Admission Date and Discharge Date (if desired)	I	N				
25	Admission Status	I	N				
26	Location	O	S	5	In the Imm. System, the location is taken from the first five characters of the patient room number.		
27	Nature of Alternative Diagnostic Code	I	N				
28	Alternative Diagnostic Code	I	N				
29	Patient Religion	I	N				
31	Marital Status	I	N				
32	Isolation Status	I	N				
33	Language	I	N				
34	Hospital Service	I	N				
35	Hospital Institution	I	N				
36	Dosage Category	I	N				

Legend:

D	Down Load	U	Up Load
R	Required	A	Always
O	Optional	S	Sometimes
I	Ignored	N	Never (empty field marked by delimiter)

Figure 8-9. Patient Record(Continued).

Download	
Host	P 1 111-11-1111 Doe^Jane^M Gilbert 010181 F B 200ParkAvenue^NewYork^NY^10002 Telnnnnnnnnn Schweitzer 5002^Surgery <CR>
Upload	
Imm. System	P 1 111-11-1111 Doe^Jane^M 010181 F 200ParkAvenue^NewYork ^NewYork Schweitzer^Albert^P 5002 <CR>

Figure 8-10. Sample Patient Record Layouts.

Field	Field Title	Direction		Max Length	Description and Valid Values		
		Imm.					
		D	U				
1	Record Type ID	R	A	1	This is a required field that contains a C or c identifying it as a comment.		
2	Sequence Number	R	A	1	The comment sequence number begins with 1 and is incremented by 1 for every additional comment record transmitted at that hierarchical level. It resets to 1 whenever a comment at another hierarchical record is sent.		
3	Comment Source	I	A	1	This field indicates the source of the comment. It will be used only on upload and has only one valid value: I-Instrument.		
4	Comment Text	R	A	60	This is a free-form field of text that is user defined. In the Imm. System the comment is used only for patients. The Imm. System will also up load any comments that were down loaded along with any comments that they, themselves, have generated.		
5	Comment Type	I	A	1	This field indicates the nature of the comment. It will be used only on upload and there is only one valid value: G-Generic.		

Legend: D Down Load U Up Load
 R Required A Always
 O Optional S Sometimes
 I Ignored N Never (empty field marked by delimiter)

Figure 8-11. Comment Record.

C|1|| First run out of range--these results w/2:1 dilution.|G|<CR>

Figure 8-12. Sample Comment Record Layout.

Field	Field Title	Direction		Max Len	Description and Valid Values		
		Imm.					
		D	U				
1	Record Type ID	R	A	1	This is a required field that contains an O or o identifying it as an order.		
2	Sequence Number	R	A	1	This field starts with 1 for the first Test Order Record and is incremented by 1 for each additional Test Order Record within the record. This will be reset to 1 whenever another patient record is transmitted.		
3	Specimen ID (SID)	R O O	A S S	20	Although the operator can manually edit this field at any time, the value of this three-component field in the Imm. System is usually assigned by the laboratory computer before down loading. The Imm. System uses and reports its results based on the assigned specimen ID. The data field contains the following components: <ul style="list-style-type: none">• Sample ID (15 characters)• Tray ID (2 characters) (0–9) (A–Z) in either position• Cup (1 character) (0–9) With the component delimiters included, the maximum length is 20.		
4	Instrument Specimen ID	I	N				

Figure 8-13. Test Order Record

Field	Field Title	Direction		Max Len	Description and Valid Values		
		Imm.					
		D	U				
5	Universal Test ID	I I I R	N N N A	Var	<p>This is a four component field:</p> <ul style="list-style-type: none"> • Test ID Code (not used) • Test ID Name (not used) • Test ID Type (not used) • Local Manufacturer's Code: this component contains multiple analyte codes indicating all the assays to be processed for the sample program. The component includes the manual dilution factor for each assay in the first position. <p>If no assays are to be processed or if the action code = C, then this field will be empty and only marked by a field delimiter.</p> <p>The general structure of the universal test ID is: ^^^MDF+ Analyte Code +TDF\ Analyte Code +TDF\ Analyte Code+TDF</p>		
6	Priority	A	A	1	<p>This field indicates the time frame in which the result is needed. In a download session, the following codes are valid values for this field:</p> <p>S – STAT or ASAP R – Routine or Callback or Pre-Operative N – Null</p> <p>For an upload, the valid values are:</p> <p>S – STAT or ASAP R – Routine or Callback or Pre-Operative</p>		
7	Request Ordered Date/Time	I	N				
8	Specimen Collect Date/Time	O	S	14	This field indicates the date and time when the specimen was collected, expressed as YYYYMMDDHHMMSS or in whatever way the analyzer is configured. For example, December 1, 1994 collection at 10 seconds after 7:05 AM would look like: 19941201070510.		
9	Collection End Time	I	N	I			
10	Collection Volume/Units	I	N	I			
11	Collector ID	I	N	I			
12	Action Code	O	S	1	<p>The Imm. System uses this field simply to indicate whether the test order record is new or there is a request to cancel. The following codes are valid values for this field:</p> <p>C – Canceled N – New</p> <p>N is the default. If C is here, the Imm. System will ignore any codes in the universal test ID. If values other than N or C are found here, the Imm. System will treat them as N.</p>		
13	Danger Code	I	N				
14	Relevant Clinical Info.	I	N				
15	Date/Time Specimen Received	I	N				

Figure 8-13. Test Order Record (Continued)

Field	Field Title	Direction		Max Len	Description and Valid Values		
		Imm.					
		D	U				
16	Specimen Type/Specimen Source	R	A	1	<p>This is a numeric field indicating the type of specimen. The Imm. System has assigned valid values different from those of other analyzers so that its specimens are unique among other Ortho- Clinical Diagnostics analyzer products.</p> <p>The Imm. System uses the following ASCII characters:</p> <p>4 – serum 5 – plasma 6 – urine 7 – blood 8 – amnio 9 – reserved by the Imm. System : – reserved by the Imm. System ; – reserved by the Imm. System > –reserved by the Imm. System</p>		
17	Ordering Physician	I	N				
18	Physician Tel. Number	I	N				
19	User Field No. 1	I	N				
20	User Field No. 2	I	N				
21	Lab Field No. 1	I	N				
22	Lab Field No. 2	I	N				
23	Date/Time Results Reported Last or Modified	I	N				
24	Instrument Charge	I	N				
25	Instrument Section ID	I	N				
26	Record Types	I	A	2	<p>This field indicates the direction of the transmission:</p> <p>O – Down Loading F – Up Loading</p>		
27	Reserved Field	I	N	I			
28	Location or Ward of Specimen Collection	I	N	I			
29	Nosocomial Infection Flag	I	N	I			
30	Specimen Service	I	N	I			
31	Specimen Institution	I	N	I			

Legend:

D	Down Load	U	Up Load
R	Required	A	Always
O	Optional	S	Sometimes
I	Ignored	N	Never (empty field marked by delimiter)

Figure 8-13. Test Order Record (Continued)

Download To	
Imm. System	0 1 SID4000^A1^1 ^1.0+032+1\033+1\034+1 R 9941201070510 N 4 O <CR>

Figure 8-14. Sample Test Order Record Layouts.

Field	Field Title	Direction		Max Len	Description and Valid Values		
		Imm. System					
		D	U				
1	Record Type ID	A		1	This is a required field that contains an R or an r identifying it as an order.		
2	Sequence Number	A	Un-limited		<p>This field starts with 1 for the first result and is incremented by 1 for each additional result within the record.</p> <p>This will be reset to 1 when the results from another test order record are being transmitted to the laboratory computer.</p>		
3	Universal Test ID	N N N A	16		<p>This is a four-component field:</p> <ul style="list-style-type: none"> • Test ID Code (reserved) • Test ID Name (not used) • Test ID Type (not used) • Local Manufacturer's Code: this field contains the description of the replicate result being sent to the LIS. The field holds the manual dilution factor, analyte code, and test dilution factor for individual test to which the result applies. <p>The structure of the universal test ID would be: ^^^MDF + Analyte Code +TDF</p>		
4	Data or Measurement Data	A	9		<p>Measurement data or assay results is a 9 character floating point field that includes the decimal point and a negative sign when applicable. The number of precision point digits will vary by test and is configurable on the analyzer. On the Imm. System, precision points vary with the magnitude of the result.</p> <p>NOTE: The string NO RESULT is reported in this field if one of a number of conditions exist, like a numerical processing error.</p>		
5	Units of Measure	A	12		This is a field of up to 12 characters that the operator defines for analyte measurement through the Options & Configuration function.		
6	Reference Ranges	S	18		This field has two components, one giving the upper limit and the other the lower limit of the range. The format for this field is N^N.		
7	Result Flags		10		<p>This is a three-component field. The first component will be empty in the Immunodiagnostic System. The second component describes the type of flagged results as either quantitative (relative to a laboratory norm) or qualitative (as specified in the analyte parameters through the Configure Analyte screen in the Options & Configuration function):</p> <ul style="list-style-type: none"> • Results flag (in ASCII characters) <ul style="list-style-type: none"> 0 – No flag 1 – Above reference range 2 – Below reference range 4 – Above dynamic range 5 – Below dynamic range 6 – Prediction failure, with value reported as NO RESULT 7 – Above supplemental range 8 – Below supplemental range A – Control result is more than two SDI but no more than 3 SDI from baseline interval mean B – Control result is more than three SDI from baseline interval mean C – No baseline interval mean or assay is not supported in the QC database. or • Result classification (qualitative) <ul style="list-style-type: none"> Q Result text 1 R Result text 2 S Result text 3 T Result text 4 U Result text 5 		

Figure 8-15. Result Record

					The third component indicates operational events causing coded results. <ul style="list-style-type: none"> • Codes (up to 8 char. codes) <p>AF – Filtered air operation did not occur during the reading of the well AR – User adj. parameters changed results CE – Calibration expired FR – Flagged replicate DE – Drop error ED – Edited result EM – Expired maintenance EP – Edit patient data ER – Computation error FC – Flagged component IC – Invalid component ID – Invalid dilution II – Insufficient inventory IS – Insufficient sample IT – Incubator temperature LS – Lot switch LT – Luminometer temperature ME – Mechanical error occurred M1 – Category 1 modified values M2 – Category 2 modified values NC – Not calibrated NF – No fluid NI – No inventory NQ – Not in QC database NW – No well NT – No tip OD – Operator requested dilution OR – Outside range PF – Prediction failure RC – Reference consistency check RD – Reflex dilution RE – Reagent expired RP – Reflex process RR – Recalculated results SC – Spread check UC – User calibrated WT – Well wash temperature out ZS – Zero set</p> <p>There can be up to 4 condition codes listed with not intervening replicate.</p>
8	Nature of Abnormality Testing	S	3		If the result is abnormal, this field indicates the nature of the abnormality: Valid values are A, S, R.
9	Result Status	A	1		The Imm. System is implementing only one valid value: V – operator verified/approved result.
10	Date of Change in Instrument Normative Values or Units	N			
11	Operator ID	A	3		
12	Date/Time Test Started	A	14		Date and time of collection. This is formatted as YYYYMMDDHHMMSS. For example, 3:35 PM on December 1, 1994 would be represented as: 19941201153500.
13	Date/Time Test Completed	A	14		Date and time of test started: formatted as YYYYMMDDHHMMSS. For example, 3:35 PM on December 1, 1994 would be represented as: 19941201153500.
14	System ID	A	12		The ID of the device that actually ran the test.
Legend:					
D Down Load U Up Load					
R Required A Always					
O Optional S Sometimes					
I Ignored N Never (empty field marked by delimiter)					

Figure 8-15. Result Record (Continued)

Upload					
IMM:		R 1 ^^^1.0+032+1 88.12 nmol/L ^0^ V 19951201153500 199751201153512 System ID<CR>			

Figure 8-16. Sample Results Record Layouts.

Field	Field Title	Direction		Max Length	Description and Valid Values		
		Imm. System					
		D	U				
1	Record Type ID	R	A	1	This is a required field that contains an upper or lower case L identifying it as a terminator record.		
2	Sequence Number	R	A	1	For a message terminator this message should always be 1.		
3	Termination Code	R	A	1	This indicates cause of termination. The following codes are valid values for the Immunodiagnostic System: Null or N – normal termination T – sender cancel R – receiver requested cancel E – unknown system error Q – error in last query I – no information available from last query F – last request for information processed		

Legend: D Down Load U Up Load
 R Required A Always
 O Optional S Sometimes
 I Ignored N Never (empty field marked by delimiter)

Figure 8-17. Message Terminator Record.

L|1|N|

Figure 8-18. Sample Message Terminator Record Layout.

9.1 Overview

This chapter summarizes the procedures and tools that you may use to assess and correct problems with communications among the VITROS Chemistry Systems, the VITROS ECi Immunodiagnostic System (Imm. System), and the laboratory computer. It also reviews issues related to asynchronous communication pertaining to these interfaces.

This chapter describes the following activities:

- How to troubleshoot hardware problems for port assignments and electrical wiring
- How to ensure communications compatibility
- How to display information on error conditions
- How to use system diagnostics tools and other tools to assess problems

9.2 Skills Required

Only individuals with experience in communication interface technology and analyzer operators trained in diagnostic procedures should attempt troubleshooting and diagnostic assessment of device communication.

9.3 Key Troubleshooting Questions

On the VITROS Chemistry Systems, the most common errors posted to error review screens are 3BJ and 3BW, which are simply communication time-outs. These errors are most often caused by incorrect selections made in cable wiring, analyzer configuration, report control, and off-line conditions.

As you begin your investigation of problems with communication interfaces, you need to ask the questions listed below, then gather the information they require.

1. Is the hardware connected appropriately and are the cables connected to the correct ports?
2. Can another analyzer successfully communicate at that port location?
3. What download messages are being generated?
4. What is the mode of communication?
 - Bidirectional using *Kermit*?
 - Bidirectional using ASTM?
 - Upload-only?
5. Whatever the mode, does it conform to its protocol's rules and is there compatibility between the connected devices?

6. What errors are posted in the transient and action error logs on the analyzers?
7. What happens when I upload results to the laboratory computer?

To answer these questions you can use a variety of analyzer features as well as tools and utilities described in this chapter.

9.4 Hardware Troubleshooting

One of the most commonly experienced problems is incorrect cable wiring. Check connectors and ports to ensure that cables are not loose, that the wiring is correct, and that devices are hooked up to the appropriate ports.

Before attaching or removing the cable from the laboratory computer, do the following procedure.

For VITROS Chemistry Systems:

1. From the Main Menu, touch Options.
2. Touch Report Control.
3. Turn off Transmit Results and Receive Tests.
4. Touch Return twice to return to the Main Menu.
5. Touch Review Results.
6. Touch Edit or Verify Results.
7. Touch Abort Report Status.
8. Touch Computer.
9. Touch Start twice.
10. Return to Main Menu.
11. Place the Laboratory Computer in No Communications mode and attach or remove cables.

For the VITROS ECi Immunodiagnostic System:

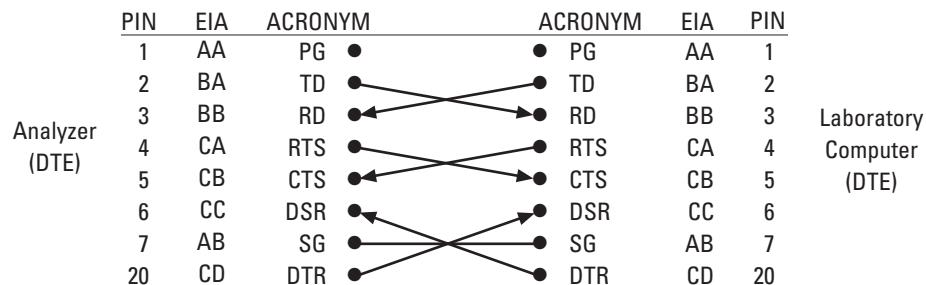
1. Access the Options & Configuration-Configure Report Control screen.
2. Set Transmit Report? to NO and Receive Requests? to NO.
3. On the Configure Ports screen, for Lab Computer Protocol select No Comm.

In figure 9-1, reproduced on the following pages from Chapter 2, we show cable wiring requirements.

Null Modem Cable Configuration Examples (DTE-DTE)

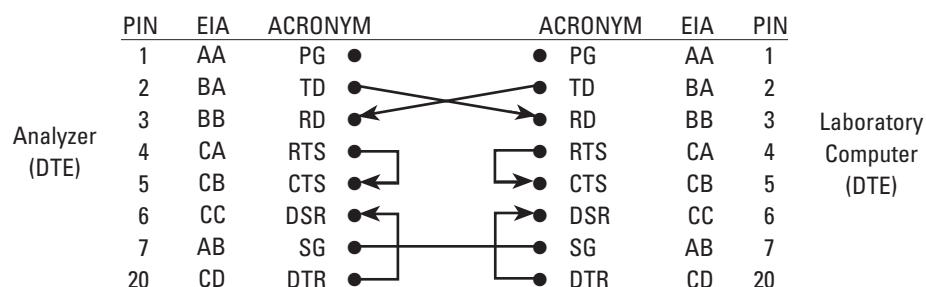
CTS Hardware Flow Control (DTS/DSR and CTS/RTS Handshake)

Applicable for systems where CTS hardware flow control is required. Half duplex transmission is allowed. On-line control is required by the laboratory computer (that is, the laboratory computer can go off-line or on-line, and it will be noticed by the analyzer).



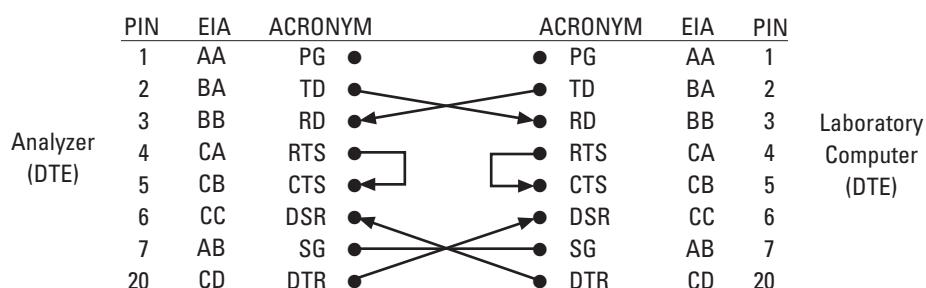
Existing 3-Wire Cable (DTS/DSR and CTS/RTS Loopback)

Applicable for installations with 3-wire cable already installed. Hardware CTS flow control is not possible. Each system interprets the other as being on-line when the system itself is on-line.



CTS Hardware Flow Not Functional (DTS/DSR Handshake and CTS/RTS Loopback)

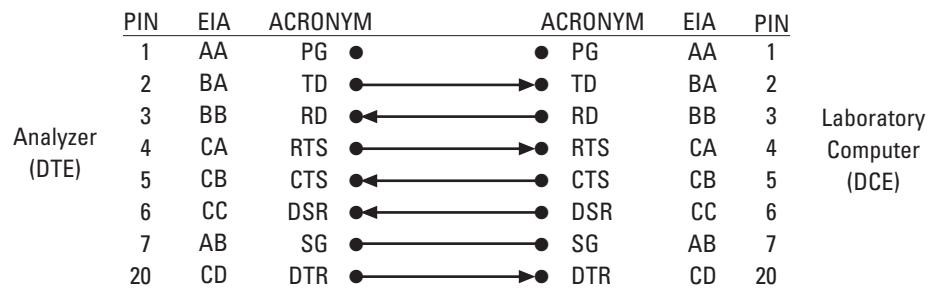
Either system can sense when the other goes on-line or off-line.



■ **Figure 9-1. Wire Cabling Connections.**

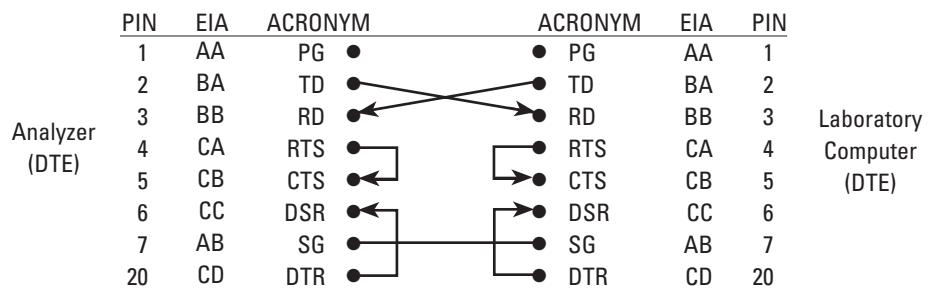
Modem Cable Configuration Examples (DTE-DCE)

Hardware Flow Control Functional (DTS/DSR and CTS/RTS Handshake)



3-Wire Capability (DTS/DSR and CTS/RTS Loopback)

Hardware CTS flow control is not possible. Each system interprets the other as being on-line when the system itself is on-line.



Hardware CTS Flow Control Not Functional (DTS/DSR Handshake and CTS/RTS Loopback)

Either system can sense when the other goes on-line or off-line.

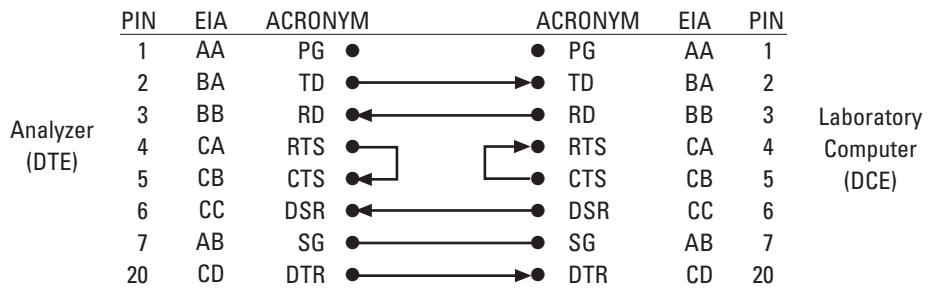


Figure 9-1. Wire Cabling Connections(Continued).

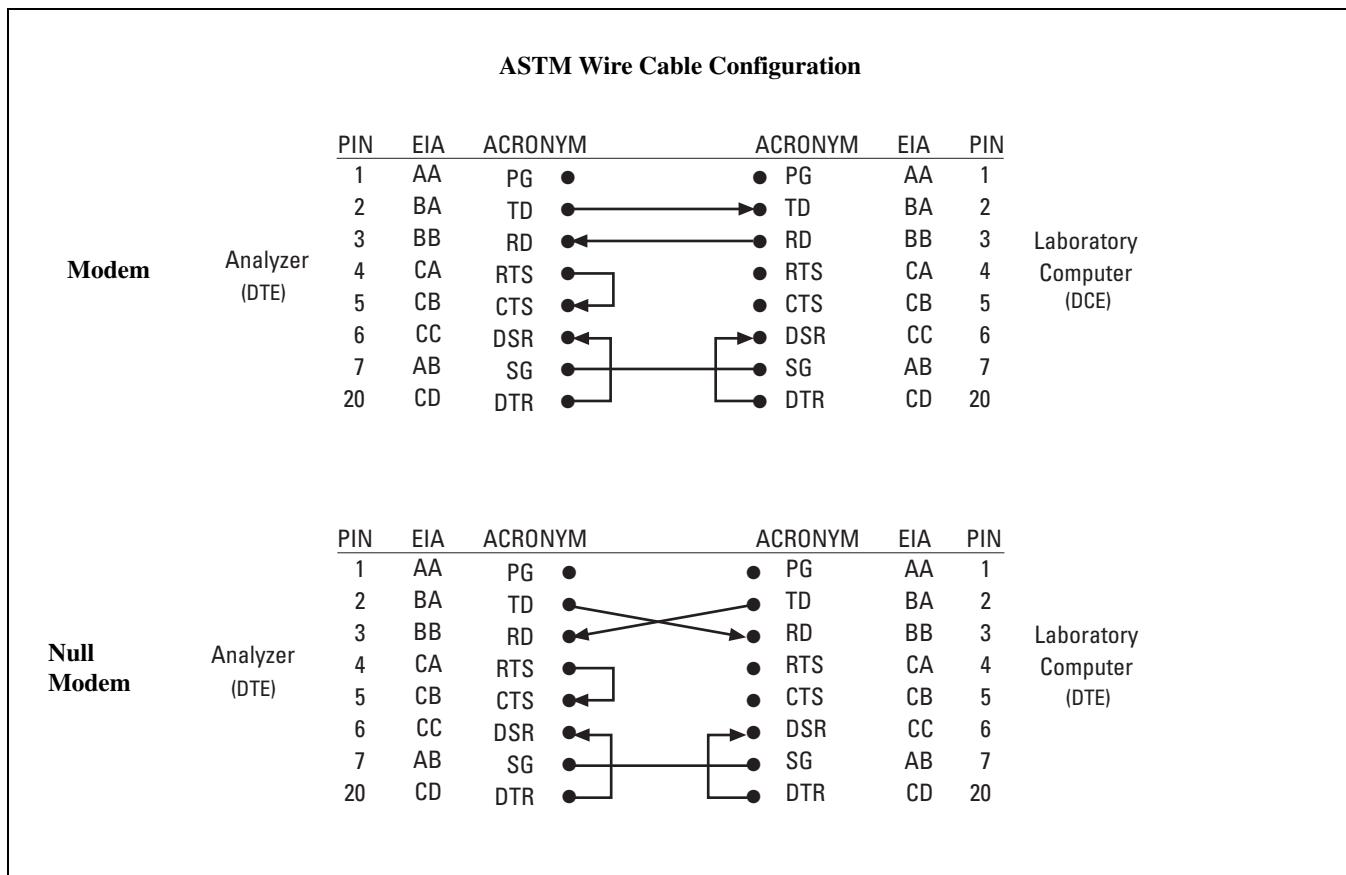


Figure 9-1. Wire Cabling Connections(Continued).

9.4.1 Correct Ports

The correct analyzer ports are listed in [figure 9-2](#).

Analyzer	Port Assignment	Port Locations
250	J3	3rd connector from top
500 series	J5	3rd connector from top
700 C series	J5	3rd connector from top
950	J5	3rd connector from top
Imm. System	J3	3rd connector from left

Figure 9-2. Port Assignment and Location.

For the correct ports on the laboratory computer, you must consult that documentation.

9.5 Configuration Troubleshooting for Analyzers

Once the physical cables and ports have been checked, you should check the configuration of each device for correctness and compatibility.

In **figure 9-3** through **figure 9-5** we provide checklists of some of the configurable options in *Kermit*, ASTM, and Upload-only modes of communication. You can use these checklists to compare them to the actual settings displayed on your analyzer.

Kermit Parameters	Correct Settings
Port Format:	
Bidirect (F4 Key)	Should be highlighted; on the Immunodiagnostic System <i>Kermit</i> should be selected.
Mode:	
NAK Zero	Should be YES/NO based on laboratory computer requirements.
Parity (F4 Key)	ODD, EVEN, MARK, SPACE, NONE. (MARK and SPACE not used for the Immunodiagnostic System)
Baud Rate* (F4 Key)	1200, 2400, 4800, 9600 used by all. 19200 and 38400 used by the Imm. System.
Stop Bits (F4 Key)	1 or 2
Data Bits (F4 Key)	7 for Chemistry Systems. 8 for the Imm. System.
Flow Control Mechanism	None or XON/XOFF or CTS/RTS also an option.
Protocol Definition:	
Analyzer Response Delay	0.00 to 9.99 seconds. 0-10 seconds for the Imm. System.
Analyzer Response Time-out	1 to 94 (0 = no time-out). 0-99 for the Imm. System.
Flow Control Time-out	0.01 to 9.59 minutes/seconds (XON/XOFF mode only). 1 to 599 sec. for the Imm. System.
Packet Retry Limit	0 to 99.
Block Checksum Type	1 or 2.
Packet Format:	
Start of Packet Marker	0 to 31decimal.
Handshake Character	1 to 31 (0 = no handshake).
*300 and 600 baud rates are not recommended and are no longer available on 950 and the Imm. System.	

Figure 9-3. Kermit Configuration Requirements Checklist.

ASTM Parameters	Correct Settings
Bi direct	Should be highlighted; on the Imm. System ASTM should be selected.
Parity	ODD, EVEN, NONE.
Baud Rate*	1200, 2400, 4800, 9600, 19200, 38400.
Data Bits	8 for the Imm. System.
Stop Bits	1 or 2.

*300 and 600 baud rates are not recommended and are no longer available on 950 and the Imm. System.

Figure 9-4. ASTM Configuration Checklist.

Upload-only Parameters	Correct Settings
Port Format:	
Bidirect	Should be NOT be highlighted; Upload - only should be highlighted or on the Imm. System Upload-Only should be selected.
Mode:	
ACK/NAK	YES should be highlighted.
Data Bits	7 for Chemistry Systems. 8 for the Imm. System.
Flow Control Mechanism	CTS/RTS is set for the Imm. System.
Parity	ODD, EVEN, MARK, SPACE, NONE. (MARK and SPACE are not used for the Imm. System).
Baud Rate*	1200, 2400, 4800, 9600 used by all. 19200 and 38400 used by the Imm. System.
Protocol Definition:	
Analyzer Response Delay	0.00 to 9.99 seconds. 1 to 10 seconds for the Imm. System.
Acknowledgment Time out	1-99 seconds (0=no time out).
Packet Marker:	
Start of Packet Marker	Set at 1 (This is not a configurable option).
*300 and 600 baud rates are not recommended and are no longer available on 950 and the Imm. System.	

Figure 9-5. Upload-only Configuration Checklist.

9.5.1 VITROS Chemistry System Configuration Information

You can compare the device's current setting with the correct settings in two ways:

- Accessing the on-line configuration information
- Checking the Configuration Report
- Pressing the F4 Key (VITROS 950 and 250 Systems)

To access on-line configuration information, follow these procedures for the VITROS Chemistry Systems:

1. From the Main Menu, touch **OPTIONS**.
2. Touch **REPORT CONTROL**.
3. Turn off **TRANSMIT RESULTS** and **RECEIVE TESTS**.

4. Touch **RETURN** twice to return to the Main Menu.
5. Touch **REVIEW RESULTS**.
6. Touch **EDIT OR VERIFY RESULTS**.
7. Touch **ABORT REPORT STATUS**.
8. Touch **COMPUTER**.
9. Touch **START** twice.
10. Return to Main Menu.
11. From the Main Menu screen, touch **OPTIONS**.
12. Enter access code and touch **ANALYZER CONFIGURATION**.
13. Touch **LAB COMPUTER CONFIGURATION** and review the appropriate settings.
14. Then return to the Analyzer Configuration screen and touch **PORT FORMAT**. Review these additional settings.
15. The analyzer checklist settings should match the settings on these two screens.

On the Chemistry Systems, you can also print the first two pages of the Configuration Report. These pages summarize all configuration settings for communication with the laboratory computer. There are only minor differences in the reports for each analyzer model.

Follow this procedure to print the report:

1. From the Main Menu screen, touch **OPTIONS**
2. Press **ENTER**.
3. Touch **PRINT CONFIGURATION REPORT** at the bottom of the Options screen.
4. Shortly after being touched, this target will change to **ABORT CONFIGURATION REPORT PRINTING**.
5. After the second page has printed, touch **ABORT CONFIGURATION REPORT PRINTING**.

To check the corresponding settings on your laboratory computer, you will need to refer to your laboratory computer vendor documentation. For the VITROS 950 and 250 Systems, follow this procedure to check the settings:

1. From any screen, press the F4 key.
2. The following laboratory computer configuration data will be displayed, along with additional analyzer information:

Communication Mode: Bidirectional, upload only, no communication.

Baud rate: 9600, 4800, 2400, 1200

Parity: Odd (O), Even (E), None (N)

Stop Bits: 1, 2

Data Bits: 7, 8

9.5.2 The VITROS ECi Immunodiagnostic System Configuration Information

You can compare the device's current setting with the correct settings in two ways:

- Accessing the on-line configuration information
- Checking the Configuration Report

To access the configuration on-line:

1. From the Main Menu screen, touch **Options & Configuration**.
2. Within the Options & Configuration function under SYSTEM SET UP, touch **Configure Ports**, then check the settings.
3. To display port format and other configuration settings:
 - For ports, touch **Lab Computer**.
 - For Lab Computer Protocol, touch the corresponding button for the protocol you wish to check (**Upload-only**, **ASTM**, or **Kermit**).
 - For ASTM the port format settings displayed on the **Configure Ports** screen will be the only settings you will need to check.
 - For Upload-only and *Kermit*, you must check additional settings. Touch **Set Lab Computer Options** in the process button area. This will display the Set Lab Computer Options dialog where the additional settings can be found.
4. Return to the Configure Ports screen. Review these settings.
5. The Imm. System checklist settings should match the settings on the screen and dialog box.

On the Immunodiagnostic System, you can also print the Configuration Report very easily.

1. From the Main Menu, touch **Options & Configuration**.
2. Within the Options & Configuration function, touch **Print Config** in the process button area.

9.5.3 Configuration Worksheets

In figure 9-6 and figure 9-7 we have provided a Configuration Worksheet to use with your configuration screens and reports. The left column contains some key parameters. Use the worksheets to log the configuration data you collect and to monitor changes you make to your configuration set up while troubleshooting. If the settings need adjusting, you can change them on the on-line screens and record the new settings in your Worksheet.

Configuration Worksheet for VITROS Chemistry Systems

In the columns at the right, log your current analyzer configuration for each of the parameters.

	Column 1	Column 2	Column 3	Column 4
Laboratory computer control				
Transmit results (or result report) enable				
Receive tests enable				
Laboratory computer configuration				
Option				
Bidirectional configuration data				
Mode				
NAK Zero				
Port format				
Parity				
Baud rate				
Stop bits				
Data bits				
Flow control mechanism				
Protocol definition				
Analyzer response delay				
Analyzer response time-out				
Flow control time-out				
Packet retry limit				
Block checksum type				
Record format				
Start of packet marker				
Handshake character				
Option				
Upload-only configuration data				
Mode				
ACK/NAK				
Port format				
Parity				
Baud rate				
Data bits				
Protocol definition				
Analyzer response delay				
Acknowledgment time-out				
Lab report	Enabled	Printer		
Calibration report	Enabled	Printer		
Patient report	Enabled	Printer		
Miscellaneous report	Enabled	Printer		
Reporting mode				
Report results to patient report	Yes	No		
Report results to lab report	Yes	No		
Report results to laboratory computer	Yes	No		
Result retention	Yes	No		
Sample program retention	Yes	No		

Figure 9-6. Configuration Worksheet for VITROS Chemistry Systems.

Configuration Worksheet for the VITROS ECi Immunodiagnostic System

In the columns at the right, log your current analyzer configuration for each of the parameters.

	Column 1	Column 2	Column 3	Column 4
Laboratory computer control	_____	_____	_____	_____
Transmit report? enabled	_____	_____	_____	_____
Receive requests? enable	_____	_____	_____	_____
Laboratory computer configuration	_____	_____	_____	_____
Option	_____	_____	_____	_____
(Kermit) Bidirectional configuration data	_____	_____	_____	_____
Mode	_____	_____	_____	_____
NAK Zero	_____	_____	_____	_____
Port format	_____	_____	_____	_____
Parity	_____	_____	_____	_____
Baud rate	_____	_____	_____	_____
Stop bits	_____	_____	_____	_____
Data bits	_____	_____	_____	_____
Flow control mechanism	_____	_____	_____	_____
Protocol definition	_____	_____	_____	_____
Analyzer response delay	_____	_____	_____	_____
Analyzer response time-out	_____	_____	_____	_____
Flow control time-out	_____	_____	_____	_____
Packet retry limit	_____	_____	_____	_____
Block checksum type	_____	_____	_____	_____
Record format	_____	_____	_____	_____
Start of packet marker	_____	_____	_____	_____
Handshake character	_____	_____	_____	_____
Option	_____	_____	_____	_____
(ASTM) Bidirectional configuration data	_____	_____	_____	_____
Port Format	_____	_____	_____	_____
Parity	_____	_____	_____	_____
Baud rate	_____	_____	_____	_____
Stop bits	_____	_____	_____	_____
Data bits	_____	_____	_____	_____
Upload-only configuration data	_____	_____	_____	_____
Mode	_____	_____	_____	_____
ACK/NAK	_____	_____	_____	_____
Port format	_____	_____	_____	_____
Parity	_____	_____	_____	_____
Baud rate	_____	_____	_____	_____
Data bits	_____	_____	_____	_____
Protocol definition	_____	_____	_____	_____
Analyzer response delay	_____	_____	_____	_____
Acknowledgment time-out	_____	_____	_____	_____
Lab report	Enabled _____	Printer _____	_____	_____
Calibration report	Enabled _____	Printer _____	_____	_____
Patient report	Enabled _____	Printer _____	_____	_____
Miscellaneous report	Enabled _____	Printer _____	_____	_____

Figure 9-7. Configuration Worksheet for the VITROS ECi Immunodiagnostic System.

Configuration Worksheet for the VITROS ECi Immunodiagnostic System

In the columns at the right, log your current analyzer configuration for each of the parameters.

Reporting mode

Report results to patient report	Yes _____	No _____	_____	_____	_____	_____
Report results to lab report	Yes _____	No _____	_____	_____	_____	_____
Report results to laboratory computer	Yes _____	No _____	_____	_____	_____	_____
Result retention	Yes _____	No _____	_____	_____	_____	_____
Sample program retention	Yes _____	No _____	_____	_____	_____	_____

Figure 9-7. Configuration Worksheet for the VITROS ECi Immunodiagnostic System.

9.6 Checking Transmission Settings and Report Configurations on the Analyzers

If you are having problems generating certain reports from your analyzer, transmitting results up to the laboratory computer or receiving downloads from the laboratory computer, you can check the report configurations to ensure that the settings are correct.

9.6.1 Transmission/Report Troubleshooting for VITROS Chemistry Systems

To access the transmission and report control information online, follow these procedures for the VITROS Chemistry Systems:

1. From the Main Menu screen, touch **REPORT CONTROL**.
2. Touch **DEVICE/REPORT CONTROL**.
3. Touch **REPORT REQUEST DEFAULTS**.

The settings should be as listed in [figure 9-8](#). It is important to know that the settings on this screen control transmission back and forth from the laboratory computer as well as control the printing of reports.

The default settings found under DEVICE/REPORT CONTROL and REPORT REQUEST DEFAULTS are used as the initial values assigned to a result. The user may override the report status defaults using Sample Programming.

The default settings for the laboratory computer effect transmission in several ways:

- If the **IMMEDIATE** and the **LAB COMPUTER** targets are highlighted in REPORT REQUEST DEFAULTS and TRANSMIT RESULTS is **ON** in DEVICE/REPORT CONTROL, then the analyzer will automatically send the result to the laboratory computer. If the TRANSMIT RESULTS is **OFF**, then the operator will need to reset this field to **ON** in order to send the result.
- If set to **DEFERRED**, the operator must intervene in order for the result to be sent to the laboratory computer by changing the status in Sample Programming or Results Review.

Reports can also be generated using functions available through the Results Review screen.

In order to print reports, the specific report must be selected and given a printer destination. The printer designated must also be set to **ON**.

To Generate Transmission	Correct Setting
Device/Report Control:	
Transmit Results	ON should be highlighted
Receive Tests	ON should be highlighted
Report Request Defaults :	
Immediate	Should be highlighted

[Figure 9-8. Transmission and Report Control Settings.](#)

To Generate Transmission	Correct Setting
Laboratory Computer	Should be highlighted
To Generate Reports	Correct Setting
Patient Report	ON should be highlighted
Laboratory Report	ON should be highlighted
Cal Report	ON Should be highlighted

[Figure 9-8. Transmission and Report Control Settings.](#)

9.6.2 The *VITROS ECi Immunodiagnostic System* Transmission/Report Control Troubleshooting

To access the report control information on-line, follow these procedures for the Immunodiagnostic System:

1. In the Immunodiagnostic System, from the Main Menu screen, touch **Options & Configuration**.
2. Within the Options & Configuration function under **SYSTEM SET UP**, touch **Configure Report Control**.
3. Check the settings.

The settings should be as listed in [figure 9-9](#). It is important to know that the settings on this screen control transmission back and forth from the laboratory computer as well as control the printing of reports.

To Generate Report	Correct Setting
Patient Report	Report Status - SEND Transmit Report?- YES
Laboratory Report	Report Status - SEND Transmit Report?- YES
To Transmit Results	Correct Setting
Laboratory Computer	Report Status - SEND Transmit Report?- YES
To Receive Downloads	Correct Setting
Laboratory Computer	Receive Requests? YES

[Figure 9-9. The Imm. System Report Control Settings.](#)

9.6.3 Default Report Status for the Imm. System

The Default Report Status settings are used as the initial values assigned to a result. The user may change the report status for a single result in Sample Programming. The report status for one or more results may be changed in Results Review.

The Default Report Status settings for the laboratory computer effect transmission in several ways:

- If set to **SEND**, the analyzer will automatically send the result to the laboratory computer. If the Transmit Report? is set to **YES**, the result will be sent immediately. If the Transmit Report? is set to **NO**, the result will be blocked from being sent to the laboratory computer until the operator sets this field to **YES**.
- If set to **DEFER**, the operator must intervene in order for the result to be sent to the laboratory computer by changing the status from **DEFER** to **SEND** in either Sample Programming or Results Review.
- If set to **OFF**, the result will not be sent to the laboratory computer.

Reports can also be generated using functions available through the Results Review screen.

9.7 Troubleshooting Conditions for Chemistry Systems

There are many ways to check conditions on the analyzer. You should first look at your transient and action error logs. These can be accessed from any screen on an analyzer.

In the VITROS Chemistry Systems, you simply touch the Status Console Display. This will route you to a screen that displays targets for the types of conditions currently logged. You can then select the types of errors you want to review. HELP will explain the condition codes.

In the VITROS ECi Immunodiagnostic System the procedures are very similar. On any screen, you touch **Condition Review**. This will route you to the Condition Review screen, which displays condition messages of all types. You can then use a filter to select any subset or type of conditions you wish to review.

Use the Error Worksheet in figure 9-10 to capture current error conditions.

Error Worksheet. Examine error log screen and record errors here.	
Action level code ()	module error pair ()
Description _____	
Action level code ()	module error pair ()
Description _____	
Action level code ()	module error pair ()
Description _____	
Download messages _____	
Error displayed by laboratory computer _____	

Figure 9-10. Error Log Worksheet.

9.8 Transmitting A Result to the Laboratory Computer

Transmitting a single result can also be useful in diagnosing communication problems. It is important to follow procedures listed in sections 9.8.1 and 9.8.2 exactly, otherwise more than one result will be transmitted, making it virtually impossible to determine problems.

9.8.1 Transmitting a Result from the VITROS Chemistry Systems

To transmit one result from the VITROS Chemistry Systems:

1. If **LAB COMP** does not appear on the status bar, you will need to reconfigure the Line 2 Display of the Status Console.

2. From the Main Menu screen, touch:
 - **OPTIONS**
 - **ANALYZER CONFIGURATION** or **ANALYZER CONFIG.**
 - **STATUS CONSOLE**
 - **LINE 2 DISPLAY** (Error Text Messages)
 - **ANALYZER STATUS**
3. **LAB COMP** should now appear on the status bar. Touch **RETURN** until the Main Menu screen is displayed.

Note: Confirm the LIS is ready to receive results transmitted by the analyzer.
4. From the Main Menu screen, touch:
 - **REVIEW RESULTS**
 - **EDIT** or **VERIFY RESULTS**
 - **START** (The number of matches are displayed.)
 - **START** (A result is displayed on the control unit screen.)
5. If this sample is not a patient result, touch **DISPLAY NEXT SAMPLE** until a patient result is displayed on the screen, then continue.
6. Touch **EDIT PATIENT DATA**.
7. Touch and highlight the **LABORATORY** and **COMPUTER** targets under the Reports Menu screen.

Note: The next action causes transmission to begin. Observe the area to the right of **LAB COMP** on the status bar of the Control Unit Screen. In the **Bidirectional** mode, a bright square containing a U appears to the right of the **LAB COMP** on the status bar. In the **Upload-only** mode, a bright square appears.
8. Touch **RETURN**.

If the U or highlighted cursor does not appear and the result is reported to the forms printer, one of the following is occurring:
 - A hardware failure prevented transmission.
 - The laboratory computer sent either an improper response or no response.
 - The analyzer may have failed to send a result to the correct port.
9. Examine the error logs for the TRANSIENT level, ACTION level, and MALFUNCTION level. Examine in detail all codes with a time stamp associated with the time of the attempted transmission.
10. Highlight the error codes on the control unit by touching the **UP** or **DOWN** targets, then touching the **HELP** target. Record or print the displayed information.
11. Examine the download messages. Touch:
 - **SAMPLE PROGRAMMING**
 - **OPTIONS**
 - **DISPLAY DOWNLOAD MESSAGES**
12. Many laboratory information systems have error-logging abilities. Examine the errors maintained in the **ERROR LOG BUFFER**. Analyze all data gathered and determine if the failure is a software issue (prefix character, baud rate, sequence number, etc.) or hardware issue (DSR-CTS not active, device offline, device timeout).

If the errors are time out, confirm the following:

- Port connections
- Laboratory computer interface is active
- Cable is good; if unconfirmed, replace cable and reinitialize LIS.

If the errors are software, confirm the following, then reboot analyzer:

- Post parameters
- Correct protocol in use

13. To further investigate this failure, refer to Section 10.11.4, “Upload-only Diagnostic,” or Section 10.11.3, “Bidirectional Diagnostic.”

9.8.2 Transmitting a Result in the VITROS ECI Immunodiagnostic System

To transmit just one result in the Immunodiagnostic System, use the following procedure:

1. Make sure the port and correct protocol are on:
 - Return to the Options & Configuration function
 - Touch **Configure Ports**
 - Make sure that the port to the laboratory computer is on and that port parameters are correct.
 - Check the appropriate protocol (if ASTM, there are no additional settings)
 - On the Set Lab Computer Options dialog check the protocol settings for either *Kermit* or Upload-only.
2. Make sure communications with the laboratory computer are on:
 - From the Main Menu screen, touch **Options & Configuration**
 - Touch **Configure Report Control**
 - Set Transmit Report to **Yes**.
3. Send one result:
 - From the Main Menu screen, touch **Results Review**
 - From Search/Review/Edit screen, touch **Review/Edit** or the **Results Review** mini-button.
 - Scroll through the result records
 - Select the result you want to send by touching the check box for the record, then touch **Set Report Status**
 - For the Lab Computer, touch **Send**
 - Touch **OK**.

9.9 System Diagnostics, Other Utilities and Diagnostic Tools

There are a number of additional utilities, diagnostic tools and system diagnostics available to help you investigate communications problems. In this section we will cover briefly the following topics:

- Breakout boxes
- Laboratory computer resident diagnostics
- *Kermit* bidirectional diagnostics
- Upload-only diagnostics
- System diagnostic procedures for the 500, 250, and 950.

- LCPA and LCPM utilities used by the 250 and 950

Determine the option that best meets the condition existing at the customer site, and refer to the appropriate procedure.

9.9.1 Breakout Boxes or Data Taps (circuit testers)

Breakout boxes can be used on VITROS Chemistry Systems and other laboratory devices.

Before attaching or removing a cable from the laboratory computer port or the analyzer, turn TRANSMIT RESULTS and RECEIVE TESTS OFF in REPORT CONTROL (computer reports have been cancelled), and place the laboratory computer in NO COMMUNICATIONS mode.

A breakout box makes it possible to perform the following activities:

- Visually confirm data leaving the analyzer on pin 2.
- Visually confirm data returning on pin 3.
- Rapidly change pin configuration.

If the TD blinks periodically and the RXD does not blink, the analyzer did not receive a response from the LIS on pin 3.

Possible causes for failure include the following problems:

- LIS did not send a response to the analyzer.
- LIS response is sent to wrong pin.
- Components between LIS and analyzer did not relay response.
- Cable failure.
- Breakout box failure.

Before connecting the breakout box, refer to the Bidirectional and Upload-only Communication Checklists to verify that the correct targets are selected for a customer site. Also, refer to the manufacturer's operating instructions to determine what the indicators on your model of breakout box show.

1. Attach the DTE connector from the breakout box to the analyzer port J5 (C Series), or J3 (250).
2. Verify that CTS (pin 4) and DSR (pin 20) are on.
3. Attach the LIS cable to the breakout box. The indicators for pins 4, 5, 6, and 20 should be on.
4. While observing TXD (pin 2) and RXD (pin 3) on the breakout box, force a transmission to the LIS using the instructions for Transmitting Results to the Laboratory Computer (Section 10.10).

If TXD blinks periodically, the analyzer is transmitting on pin 2.

If TXD does not blink, the analyzer is not transmitting on pin 2. This is an analyzer failure. Follow normal procedure for contacting Service.

Possible causes for failure include the following problems:

- Tester is not connected to analyzer computer port
- Analyzer configuration is incorrect

- Hardware failure
- Breakout box failure

9.9.2 Laboratory Computer Resident Diagnostics

Enabling the line monitoring capability, also called a port watch or trace file, of the laboratory computer allows examination of data packet or frame format. The laboratory computer must be able to perform these tasks:

- Respond to an S packet with a Y packet (Kermit)
- Respond to an <ENQ> with an ACK/NAK (ASTM)
- Respond to an ANSI II upload with an ACK/NAK (Upload-only)
- Display data received
- Display data returned to the analyzer

Consult with the supplier of the laboratory computer software or the laboratory computer interface specialist at the customer site for assistance.

9.9.3 Bidirectional Diagnostics (except 950)

Kermit bidirectional diagnostics, available in analyzer software, make it possible to do the following checking:

- Verify CTS and DSR are active
- Send an S packet from the serial communications port
- Display the S packet sent from the serial port
- Display the Y packet response from the LIS
- Display the S packet sent from the LIS

Follow the prompts on the screen to select the proper port parameters. They should match the laboratory computer communication parameters. In addition to the baud rate and parity, two additional setup values are required for the bidirectional test:

- STOP BITS - normally 1, but can be set to 1 or 2
- START OF PACKET MARKER - normally 1 (ANSI II control/A character - SOH), but can be set from 0 to 31 (ANSI II control range)

Once the four configurable parameters have been set up, the test can be started.

Possible results include the following:

- No transmission. The diagnostic checks DSR and CTS before transmitting. If the lines do not come high within 30 seconds, one or both of the following messages may occur:
***The DSR control line was not active from the laboratory computer.
***The CTS control line was not active from the laboratory computer.
- Session START packet transmitted. If DSR and CTS are active, the following *Kermit* packet will be output to pin 2 of the laboratory computer port and displayed on the Control Unit screen:

SOH

+S~ @-#N1L

CR

- Acknowledgment packet received. If the session start packet is received by the laboratory computer and a response is transmitted to the analyzer on pin 3, a positive acknowledgment packet similar to the following will be displayed on the analyzer screen:

SOH

,Y~ @-#N1A

CR

- If no response is displayed for the laboratory computer, check:
Cabling - analyzer must receive on pin 3
Configuration
LIS software may not be responding. Laboratory computer personnel should be involved in troubleshooting this malfunction.

(See the Operator's Manual.)

9.9.4 Bidirectional Diagnostics (950 Only)

Kermit bidirectional diagnostics, available in analyzer software, make it possible to do the following checking:

- Verify CTS and DSR are active
- Send an S packet from the serial communications port
- Display the S packet sent from the serial port
- Display the Y packet response from the LIS
- Display the S packet sent from the LIS

Follow the prompts on the screen to select the parity, stop bits, baud rate, and start of packet marker to match the laboratory computer communication parameters. Once the four configurable parameters have been set up, the test can be started.

Possible results include the following:

- No transmission. The diagnostic checks DSR and CTS before transmitting. If the lines do not come high within 30 seconds, one or both of the following messages may occur:
***The DSR control line was not active from the laboratory computer.
***The CTS control line was not active from the laboratory computer.
- Session START packet transmitted. If DSR and CTS are active, a packet similar to the following *Kermit* packet will be output to pin 2 of the laboratory computer port and displayed on the Control Unit screen.

The following data was sent out the laboratory computer port:

+ S~ @-#N1L

- Acknowledgment packet received. If the session start packet is received by the laboratory computer and a response is transmitted to the analyzer on pin 3, a positive acknowledgment packet similar to the following will be displayed on the analyzer screen:

+ Y~ @-#N1A

- If no response is displayed for the laboratory computer, check:
Cabling - analyzer must receive on pin 3
Configuration
LIS software may not be responding. Laboratory computer personnel should be involved in troubleshooting this malfunction.
(See the Operator's Manual.)

9.9.5 Upload-only Diagnostics

Upload-only diagnostics make it possible to do the following checking:

- Verify CTS and DSR are active.
- Display header sent by an analyzer in an Upload-only mode.
- Display ACK/NAK returned by the LIS.

This diagnostic will allow a header record to be sent to the laboratory computer. Set up the baud rate and parity to meet the LIS requirement. The LIS response (ACK/NAK) can be displayed on the screen if the RECEIVE DATA option is used. Follow the instructions on the analyzer screen.

Possible results include the following:

- No transmission. The diagnostic checks the DSR (pin 6) and the CTS (pin 5) lines on the laboratory computer port before attempting data transmission. If the lines do not come high within 30 seconds after starting the test, one or both of the following messages will appear:
***The DSR control line was not active from the laboratory computer.
***The CTS control line was not active from the laboratory computer.
Check the cabling and connectors between the analyzer and the laboratory computer. If the LIS controls these lines, confirm that the LIS is operating correctly.
- Header Transmitted. If DSR and CTS are active, the following record will be output to pin 2 of the laboratory computer port and displayed on the control unit screen:
!000a020000*e250*1124108507103097211096 11 2b301
FF01.000 5D
- Acknowledgment received (if receive data is chosen). If the header record is received by the laboratory computer and a response is transmitted to the analyzer (on pin 3), one of the following acknowledgments could be displayed:
Positive acknowledgment <ACK>: !000+ 007C
or
Negative acknowledgment <NAK>: !000- 007E

9.9.6 Entering System Diagnostics

Establish the type of analyzer involved or the designated instrument and then refer to the appropriate procedures.

IMPORTANT: A loopback connector, part no. 340031 in the customer spare parts kit, is required to complete the loopback tests included in this diagnostic.

9.9.6.1 VITROS 500 or 700C Series Systems

1. To enter System Diagnostics from the Main Menu screen, touch **RETURN TO STANDBY**.

Note: 45 seconds after actuating the **PROGRAM LOAD/RESET** switch, test data will appear on the screen. Approximately two minutes and 30 seconds after the **PROGRAM LOAD/RESET** switch is activated, the prompt:

Autoboot In Progress; Touch Enter To Abort

will appear on the screen for about 10 seconds. You must press the ENTER key while this prompt is displayed.

2. After reaching the Standby state, actuate the **PROGRAM LOAD/RESET** switch located on the circuit breaker panel.
3. Press **ENTER**.
If you do not press **ENTER** quickly, you will need to actuate the **PROGRAM LOAD/RESET** switch again.
4. From the displayed menu, touch **STANDALONE ELECTRONIC DIAGNOSTIC**.
5. Select this value:

2 - Serial Devices

Note: The loopback test will check the serial port selected for proper continuity and control line assertion. The laboratory computer test will demonstrate the ability to transmit and receive data in the Upload-only and bidirectional modes.

5 - Loopback

6. Follow the prompts on the screen to complete the loopback test for the laboratory computer port.
A Q49 code will be displayed. This is normal and should be ignored.
Observe the Tests Completed and the Tests Failed totals. Test failures indicate an analyzer malfunction.
7. Press **RETURN** to access the Serial Devices menu.
8. Select this value:
1 - LAB COMPUTER
9. Select these value:
 - **UPLOAD** if this is the mode used by the customer. (See Section 10.11.4 Upload-only Diagnostics.)
 - **Bidirectional** if this is the mode used by the customer. (See Section 10.11.3 Bidirectional Diagnostic.)
10. Note: The values on the Port Format screen must agree with the laboratory computer setting the laboratory computer interface vendor has provided.

You will be prompted to select the correct setting for these items:

- Parity
- Stop bits
- Baud rate
- Start Of Packet Marker (bidirectional only)

11. Touch **CONTINUE** to run diagnostics.

9.9.6.2 VITROS 250 System

1. To enter System Diagnostics from the Main Menu screen, touch **DIAGNOSTICS**.
2. Touch **STANDALONE DIAGNOSTIC TESTS**.
3. Press Prt Scrn on the keyboard, and follow the instructions on the printout.
4. Select these values:
 - 3 - Serial devices
 - 1 - Loopback tests
 - 3 - AT4 boardFollow the prompts on the screen.
5. Observe the Test Completed and Tests Failed totals. Test failures indicate an analyzer malfunction.
6. Select this value:
 - 4 - Lab Computer tests
7. Select these values:
 - 1 - Upload-only Communication Test if this mode is used by the customer.
 - 2 - Bidirectional Communication Test if this mode is being used by the customer.

9.9.6.3 VITROS 950 System

1. To enter System Diagnostics from the Boot Menu, touch **RETURN TO STANDBY** from the Main Menu screen.
The following message appears:
Transition to Standby Mode in Progress.
2. Touch **SHUTDOWN ANALYZER**.
3. Enter a Y at the following prompt and press ENTER:
This function will require a reset. Do you wish to continue (Y/N).
The following message appears:
The analyzer has been shut down. Reset or power down is required.
4. Turn system power off by pressing the On/Off switch, located on the left side panel of the 950 System, to the **OFF** position.
The system powers down, and the screen goes blank. Wait one minute.
5. Turn system power on by pressing the On/Off switch to the **ON** position. The system will perform power-on self-tests followed by system initialization.
IMPORTANT: Watch the bottom of the screen for the following message:
Auto boot in progress, press Enter key to abort.

6. Press **ENTER**.

Note: You have only 10 seconds to press **ENTER**. After 10 seconds you are returned to the Boot Menu.

7. From the Boot Menu, touch **STANDALONE ELECTRONIC DIAGNOSTICS**.
8. From the Electronic Main Menu, select this value and press **ENTER**:
 - 3 - Serial Devices
9. From the Serial Device Main Menu, select this value and press **ENTER**:
 - 1 - Lab Computer
10. From the Lab Computer Serial Line Diagnostic Menu, select these values:
 - 1 - Upload Communication Test if this mode is used by the customer (refer to [Section 9.9.5](#)).
 - 2 - Bidirectional Communication Test if this mode is being used by the customer (refer to [Section 9.9.4](#)).

9.9.7 System Diagnostics in the VITROS ECi Immunodiagnostic System

To use system diagnostics for standalone, serial port tests in the Immunodiagnostic System, follow these procedures:

1. Touch **DIAGNOSTICS** from the Main Menu.
2. Touch **INTERFACE TESTS** under the **SYSTEM DIAGNOSTICS** section title.
3. Touch **TEST SERIAL LOOPBACK**.
4. Touch **TEST SERIAL PORT**.
5. Touch **LAB COMPUTER** and then **START**. The individual pass/ fail status of each bit tested will then display. Test failures indicate an analyzer malfunction.

9.9.8 The Laboratory Computer Protocol Analyzer and Monitor

The VITROS 250 and 950 Systems both have on-line utilities that provide the basic functionality of a protocol analyzer. In the 250, it is called the Laboratory Computer Protocol Analyzer (LCPA) and in the 950, it is called the Laboratory Computer Protocol Monitor (LCPM). Both diagnose data transfer problems between the laboratory computer and its respective analyzers. They function in very similar ways and for purposes of discussion, we are not making distinctions here.

The LCPA and LCPM are tools that can be used by laboratory computer specialists, field engineers, and technical support personnel to resolve problems that previously could not be solved without the use of a protocol analyzer.

Flow control status. A plus (+) sign will appear to the right of the DSR and CTS indicators at the top of the screen when these

lines are active. This is an indication that the hardware flow control between the laboratory computer and the 250 and 950 Systems are correct and the cables are configured properly. A minus (-) sign will appear if the flow control is incorrect.

Configure Port Parameters. All the configurable laboratory computer port parameters can be accessed via this feature, thus allowing the user to change parameters and observe the subsequent effects on the performance of the interfaces. This feature is linked directly to the Options dialog, and any changes made will also be made to the permanent Options screen configuration. Before making a parameter change from this screen, turn off transmit and receive, and cancel computer reports.

Bidirectional Display. The 96 bytes of data displayed on each screen is divided into three lines of 32 bytes each. Each line can display the transmitted and received data and is labeled 250 or 950 analyzer and LIS for convenience.

Limitations. The storage capacity of the corresponding buffers is 64,000 bytes of data per analyzer. If the data captured exceeds 64,000 bytes, the utility will overwrite the previously captured data. The buffer will not be erased.

ASCII characters decimal 0 to 31 and 127 are not printable and therefore cannot be displayed on the monitor. Any of these characters transmitted across the interface will be captured and displayed in its decimal equivalent value. For convenience, the space character is displayed as decimal 32.

To access the LCRA for 250 and 950, follow these procedures:

WARNING

A general protection fault will occur and result in a system shutdown if the interface cable is removed without first turning OFF the interface in the Options dialog.

To turn off the interface before disconnecting the cable, touch:

- **OPTIONS**
- **(Enter Access Code)**
- **REPORT CONTROL**
- **DEVICE/REPORT CONTROL**

Under Report Laboratory Computer:

- **TRANSMIT RESULTS—OFF**
- **RECEIVE RESULTS—ON**
- **PRESS RETURN**
- **PRESS RETURN**
- **REVIEW RESULTS**
- **EDIT OR VERIFY**
- **ABORT REPORT STATUS**
- **COMPUTER**
- **START**
- **START**
- **RETURN**
- **OPTIONS**
- **(Enter Access Code)**
- **ANALYZER CONFIGURATION**
- **LAB COMPUTER CONFIGURATION**
- **NO COMM**
- **PRESS RETURN**
- **PRESS RETURN**

1. Touch **DIAGNOSTICS** on the Main Menu screen.

2. Type the access code, and press **ENTER**.

3. Touch **LAB COMP PROTOCOL ANALYZER**.

- To enable the software utility, touch **CAPTURE ON/OFF** until ON is illuminated. Then press **RETURN** two times to reach the Main Menu screen. The LCRA will remain enabled during normal operation and until the software utility is manually disabled. The data flow will be recorded in the buffer.
- To disable the software utility, touch **CAPTURE ON/OFF** to illuminate the work OFF. Then press **RETURN** two times to reach the Main Menu screen. The LCRA will remain disabled and no data will be recorded in the buffer.
- To determine status of the “Data Set Ready” signal, observe the “DSR—” area at the top of the menu. If a “+” character is displayed, the signal is enabled. If a “-” character is displayed, the signal is disabled.
- To determine status of the “Clear to Send” signal, observe the “CTS—” area at the top of the menu. If a “+” is displayed, the signal is enabled. If a “-” is displayed, the signal is disabled.
- To display the first screen of 96 bytes, touch **START DATA DISPLAY**.

- To display additional screens of data, touch **DISPLAY NEXT SCREEN**.
- To obtain access to the same communications options displayed on the Options menu for Laboratory Computer Communications Configuration, touch **CONFIGURE PORT PARAMETERS**. If any communications options are changed on the screens in the **LAB COMP PROTOCOL ANALYZER**, the new options, mode, and parameters will become permanent.
- Use the **HELP** target for additional on-line information.

The LCPA and LCPM allow field personnel to select or change:

- Options
 - If the **BIDIRECT** target is touched, the communication will occur in two directions.
 - If the **UPLOAD-ONLY** target is touched, communication will occur in one direction (from the 250 Analyzer to the laboratory computer).
 - If the **NO COMMUN** target is touched, no

communication will occur in either direction.

- Modes
 - If YES is illuminated in the **ACK/NAK YES NO** target, the 250 Analyzer will wait to acknowledge a transmission from the laboratory computer.
 - If NO is illuminated in the **ACK/NAK YES NO** target, the 250 Analyzer will not wait to acknowledge a transmission from the laboratory computer and will not display a time-out message.
- Parameters
 - If the **PORT FORMAT** target is touched, the baud rate, parity, and stop bits are displayed together with targets for the values of these parameters.
 - If the **PROTOCOL DEFINITION** target is touched, the screen displays a list of parameters and the corresponding ranges of possible values to select and enter.
 - The screen also has a **PACKET FORMAT** target for the “Start of Packet Marker” and “Handshake Character” parameters.

Examples

The screen shown in figure 9-11 is an example of a file that was downloaded to the 250.

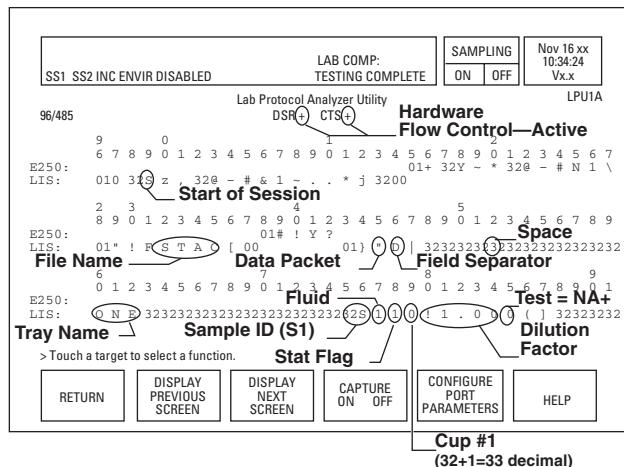


Figure 9-11. Download File.

The screen in figure 9-12 shows what the data looks like when captured by the LCPA utility.

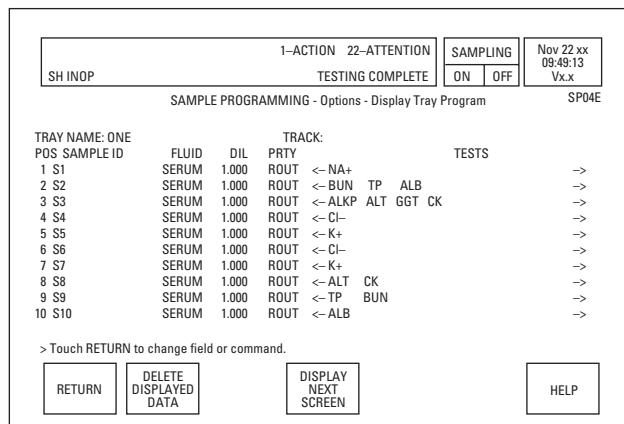


Figure 9-12. Data Steam.

The following screen is an example of a partial download record.

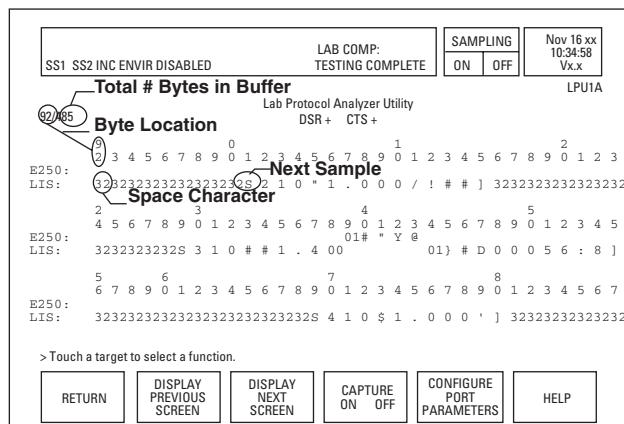


Figure 9-13. Partial Download.

Additional examples follow.

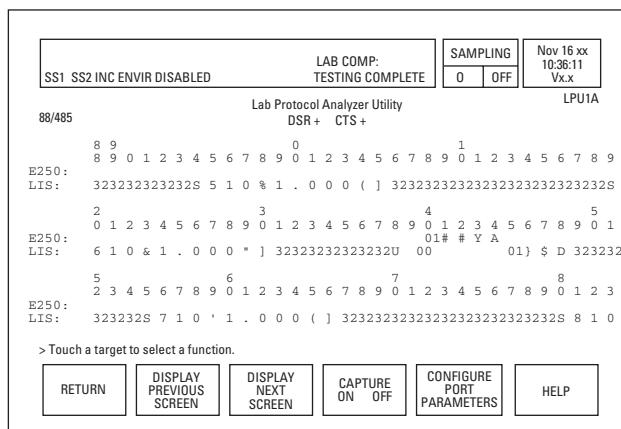


Figure 9-14. Additional Example 1.

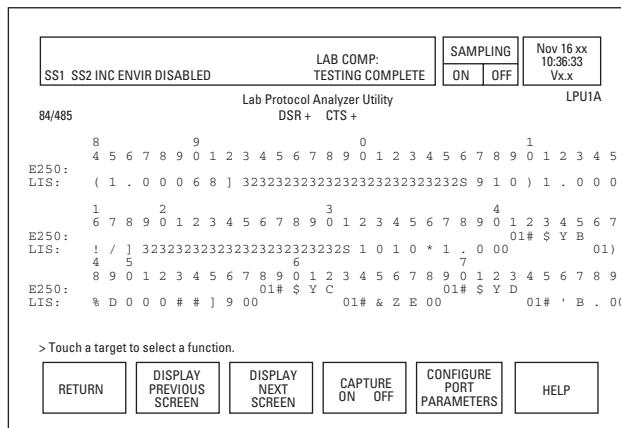


Figure 9-15. Additional Example 2.

9.10 Summary of Common Implementation Oversights

For your easy reference, this section summarizes common oversights encountered during installation of laboratory information systems.

Software. *Kermit* Protocol, ASTM, or an equivalent must be implemented in the laboratory information system. Refer to Section 1.5 for details on how to obtain current *Kermit* specifications documents and ASTM specifications documents.

Port configuration. The baud rate, parity, stop bits, and flow control mechanism must be decided on before implementation. For communications between the laboratory computer and an

analyzer, the configuration must match exactly for the devices directly connected to each other and sharing a transfer protocol.

Protocol definition. Customer site requirements must be evaluated to determine the appropriate settings for analyzer response delay, analyzer response time out, flow control time out, packet retry limit, and block checksum type. Refer to Chapter 3 for Upload-only communications detail, Chapter 5 for *Kermit* communications, and Chapter 7 for ASTM communications detail in this publication.

Cable. Should match a configuration represented in the interface specifications section of the Operator's Manual. The interface vendor must provide the cable needed for the application. Refer to Section 2.2 in this publication for more details.

Fluid type. For Chemistry Systems, the fluid type must be '1', '2', or '3' with '0', or '4' as invalid. For the Imm. System, the fluid type can be '4' – '9', ':', ';', '>' with '0' – '3' invalid. Refer to Sections 4.3.2 and 4.3.10 as well as Sections 6.1.2, 6.2.2, and 8.5 for bidirectional application.

File size. Because sample trays hold 10 samples, the analyzer software is formatted to receive files containing no more than 10 sample IDs. You must limit the file size to 10 sample IDs.

- A *Kermit* file will contain no more than 10 packets. One of the packets will be the F packet and one will be the Z packet. This means the file will contain as many as eight data packets, one F packet and one Z packet.

Packet sequence number for Kermit. Packet sequence numbers should wrap around to zero after each group of 64 packets (modulo 64). The sequence field should never exceed 63. Refer to Section 5.7.6 for more details.

Power on protocol. The laboratory information system must be in a fully operational state (ready to receive data or transmit data), before the analyzer is powered on or the communication port is enabled. If the state of the data line connected to the analyzer computer ports is going to change state, it is recommended to place the analyzer in the **NO COMMUNICATION** mode and to turn the laboratory computer off.

Quoting. When a pound sign (#) is used in a data field, it must be quoted. Albumin should appear as ##. When the number 3 is needed, the ASCII value is # and must be quoted. Refer to Section 5.6.10 for more details.

Bar Coding. Do not download a tray name or cup or slide location with bar coded samples. Doing so negates the advantage of random sample placement, which is a benefit of the Sample Management System.

9.11 Downloaded Messages for All VITROS Chemistry Systems

Code Number	Message	Meaning	Action																														
01	Missing Sample ID	Sample program has blank sample ID field.	Add sample ID to program and down load program again.																														
02	Invalid Message	Sample program has invalid characters.	Refer to Chapters 4, 6, and 9 for listings of valid characters, then down load sample program again.																														
03	More than 10 Samples in File	The <i>Kermit</i> file in which this sample program was included had more than 10 programs assigned to it.	Downloaded <i>Kermit</i> file can have a maximum of 10 sample programs. Down load this sample program in another sample file.																														
04	Tray Name or Cup or Slide Missing	Tray name was specified, but sample program did not have an assigned slide position. Sample program had a slide position but no tray name specified.	Add slide position and down load program again. Delete slide position or add tray name, then down load sample again.																														
05	File with Mixed Trays	More than one sample program in the file has a tray Name specified.	Delete Tray Name from all programs except the first in the file; then down load file again.																														
06	Sample/Patient Name Mismatch	Sample program has the same sample ID as a program already in sample file, but patient names do not match.	Patient name cannot be edited from the laboratory computer; it can be edited using the sample programming dialog. To edit a sample program from the laboratory computer, the sample ID and patient name in the edited program must match the information originally sent.																														
07	Sample/Cup or Slide Do Not Match	The sample program has a slide position that has already been assigned to another program.	Change the sample ID or slide position, then down load the sample program again.																														
08	Tray Has No Downloaded Samples	The sample program has been assigned to a tray that is not considered a downloaded tray (a tray is considered down loaded if it was down loaded from the laboratory computer or it has a sample program assigned that was down loaded).	Assign the sample to a tray that is considered a downloaded tray; then down load sample program again.																														
09	STAT Change Not Accepted	The sample program has already been loaded and changes to the STAT field and another field(s) have been down loaded.	Only a STAT field change can be down loaded for an already-loaded sample program. Change the STAT field using the sample programming dialog.																														
10	Sample/Tray is Loaded	The sample program has already been loaded and changes have been down loaded for it.	Use the sample programming dialog to make changes to the sample program.																														
11	Sample/Tray Not Available	A new or edited sample program was down loaded while the sample program/tray was displayed on the control screen.	Down Load the sample program again after the sample program/tray has been returned to the sample file.																														
12	Sample Manually Edited	An attempt was made to edit the sample program from the laboratory computer after it had been edited using the sample programming dialog.	Edit the sample program using the sample programming dialog.																														
13	No Tests Requested	The sample program was down loaded with no test requests (no sample program was currently in the sample file to be deleted).	Add test requests to sample program and down load program again.																														
14	Invalid Test Requested	A test was requested that is currently not supported by the analyzer.	Edit test requests and down load sample program again.																														
15	Derived Test Replicated	The sample program included a request to replicate a derived test.	Delete request for replicate of derived test and down load sample program again.																														
16	Too Many Tests Requested	The sample program has more than maximum test results requested.	Edit test request so that sample program has maximum test results requested and down load program again.																														
		<table border="1"> <thead> <tr> <th rowspan="2">Analyzer</th> <th colspan="3">Maximum</th> </tr> <tr> <th>Test</th> <th>Results</th> <th>Derived</th> </tr> </thead> <tbody> <tr> <td>250–750</td> <td>30</td> <td>30</td> <td>16</td> </tr> <tr> <td>950</td> <td>40</td> <td>40</td> <td>16</td> </tr> </tbody> </table>	Analyzer	Maximum			Test	Results	Derived	250–750	30	30	16	950	40	40	16	<table border="1"> <thead> <tr> <th rowspan="2">Analyzer</th> <th colspan="3">Maximum</th> </tr> <tr> <th>Test</th> <th>Results</th> <th>Derived</th> </tr> </thead> <tbody> <tr> <td>250–750</td> <td>30</td> <td>30</td> <td>16</td> </tr> <tr> <td>950</td> <td>40</td> <td>40</td> <td>16</td> </tr> </tbody> </table>	Analyzer	Maximum			Test	Results	Derived	250–750	30	30	16	950	40	40	16
Analyzer	Maximum																																
	Test	Results	Derived																														
250–750	30	30	16																														
950	40	40	16																														
Analyzer	Maximum																																
	Test	Results	Derived																														
250–750	30	30	16																														
950	40	40	16																														
17	Sample Tray Changed	Sample program has been assigned to another tray.	Place sample on tray to which the sample program has been assigned.																														

Figure 9-16. Download Messages for VITROS Chemistry Systems.

Code Number	Message	Meaning	Action
18	Sample Taken Off Tray	Sample program will be assigned to another tray.	Remove sample from tray specified in downloaded program.
19	No Tests; Sample Deleted	The test requests were deleted from the sample program by the laboratory computer.	Remove the sample from the tray.
20	Dilution Out of Range	The dilution for this sample program is not between 0.0001–9999. and includes the decimal point.	Change the dilution factor and down load sample program again.
21	Invalid MSDT Sample ID	a) When requesting a MSDT, the sample ID is appended with a “z” or “y”. If the ID is too long, this appending cannot take place. b) The Sample ID name is all blanks.	Shorten the Sample ID
22	Cannot Edit MSDT Pretreat	An attempt was made to edit a MSDT Sample ID	MSDT Sample ID's cannot be edited.
23	Pretreated ID is in Use	An unresulted pretreated sample ID is in memory	Delete the sample ID
24	See Error Display	This error is associated with another error.	None
25	Test in Progress for ID	An attempt was made to edit a Sample ID after the MSDT pretreated sample has been resulted.	None

Figure 9-16. Download Messages for VITROS Chemistry Systems.

9.12 Download Messages for the VITROS ECi Immunodiagnostic System

Code Number	Message	Condition	Action
0	No download condition.		
1	Missing sample ID.	The sample program has a blank sample ID field.	Add a sample ID to the program and down load the program again.
2	Invalid characters in sample.	The sample program has invalid characters.	Refer to Chapters 4, 6, and 9 in this publication for a listing of valid characters, then down load the sample program again.
3	More than 10 sample in file.	The file in which this sample program was included had more than 10 programs assigned to it.	Downloaded files can have a maximum of 10 sample programs. Down Load this sample program in another sample file.
4	Tray name or cup missing.	<ul style="list-style-type: none"> • The tray name was specified but the sample program does not have an assigned sample position. • The sample program has a sample position but no tray name specified. 	<ul style="list-style-type: none"> • Add the sample position and down load program again. • Delete the sample position or add a tray name, then down load the sample program again.
5	File with mixed trays.	More than one sample program in the file has a tray name specified.	Delete the tray name from all programs except the first in the file; then down load the file again.
6	Sample/patient name mismatch.	The sample program has the same sample ID as a program already in the sample file but the patient names do not match.	The patient name cannot be edited from the laboratory computer; it can be edited using the Sample Programming screen. To edit a sample program from the laboratory computer, the sample ID and patient name in the edited program must match the information originally sent.
7	Sample program/cup mismatch.	The sample program has a position that has already been assigned to another program or is attempting to edit the assays for a previously downloaded sample program.	Change the sample ID or sample position, then down load the sample program again.
8	Tray without sample programs.	The sample program has attempted to be assigned to a tray that is not considered a downloaded tray. A tray is considered downloaded if it was down loaded from the laboratory computer or it has a sample program assigned that was down loaded.	Assign the sample program to a tray that is considered a downloaded tray; then down load sample program again.

Figure 9-17. Download Messages for the VITROS ECi Immunodiagnostic System .

Code Number	Message	Condition	Action
9	STAT change not accepted.	The laboratory computer has attempted to edit a downloaded sample program, in progress, to a STAT and changes to the STAT field and another field have been down loaded.	Only a STAT field change can be down loaded for an already-loaded sample program. Use the Sample Programming screen to make any changes.
10	Sample program is active.	The sample program has attempted to edit a downloaded program that is in progress and changes have been down loaded for it.	Use the Sample Programming screen to make the changes to the sample program.
11	Sample program not available.	A new or edited sample program was down loaded while the sample program/tray program is unavailable.	Down load the sample program again after the sample program/tray has been returned to the sample file.
12	Sample manually edited.	An attempt was made to edit the sample program from the laboratory computer after it had been edited using the Sample Programming screen.	Edit the sample program using the Sample Programming screen.
13	No assays requested.	The sample program was down loaded with no assay requests.	Add assays to the sample program and down load the program again.
14	Invalid assay requested.	An assay was requested which is currently not supported by the Imm. System. The program is accepted but the unsupported assay is deleted from the program.	Refer to Chapter 6 of this document for a list of supported assays. Edit assay requests and down load the sample program again.
15	Derived test replicated.	The sample program included a request to replicate a derived test.	Delete requests for replicating of derived tests and down load sample program again. (Derived tests are not allowed to be replicated.)
16	Too many assays.	The sample program has more than 20 assays or replicates requested.	Edit assay requests so that the sample program has a maximum of 20 assays requested and down load the program again.
17	Sample/tray program changed.	The sample program has been assigned to another tray.	Place sample on tray to which the sample program has been assigned.
18	Sample program taken off tray.	The sample program will be assigned to another tray.	Remove sample from the tray specified in the downloaded program.
19	No assays: sample deleted.	The sample program did not include any assays and was deleted by the laboratory computer.	Remove the sample from the tray.
20	Dilution out of range.	The dilution for this sample program is not between 1 and 9999.	Change the dilution factor and down load the sample program again.
21	Incorrect sample type.	The sample program included a sample type other than patient. (Calibrator and control sample programs cannot be down loaded.)	Change the sample type and down load the program again.
22	Body fluid unknown.	The sample program included a body fluid that the system does not currently support.	Scan the protocol or reagent lot calibration card.

Figure 9-17. Download Messages for the VITROS ECi Immunodiagnostic System (Continued).

**APPENDIX
A**

ASCII Chart

ASCII Codes in Ascending Order

ASCII	DECIMAL	HEXA-DECIMAL	ASCII	DECIMAL	HEXA-DECIMAL	ASCII	DECIMAL	HEXA-DECIMAL
NUL	0	00	+	43	2B	V	86	56
SOH	1	01	,(comma)	44	2C	W	87	57
STX	2	02	-	45	2D	X	88	58
ETX	3	03	.	46	2E	Y	89	59
EOT	4	04	/	47	2F	Z	90	5A
ENQ	5	05	0	48	30	[91	5B
ACK	6	06	1	49	31	\	92	5C
BEL	7	07	2	50	32]	93	5D
BS	8	08	3	51	33	Λ (or ↑)	94	5E
HT	9	09	4	52	34	–(underscore)	95	5F
LF	10	0A	5	53	35	‘(left apostrophe)	96	60
VT	11	0B	6	54	36	a	97	61
FF	12	0C	7	55	37	b	98	62
CR	13	0D	8	56	38	c	99	63
SO	14	0E	9	57	39	d	100	64
SI	15	0F	:	58	3A	e	101	65
DLE	16	10	;	59	3B	f	102	66
DC1	17	11	<	60	3C	g	103	67
DC2	18	12	=	61	3D	h	104	68
DC3	19	13	>	62	3E	i	105	69
DC4	20	14	?	63	3F	j	106	6A
NAK	21	15	@	64	40	k	107	6B
SYN	22	16	A	65	41	l	108	6C
ETB	23	17	B	66	42	m	109	6D
CAN	24	18	C	67	43	n	110	6E
EM	25	19	D	68	44	o	111	6F
SUB	26	1A	E	69	45	p	112	70
ESC	27	1B	F	70	46	q	113	71
FS	28	1C	G	71	47	r	114	72
GS	29	1D	H	72	48	s	115	73
RS	30	1E	I	73	49	t	116	74
US	31	1F	J	74	4A	u	117	75
SP(space)	32	20	K	75	4B	v	118	76
!	33	21	L	76	4C	w	119	77
“	34	22	M	77	4D	x	120	78
#	35	23	N	78	4E	y	121	79
\$	36	24	O	79	4F	z	122	7A
%	37	25	P	80	50	{	123	7B
&	38	26	Q	81	51		124	7C
‘(apostrophe)	39	27	R	82	52	}	125	7D
(40	28	S	83	53	~	126	7E
)	41	29	T	84	54	DEL	127	7F
*	42	2A	U	85	55			

Figure A-1. ASCII Codes in Ascending Order.

Checklist for Configurable Options

The following checklist summarizes the configurable options available for the laboratory computer interface; these options are fully described in the indicated sections. Default selections are shown in *italics*. It is recommended that the laboratory selections be recorded here to facilitate Chemistry System configuration at installation and, thereafter, to be retained for reference purposes.

Communications Modes (Refer to Section 1.2)

- NO COMMUN** (for no communications)*
- UPLOAD-ONLY** (for upload-only mode)
- BIDIRECT** (for bidirectional mode)

*If analyzer is in the “no communications” mode, proceed no further on this checklist.

Upload-Only Mode Configurable Options

1. Parity (Refer to section 3.3)

- ODD** (for odd parity; *default for Chemistry Systems*)
- EVEN** (for even parity)
- MARK** (if the parity bit is to be binary 1)
(not used in Imm. System)
- SPACE** (if the parity bit is to be binary 0)
(not used in Imm. System)
- NONE** (if parity is not desired; 8 bits are sent per character, the parity or eighth bit is ignored; *default for the Imm. System*)

2. Baud Rate (Refer to section 3.4)

- 300
- 600
- 1200 (default for Chemistry Systems)**
- 2400
- 4800
- 9600 (default for Imm. System)**
- 19200
- 38400

3. ACK/NAK (Refer to section 3.6.1)

- YES** (if the analyzer expects acknowledgment messages)
- NO** (if the analyzer does not expect acknowledgment messages)

4. Analyzer Response Delay (Pacing Timer) (Refer to section 3.6.2)

This option is available to accommodate laboratory computers that require additional time for message preparation. The default setting is recommended for laboratory computers that do not require any additional delay.

- (0.00 to 9.99 seconds or 1 to 10 seconds for the Imm. System)

Default Configuration: 0.00 seconds or 1 to 10 seconds for the Imm. System.

5. Acknowledgment Timeout (Response Timer)

(Refer to section 3.6.3)

Used when ACK/NAK has been selected (**YES**).

- (1 to 99 seconds)

Note: The analyzer will wait forever for a response from the laboratory computer if the value of zero (0) is entered.

Default Configuration: 15 seconds.

Kermit and ASTM Configurable Options

1. Number of Stop Bits (Refer to section 5.4)

- 1 stop bit
- 2 stop bits

2. Parity (Refer to section 5.3)

- ODD** (for odd parity, *default for Chemistry Systems*)
- EVEN** (for even parity)
- MARK** (if the parity bit is to be binary 1)
(not used in Imm. System)
- SPACE** (if the parity bit is to be binary 0)
(not used in Imm. System)
- NONE** (if parity is not desired; 8 bits are sent per character, the parity or eighth bit is ignored, *default for the Imm. System*)

3. Baud Rate (Refer to section 5.4)

- 300 (no longer recommended)
- 600 (no longer recommended)
- 1200 (*default for 250, 500, 700 series, 950*)
- 2400
- 4800
- 9600 (*default Imm. System*)
- 19200 (only Imm. System)
- 38400 (only Imm. System)

4. Checksum Method (Refer to section 5.5.9)

- One-character checksum (*default for all analyzers*)
- Two-character checksum

Kermit Only

1. NAK ZERO (Download Solicitation) (Refer to section 5.5.6)

- YES (enabled)
- NO (*disabled*)

2. Flow Control Mechanism

- NONE
- XON/XOFF (enabled)

3. Flow Control Timeout(Make a selection here if **XON/XOFF** was selected for #2.)

- 0:01 to 9:59 (minutes:seconds)
- 1 to 599 seconds for the Imm. System

*Default Configuration: 30 seconds***4. Analyzer Response Delay (Pacing Timer)**

This option is available to accommodate laboratory computers that require additional time for message preparation. The default setting is recommended for laboratory computers that do not require any additional delay.

- (0.00 to 9.99 seconds)
(0 to 10 seconds for the Imm. System)

*Default Configuration: 0.00 or 0 seconds***5. Analyzer Response Timeout (Response Timer)**

- 1 to 99 seconds, or zero (0) to wait forever

*Default Configuration: 25 seconds.***6. Packet Retry Limit**

- 0 to 99

*Default Configuration: 5***7. Analyzer Start-of-Packet Marker**

- All valid entries are in the ASCII control character range. The character specified must not be the same as that selected for the handshake character or the EOL character exchanged at session initialization.

*Default Configuration: 01 hex (Control A)***8. Handshake Character**

- All ASCII control characters are valid. 0 (zero) indicates no handshake. (Do not specify the XOFF [ASCII DC3])

Default Configuration: 0 (that is, no handshake)

Examples of Kermit Sessions

Example of a VITROS Chemistry System Download Session using Kermit

0	10	20	30	40	50	60	70	80	90	100	110
<u>s</u> •S~R•@-#N1• <u>c</u> r	(15 Bytes)										
<u>s</u> ••Y~••@-#N1R <u>c</u> r	(14 Bytes)										
0	10	20	30	40	50	60	70	80	90	100	110
<u>s</u> *!FSFILE1.D <u>c</u> r	(13 Bytes)										
<u>s</u> #!Y? <u>c</u> r	(6 Bytes)										
0	10	20	30	40	50	60	70	80	90	100	110
<u>s</u> z“D Very•First•TrayFirst•Sample•ID10!.0001•!”##\$%&‘()•+-.0123456789;;•this•name•is•maximum% <u>c</u> r	(93 Bytes)										
<u>s</u> #“Y@ <u>c</u> r	(6 Bytes)										
0	10	20	30	40	50	60	70	80	90	100	110
<u>s</u> z#Dm•size]••••2nd•Sample11“9999. `abcf]••••3rd•Sample10##1.000e]••••4th.Sample10\$1.000d]V <u>c</u> r	(93 Bytes)										
<u>s</u> ##YA <u>c</u> r	(6 Bytes)										
0	10	20	30	40	50	60	70	80	90	100	110
<u>s</u> z\$D••••5th•Sample11%.0001‘)•a]••••6th•Sample30&9999. •&(-./2]•7th.Sample30‘1.000).]V <u>c</u> r	(93 Bytes)										
<u>s</u> ##\$YB <u>c</u> r	(6 Bytes)										
0	10	20	30	40	50	60	70	80	90	100	110
Note: 9th sample intentionally skipped											
<u>s</u> U%D••••8th•Sample20).0001•]••••10th•Sample21*9999. •]G <u>c</u> r	(59 Bytes)										
<u>s</u> ##%YC <u>c</u> r	(6 Bytes)										
0	10	20	30	40	50	60	70	80	90	100	110
<u>s</u> ##&ZE <u>c</u> r	(6 Bytes)										
<u>s</u> ##&YD <u>c</u> r	(6 Bytes)										
0	10	20	30	40	50	60	70	80	90	100	110
<u>s</u> ##B <u>c</u> r	(6 Bytes)										
<u>s</u> ##YE <u>c</u> r	(6 Bytes)										

Example of an VITROS Chemistry System Upload Session using Kermit

0 10 20 30 40 50 60 70 80 90 100 110

\$ h+S~@-#N1L c
(14 Bytes)

0 10 20 30 40 50 60 70 80 90 100 110

\$ h,*Y-R@-#N1* c
(15 Bytes)

0 10 20 30 40 50 60 70 80 90 100 110

\$ h+!FR0000003W c
(14 Bytes)

0 10 20 30 40 50 60 70 80 90 100 110

\$ h#!Y? c
(6 Bytes)

0 10 20 30 40 50 60 70 80 90 100 110

\$ h~"D1222291216Test•10•••••Sample2•••••30~41.000••••85.0•000IT)&NO•RESULT060MEPF)/••••46.2 c
(97 Bytes)

0 10 20 30 40 50 60 70 80 90 100 110

\$ h#“Y@ c
(6 Bytes)

0 10 20 30 40 50 60 70 80 90 100 110

\$ h~#D44•200IT).••••1.2•000IT)2••••9.7•000IT)—••180.0•120IT))NO•RESULT061ERITFC}••••1000.0•053OT c
(97Bytes)

0 10 20 30 40 50 60 70 80 90 100 110

\$ h##YA c
(6 Bytes)

0 10 20 30 40 50 60 70 80 90 100 110

\$ h\$DRITUC){950•••••]V c
(12 Bytes)

0 10 20 30 40 50 60 70 80 90 100 110

\$ h#\$YB c
(6 Bytes)

0 10 20 30 40 50 60 70 80 90 100 110

\$ h%ZD c
(6 Bytes)

0 10 20 30 40 50 60 70 80 90 100 110

\$ h%YC c
(6 Bytes)

0 10 20 30 40 50 60 70 80 90 100 110

\$ h&B- c
(6 Bytes)

0 10 20 30 40 50 60 70 80 90 100 110

\$ h&YD c
(6 Bytes)

Example of a VITROS ECi Immunodiagnostic System Download Session using Kermit

0 10 20 30 40 50 60 70 80 90 100 110
S b •Sp/*-#N1-C (14 Bytes)

S++Y-9@@-#N1.C
(14 Bytes)

0 10 20 30 40 50 60 70 80 90 100 110
S_b+IESEII E1••W_C (14 Bytes)

(6 Bytes)

^Sn^uDIV/verFirstTroyFirstSampleID401_0001001002054027002002002005005005006006S (82 Bytes)

(6 Bytes)

(6 Bytes)

Sample#150014513rd S 10001451 S 10001451 C (82 Bytes)

S#SYRC (6 Bytes)

0 10 20 30 40 50 60 70 80 90 100 110
S105/DE15510515H_C_L_11_5105_20010001051_C_(51_P_1)

6.4% XC₆ (6 Bytes)

(C-Dates)

b#&YD C (6 Bytes)

0 10 20 30 40 50 60 70 80 90 100 110
h # B C (6 Bytes)

(6 Bytes)

Example of an VITROS ECi Immunodiagnostic System Upload Session using Kermit

0 10 20 30 40 50 60 70 80 90 100 110

\$ h+*S~~@-#N1L c
(14 Bytes)

\$ h,*Y-R@-#N1* c
(15 Bytes)

0 10 20 30 40 50 60 70 80 90 100 110

\$ h+!FR0000000T c
(14 Bytes)

\$ h#!Y? c
(6 Bytes)

0 10 20 30 40 50 60 70 80 90 100 110

\$ h~"D1 057260630Tray*10*****Sample2*****60!41.000001*****85.000001T)002*****46.4200T)003***& c
(97 Bytes)

\$ h#!Y@ c
(6 Bytes)

0 10 20 30 40 50 60 70 80 90 100 110

\$ h~#D4***1.2000TI)054*****9.7000IT) 024NO•RESULT060MEPF)012 ***180.0 • 120IT)005 NO •RESULT 061ERITFC)0X c
(97Bytes)

\$ h##YA c
(6 Bytes)

0 10 20 30 40 50 60 70 80 90 100 110

\$ h A\$D10**1000.0•53ORITUC)IJEMINI]4 c
(12 Bytes)

\$ h#\$YB c
(6 Bytes)

0 10 20 30 40 50 60 70 80 90 100 110

\$ h%ZD c
(6 Bytes)

\$ h%YC c
(6 Bytes)

0 10 20 30 40 50 60 70 80 90 100 110

\$ h#&B- c
(6 Bytes)

\$ h#&YD c
(6 Bytes)

**APPENDIX
D****ASTM Record Layouts**

Download Record	
Host	H \^& HOST 19950301153500<CR>
Upload Record	
Imm. System	H \^& VITROS 19950301154000<CR>

■ Figure D-1. Sample Header Record Layouts.

Download Record	
Host	P 1 111-11-1111 Doe^Jane^M Gilbert 010181 FB 200ParkAvenue^NewYork^NY^10002 Telnnnnnnnnnnn Schweitzer 5002^Surgery <CR>
Upload Record	
Imm. System	P 1 111-11-1111 Doe^Jane^M 010181 F 200ParkAvenue^NewYork ^NewYork Schweitzer^Albert^P 5002 <CR>

■ Figure D-2. Sample Patient Record Layouts.

C | 1 | I | First run out of range--these results w/2:1 dilution. | G | <CR>

Figure D-3. Sample Comment Record Layout.

Download Record	
Imm. System	0 1 SID4000^A1^1 ^^^ 1.0+032+1\033+1\034+1 R 9941201070510 N 4 O <CR>

■ Figure D-4. Sample Test Order Record Layouts.

R | 1 | ^^^1.0+32+1 | 88.12 | nmol/L | | ^0^ | V ||| 19951201153500Vitros<CR>

Figure D-5. Sample Results Record Layout.

L | 1 | N

Figure D-6. Sample Message Terminator Record Layout.

APPENDIX
E

Test Codes and Results Codes

VITROS Chemistry Systems

ASCII DECIMAL VALUE	ASCII CHARACTER	REPORT NAME	TEST NAME	700‡	700XR‡	700P‡	700S‡	500	250	950
32	space	GLU	Glucose	X	X	X	X	X	X	X
33	!	TP	Total Protein	X	X	X	X	X	X	X
34	"	URIC	Uric Acid	X	X	X	X	X	X	X
35	#* (Refer to Note below)	ALB	Albumin	X	X	X	X	X	X	X
36	\$	TRIG	Triglycerides	X	X	X	X	X	X	X
37	%	CHOL	Cholesterol	X	X	X	X	X	X	X
38	& (ampersand)	AMYL	Amylase	X	X	X	X	X	X	X
39	' (apostrophe)	Cl	Chloride	X	X		X	X	X	X
40	(K+	Potassium	X	X		X	X	X	X
41)	Na+	Sodium	X	X		X	X	X	X
42	*	ECO2	Enzymatic CO2	X	X	X	X	X	X	X
43	+	PHOS	Phosphorus	X	X	X	X	X	X	X
44	, (comma)	LAC	Lactate	X	X	X	X	X	X	X
45	- (dash, hyphen, minus sign)	NH3	Ammonia	X	X	X	X	X	X	X
46	. (period, dot)	CREA	Creatinine	X	X	X	X	X	X	X
47	/ (slash)	BUN†	Urea Nitrogen	X	X	X	X	X	X	X
48	0	HDLC	HDL Cholesterol	X	X	X	X	X	X	X
49	1	Bu	Unconjugated Bilirubin	X	X	X	X	X	X	X
50	2	Ca	Calcium	X	X	X	X	X	X	X
51	3	TBIL	Total Bilirubin	X	X	X	X	X	X	X
52	4	AST	Aspartate Aminotransferase	X	X	X		X	X	X
53	5	ALKP	Alkaline Phosphatase	X	X	X		X	X	X
54	6	ALT	Alanine Aminotransferase	X	X	X		X	X	X
55	7	LDH	Lactate Dehydrogenase	X	X	X		X	X	X
56	8	CK	Creatinine Kinase	X	X	X		X	X	X
57	9	LIPA	Lipase	X	X	X	X	X	X	X
58	: (colon)	GGT	Gamma Glutamyltransferase	X	X	X		X	X	X
59	; (semicolon)	Bc	Conjugated Bilirubin	X	X	X	X	X	X	X
60	<	THEO	Theophylline	X	X	X	X	X	X	X
61	=	CKMB	CKMB	X	X	X		X	X	X
62	>	Mg	Magnesium	X	X	X	X	X	X	X
63	?	Fe	Iron	X	X	X	X	X	X	X
64	@	TIBC	Total Iron Binding Capacity	X	X	X	X	X	X	X
65	A	PROT	CSF Protein	X	X	X	X	X	X	X
66	B	SALI	Salicylate	X	X	X	X	X	X	X
67	C	ALC	Alcohol	X	X	X		X	X	X
68	D	AMON	Ammonia	X	X	X	X	X	X	X
69	E	CHE	Cholinesterase	X	X	X		X	X	X
70	F	ACP	Acid Phosphatase	X	X	X	X	X		X
71	G (no longer used)	ACPB	Acid Phosphatase Blank	X	X	X	X	X	X	X
72	H	Li	Lithium	X	X	X	X	X	X	X
73	I	DGXN	Digoxin						X	X
74	J	PHBR	Phenobarbital						X	X
75	K	PHYT	Phenytoin						X	X
76	L	CRP	C Reactive Protein						X	X

Figure E-1. ASCII Characters for Measured Tests for VITROS Chemistry Systems (from figure 6-3).

ASCII DECIMAL VALUE	ASCII CHARACTER	REPORT NAME	TEST NAME	700‡	700XR‡	700P‡	700S‡	500	250	950
77	M	CRBM	Carbamazepine						X	X
79	O	ACET	Acetaminophen	X	X	X		X	X	X
80	P	UPRO	Urine Protein	X	X	X	X	X	X	X
86	V	CRPJ	C Reactive Protein						X	X
87	W	ALTJ	Alanine Aminotransferase						X	X
88	X	ASTJ	Aspartate Aminotransferase						X	X
89	Y	dHDL	Direct HDLC						X	X

Note: The # character is used as the quote symbol for control characters. In a data field, the # character must be repeated; for example, ## = ALB. ## = Cup Position 3. Refer to section 5.6.10, "QCTL."

O = VITROS Analyzers with VITROS

Data Enhancement Package / (DEP) accessory option only.

X = standard chemistry.

* U/CR if Standard International.

† UREA/Creatinine Ratio if Standard International.

‡ VITROS 700 Series Chemistry System and

VITROS 700 C Series Chemistry Systems instruments.

Figure E-1. ASCII Characters for Measured Tests for VITROS Chemistry Systems (from figure 6-3) (Continued).

ASCII DECIMAL VALUE	ASCII CHARACTER	REPORT NAME	TEST NAME	700‡	700XR‡	700P‡	700S‡	500	250	950
96	' (left apostrophe)	B/CR	Bun/Creatinine	X	X	X	X	X	X	X
97	a (lower case)	AGPK	Anion Gap (K+)	X	X	X	X	X	X	X
98	b	AGP	Anion Gap	X	X	X	X	X	X	X
99	c	A/G	A/G Ratio	X	X	X	X	X	X	X
100	d	NBIL	Neonatal Bilirubin	X	X	X	X	X	X	X
101	e	DBIL	Direct Bilirubin	X	X	X	X	X	X	X
102	f	DELB	Delta Bilirubin	X	X	X	X	X	X	X
103	g	%MB	% CK-MB	X	X	X	X	X	X	X
104	h	OSMO	Osmolality	O	O	O	O	O	X	X
105	i	%SATU	% Saturation	O	O	O	O	O	X	X
106	j	GLOB	Globulin	O	O	O	O	O	X	X
107	k	LDL	LDL	O	O	O	O	O	X	X
108	l	VLDL	VLDL	O	O	O	O	O	X	X
109	m	C/H	Chol/HDL ratio	O	O	O	O	O	X	X

NOTE: The following ASCII Decimal Values are on software versions v4.0 (950) and v8.0 (250) and above:

- LDL results derived from HDLC are reported as LDLC
- C/H results derived from HDLC are reported as C/HC
- LDL results derived from dHDL are reported as LDL
- C/H results derived from dHDL are reported as C/H

107	k	LDLC	LDLC						X	X
108	l	VLDL	VLDL						X	X
109	m	C/HC	CHOL/HDLC						X	X
110	n	LDL	LDL						X	X
111	o	C/H	CHOL/dHDL						X	X

O = VITROS Chemistry Systems with VITROS

Data Enhancement Package / (DEP) accessory option only

X = standard chemistry

Figure E-2. ASCII Characters for Derived Tests for the VITROS Chemistry Systems (from figure 6-4).

Starting Location	Number of Characters	Description			
1	1	Start Character: !			
2	3	Record Sequence Number (within message): 001 to 999.			
5	1	Record Type: f. This character identifies the record as a test results record.			
6	4	Test Name (left-justified): This field identifies the test for which the result is being reported. The test name is abbreviated as in the laboratory report format (maximum of four characters):			
		<i>Test Name</i>	<i>Report Name</i>	<i>Test Name</i>	<i>Report Name</i>
		Glucose	GLU	Total Protein	TP
		Urea Nitrogen	BUN	Albumin	ALB
			(UREA if SI)	Aspartate Aminotransferase	AST
		Creatinine	CREA	Alanine Aminotransferase	ALT
		Sodium	Na+	Lactate Dehydrogenase	LDH
		Potassium	K+	Creatine Kinase	CK
		Chloride	Cl-	Alkaline Phosphatase	ALKP
		Carbon Dioxide	CO ₂	Gamma Glutamyltransferase	GGT
		Amylase	AMYL	Total Bilirubin	TBIL
		Lipase	LIPA	Bilirubin, Unconjugated	Bu
		Calcium	Ca	Bilirubin, Conjugated	Bc
		Phosphorus	PHOS	Magnesium	Mg
		Cholesterol	CHOL	Iron	Fe
		Triglycerides	TRIG	Total Iron Binding Capacity	TIBC
		HDL Cholesterol	HDLC	CSF Protein	PROT
		Uric Acid	URIC	Lactate	LAC
		CK-MB	CKMB	Cholinesterase	CHE
		Theophylline	THEO	Digoxin	DGXN
		Enzymatic CO ₂	ECO ₂	Phenobarbital	PHBR
		Alcohol	ALC	Phenytoin	PHYT
		Salicylate	SALI	C Reactive Protein	CRP
		Ammonia	AMON	Acetaminophen	ACET
		Lithium	Li	Carbamazepine	CRBM
		Acid Phosphate	ACP	Urine Protein	UPRO
		C Reactive Protein	CRPJ		
		Alanine	ALTJ		
		Aminotransferase			
		Aspartate	ASTJ		
		Aminotransferase			
		Direct HDLC	dHDL		
10	9	Test Result: The test result is a 9-character floating-point field that includes the decimal point and a negative sign when applicable. The number of precision point digits will vary by test and is configurable on the analyzer. If the test result is less than 9 characters, this field will be padded with blanks preceding the result. Significant digits displayed are the same as in the laboratory report. Derived test results have a maximum of nine character spaces. NOTE: If the field contains question marks (?), an error has occurred. If the field contains 99999.99, a prediction failure has occurred.			
19	8	Reporting Units (left-justified).			

Figure E-3. (Upload-only) Results Record for the VITROS Chemistry Systems (from figure 4-6) .

Starting Location	Number of Characters	Description
27	1	<p>Error Flags (in ASCII characters):</p> <ul style="list-style-type: none"> 0 No error 1 Above laboratory's range 2 Below laboratory's range 3 Outside dynamic range 4 Above analyzer's range (the value reported is the maximum limit of the range) 5 Below analyzer's range (the value reported is the minimum limit of the range) 6 Prediction failure (floating point test result, starting location 10, becomes 99999.99)* 7 Outside Supplementary Range A Control result is more than 2 SDI from baseline interval mean, but no more than 3 SDI B Result is more than 3 SDI from baseline interval mean C No baseline interval mean and SDI, or test is not supported in QC database D Below QC range E Above QC range <p><i>For future implementation on VITROS 250 and VITROS 950 Systems:</i></p> <ul style="list-style-type: none"> F Above dynamic range G Below dynamic range H Above Supplementary Range I Below Supplementary Range
28	1	<p>Warning Flags (in ASCII characters):</p> <ul style="list-style-type: none"> 0 No warning 1 Analyzer-generated warning. The causes of this warning are: <ul style="list-style-type: none"> • Result outside dynamic range • Result above or below analyzer range • High concentration of blank analyte detected for blank-corrected test • Rate is drifting out and in trim window, or the kinetic curve exhibits excessive noise or lack of fit • Component flagged 2 Operator-induced warning. The causes of this warning are the following states: <ul style="list-style-type: none"> • Result above or below hospital range • Result above or below supplementary range • User calibrated • Adjusted result • Edited result 3 Both analyzer and operator warning
29	2	Checksum: 00 to FF (ASCII). The two-character checksum is computed on bytes 1 through 27.
31	2	End Characters: CR-LF.

Figure E-3. (Upload-only) Results Record for the VITROS Chemistry Systems (from figure 4-6) (Continued).

Starting Location	Number of Characters	Description																																		
1	1	Start Character: !.																																		
2	3	Record Sequence Number (within message): 001 to 999.																																		
5	1	Record Type: g. This character identifies the record as a derived test result record.																																		
6	4	<p>Derived Test Name (left-justified): This field identifies the derived test for which the result is being reported. The derived test name is abbreviated as in the laboratory report format (maximum of four characters):</p> <table> <thead> <tr> <th>Test Name</th> <th>Report Name</th> </tr> </thead> <tbody> <tr> <td>BUN/Creatinine Ratio</td> <td>B/CR (U/CR if SI)</td> </tr> <tr> <td>Anion Gap with K+</td> <td>AGPK</td> </tr> <tr> <td>Anion Gap without K+</td> <td>AGP</td> </tr> <tr> <td>A/G Ratio</td> <td>A/G</td> </tr> <tr> <td>Neonatal Bilirubin</td> <td>NBIL</td> </tr> <tr> <td>Direct Bilirubin</td> <td>DBIL</td> </tr> <tr> <td>Delta Bilirubin</td> <td>DelB</td> </tr> <tr> <td>% CK-MB</td> <td>% MB</td> </tr> <tr> <td>Osmolality</td> <td>OSMO</td> </tr> <tr> <td>Globulin</td> <td>GLOB</td> </tr> <tr> <td>VLDL</td> <td>VLDL</td> </tr> <tr> <td>Chol/HDLC Ratio</td> <td>C/HC</td> </tr> <tr> <td>LDLC</td> <td>LDLC</td> </tr> <tr> <td>% Saturation</td> <td>% SAT</td> </tr> <tr> <td>CHOL/dHDL</td> <td>C/H</td> </tr> <tr> <td>LDL</td> <td>LDL</td> </tr> </tbody> </table>	Test Name	Report Name	BUN/Creatinine Ratio	B/CR (U/CR if SI)	Anion Gap with K+	AGPK	Anion Gap without K+	AGP	A/G Ratio	A/G	Neonatal Bilirubin	NBIL	Direct Bilirubin	DBIL	Delta Bilirubin	DelB	% CK-MB	% MB	Osmolality	OSMO	Globulin	GLOB	VLDL	VLDL	Chol/HDLC Ratio	C/HC	LDLC	LDLC	% Saturation	% SAT	CHOL/dHDL	C/H	LDL	LDL
Test Name	Report Name																																			
BUN/Creatinine Ratio	B/CR (U/CR if SI)																																			
Anion Gap with K+	AGPK																																			
Anion Gap without K+	AGP																																			
A/G Ratio	A/G																																			
Neonatal Bilirubin	NBIL																																			
Direct Bilirubin	DBIL																																			
Delta Bilirubin	DelB																																			
% CK-MB	% MB																																			
Osmolality	OSMO																																			
Globulin	GLOB																																			
VLDL	VLDL																																			
Chol/HDLC Ratio	C/HC																																			
LDLC	LDLC																																			
% Saturation	% SAT																																			
CHOL/dHDL	C/H																																			
LDL	LDL																																			
10	9	<p>Derived Test Result: The test result is a 9-character floating-point field that includes the decimal point and a negative sign when applicable. The number of precision point digits will vary by test and is configurable on the analyzer. If the test result is less than 9 characters, this field will be padded with blanks preceding the result. Significant digits displayed are the same as in the laboratory report. Derived test results have a maximum of nine character spaces.</p> <p>NOTE: If the field contains question marks (?), an error has occurred.* If the field contains 99999.99, a prediction failure has occurred</p>																																		
19	8	Reporting Units (left justified).																																		
27	1	<p>Error Flags (in ASCII characters):</p> <ul style="list-style-type: none"> 0 No error 1 Above laboratory's range 2 Below laboratory's range 3 Edited test result 4 Unusable component for derived test result 5 Prediction failure (floating point test result, starting location 10, becomes 99999.99) 7 Outside Supplementary Range 8 Pre-treated Multiple Sample Derived Test (MSDT) A Control result is more than 2 SDI from baseline interval mean, but no more than 3 SDI B Result is more than 3 SDI from baseline interval mean C No baseline interval mean and SDI, or test is not supported in QC database D Control result below QC range E Control result above QC range 																																		
28	2	Checksum: 00 to FF (ASCII). The two-character checksum is computed on bytes 1 through 27.																																		
30	2	End Characters: CR-LF.																																		

Figure E-4. (Upload-only) Results Record for VITROS Chemistry Systems (from figure 4-7).

Starting Location	Number of Characters	Description
*The characters PS are transmitted when the neat (untreated) sample result is available, but the pretreated sample result is unavailable. When the pretreated sample result is available, the calculated value for the Derived Test Result is then retransmitted.		

Figure E-4. (Upload-only) Results Record for VITROS Chemistry Systems (from figure E-4).

Field Description	Number of Characters	Beginning Position		Ending Position		ASCII Values (in decimals)
		Min	Max	Min	Max	
Test ID: Test identification expressed as an ASCII value. (See figure E-7 for specific ASCII values for measured tests; see figure E-2 for ASCII values for derived tests.)	1	1	1	1	1	32-62, 96-109
Test Result: Result is reported exactly as it appears on the laboratory report.* The test result is a 9-character floating-point field that includes the decimal point and a negative sign when applicable. The number of precision point digits will vary by test and is configurable on the analyzer. If the test result is less than 9 characters, this field will be padded with blanks preceding and trailing the result as needed to fill the field. Significant digits displayed are the same as in the laboratory report. Derived test results have a maximum of nine character spaces. NO RESULT is reported in this field if there is a numerical processing error or if the test is not supported.	9	2	2	10	10	32,45,46, 48-57 80, 83
Reporting Units: 0 Conventional Units 1 SI Units 2 Alternate Conventional Units	1	11	11	11	11	48-50
Error Flags for Measured Tests (in ASCII characters): ASCII characters 0-7, A, B, and C are used as follows: 0 No error 1 Above laboratory's range 2 Below laboratory's range 3 Outside dynamic range 4 Above analyzer's range (the value reported is the maximum limit of the range) 5 Below analyzer's range (the value reported is the minimum limit of the range) 6 Prediction failure (reported as NO RESULT) 7 Outside Supplementary Range A Control result is more than 2 SDI from baseline interval mean but no more than 3 SDI B Result is more than 3 SDI from baseline interval mean C No baseline interval mean and SDI; or test is not supported in QC database D Control result below QC range E Control result above QC range <i>For future implementation on VITROS 250 and VITROS 950 Systems:</i> F Above dynamic range G Below dynamic range H Above Supplementary Range I Below Supplementary Range	1	12	12	12	12	48-55, 65-69

*The characters PS are transmitted when the neat (untreated) sample result is available, but the pretreated sample result is unavailable. When the pretreated sample result is available, the calculated value for the Derived Test Result is then retransmitted.

Figure E-5. (Kermit) Results Record for the VITROS Chemistry Systems (from figure 6-2).

Field Description	Number of Characters	Beginning Position		Ending Position		ASCII Values (in decimals)	
		Min	Max	Min	Max		
Error Flags for Derived Tests (in ASCII characters):							
0 No error 1 Above derived test hospital range 2 Below derived test hospital range 3 Edited derived test result 4 Bad derived test component 5 No derived test result 7 Outside derived test supplement range 8 Pre-treated Multiple Sample Derived Test (MSDT) A Above 2 SD from mean B Above 3 SD from mean C Not supported in QC database D Below QC range E Above QC range							
Warning Flags: ASCII characters 0-3 are used as follows: 0 No warning 1 Analyzer-generated warning. The causes of this warning are: <ul style="list-style-type: none">• Result outside dynamic range• Result above or below analyzer range• High concentration of blank analyte detected for blank-corrected test• Rate is drifting out and in trim window or the kinetic curve exhibits excessive noise or lack of fit• Component flagged 2 Operator-induced warning. The causes of this warning are: <ul style="list-style-type: none">• Result above or below hospital range• Result above or below supplementary range• User calibrated• Adjusted result• Edited result 3 Both analyzer and operator warning	1	13	13	13	13	48-51	
Error Codes: (Optional Field; that is, only transmitted if an error has occurred)		0-8	14	14	14	21	65-90
For Measured Tests: AR Adjusted Results DD Drop Detection Disabled DP Sub Depletion Error ED Edited Result EM Expired Maintenance EP Edit Patient Data ER Math Error FC Derived test includes a component which is flagged HB High Blank HN High Noise in Kinetic (multiple windows, SDR dot t (error) IC Blank Prediction Failed ID Invalid Dilution IR Slide Read Error IS Insufficient Sample IT Incubator Temperature Warning KE Kinetic Error		NC Not Calibrated ND No Drop NF No Fluid NQ Not in QC Data Base NS Slide Not Available NT No Tip OD Out-of-Range Dilution OR Range Error (outside dynamic range, above analyzer range, below analyzer range, outside supplementary range) OS Outside Spline Range PD Pressure Detector Disabled PF Prediction Failure PI Potential Interferent SD Standard Dilution SP Multiple Spike ST Slide Time-Out TR Trim Error					

Figure E-5. (Kermit) Results Record for the VITROS Chemistry Systems (from figure 6-2) (Continued).

Field Description	Number of Characters	Beginning Position		Ending Position		ASCII Values (in decimals)
		Min	Max	Min	Max	
LS Lot Switch	UC	User Calibrated				
ME Mechanical Error Failure	UD	Unconfigured Diluent				
M1 Category 1 modified values	WD	Wetness Detector Disabled				
M2 Category 2 modified values	WE	IR Wash Error				
For Derived Tests:						
ED Edited Result	FC	Flagged Component				
EM Expired Maintenance	IC	Invalid Component				
EP Edit Patient Data	NQ	Not in QC Data Base				
ER No Test Result	OR	Range Error (outside supplementary range)				
For a more detailed description of the error codes, see your operator's manual.						
Field Separator		1	14	22	14	22
						125, } character

Figure E-5. (Kermit) Results Record for the VITROS Chemistry Systems (from figure 6-2) (Continued).

VITROS ECi Immunodiagnostic System

Test Code	REPORT NAME	ASSAY NAME
001	TSH	TSH
002	TT4	Total T4
003	TT3	Total T3
004	FT4	Free T4
005	FT3	Free T3
006	T3U	T3 Uptake
007	TBG	TBG
008	E2	Estradiol
009	LH	LH
010	FSH	FSH
011	Prol	Prolactin
012	Prog	Progesterone
013	B-hCG	Total B-hCG
014	Testo	Testosterone
015	AFP	AFP
016	CEA	CEA
017	HBsAg	HBsAg
018	aHBs	Anti-HBs
019	aHBc	Anti HBC
020	HBC M	Anti-HBc IgM
021	HBeAg	HBeAg
022	HAV M	Anti-HAV IgM
023	aHCV	Anti-HCV
024	aHIV	Anti-HIV 1+2
025	Rub G	Rubella IgG
026	Rub M	Rubella IgM
027	Tox G	Toxoplasma IgG
028	Tox M	Toxoplasma IgM
029	CK-MB	CK-MB
030	Trop	Troponin I
031	Ferr	Ferritin
032	B12	Vitamin B12
033	Folat	Folate

Figure E-6. Test Code for Assays on the VITROS ECi Immunodiagnostic System (from figure E-7). Availability of some of these assays are pending regulatory clearance or approval.

Test Code	REPORT NAME	ASSAY NAME
034	Cort	Cortisol
035	FBhCG	Free B-hCG
036	PSA	PSA
037	F PSA	Free PSA
038	CA125	CA 125 II
039	CA153	CA 15-3
040	CA199	CA 19-9
041	CA724	CA 72-4
042	-	Unassigned
043	aHBe	Anti-HBe
044	NTx	N-Telopeptide
045	-	Reserved for internal use
046	TSH30	TSH30
049	HBCon	HBsAg Confirmatory
051	Myog	Myoglobin
055	FT3 II	Free T3 II
056	trak C	trak C - Total HCV Ag
058	-	Reserved for internal use
061	HAV T	Anti-HAV Total

Figure E-6. Test Code for Assays on the VITROS ECi Immunodiagnostic System (from figure E-7). Availability of some of these assays are pending regulatory clearance or approval.

Test Code	REPORT NAME	DERIVED TEST NAME
165	T3/T4	TT3/TT4 Ratio
168	FT4I	FT4 Index
169	FT3I	FT3 Index
171	L/F	LH/FSH Ratio

Figure E-7. Test Code Characters for Derived Tests on the VITROS ECi Immunodiagnostic System (from figure 6-10). Availability of some of these assays are pending regulatory clearance or approval.

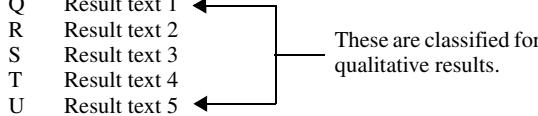
Starting Location	Number of Characters	Description
1	1	Start Character: !
2	3	Record Sequence Number (within message): 001 to 999.
5	1	Record Type: f. This character identifies the record as a assay result record.
6	5	Test Name (left-justified): This field identifies the assay for which the result is being reported. The assay name is abbreviated as in the laboratory report format (maximum of five characters) Refer to Appendix E for the names of Immunodiagnostic System assays.
11	9	Test Results: The assay result is a 9-character floating-point field that includes the decimal point and a negative sign when applicable. The number of precision point digits will vary by assay and is configurable on the Immunodiagnostic System. If the assay result is less than 9 characters, this field will be padded with blanks preceding the result. NOTE: The string NO RESULT is reported in this field if one of a number of conditions exist, like a numerical processing error.
20	12	Reporting Units (left-justified): Blank if not applicable; for qualitative results see "Q"-"R" below in Flags.
32	1	Result Flags (in ASCII characters): 0 No flag 1 Above reference range 2 Below reference range 4 Above dynamic range (the value reported is the maximum limit of the range) 5 Below dynamic range (the value reported is the minimum limit of the range) 6 Prediction failure (floating-point assay result, starting location 10, becomes 99999.99) 7 Above supplementary range 8 Below supplementary range A Control result is more than 2 SDI from baseline interval mean, but no more than 3 SDI B Result is more than 3 SDI from baseline interval mean C No baseline interval mean and SDI, or assay is not supported in QC database Q Result text 1 ← R Result text 2 ← S Result text 3 ← T Result text 4 ← U Result text 5 ← 
32	1	Warning Flags (in ASCII characters): 0 No warning 1 Analyzer-generated warning. The causes of this warning are: <ul style="list-style-type: none"> • Result outside dynamic range • Component flagged 2 Operator-induced warning. The causes of this warning are: <ul style="list-style-type: none"> • Result above or below lab normal range • Result above or below supplementary range • User calibrated • Adjusted result • Edited result 3 Both analyzer and operator warning
34	2	Checksum: 00 to FF (ASCII). The two-character checksum is computed on bytes 1–33
36	2	End Characters: CR-LF.

Figure E-8. (Upload-only) Results Record for the VITROS ECi Immunodiagnostic System (from figure 4-14).

Field Description	Number of Characters	Beginning Position		Ending Position		ASCII Values (in decimals)
		Min	Max	Min	Max	
Test ID: Assay identification is a 3-character field with leading zeros, expressed as an ASCII value. Refer to figure 6-9 for specific test code for assays and figure E-7 for ASCII values for derived tests.	3	1	3	3	3	48-57 (or 001-255 in numeric range)
Test Result: The assay result is 9-character floating-point field that includes the decimal point and a negative sign when applicable. The number of precision point digits will vary by assay and is configurable on the Imm. System. If the assay result is less than 9 characters, this field will be padded with blanks preceding the result. NOTE: The string NO RESULT is reported in this field if one of a number of flagged conditions exist, such as a numerical processing error.	9	4	4	12	12	32,45,46, 48-57, 80, 83
Reporting Units: 0 Conventional Units 1 Alternate	1	13	13	13	13	48-50
Result Flags for Measured Test in ASCII characters: 0 No flag 1 Above reference range 2 Below reference range 4 Above dynamic range (the value reported is the maximum limit of the range) 5 Below dynamic range (the value reported is the minimum limit of the range) 6 Prediction failure (floating point assay result, starting location 10, becomes NO RESULT) 7 Above supplementary range 8 Below supplementary range A Control result is more than 2 SDI from baseline interval mean, but no more than 3 SDI B Result is more than 3 SDI from baseline interval mean C No baseline interval mean and SDI, or assay is not supported in QC database Q Result text 1 R Result text 2 S Result text 3 T Result text 4 U Result text 5	1	14	14	14	14	48-57 and 65-67 and 81-85

Figure E-9. (Kermit) Results Record for the VITROS ECi Immunodiagnostic System (from figure 6-8).

Field Description	Number of Characters	Beginning Position		Ending Position		ASCII Values (in decimals)
		Min	Max	Min	Max	
Result Flags for Derived Tests in ASCII characters:						
0 No flag 1 Above reference range 2 Below reference range 4 Above dynamic range (the value reported is the maximum limit of the range) 5 Below dynamic range (the value reported is the minimum limit of the range) 6 Prediction failure (floating point assay result, starting location 10, becomes NO RESULT) 7 Above supplementary range 8 Below supplementary range A Control result is more than 2 SDI from baseline interval mean, but no more than 3 SDI B Result is more than 3 SDI from baseline interval mean C No baseline interval mean and SDI, or test is not supported in QC database						
Q Result text 1 ← R Result text 2 ← S Result text 3 ← T Result text 4 ← U Result text 5 ←	These are classified for qualitative results.					
Warning Flags: ASCII characters 0-3 are used as follows: 0 No warning 1 Analyzer-generated warning. The causes of this warning are: <ul style="list-style-type: none">• Result outside dynamic range• Component flagged 2 Operator-induced warning. The causes of this warning are: <ul style="list-style-type: none">• Result above or below reference range• Result above or below supplementary range• User calibrated• Adjusted result• Edited result 3 Both analyzer and operator warning	1	15	15	15	48-51	
Codes: Optional Field, that is, it is only transmitted if a code was generated.	0-8	16	16	16	23	65-90
AF The filtered air operation did not occur during the reading of the well AR User adjusted parameters changed results CE Calibration Expired FR Flagged replicate DE Drop error ED Edited result EM Expired maintenance EP Edit patient data FC Flagged component IC Invalid component ID Invalid dilution II Insufficient inventory IS Insufficient sample IT Incubator temperature LS Lot switch LT Luminometer temperature out ME Mechanical error occurred M1 Category 1 modified values M2 Category 2 modified values For a more detailed description of the error codes, see your operator's manual.	NC Not calibrated NF No fluid NI No inventory NQ Not in QC database NW No well NT No tip OD Operator requested dilution OR Outside range PF Prediction failure RC Reference consistency check RD Reflex dilution RE Reagent expired RP Reflex process RR Recalculated result SC Spread check UC User calibrated WT Well wash temperature out ZS Zero set					
Field Separator:	1	16	24	16	24	125, } character

Figure E-9. (Kermit) Results Record for the VITROS ECi Immunodiagnostic System (from figure 6-8) (Continued).

Field	Field Title	Direction		Max Len	Description and Valid Values		
		Imm. System					
		D	U				
1	Record Type ID		A	1	This is a required field that contains an R or an r identifying it as an order.		
2	Sequence Number		A	1	This field starts with 1 for the first result and is incremented by 1 for each additional result within the record. This will be reset to 1 when the results from another test order record are being transmitted to the laboratory computer.		
3	Universal Test ID		N N N A	16	<p>This is a four-component field:</p> <ul style="list-style-type: none"> • Test ID Code (reserved) • Test ID Name (not used) • Test ID Type (not used) • Local Manufacturer's Code: this field contains the description of the replicate result being sent to the LIS. The field holds the manual dilution factor, analyte code, and test dilution factor for individual test to which the result applies. <p>The structure of the universal test ID would be: ^^^MDF + Analyte Code +TDF</p>		
4	Data or Measurement Data		A	9	<p>Measurement data or assay results is a 9 character floating point field that includes the decimal point and a negative sign when applicable. The number of precision point digits will vary by test and is configurable on the analyzer. If the test result is less than 9 characters, this field will be padded with blanks preceding the result.</p> <p>The string NO RESULT is reported in this field if one of a number of conditions exist, like a numerical processing error.</p>		
5	Units of Measure		A	12	This is a field of up to 12 characters that the operator defines for analyte measurement through the Options & Configuration function.		
6	Reference Ranges		S	18	This field has two components, one giving the upper limit and the other the lower limit of the range. The format for this field is N^N.		
7	Result Flags			10	<p>This is a three-component field. The first component will be empty in the Imm. System. The second component describes the type of flagged results as either quantitative (relative to a laboratory norm) or qualitative (as specified in the analyte parameters through the Configure Analyte screen in the Options & Configuration function):</p> <ul style="list-style-type: none"> • Results flag (in ASCII characters) <ul style="list-style-type: none"> 0 – No flag 1 – Above reference range 2 – Below reference range 4 – Above dynamic range 5 – Below dynamic range 6 – Prediction failure, with value reported as NO RESULT 7 – Above supplemental range 8 – Below supplemental range A – Control result is more than two SDI but no more than 3 SDI from baseline interval mean B – Control result is more than three SDI from baseline interval mean C – No baseline interval mean or assay is not supported in the QC database. or • Result classification (qualitative) <ul style="list-style-type: none"> Q Result text 1 R Result text 2 S Result text 3 T Result text 4 U Result text 5 		

Figure E-10. (ASTM) Results Record for the VITROS ECi Immunodiagnostic System (from figure 8-15).

					The third component indicates operational events causing coded results. <ul style="list-style-type: none"> • Codes (up to 8 char. codes) <ul style="list-style-type: none"> AF – The filtered air operation did not occur during the reading of the well AR – User adj. parameters changed results CE – Calibration expired FR – Flagged replicate DE – Drop error ED – Edited result EM – Expired maintenance EP – Edit patient data ER – Computation error FC – Flagged component IC – Invalid component ID – Invalid dilution II – Insufficient inventory IS – Insufficient sample IT – Incubator temperature LS – Lot switch LT – Luminometer temperature ME – Mechanical error occurred M1 – Category 1 modified values M2 – Category 2 modified values NC – Not calibrated NF – No fluid NI – No inventory NQ – Not in QC database NT – No tip NW – No well OD – Operator requested dilution OR – Outside range PF – Prediction failure RC – Reference consistency check RD – Reflex dilution RE – Reagent expired RP – Reflex process RR – Recalculated results SC – Spread check UC – User calibrated WT – Well wash temperature out ZS – Zero set
					There can be up to 4 condition codes listed with not intervening replicate.
8	Nature of Abnormality Testing	S	3		If the result is abnormal, this field indicates the nature of the abnormality: Valid values are A, S, R.
9	Result Status	A	1		The Imm. System is implementing only one valid value: V – operator verified/approved result.
10	Date of Change in Instrument Normative Values or Units	N			
11	Operator ID	A	3		
12	Date/Time Test Started	A	14		Date and time of collection. This is formatted as YYYYMMDDHHMMSS. For example, 3:35 PM on December 1, 1994 would be represented as: 19941201153500.
13	Date/Time Test Completed	A	14		Date and time of test started: formatted as YYYYMMDDHHMMSS. For example, 3:35 PM on December 1, 1994 would be represented as: 19941201153500.
14	Instrument ID	A	12		The ID of the device that actually ran the test.
Legend: D Down Load U Up Load O Optional S Sometimes R Required A Always I Ignored N Never (empty field marked by delimiter)					

Figure E-10. (ASTM) Results Record for the VITROS ECi Immunodiagnostic System (from figure 8-15) (Continued).

```
R|1|^^^1.0+32+1|88.12|nmol/L||^0||V|||19951201153500|VITROS<CR>
```

Figure E-11. (ASTM) Sample Results Record Layout (from figure 8-16).

Results Decimal Positions for 500 series, 700, 700C series

Chem	CU Units	N/P Prec.	SI Units	N/P Prec.	ACU Units	N/P Prec.
GLU	mg/dL	0,1	mmol/L	1,2	g/L	1,2
TP	g/dL	1,2	g/L	0,1		
URIC	mg/dL	1,2	umol/L	0,1	mg/L	0,1
ALB	g/dL	1,2	g/L	0,1	umol/L	2,2
TRIG	mg/dL	0,1	umol/L	2,2	g/L	1,2
CHOL	mg/dL	0,0	umol/L	1,2	g/L	1,2
AMYL	U/L	0,0	U/L	0,0	ukat/L	1,2
CL-	umol/L	0,1	umol/L	0,1		
K+	umol/L	1,2	umol/L	1,2		
Na+	umol/L	0,1	umol/L	0,1		
PHOS	mg/dL	1,2	umol/L	2,2	mg/L	0,1
LAC	umol/L	1,2	umol/L	1,2	mg/dL	1,2
CREA	mg/dL	1,2	umol/L	0,1	mg/L	0,1
BUN	mg/dL	0,1	mmol/L	1,2	mg/dL	1,2
HDLC	mg/dL	0,1	mmol/L	1,2	g/L	1,2
Bu	mg/dL	1,2	umol/L	0,1	mg/L	0,1
Ca	mg/dL	1,2	mmol/L	2,2	mg/L	0,1
TBIL	mg/dL	1,2	umol/L	0,1	mg/L	0,1
AST	U/L	0,0	U/L	0,0	ukat/L	1,2
ALKP	U/L	0,0	U/L	0,0	ukat/L	1,2
ALT	U/L	0,0	U/L	0,0	ukat/L	1,2
LDH	U/L	0,0	U/L	0,0	ukat/L	1,2
CK	U/L	0,0	U/L	0,0	ukat/L	1,2
LIPA	U/L	0,0	U/L	0,0	ukat/L	1,2
GGT	U/L	0,0	U/L	0,0	ukat/L	1,2
Bc	mg/dL	1,2	umol/L	0,1	mg/L	0,1
THEO	ug/mL	1,2	umol/L	1,2		
CKMB	U/L	0,1	U/L	0,1	ukat/L	1,2
Mg	mg/dL	1,2	mmol/L	1,2	mEq/L	1,2
Fe	ug/dL	0,1	umol/L	1,2	mg/L	1,2
TIBC	ug/dL	0,1	umol/L	1,2	mg/L	1,2
PROT	mg/dL	0,1	mg/L	0,1	g/L	1,2
SALI	mg/dL	0,1	mmol/L	1,2	mg/L	0,1
ALC	mg/dL	0,1	mmol/L	0,1	gm/L	1,2
AMON	umol/L	0,1	umol/L	0,1	ugm/dL	0,1
CHE	U/mL	2,2	U/L	0,0	kU/L	2,2
ACP	U/L	1,1	U/L	1,1	nkat/L	1,1
ACPB	U/L	1,1	U/L	1,1	nkat/L	1,1
CRBM	ug/mL	1,2	umol/L	1,2	mg/L	1,2
ACET	ug/mL	0,1	umol/L	0,0	mg/dL	1,2
UPRO	mg/dL	0,1	g/L	1,2	mg/L	0,1

Key: CU Conventional SI Standard International
 ACU Alternate Conventional N/P Normal/Precise decimal precision

Note: Quality Control results are always transmitted in the precise mode regardless of the mode selected in the test/fluid configuration.

Figure E-12. Results Decimal Positions for 500 series, 700, 700C series.

Results Decimal Positions for 250 and 950

Chem	CU Units	N/P Prec.	Si Units	N/P Prec.	ACU Units	N/P Prec.
GLU	mg/dL	0,1	mmol/L	1,2	g/L	1,2
TP	g/dL	1,2	g/L	0,1		
URIC	mg/dL	1,2	umol/L	0,1	mg/L	0,1
ALB	g/dL	1,2	g/L	0,1	umol/L	0,0
TRIG	mg/dL	0,1	umol/L	2,2	g/L	1,2
CHOL	mg/dL	0,0	mmol/L	1,2	g/L	1,2
AMYL	U/L	0,0	U/L	0,0	ukat/L	1,2
CL-	umol/L	0,1	mmol/L	0,1		
K+	umol/L	1,2	mmol/L	1,2		
Na+	umol/L	0,1	mmol/L	0,1		
CO2	umol/L	0,1	mmol/L	0,1		
PHOS	mg/dL	1,2	mmol/L	2,2	mg/L	0,1
LAC	umol/L	1,2	mmol/L	1,2	mg/dL	1,2
CREA	mg/dL	1,2	umol/L	0,1	mg/L	0,1
BUN	mg/dL	0,1	mmol/L	1,2	mg/dL	1,2
HDLC	mg/dL	0,1	mmol/L	1,2	g/L	1,2
Bu	mg/dL	1,2	umol/L	0,1	mg/L	0,1
Ca	mg/dL	1,2	mmol/L	2,2	mg/L	0,1
TBIL	mg/dL	1,2	umol/L	0,1	mg/L	0,1
AST	U/L	0,0	U/L	0,0	ukat/L	1,2
ALKP	U/L	0,0	U/L	0,0	ukat/L	1,2
ALT	U/L	0,0	U/L	0,0	ukat/L	1,2
LDH	U/L	0,0	U/L	0,0	ukat/L	1,2
CK	U/L	0,0	U/L	0,0	ukat/L	1,2
LIPA	U/L	0,0	U/L	0,0	ukat/L	1,2
GGT	U/L	0,0	U/L	0,0	ukat/L	1,2
Bc	mg/dL	1,2	umol/L	0,1	mg/L	0,1
THEO	ug/mL	1,2	umol/L	1,2		
CKMB	U/L	0,1	U/L	0,1	ukat/L	1,2
Mg	mg/dL	1,2	mmol/L	1,2	mEq/L	1,2
Fe	ug/dL	0,1	umol/L	1,2	mg/L	1,2
TIBC	ug/dL	0,1	umol/L	1,2	mg/L	1,2
PROT	mg/dL	0,1	mg/L	0,1	g/L	1,2
SALI	mg/dL	0,1	mmol/L	1,2	mg/L	0,1
ALC	mg/dL	0,1	mmol/L	0,1	gm/L	1,2
AMON	umol/L	0,1	umol/L	0,1	ugm/dL	0,1
CHE	U/mL	2,2	U/L	0,0	kU/L	2,2
ACP	U/L	1,1	U/L	1,1	nkat/L	1,1
CRP	mg/L	0,1	mg/dL	1,2	ug/dL	0,1
Li	mmol/L	1,2	mmol/L	1,2	mEq/L	1,2
DGXN	ng/mL	1,1	nmol/L	1,2	ug/L	1,2
PHBR	ug/L	1,2	umol	1,2		
PHYT	ug/mL	1,2	umol/L	1,2	mg/mL	1,2
ALTJ	U/L	0,0	U/L	0,0	ukat/L	1,2
ASTJ	U/L	0,0	U/L	0,0	ukat/L	1,2
CRPJ	mg/L	0,1	mg/dL	1,2	ug/dL	0,1
dHDL	mg/dL	0,1	mmol/L	1,2	g/L	1,2

Figure E-13. Results Decimal Positions for 250 and 950.

Chem	CU Units	N/P Prec.	Si Units	N/P Prec.	ACU Units	N/P Prec.
-------------	-----------------	------------------	-----------------	------------------	------------------	------------------

Key: CU Conventional SI Standard International
 ACU Alternate Conventional N/P Normal/Precise decimal precision

Note: Quality Control Results are always transmitted in the precise mode regardless of the mode selected in the test/fluid configuration.

Figure E-13. Results Decimal Positions for 250 and 950.

Results Units for the VITROS ECI Immunodiagnostic System

NOTE: Normal and precise decimal positions are not listed; precision varies with the assay and the magnitude of the result.

Figure E-14. Results Units for the VITROS ECi Immunodiagnostic System.

Results Units for Derived Tests for the VITROS ECI Immunodiagnostic System

Short Name	Long Name	Equation	Conv. Units	Alternate Units
T3/T4	TT3/TT4 Ratio	TT3/TT4	None	None
FT4I	FT4 Index	a) T3U(%) x TT4 b) <u>TT4</u> T3U (unit value) c) <u>T3U (%) x TT4</u> 100	nmol/L	µg/dL

Figure E-15. Results Units for Derived Tests for the VITROS ECI Immunodiagnostic System.

Short Name	Long Name	Equation	Conv. Units	Alternate Units
FT3I	FT3 Index	a) T3U(%) x TT3 b) <u>TT3</u> T3U (unit value) c) <u>T3U (%) x TT3</u> 100	nmol/L	ng/mL
L/F	LH/FSH Ratio	LH/FSH	None	None

Figure E-15. Results Units for Derived Tests for the VITROS ECi Immunodiagnostic System.

VITROS Chemistry Systems

Starting Location	Number of Characters	Description
27	1	Flags (in ASCII characters): 0 No flag 1 Above laboratory's range 2 Below laboratory's range 3 Outside dynamic range 4 Above analyzer's range (the value reported is the maximum limit of the range) 5 Below analyzer's range (the value reported is the minimum limit of the range) 6 Prediction failure (floating point test result, starting location 10, becomes 99999.99)* 7 Outside Supplementary Range A Control result is more than 2 SDI from baseline interval mean, but no more than 3 SDI B Result is more than 3 SDI from baseline interval mean C No baseline interval mean and SDI, or test is not supported in QC database
28	1	Warning Flags (in ASCII characters): 0 No warning 1 Analyzer-generated warning. The causes of this warning are: <ul style="list-style-type: none">• Result outside dynamic range• Result above or below analyzer range• High concentration of blank analyte detected for blank-corrected test• Rate is drifting out and in trim window, or the kinetic curve exhibits excessive noise or lack of fit• Component flagged 2 Operator-induced warning. The causes of this warning are the following states: <ul style="list-style-type: none">• Result above or below hospital range• Result above or below supplementary range• User calibrated• Adjusted result• Edited result 3 Both analyzer and operator warning
29	2	Checksum: 00 to FF (ASCII). The two-character checksum is computed on bytes 1 through 27.
31	2	End Characters: CR-LF.

Figure F-1. (Upload-only) Test Results Conditions and Warning Codes for the VITROS Chemistry Systems from Figure 4-6 .

Starting Location	Number of Characters	Description
19	8	Reporting Units (left justified).
27	1	Flags (in ASCII characters): <ul style="list-style-type: none"> 0 No flag 1 Above laboratory's range 2 Below laboratory's range 3 Edited test result 4 Unusable component for derived test result 5 Prediction failure (floating point test result, starting location 10, becomes 99999.99) 7 Outside Supplementary Range 8 Pre-treated Multiple Sample Derived Test (MSDT) A Control result is more than 2 SDI from baseline interval mean, but no more than 3 SDI B Result is more than 3 SDI from baseline interval mean C No baseline interval mean and SDI, or test is not supported in QC database D Control result below QC range # E Control result above QC range #
28	2	Checksum: 00 to FF (ASCII). The two-character checksum is computed on bytes 1 through 27.
30	2	End Characters: CR-LF.

#The characters PS are transmitted when the neat (untreated) sample result is available, but the pretreated sample result is unavailable. When the pretreated sample result is available, the calculated value for the Derived Test Result is then retransmitted.

Figure F-2. (Upload-only) Derived Test Results Conditions and Warning Codes for VITROS Chemistry Systems from Figure 4-7.

Field Description	Number of Characters	Beginning Position		Ending Position		ASCII Values (in decimals)
		Min	Max	Min	Max	
Flags for Measured Tests (in ASCII characters): ASCII characters 0-7, A, B, and C are used as follows: 0 No flag 1 Above laboratory's range 2 Below laboratory's range 3 Outside dynamic range 4 Above analyzer's range (the value reported is the maximum limit of the range) 5 Below analyzer's range (the value reported is the minimum limit of the range) 6 Prediction failure (reported as NO RESULT) 7 Outside Supplementary Range A Control result is more than 2 SDI from baseline interval mean but no more than 3 SDI B Result is more than 3 SDI from baseline interval mean C No baseline interval mean and SDI; or test is not supported in QC database D Control result below QC range # E Control result above QC range # <i>The following flags are for future implementation on VITROS 250 and VITROS 950 Systems. They are optional flags; if configured, they replace Flags 3 and 7.</i> F Above dynamic range G Below dynamic range H Above Supplementary Range I Below Supplementary Range	1	12	12	12	12	48-55, 65-69
Flags for Derived Tests (in ASCII characters): 0 No flag 1 Above derived test hospital range 2 Below derived test hospital range 3 Edited derived test result 4 Bad derived test component 5 No derived test result 7 Outside derived test supplement range 8 Pre-treated Multiple Sample Derived Test (MSDT) A Above 2 SD from mean B Above 3 SD from mean C Not supported in QC database D Below QC range E Above QC range <i>The following flags are for future implementation on VITROS 250 and VITROS 950 Systems. They are optional flags; if configured, they replace Flag 7.</i> H Above Supplementary Range I Below Supplementary Range						

Figure F-3. (Kermit) Test Results Conditions and Warning Codes for VITROS Chemistry System from Figure 6-2 .

Field Description	Number of Characters	Beginning Position		Ending Position		ASCII Values (in decimals)
		Min	Max	Min	Max	
Warning Flags: ASCII characters 0-3 are used as follows: 0 No warning 1 Analyzer-generated warning. The causes of this warning are: <ul style="list-style-type: none">• Result outside dynamic range• Result above or below analyzer range• High concentration of blank analyte detected for blank-corrected test• Rate is drifting out and in trim window or the kinetic curve exhibits excessive noise or lack of fit• Component flagged 2 Operator-induced warning. The causes of this warning are: <ul style="list-style-type: none">• Result above or below hospital range• Result above or below supplementary range• User calibrated• Adjusted result• Edited result 3 Both analyzer and operator warning	1	13	13	13	13	48-51
Codes: (Optional Field; that is, only transmitted if a flag has been generated)	0-8	14	14	14	21	65-90
For Measured Tests:						
AR Adjusted Results	NC Not Calibrated					
DD Drop Detection Disabled	ND No Drop					
DP Sub Depletion Error	NF No Fluid					
ED Edited Result	NQ Not in QC Data Base					
EM Expired Maintenance	NS Slide Not Available					
EP Edit Patient Data	NT No Tip					
ER Math Error	OD Out-of-Range Dilution					
FC Derived test includes a component which is flagged	OR Range Error (outside dynamic range, above analyzer range, below analyzer range, outside supplementary range)					
HB High Blank	OS Outside Spline Range					
HN High Noise in Kinetic (multiple windows, SDR dot t (error)	PD Pressure Detector Disabled					
IC Blank Prediction Failed	PF Prediction Failure					
ID Invalid Dilution	PI Potential Interferent					
IR Slide Read Error	SD Standard Dilution					
IS Insufficient Sample	SP Multiple Spike					
IT Incubator Temperature Warning	ST Slide Time-Out					
KE Kinetic Error	TR Trim Error					
LS Lot Switch	UC User Calibrated					
ME Mechanical Error Failure	UD Unconfigured Diluent					
M1 Category 1 modified values	WD Wetness Detector Disabled					
M2 Category 2 modified values	WE IR Wash Error					
For Derived Tests:						
ED Edited Result	FC Flagged Component					
EM Expired Maintenance	IC Invalid Component					
EP Edit Patient Data	NQ Not in QC Data Base					
ER No Test Result	OR Range Error (outside supplementary range)					
For a more detailed description of the codes, see your operator's manual.						
Field Separator	1	14	22	14	22	125, } character

Figure F-3. (Kermit) Test Results Conditions and Warning Codes for VITROS Chemistry System from Figure 6-2 (Continued).

Code Number	Message	Problem	Action																								
01	Missing Sample ID	Sample program has blank sample ID field.	Add sample ID to program and down load program again.																								
02	Invalid Message	Sample program has invalid characters.	Refer to Chapters 4, 6, and 9 in this publication for listings of valid characters, then down load sample program again.																								
03	More than 10 Samples in File	The <i>Kermit</i> file in which this sample program was included had more than 10 programs assigned to it.	Downloaded <i>Kermit</i> file can have a maximum of 10 sample programs. Down load this sample program in another sample file.																								
04	Tray Name or Cup or Slide Missing	Tray name was specified, but sample program did not have an assigned slide position. Sample program had a slide position but no tray name specified.	Add slide position and down load program again. Delete slide position or add tray name, then down load sample again.																								
05	File with Mixed Trays	More than one sample program in the file has a tray Name specified.	Delete Tray Name from all programs except the first in the file; then down load file again.																								
06	Sample/Patient Name Mismatch	Sample program has the same sample ID as a program already in sample file, but patient names do not match.	Patient name cannot be edited from the laboratory computer; it can be edited using the sample programming dialog. To edit a sample program from the laboratory computer, the sample ID and patient name in the edited program must match the information originally sent.																								
07	Sample/Cup or Slide Do Not Match	The sample program has a slide position that has already been assigned to another program.	Change the sample ID or slide position, then down load the sample program again.																								
08	Tray Has No Downloaded Samples	The sample program has been assigned to a tray that is not considered a downloaded tray (a tray is considered down loaded if it was down loaded from the laboratory computer or it has a sample program assigned that was down loaded).	Assign the sample to a tray that is considered a downloaded tray; then down load sample program again.																								
09	STAT Change Not Accepted	The sample program has already been loaded and changes to the STAT field and another field(s) have been down loaded.	Only a STAT field change can be down loaded for an already-loaded sample program. Change the STAT field using the sample programming dialog.																								
10	Sample/Tray is Loaded	The sample program has already been loaded and changes have been down loaded for it.	Use the sample programming dialog to make changes to the sample program.																								
11	Sample/Tray Not Available	A new or edited sample program was down loaded while the sample program/tray was displayed on the control screen.	Down Load the sample program again after the sample program/tray has been returned to the sample file.																								
12	Sample Manually Edited	An attempt was made to edit the sample program from the laboratory computer after it had been edited using the sample programming dialog.	Edit the sample program using the sample programming dialog.																								
13	No Tests Requested	The sample program was down loaded with no test requests (no sample program was currently in the sample file to be deleted).	Add test requests to sample program and down load program again.																								
14	Invalid Test Requested	A test was requested that is currently not supported by the analyzer.	Edit test requests and down load sample program again.																								
15	Derived Test Replicated	The sample program included a request to replicate a derived test.	Delete request for replicate of derived test and down load sample program again.																								
16	Too Many Tests Requested	The sample program has more than maximum test results requested.	Edit test request so that sample program has maximum test results requested and down load program again.																								
		Maximum <table border="1"> <thead> <tr> <th>Analyzer</th> <th>Test</th> <th>Results</th> <th>Derived</th> </tr> </thead> <tbody> <tr> <td>250–750</td> <td>30</td> <td>30</td> <td>16</td> </tr> <tr> <td>950</td> <td>40</td> <td>40</td> <td>16</td> </tr> </tbody> </table>	Analyzer	Test	Results	Derived	250–750	30	30	16	950	40	40	16	Maximum <table border="1"> <thead> <tr> <th>Analyzer</th> <th>Test</th> <th>Results</th> <th>Derived</th> </tr> </thead> <tbody> <tr> <td>250–750</td> <td>30</td> <td>30</td> <td>16</td> </tr> <tr> <td>950</td> <td>40</td> <td>40</td> <td>16</td> </tr> </tbody> </table>	Analyzer	Test	Results	Derived	250–750	30	30	16	950	40	40	16
Analyzer	Test	Results	Derived																								
250–750	30	30	16																								
950	40	40	16																								
Analyzer	Test	Results	Derived																								
250–750	30	30	16																								
950	40	40	16																								
17	Sample Tray Changed	Sample program has been assigned to another tray.	Place sample on tray to which the sample program has been assigned.																								

Figure F-4. Download Messages for VITROS Chemistry Systems. from Figure 9-16)

Code Number	Message	Problem	Action
18	Sample Taken Off Tray	Sample program will be assigned to another tray.	Remove sample from tray specified in downloaded program.
19	No Tests; Sample Deleted	The test requests were deleted from the sample program by the laboratory computer.	Remove the sample from the tray.
20	Dilution Out of Range	The dilution for this sample program is not between 0.0001–9999. and includes the decimal point.	Change the dilution factor and down load sample program again.
21	Invalid MSDT Sample ID	a) When requesting a MSDT, the sample ID is appended with a “z” or “y”. If the ID is too long, this appending cannot take place. b) The Sample ID name is all blanks.	Shorten the Sample ID
22	Cannot Edit MSDT Pretreat	An attempt was made to edit a MSDT Sample ID	MSDT Sample ID's cannot be edited.
23	Pretreated ID is in Use	An unresulted pretreated sample ID is in memory	Delete the sample ID
24	See Error Display	This error is associated with another error.	None
25	Test in Progress for ID	An attempt was made to edit a Sample ID after the MSDT pretreated sample has been resulted.	None

Figure F-4. Download Messages for VITROS Chemistry Systems. (from Figure 9-16) (Continued)

VITROS ECi Immunodiagnostic System

Starting Location	Number of Characters	Description
32	1	<p>Result Flags (in ASCII characters):</p> <p>0 No flag 1 Above reference range 2 Below reference range 4 Above dynamic range (the value reported is the maximum limit of the range) 5 Below dynamic range (the value reported is the minimum limit of the range) 6 Prediction failure (floating-point assay result, starting location 10, becomes 99999.99) 7 Above supplementary range 8 Below supplementary range A Control result is more than 2 SDI from baseline interval mean, but no more than 3 SDI B Result is more than 3 SDI from baseline interval mean C No baseline interval mean and SDI, or assay is not supported in QC database</p> <p>Q Result text 1 ← R Result text 2 ← S Result text 3 ← T Result text 4 ← U Result text 5 ←</p> <p>These are classified for qualitative results.</p>
32	1	<p>Warning Flags (in ASCII characters):</p> <p>0 No warning 1 Analyzer-generated warning. The causes of this warning are: • Result outside dynamic range • Component flagged 2 Operator-induced warning. The causes of this warning are: • Result above or below lab normal range • Result above or below supplementary range • User calibrated • Adjusted result • Edited result 3 Both analyzer and operator warning</p>
34	2	Checksum: 00 to FF (ASCII). The two-character checksum is computed on bytes 1–33
36	2	End Characters: CR-LF.

Figure F-5. (Upload-only) Assay Results Conditions and Warning Codes for the VITROS ECi Immunodiagnostic System from Figure 4-14 .

Starting Location	Number of Characters	Description
32	1	<p>Result Flags (in ASCII characters):</p> <p>0 No flag 1 Above reference range 2 Below reference range 4 Above dynamic range (the value reported is the maximum limit of the range) 5 Below dynamic range (the value reported is the minimum limit of the range) 6 Prediction failure (floating point test result, starting location 10, becomes 99999.99) 7 Above supplementary range 8 Below supplementary range A Control result is more than 2 SDI from baseline interval mean, but no more than 3 SDI B Result is more than 3 SDI from baseline interval mean C No baseline interval mean and SDI, or assay is not supported in QC database</p> <p>Q Result text 1 ← R Result text 2 ← S Result text 3 ← T Result text 4 ← U Result text 5 ←</p> <p>These are classified for qualitative results.</p>
33	2	Checksum: 00 to FF (ASCII). The two-character checksum is computed on bytes 1–33
35	2	End Characters: CR-LF.

Figure F-6. (Upload-only) Derived Test Results Conditions and Warning Codes for the VITROS ECi Immunodiagnostic System from Figure 4-15.

Field Description	Number of Characters	Beginning Position		Ending Position		ASCII Values (in decimals)
		Min	Max	Min	Max	
Flags for Measured Test in ASCII characters: 0 No flag 1 Above reference range 2 Below reference range 4 Above dynamic range (the value reported is the maximum limit of the range) 5 Below dynamic range (the value reported is the minimum limit of the range) 6 Prediction failure (floating point assay result, starting location 10, becomes NO RESULT) 7 Above supplementary range 8 Below supplementary range A Control result is more than 2 SDI from baseline interval mean, but no more than 3 SDI B Result is more than 3 SDI from baseline interval mean C No baseline interval mean and SDI, or assay is not supported in QC database Q Result test 1 ← R Result test 2 ← S Result test 3 ← T Result test 4 ← U Result test 5 ←	1	14	14	14	14	48-57 and 65-67 and 81-85
Flags for Derived Tests in ASCII characters: 0 No flag 1 Above reference range 2 Below reference range 4 Above dynamic range (the value reported is the maximum limit of the range) 5 Below dynamic range (the value reported is the minimum limit of the range) 6 Prediction failure (floating point assay result, starting location 10, becomes NO RESULT) 7 Above supplementary range 8 Below supplementary range A Control result is more than 2 SDI from baseline interval mean, but no more than 3 SDI B Result is more than 3 SDI from baseline interval mean C No baseline interval mean and SDI, or test is not supported in QC database Q Result test 1 ← R Result test 2 ← S Result test 3 ← T Result test 4 ← U Result test 5 ←						

Figure F-7. (Kermit) Assay Results Conditions and Warning Codes for the VITROS ECi Immunodiagnostic System from Figure 6-8

Field	Field Title	Direction		Max Len	Description and Valid Values		
		Imm. System					
		D	U				
7	Result Flags			10	<p>This is a three-component field. The first component will be empty in the Imm. System. The second component describes the type of flagged results as either quantitative (relative to a laboratory norm) or qualitative (as specified in the analyte parameters through the Configure Analyte screen in the Options & Configuration function):</p> <ul style="list-style-type: none"> • Results flag (in ASCII characters) <ul style="list-style-type: none"> 0 – No flag 1 – Above reference range 2 – Below reference range 4 – Above dynamic range 5 – Below dynamic range 6 – Prediction failure, with value reported as NO RESULT 7 – Above supplemental range 8 – Below supplemental range A – Control result is more than two SDI but no more than 3 SDI from baseline interval mean B – Control result is more than three SDI from baseline interval mean C – No baseline interval mean or assay is not supported in the QC database. or • Result classification (qualitative) <ul style="list-style-type: none"> Q – Result text 1 R – Result text 2 S – Result text 3 T – Result text 4 U – Result text 5 		

Figure F-8. (ASTM) Assay Results Conditions and Warning Codes from Figure 9-7).

Field	Field Title	Direction		Max Len	Description and Valid Values		
		Imm. System					
		D	U				
					<p>The third component indicates operational events causing coded results.</p> <p>Codes (up to 8 char. codes)</p> <ul style="list-style-type: none"> AF – Filtered air operation did not occur during the reading of the well AR – User adj. parameters changed results CE – Calibration expired FR – Flagged replicate DE – Drop error ED – Edited result EM – Expired maintenance EP – Edit patient data ER – Computation error FC – Flagged component IC – Invalid component ID – Invalid dilution II – Insufficient inventory IS – Insufficient sample IT – Incubator temperature LS – Lot switch LT – Luminometer temperature ME – Mechanical error occurred M1 – Category 1 modified values M2 – Category 2 modified values NC – Not calibrated NF – No fluid NI – No inventory NQ – Not in QC database NW – No well NT – No tip OD – Operator requested dilution OR – Outside range PF – Prediction failure RC – Reference consistency check RD – Reflex dilution RE – Reagent expired RP – Reflex process RR – Recalculated results SC – Spread check UC – User calibrated WT – Well wash temperature out ZS – Zero set <p>There can be up to 4 condition codes listed with not intervening replicate.</p>		

Figure F-8. (ASTM) Assay Results Conditions and Warning Codes from Figure 9-7) (Continued).

Download Messages for the VITROS ECi Immunodiagnostic System

Code Number	Message	Condition	Action
0	No download condition.		
1	Missing sample ID.	The sample program has a blank sample ID field.	Add a sample ID to the program and down load the program again.
2	Invalid characters in sample.	The sample program has invalid characters.	Refer to Chapters 4, 6, and 9 in this publication for a listing of valid characters, then down load the sample program again.

Figure F-9. Download Messages for the VITROS ECi Immunodiagnostic System from Figure 9-17 .

Code Number	Message	Condition	Action
3	More than 10 sample in file.	The file in which this sample program was included had more than 10 programs assigned to it.	Downloaded files can have a maximum of 10 sample programs. Down Load this sample program in another sample file.
4	Tray name or cup missing.	The tray name was specified but the sample program does not have an assigned sample position. The sample program has a sample position but no tray name specified.	Add the sample position and down load program again. Delete the sample position or add a tray name, then down load the sample program again.
5	File with mixed trays.	More than one sample program in the file has a tray name specified.	Delete the tray name from all programs except the first in the file; then down load the file again.
6	Sample/patient name mismatch.	The sample program has the same sample ID as a program already in the sample file but the patient names do not match.	The patient name cannot be edited from the laboratory computer; it can be edited using the Sample Programming screen. To edit a sample program from the laboratory computer, the sample ID and patient name in the edited program must match the information originally sent.
7	Sample program/cup mismatch.	The sample program has a position that has already been assigned to another program or is attempting to edit the assays for a previously downloaded sample program.	Change the sample ID or sample position, then down load the sample program again.
8	Tray without sample programs.	The sample program has attempted to be assigned to a tray that is not considered a downloaded tray. A tray is considered downloaded if it was down loaded from the laboratory computer or it has a sample program assigned that was down loaded.	Assign the sample program to a tray that is considered a downloaded tray; then down load sample program again.
9	STAT change not accepted.	The laboratory computer has attempted to edit a downloaded sample program, in progress, to a STAT and changes to the STAT field and another field have been down loaded.	Only a STAT field change can be down loaded for an already-loaded sample program. Use the Sample Programming screen to make any changes.
10	Sample program is active.	The sample program has attempted to edit a downloaded program that is in progress and changes have been down loaded for it.	Use the Sample Programming screen to make the changes to the sample program.
11	Sample program not available.	A new or edited sample program was down loaded while the sample program/tray program is unavailable.	Down load the sample program again after the sample program/tray has been returned to the sample file.
12	Sample manually edited.	An attempt was made to edit the sample program from the laboratory computer after it had been edited using the Sample Programming screen.	Edit the sample program using the Sample Programming screen.
13	No assays requested.	The sample program was down loaded with no assay requests.	Add assays to the sample program and down load the program again.
14	Invalid assay requested.	An assay was requested which is currently not supported by the Immunodiagnostic System. The program is accepted but the unsupported assay is deleted from the program.	Refer to Chapter 6 of this document for a list of supported assays. Edit assay requests and down load the sample program again.
15	Derived test replicated.	The sample program included a request to replicate a derived test.	Delete requests for replicating of derived tests and down load sample program again. (Derived tests are not allowed to be replicated.)
16	Too many assays.	The sample program has more than 20 assays or replicates requested.	Edit assay requests so that the sample program has a maximum of 20 assays requested and down load the program again.
17	Sample/tray program changed.	The sample program has been assigned to another tray.	Place sample on tray to which the sample program has been assigned.
18	Sample program taken off tray.	The sample program will be assigned to another tray.	Remove sample from the tray specified in the downloaded program.
19	No assays: sample deleted.	The sample program did not include any assays and was deleted by the laboratory computer.	Remove the sample from the tray.
20	Dilution out of range.	The dilution for this sample program is not between 1 and 9999.	Change the dilution factor and down load the sample program again.

Figure F-9. Download Messages for the VITROS ECi Immunodiagnostic System from Figure 9-17 (Continued).

Asynchronous Condition Messages

Condition messages sent by X packets have the general structure:

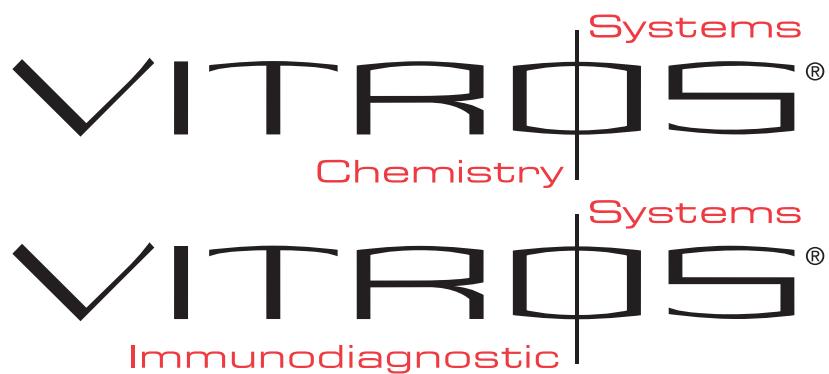
XEaaaabbccdef*s*f

where

- aaa** 3 ASCII digits containing a module number.
- bbb** 3 ASCII digits containing a condition number.
- c** 1 ASCII character containing the severity.
where valid values for c can be
 - a for action
 - n for attention
 - m for malfunction
 - s for shutdown
- d** Will have valid values of “1,” “2,” “3,” or “4” for a quadrant number if the condition message relates to a test.
or
Will have a value of “-”, if the condition does not relate to a test or the quadrant or cup values are not consistent with valid values.
- e** Will have valid values of “1”-“9” or a “0”, representing 10, for the current cup position.
or
Will have a value of “-” if the condition does not relate to a test or the quadrant or cup values are not consistent with valid values.
- f** Length of the text that follows.
- s*** The actual text of the condition message up to 79 characters.

Conditions caused by problems in the laboratory computer interface and transient conditions will not be reported to the laboratory computer in X packets.

Bar Code Specifications for Positive Sample Identification (PSID)



Revision History

Revision Date	Description
09/02	<ul style="list-style-type: none">Changed Symbol Length requirements on illustration and reference to maximum symbol length.Incorporated ISBT 128 bar code symbology from the Software v2.3.8 Release Notes.Added the Revision History section to the Guide.Converted the document from a PageMaker format to a FrameMaker format. Included converting images and text styles to complement the other section of this guide.

List of Revised Pages

Each page in your manual should be at the effective date listed below:

Release Date	Section	Page	Effective Date
09/02	All sections	All pages	09/02

Table of Contents

CHAPTER 1 INTRODUCTION	1-1
1.1 General	1-1
1.2 Applicable Specifications	1-1
CHAPTER 2 LABEL REQUIREMENTS	2-1
2.1 Label Stock	2-1
2.2 Label Adhesive	2-1
2.3 Printed Image	2-1
2.4 Over-Laminate	2-1
2.5 Optical Parameters	2-1
CHAPTER 3 SAMPLE IDENTIFICATION NUMBER	3-1
3.1 Bar Code	3-1
3.2 Human Readable Interpretation	3-1
CHAPTER 4 PSID LABEL FORMAT	4-1
4.1 Label Data	4-1
4.2 Additional Label Information	4-1
4.3 Barcode Information	4-1
4.4 Label Width	4-2
4.5 Label Length	4-2
4.6 Label Location	4-2
4.7 Label Skew	4-2
CHAPTER 5 BARCODES	5-1
5.1 Compatible Bar Code Symbologies	5-1
5.2 Bar Code Discrimination	5-4
5.3 Check Character	5-4
5.4 Bar Code Decoding	5-4
CHAPTER 6 SCANNING WAVELENGTH	6-1
6.1 PSID Bar Code Scanner Types	6-1
CHAPTER 7 USER REQUIREMENTS	7-1
7.1 Printers and Printer Drives	7-1
7.2 Label Quality and Integrity	7-1

GLOSSARY	G- 1
APPENDIX: IN-DEPTH DESCRIPTION OF BAR CODES	A-1
1.0 Bar Code Symbologies	A-1
1.1 Interleaved 2 of 5	A-1
1.2 Code 39	A-1
1.3 Codabar	A-2
1.4 Code 128	A-2
1.5 ISBT 128	A-3
2. 0 Check Characters.....	A-4
2.1 Interleaved 2 of 5.....	A-4
2.2 Code 39 Check Character	A-4
2.3 Codabar Check Character	A-5
2.4 Code 128 Check Character	A-5
3. 0 Optical Parameters.....	A-6
3.1 Bar Code Reflectance	A-6
3.2 Print Contrast Signal (PCS).....	A-7
3.3 Spots and Voids	A-7
4. 0 Measurement Methodologies	A-7
4.1 Reflectivity.....	A-7
4.2 Opacity.....	A-7
4.3 Reflectance	A-7
4.4 Element Width Measurement	A-7
5. 0 Determination of Conformance	A-8
5.1 Verification Techniques	A-8
5.2 Scan Criteria	A-8
5.3 Symbol Acceptance Criteria	A-8
5.4 Sampling Methods and Levels.....	A-8

1.1 General

This publication provides the bar code specifications for VITROS Chemistry Systems with Positive Sample Identification (PSID). These specifications cover:

- label stock
- adhesive
- over-laminate
- Label format
- label placement

The bar code symbologies that you can use are also discussed in detail. Refer to your operator's manual for an explanation of terms.

1.2 Applicable Specifications

USS-39, USS-I 2/5, USS-Codabar, Automatic Identification Manufacturers, Inc. (AIM).

"Bar Code Symbols on Transport Packages and Unit Loads," ANSI MH 10.8M-1983, American National Standards Institute.

"Committee for Commonality in Blood Banking Automation Final Report 1977,": Volume III ABC Symbol, American Blood Commission.

"The Health Industry Bar Code Provides Applications Standard," September 5, 1985, Health Industry Bar Code Council.

"Health Industry Bar Code (HIBC) Guidelines Manual," Version 1.0, 1986, Health Industry Bar Code Council.

USS-128, "Uniform Symbology Specification-128," 1986, Automatic Identification Manufacturers, Inc.

ISBN 0-912035-06-4, "Laser Safety Guide," Sixth Edition, First Printing March 1987, Laser Institute of America.

2

LABEL REQUIREMENTS

2.1 Label Stock

- **Surface**

The label stock chosen may have a surface on which variable information can be placed using a marker pen or grease pencil.

- **Label Stock Opacity**

The label stock opacity must be at least 85%, with a maximum variation of 6%, to minimize readability problems caused by show through. Your label vendor can provide you with information about the opacity of your label stock.

- **Label Stock Gloss**

Glossy surfaces increase specular reflection and decrease read reliability. Therefore, glossy label stock is not recommended.

2.2 Label Adhesive

Choose a label adhesive that meets the following requirements:

- **Moisture Resistance**

The label adhesive must be moisture resistant from 5% relative humidity to 100% relative humidity (condensing conditions).

Temperature Resistance

The label adhesive must be resistant within temperatures ranging from 0 degrees F to 120 degrees F. The required temperature may be below 0 degrees F for special applications involving long-term storage of samples.

Sample Container Surface Temperatures

The adhesive must stick to sample containers with surface temperatures ranging from 32 degrees F to 100 degrees F.

Container Surface Requirements

The adhesive must be compatible with glass and plastic blood collection container surfaces, including silicon coated surfaces.

Pressure Sensitive

The adhesion must be temporary so the label can be repositioned after initial contact with the sample container. After correct positioning, apply pressure to the label to permanently attach it to the sample container.

2.3 Printed Image

The printed image must be abrasion and smudge resistant immediately after the label is printed.

2.4 Over-Laminate

An over-laminate is not recommended because it causes specular reflection, which decreases read reliability.

2.5 Optical Parameters

The bar code should meet the optical requirements listed in the Appendix.

3

SAMPLE IDENTIFICATION NUMBER

The sample identification number (SID) is used by VITROS Systems to identify a specific sample, find the sample's programming, and track the test results of the sample. The tray and cup position do not need to be entered by the operator.

3.1 Bar Code

The SID is represented in the configured bar code symbology (see Section 5). If additional data are included in the bar code (for example, a concatenated multiple data field), the VITROS System considers the whole multiple data field format as the SID. Manual entry or bidirectional download must enter the complete data field as a SID.

All bar codes will be checked for a specified character length to increase SID integrity. The character length is defined during analyzer configuration and has a range of 3 to 15 characters. Character length configuration is discussed in your operator's manual.

If the character length configuration is longer than the SID, we recommend preceding the SID by zeros so it matches the character configuration. For example, if the character length configuration is six characters and the SID is three characters, add three zeros to the SID (e.g., a SID of "105" would become "000105").

If the analyzer is equipped with a PSID scanner that features autodiscrimination, the character length need not be configured. The acceptable range remains 3 to 15 characters with the following exceptions:

- Interleaved 2-of-5, which has a minimum character length of 4 and a maximum of 14 if check digit is disabled, and a minimum length of 3 and maximum length of 15 characters if check digit is enabled.

or
- For ISBT 128, which has a fixed length of 13 characters and cannot be configured.

Bar code symbology does not have to be configured when in the autodiscrimination mode.

Note: If you process multiple-sample derived test (MSDT) samples, code length is limited to 14 characters.

3.2 Human Readable Interpretation

Any human readable interpretation of the SID bar code should be printed clearly and positioned so that the corresponding bar code, representing the encoded characters, is easily identified. The check digit and start/stop characters are suppressed. The human readable interpretation of the bar code should be located directly below the bar code, as illustrated in Figure 1. We recommend that the interpretation of the zero be represented as "0."

4.1 Label Data

Labels can be pre-printed or printed-on-demand. The SID, printed in bar code symbology, and the alphanumeric representation of the SID must be contained on each label.

4.2 Additional Label Information

Additional written information and graphics can be placed on the label as long as they do not interfere with the bar code, bar code quiet zone, or the human readable interpretation of the bar code. The only acceptable area for additional information or graphics is in the area below the dashed line indicated in figure 4-1. The additional information or graphics can be placed in any orientation.

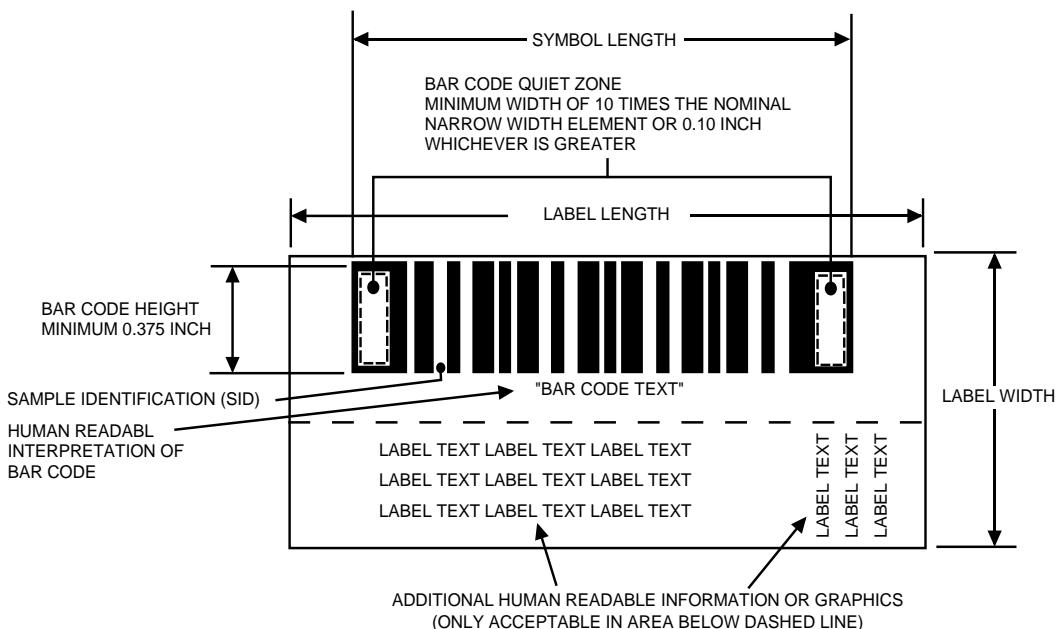


Figure 4-1. PSID Label Format.

4.3 Barcode Information

The PSID bar code must be printed with the bars perpendicular to the label length. See figure 1.

- **Bar Code Height**

The bar code height must be a minimum of 0.375 inches (9.5mm).

- **Narrow Element Width**

The minimum nominal narrow element width must be 0.0075 inch (0.19mm). The maximum nominal narrow element width must be 0.020 inch (0.51mm).

Element Ratio

The nominal ratio of the width of the wide elements to the width of the narrow elements must be from 2.2:1 to 3:1.

- **Bar Code Quiet Zone**

The leading and trailing quiet zones of the bar code shall have a minimum width of ten times the nominal narrow element width or 0.10 inch (2.5mm), whichever is greater.

• Symbol Length

The overall symbol length, **including** data characters, check digit (if used), start and stop characters, and quiet zones (2), is dependent on the length of the container, as indicated in the following table:::

Container Size	Maximum Symbol Length
16mm Diameter	2.125"
13mm Diameter	2.125"
10.25mm Diameter	2.125"
7mm Diameter (Microcollection)	See below

Refer to the requirements described in Section 4.6 for further information to determine the maximum symbol length.

The bar code must be positioned so that it remains within the scanner read zone and container length.

For microcollection containers, the symbol length must not exceed the actual cylindrical container length. The bar code must be entirely visible through the adaptor window, as appropriate. Refer to the Operator's Guide for your VITROS System for details on using adaptors with microcollection containers.

4.4 Label Width

The label width will be defined by the user and depends upon the number of additional lines of human readable data printed. Consideration should be given to the circumference of the container so that the label width does not exceed 60-70% of the circumference. The label should not block visual access to the fluid level and condition.

4.5 Label Length

The nominal label length may vary depending upon the bar code format, bar code density, and amount of information encoded. The length of the label must not exceed or be positioned beyond the container length.

4.6 Label Location

The label must be positioned so that it extends along the length of the sample container, starting within 0.125 inch (3.2mm) of the rim. **Ensure that the label does not interfere with placement of the stopper, and that the stopper does not obscure any portion of the bar code.** If using a sample container with a stopper that does not allow label placement within 0.125 inches of the top rim of the tube, be careful to observe the lower limit of label placement. The label must not extend beyond the cylindrical surface. See figure 2. Do not place bar code labels on top of other bar code labels. This requirement eliminates the possibility of the scanner reading through the outer label and decoding all or part of the inner label.

4.7 Label Skew

The label skew must be less than ± 5 degrees with respect to the axis of the sample container. See [figure 4-2](#).

Note: Interleaved 2 of 5 symbology without check digit usage is specifically sensitive to label placement and skew. Be aware of this sensitivity when using this symbology.

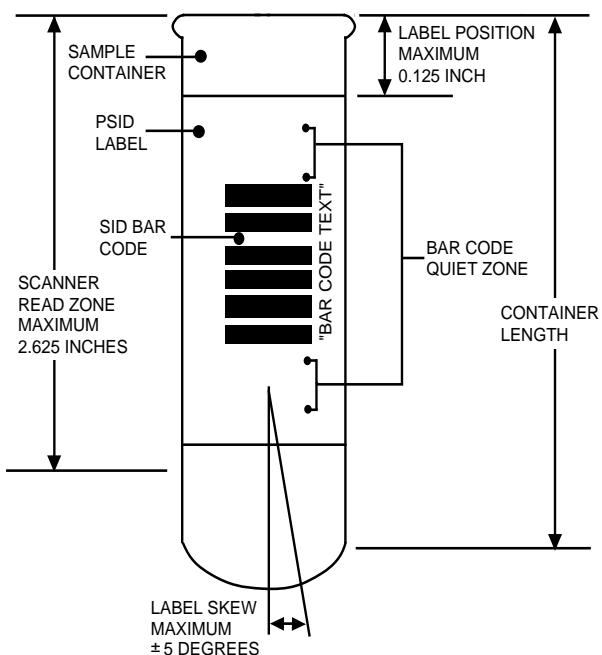


Figure 4-2. Label Position

5.1 Compatible Bar Code Symbolologies

The bar codes that can be used with all PSID bar code readers for VITROS Systems are:

- Interleaved 2 of 5
- Code 39
- Codabar

The PSID bar code reader for the VITROS 250 and 950 Chemistry Systems and the ECi Immunodiagnostic System can also use Code 128.

Interleaved 2 of 5

Interleaved 2 of 5 is a numeric only bar code symbology. The characters are interleaved together using the bars to represent data characters in the odd positions. Because characters are interleaved in pairs, Interleaved 2 of 5 always represents an even number of characters. (note that the check digit is considered to be a character). If an odd number of characters is to be encoded, a leading zero should be added to change the number of characters to an even number (see figure 5-1).

Interleaved 2 of 5 Code Symbology	
Character	Code
0	00110
1	10001
2	01001
3	11000
4	00101
5	10100
6	01100
7	00011
8	10010
9	01010

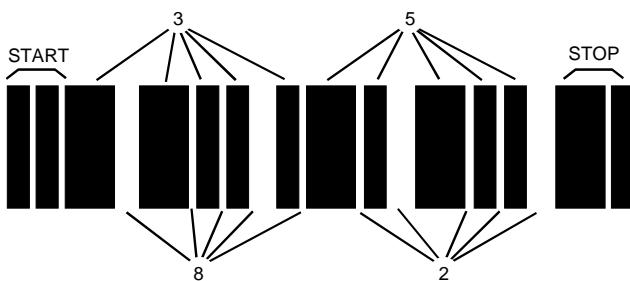


Figure 5-1. Interleaved 2 of 5 Code Symbology.

Code 39

Code 39, also referred to as Code 3 of 9, is an alphanumeric symbology consisting of 43 data characters. The Health Industry Bar Code/Provider Applications Standard utilizes Code 39 symbology (see figure 5-2).

Character	Pattern	Bars	Spaces
1		10001	0100
2		01001	0100
3		11000	0100
4		00101	0100
5		10100	0100
6		01100	0100
7		00011	0100
8		10010	0100
9		01010	0100
0		00110	0100
A		10001	0010
B		01001	0010
C		11000	0010
D		00101	0010
E		10100	0010
F		01100	0010
G		00011	0010
H		10010	0010
I		01010	0010
J		00110	0010
K		10001	0001
L		01001	0001
M		11000	0001
N		00101	0001
O		10100	0001
P		01100	0001
Q		00011	0001
R		10010	0001
S		01010	0001
T		00110	0001
U		10001	1000
V		01001	1000
W		11000	1000
X		00101	1000
Y		10100	1000
Z		01100	1000
-		00011	1000
.		10010	1000
SPACE		01010	1000
*		00110	1000
\$		00000	1110
/		00000	1101
+		00000	1011
%		00000	0111

Figure 5-2. Code 3 of 9 Code Symbology.

Codabar

Codabar is a bar code symbology of ten numeric and the six additional characters / .: + - \$.

Binary Encoded Representation Character (B S B S B S B)	Bar and Space Pattern
0 0000011	
1 0000110	
2 0001001	
3 1100000	
4 0010010	
5 1000010	
6 0100001	
7 0100100	
8 0110000	
9 1001000	
- 0001100	
\$ 0011000	
: 1000101	
/ 1010001	
. 1010100	
+ 0010101	
A/a/T/t 0011010	
B/b/N/n 0101001	
C/c/* 0001011	
D/d/E/e 0001110	

Figure 5-3. Rationalized Codabar Code Symbology.

Character	Bar 1 (inch) (nm)		Space 1 (inch) (nm)		Bar 2 (inch) (nm)		Space 2 (inch) (nm)		Bar 3 (inch) (nm)		Space 3 (inch) (nm)		Bar 4 (inch) (nm)	
1	0.0065	0.165	0.0104	0.264	0.0065	0.165	0.0104	0.264	0.0179	0.455	0.0243	0.617	0.0065	0.165
2	0.0065	0.165	0.0100	0.254	0.0065	0.165	0.0244	0.620	0.0065	0.165	0.0100	0.254	0.0186	0.472
3	0.0179	0.455	0.0243	0.617	0.0065	0.165	0.0104	0.264	0.0065	0.165	0.0104	0.264	0.0065	0.165
4	0.0065	0.165	0.0104	0.264	0.0179	0.455	0.0104	0.264	0.0065	0.165	0.0243	0.617	0.0065	0.165
5	0.0179	0.455	0.0104	0.264	0.0065	0.165	0.0104	0.264	0.0065	0.165	0.0243	0.617	0.0065	0.165
6	0.0065	0.165	0.0243	0.617	0.0065	0.165	0.0104	0.264	0.0065	0.165	0.0104	0.264	0.0179	0.455
7	0.0065	0.165	0.0243	0.617	0.0065	0.165	0.0104	0.264	0.0179	0.455	0.0104	0.264	0.0065	0.165
8	0.0065	0.165	0.0243	0.617	0.0179	0.455	0.0104	0.264	0.0065	0.165	0.0104	0.264	0.0065	0.165
9	0.0186	0.472	0.0100	0.254	0.0065	0.165	0.0244	0.620	0.0065	0.165	0.0100	0.254	0.0065	0.165
0	0.0065	0.165	0.0104	0.264	0.0065	0.165	0.0104	0.264	0.0065	0.165	0.0243	0.617	0.0179	0.455
\$	0.0065	0.165	0.0100	0.254	0.0186	0.472	0.0244	0.620	0.0065	0.165	0.0100	0.254	0.0065	0.165
-	0.0065	0.165	0.0100	0.254	0.0065	0.165	0.0244	0.620	0.0186	0.472	0.0100	0.254	0.0065	0.165
:	0.0167	0.424	0.0093	0.236	0.0065	0.165	0.0093	0.236	0.0167	0.424	0.0093	0.236	0.0147	0.373
/	0.0147	0.373	0.0093	0.236	0.0167	0.424	0.0093	0.236	0.0065	0.165	0.0093	0.236	0.0167	0.424
.	0.0136	0.345	0.0101	0.257	0.0149	0.378	0.0101	0.257	0.0172	0.437	0.0101	0.257	0.0065	0.165
+	0.0065	0.165	0.0101	0.257	0.0172	0.437	0.0101	0.257	0.0149	0.378	0.0101	0.257	0.0136	0.345
A/a/T/t	0.0065	0.165	0.0080	0.203	0.0196	0.498	0.0194	0.493	0.0065	0.165	0.0161	0.409	0.0065	0.165
B/b/N/n	0.0065	0.165	0.0161	0.409	0.0065	0.165	0.0194	0.493	0.0065	0.165	0.0080	0.203	0.0196	0.498
C/c/*	0.0065	0.165	0.0080	0.203	0.0065	0.165	0.0194	0.493	0.0065	0.165	0.0161	0.409	0.0196	0.498
D/d/E/e	0.0065	0.165	0.0080	0.203	0.0065	0.165	0.0194	0.493	0.0196	0.498	0.0161	0.409	0.0065	0.165

Note: These dimensions yield 10 characters per inch. They may be scaled upward uniformly.

Figure 5-4. Traditional Codabar Bar Code Symbology.

Four different start and stop combinations are designated; however, PSID for VITROS Systems does not differentiate the various start/stop combinations.

Code 128

Uniform Symbology Specification 128 (Code 128) is a full 128 ASCII character set. This code contains an encodable character set, four non-data function characters, four code-set selection function characters, three start characters, and one stop character.

VALUE	CODE A	CODE B	CODE C	BAR PATTERN					
				B	S	B	S	B	S
0	SP	SP	00	2	1	2	2	2	2
1	!	!	01	2	2	2	1	2	2
2	"	"	02	2	2	2	2	2	1
3	#	#	03	1	2	1	2	2	3
4	\$	\$	04	1	2	1	3	2	2
5	%	%	05	1	3	1	2	2	2
6	&	&	06	1	2	2	2	1	3
7	'	'	07	1	2	2	3	1	2
8	((08	1	3	2	2	1	2
9))	09	2	2	1	2	1	3
10	.	.	10	2	2	1	3	1	2
11	+	+	11	2	3	1	2	1	2
12	,	,	12	1	1	2	2	3	2
13	-	-	13	1	2	2	1	3	2
14	.	.	14	1	2	2	2	3	1
15	/	/	15	1	1	3	2	2	2
16	0	0	16	1	2	3	1	2	2
17	1	1	17	1	2	3	2	2	1
18	2	2	18	2	2	3	2	1	1
19	3	3	19	2	2	1	1	3	2
20	4	4	20	2	2	1	2	3	1
21	5	5	21	2	1	3	2	1	2
22	6	6	22	2	2	3	1	1	2
23	7	7	23	3	1	2	1	3	1
24	8	8	24	3	1	1	2	2	2
25	9	9	25	3	2	1	1	2	2
26	:	:	26	3	2	1	2	2	1
27	;	;	27	3	1	2	2	1	2
28	<	<	28	3	2	2	1	1	2
29	=	=	29	3	2	2	2	1	1
30	>	>	30	2	1	2	1	2	3
31	?	?	31	2	1	2	3	2	1
32	@	@	32	2	3	2	1	2	1
33	A	A	33	1	1	1	3	2	3
34	B	B	34	1	3	1	1	2	3
35	C	C	35	1	3	1	3	2	1
36	D	D	36	1	1	2	3	1	3
37	E	E	37	1	3	2	1	1	3
38	F	F	38	1	3	2	3	1	1
39	G	G	39	2	1	1	3	1	3
40	H	H	40	2	3	1	1	1	3
41	I	I	41	2	3	1	3	1	1
42	J	J	42	1	1	2	1	3	3
43	K	K	43	1	1	2	3	3	1
44	L	L	44	1	3	2	1	3	1
45	M	M	45	1	1	3	1	2	3
46	N	N	46	1	1	3	3	2	1
47	O	O	47	1	3	3	1	2	1
48	P	P	48	3	1	3	1	2	1
49	Q	Q	49	2	1	1	3	3	1
50	R	R	50	2	3	1	1	3	1
51	S	S	51	2	1	3	1	1	3
52	T	T	52	2	1	3	3	1	1
53	U	U	53	2	1	3	1	3	1
54	V	V	54	3	1	1	1	2	3
55	W	W	55	3	1	1	3	2	1

Figure 5-5. Code 128 Bar Code Symbology.

VALUE	CODE A	CODE B	CODE C	BAR PATTERN					
				B	S	B	S	B	S
56	X	X	56	3	3	1	1	2	1
57	Y	Y	57	3	1	2	1	1	3
58	Z	Z	58	3	1	2	3	1	1
59	[[59	3	3	2	1	1	1
60	\	\	60	3	1	4	1	1	1
61]]	61	2	2	1	4	1	1
62			62	4	3	1	1	1	1
63			63	1	1	1	2	2	4
64	NUL		64	1	1	1	4	2	2
65	SOH	a	65	1	2	1	1	2	4
66	STX	b	66	1	2	1	4	2	1
67	ETX	c	67	1	4	1	1	2	2
68	EOT	d	68	1	4	1	2	2	1
69	ENQ	e	69	1	1	2	2	1	4
70	ACK	f	70	1	1	2	4	1	2
71	BEL	g	71	1	2	2	1	1	4
72	BS	h	72	1	2	2	4	1	1
73	HT	i	73	1	4	2	1	1	2
74	LF	j	74	1	4	2	2	1	1
75	VT	k	75	2	4	1	2	1	1
76	FF	l	76	2	2	1	1	1	4
77	CR	m	77	4	1	3	1	1	1
78	SO	n	78	2	4	1	1	1	2
79	SI	o	79	1	3	4	1	1	1
80	DLE	p	80	1	1	1	2	4	2
81	DC1	q	81	1	2	1	1	4	2
82	DC2	r	82	1	2	1	2	4	1
83	DC3	s	83	1	1	4	2	1	2
84	DC4	t	84	1	2	4	1	1	2
85	NAK	u	85	1	2	4	2	1	1
86	SYN	v	86	4	1	1	2	1	2
87	ETB	w	87	4	2	1	1	1	2
88	CAN	x	88	4	2	1	2	1	1
89	EM	y	89	2	1	2	1	4	1
90	SUB	z	90	2	1	4	1	2	1
91	ESC	{	91	4	1	2	1	2	1
92	FS		92	1	1	1	1	4	3
93	GS	}	93	1	1	1	3	4	1
94	RS	~	94	1	3	1	1	4	1
95	US	DEL	95	1	1	4	1	1	3
96	FNC 3	FNC 3	96	1	1	4	3		
97	FNC 2	FNC 2	97	4	1	1	1	1	3
98	SHIFT	SHIFT	98	4	1	1	3	1	1
99	CODE C	CODE C	99	1	1	3	1	4	1
100	CODE B	FNC 4	CODE B	1	1	4	1	3	1
101	FNC 4	CODE A	CODE A	3	1	1	1	4	1
102	FNC 1	FNC 1	FNC 1	4	1	1	1	3	1
103	START (CODE A)			B	S	B	S	B	S
104	START (CODE B)			2	1	1	2	1	4
105	START (CODE C)			2	1	1	2	3	2
				B	S	B	S	B	S
				2	3	3	1	1	1

Figure 5.5 Continued

ISBT 128

ISBT 128 bar code symbology uses a specific format for labels that contain the Donation Identification Number and is implemented using code 128 symbology (see figure 5-5).

5.2 Bar Code Discrimination

When equipped with the autodiscrimination feature, the analyzer determines the bar code symbology automatically. For those analyzers not equipped with the autodiscrimination feature, the user is required to select a particular bar code symbology during PSID configuration.

5.3 Check Character

Using the check character algorithms that are defined for each symbology significantly increases bar code integrity and reduces the probability of a misread. **We strongly recommend check character use.** Where conforming to the HIBC/PA standards, the check character is a requirement of that standard. **The check character algorithm should be disabled only where bar code compatibility with non-check character instrumentation takes precedence over code integrity.** The PSID option will allow enabling or disabling of the check character algorithm test during analyzer configuration. Details regarding the check digit algorithms for each symbology are contained in the Appendix.

IMPORTANT: For analyzers equipped with the autodiscrimination feature, the check digit configuration must be the same within a bar code symbology.

For example, if the Code 39 configuration is set for "check digit on," **all** Code 39 bar codes must contain a check digit. If a sample ID is encoded **without** a check digit **and** the last digit of the sample ID satisfies the check digit algorithm of the symbology, the analyzer **may** match that sample ID with the incorrect sample program.

Conversely, if the check digit is configured as "check digit off", **no** Code 39 bar codes can contain a check digit. If a sample ID is encoded with a check digit in this case, the last digit of the bar code **will** be interpreted as an addition sample ID digit. In this situation, the analyzer would not be able to match that sample ID with the correct sample program.

5.4 Bar Code Decoding

For PSID interpretation of the bar code, only the data characters are used. **The check character (if used) and the start/stop characters are not transmitted as data characters.**

6

Scanning Wavelength

6.1 PSID Bar Code Scanner Types

PSID for the VITROS System may be equipped with one of the following types of red light-emitting scanners:

- Class IIa Laser, emitting a low power, visible beam at a wavelength of 633 nanometers
- Class II Laser, emitting a low power, visible beam at a wavelength of 670 nanometers
- CCD Light Emitting Diode (LED), emitting low power visible light at a wavelength of 645 nanometers

For further information, refer to the Laser Institute of America "Laser Safety Guide" (see "Applicable Specifications" on page 1 of this Guide).

7.1 Printers and Printer Drives

Where on-demand bar code label printing is desired, it is your responsibility to procure bar code printers and software drivers that satisfy user throughput requirements and meet the requirements of this label specification.

7.2 Label Quality and Integrity

- It is your and the printer/LIS vendor's responsibility to install and maintain label printing equipment such that bar code quality satisfies this specification. Ortho-Clinical Diagnostics makes no claim regarding scanner read reliability where the check character algorithm is disabled or bar code labels do not meet the requirements of the label specification. Where questions of conformance to this specification arise, measurement of bar codes shall be determined by manual and automatic inspection techniques using optical parameters and methodologies described in “[Measurement Methodologies](#)” on page 7 of the Appendix, “
- The PSID label must be placed onto the sample container in the orientation and within the specified dimensions to obtain satisfactory read reliability.
- The bar code must **be fully** visible through the open side of the primary tube tray and its adapters to obtain satisfactory read reliability, otherwise reading of the SID may be unreliable.

GLOSSARY

Alphanumeric. The character set that contains letters, numbers, and usually other characters such as punctuation marks.

Aperture. The opening in an optical system defined by a lens or baffle that establishes the field of view.

ASCII. The character set and code described in American National Standard Code for Information Interchange, ANSI X3.4-1977. Each ASCII character is encoded with 7 bits (8 bits including parity check). The ASCII character set is used for information interchange between data processing systems, communication systems, and associated equipment. The ASCII set consists of both control and printing characters.

Autodiscrimination. The ability of bar code reading equipment to recognize and correctly decode more than one symbology.

Background. The lighter portion of a bar code symbol, including the quiet zones.

Bar. One of two types of elements that make up a bar code symbol. A bar element is the element type that has the lower average value of reflectance.

Bar Code. An array of parallel, rectangular bars and spaces that together represent a single data character in a particular symbology. The bars and spaces are arranged in a predetermined pattern following unambiguous rules defined by the symbology.

Bar Code Character. A single group of bars and spaces that represent an individual number, letter, punctuation mark, or other symbol.

Bar Code Density. The number of characters that can be represented in a linear unit of measure. Bar code density is often expressed in characters per inch.

Bar Code Label. A label that carries a bar code symbol to be affixed to an article.

Bar Code Reader. A device used to read a bar code symbol.

Bar Code Symbol. See Symbol.

Bar Height. The longer dimension of a bar.

Bar Width. The thickness of a bar measured from the edge closest to the symbol star character to the trailing edge of the same bar.

Bidirectional. A bar code capable of being read successfully, independent of scanning direction.

Binary. The number system that uses only 1's and 0's.

Bit. An abbreviation for "binary digit." A single element (0 or 1) in a binary number.

CCD. See Charged Couple Device.

Character. (1) A single group of bars and spaces that represent an individual number, letter, punctuation mark, or other symbol. (2) A graphic shape representing a letter, number, or symbol. (3) A letter, digit, or other symbol that is used as part of the organization, control, or representation of data.

Character Set. Those characters available for encodation in a particular bar code symbology.

Charged Coupled Device (CCD). An electro-optical device which scans a code electronically.

Check Character. A character included within a symbol whose value is used for the purpose of performing a mathematical check to ensure the accuracy of the read.

Code. A set of unambiguous rules specifying the way in which data may be represented.

Code 39. A variable length, bidirectional, discrete, self-checking, alphanumeric bar code. Its data character set contains 43 characters: 0-9, A-Z, -, ., \$, /, +, %, and space. The name (also known as "Code 3 of 9") derives from the method of encodation—each character has nine elements, three of which are always wide.

Code 128. A variable length, bidirectional, continuous, self-checking, alphanumeric bar code capable of encoding the full 128 ASCII character set. This code also encodes four non-data function characters. The start/stop characters are also not data characters.

Continuous Code. A bar code symbol where all spaces within the symbol are parts of characters, (for example, USS-1-2/5). There is no intercharacter gap in a continuous code.

Data Characters. Those characters within the bar code that transmit data, but are not used to transmit control information (see Message Characters).

Decoder. As part of a bar code reading system, the electronic package which receives the signals from the scanner, performs the algorithm to interpret the signal into meaningful data and provides the interface to other devices.

Depth of Field. The distance between the maximum and minimum plane in which a bar code reader is capable of reading symbols.

Diffuse Reflection. The component of reflected light which emanates in all directions from the reflecting surface.

Discrete Code. A bar code symbol where the spaces between characters (intercharacter gap) are not part of the code.

Element. A generic term used to refer to either a bar or space that encodes data.

Element Edge. The element edge is defined as the location of the center of the measuring aperture when the aperture is in a position such that the observed reflectance is midway between the maximum reflectance of the adjacent space and the minimum reflectance of the adjacent bar.

Element Reflectance Uniformity (ERU). The range of reflectance within each bar and space.

$$\text{ERU (space)} = \text{Rs(max)} - \text{Rs(min)}$$

$$\text{ERU (bar)} = \text{Rb(max)} - \text{Rb(min)}$$

Font. A specific size and style of printer's type.

Gloss. A phenomenon related to the specular reflection of incident light. The effect of gloss is to reflect more of the incident light in a specular manner, and to scatter less. It occurs at all angles of incidence and should not be confused with the grazing angle, which is the specular reflection often referred to as sheen.

Helium-Neon Laser. The type of laser most commonly used in bar code scanners. It emits coherent red light at a wavelength of 633nm.

Infinite Pad Method. The infinite pad method for measuring reflectance is the method in which the sample substrate being measured is backed with enough thickness of the same type of substrate so that doubling the number of sheets does not change the measured value of reflectance.

Inspection Band. An area of the bar code symbol over which measurements shall be taken.

Intercharacter Gap. The space between two adjacent bar code characters in a discrete code.

Laminate. See "Over-Laminate."

Light Emitting Diode (LED). A semiconductor diode that produces light at a wavelength determined by its chemical composition. The light source commonly used in wand-type readers.

Maximum Bar Reflectance (Rb(max)). The maximum reflectance within any bar when the measuring aperture is wholly contained within a bar. When the diameter of the measuring aperture is larger than a bar width, the maximum bar reflectance is measured when the center of the aperture is located at the center of the bar.

Maximum Space Reflectance (Rs(max)). The maximum reflectance within any space.

Message Characters. Includes all those characters in the bar code; that is, data characters, check characters once computed (if present), and start/stop characters.

Minimum Bar Reflectance (Rb(min)). The minimum reflectance within any bar.

Minimum Reflectivity Difference (MRD). The Minimum Reflectivity Difference (MRD) between bars and spaces is the difference between the smallest space reflectance value

and the largest bar reflectance value as measured across the entire symbol.

$$\text{MRD} = \text{Min(Rs(min)} - \text{Max (Rb(max))}$$

Bar, space, quiet zone, and MRD reflectance can be expressed as percentages or in decimal form. If the maximum bar reflectance was determined to be 2 percent and the minimum space reflectance was determined to be 90 percent, then the MRD would equal 88 percent.

$$\text{MRD} = 90 \text{ percent} - 2 \text{ percent}$$

$$= 88 \text{ percent}$$

Minimum Space Reflectance (Rs(min)). The minimum reflectance within any space or quiet zone when the measuring aperture is wholly contained within a space. When the diameter of the measuring aperture is larger than a space width, the space reflectance is measured when the center of the aperture is located at the center of the space.

Misread. A condition that occurs when the data output of a reader does not agree with the data encoded in the bar code symbol.

Module. The narrowest nominal unit of measure in a bar code.

Nanometer (nm). A unit of measure used to define the wavelength of light. It is equal to 10⁻⁹ meter.

Nominal. The exact (or ideal) intended value for a specified parameter. Tolerances are specified as positive and negative deviations from this value.

Non-Read. The absence of data at the reader's output after an attempted scan due to no code, defective code, reader failure, or operator error.

Numeric. A character set that includes only numbers.

Opacity. The property of a substrate material that minimizes show-through from the back side on the next sheet. The ratio of the reflectance with a black backing to the reflectance with a white backing. Ink opacity is the property of an ink that prevents the substrate from showing through.

Overhead. The fixed number of characters required for start, stop, and check in a given symbol. For example, a symbol requiring a start/stop and two check characters contains four characters of overhead. Thus, to encode three characters, seven characters are required.

Positive Sample Identification (PSID). A means of identifying a sample via a bar code label on the sample container. The bar code label contains an alphanumeric identifier, which identifies the sample and its corresponding sample program.

Preprinted Symbol. A symbol that is printed in advance of an application either on a label or on the article to be identified.

Quiet Zone. A clear space, containing no dark marks, that precedes the start character of a symbol and follows the stop character.

Reflectance. The ratio of the amount of light of a specified wavelength or series of wavelengths reflected from a surface to the amount of light reflected from a barium oxide or magnesium oxide standard.

Resolution. The narrowest element dimension that can be distinguished by a particular reading device or printed with a particular device or method.

Scanner. A reader that optically or mechanically sweeps a reader beam across a bar code label negating the need to move the reader with respect to a label.

Self-checking. A bar code symbol using a checking algorithm that can be independently applied to each character to guard against undetected errors.

Show-through. The undesirable property of a substrate that permits underlying markings to be seen.

Space. One of two types of elements that make up a bar code symbol. A space element is the element type that has the higher average value of reflectance.

Space Width. The thickness of a space measured from the edge closest to the symbol start character to the trailing edge of the same space.

Spectral Response. The variation in sensitivity of a reading device to light of different wavelengths.

Specular Reflection. The mirror-like reflection of light from a surface.

Spots. Unwanted dark areas in the spaces, quiet zones, and intercharacter gaps of bar code symbol that may be caused by such conditions as the presence of extraneous ink, printing errors, or dirt.

Start-Stop Character. A special set of bar code elements that provides the scanner with start and stop reading instructions and scanning direction. The start character is normally at the left end of a horizontally-oriented symbol. The stop character is normally at the right end of a horizontally-oriented symbol.

Substitution Error. A mis-encoding, mis-read, or human key entry error where a character that was to be entered is substituted with erroneous information. For example:

Correct information — 1, 2, 3, 4

Substitution — 1, 2, 3, 5.

Substrate. The surface on which a bar code symbol is printed.

Symbol. A combination of characters including start/stop characters, quiet zones, and data characters that form a complete, scannable entity.

Symbol Length. The distance between the outside edges of the quiet zones.

Symbol Reflectance Uniformity of Bars (SRUB). The difference between the largest maximum bar reflectance value and the smallest minimum bar reflectance value as measured across the entire symbol.

$$\text{SRUB} = \text{Max}(Rb(\text{Max})) - \text{Min}(Rb(\text{Min}))$$

Symbol Reflectance Uniformity of Spaces (SRUS). The difference between the largest maximum space reflectance value and the smallest minimum space reflectance value as measured across the entire symbol.

$$\text{SRUS} = \text{Max}(Rs(\text{Max})) - \text{Min}(Rs(\text{Min}))$$

Voids. Unwanted light areas wholly contained within the dark elements of a positive bar code symbol. When such areas lie along the element's edge, they are to be considered as edge irregularities.

X Dimension. The nominal narrow element width.

APPENDIX: IN-DEPTH DESCRIPTION OF BAR CODES

1.0 Bar Code Symbologies

1.1 Interleaved 2 of 5

Interleaved 2 of 5 bar code is a bidirectional, continuous, and self-checking numeric bar code. Different start and stop characters are used. The bar code uses a series of wide and narrow elements to represent each character. These elements can be either bars or spaces. Wide elements are given a binary value of 1, and narrow elements are given a binary value of 0. The characters are interleaved together using the bars to represent data characters in the odd positions and using spaces to represent characters in the even positions, starting with the first character after the start character. The interleaving process requires an even number of characters in the bar code. If an odd number of characters is to be encoded, a leading zero would be added to change the number of characters to an even number.

Each data character is composed of five elements, two of which are wide and three of which are narrow. The numbers 0 through 9 can be encoded in Interleaved 2 of 5 bar code. Figure 3 (see page 9) shows the code symbology for the characters 0 through 9. Start characters are encoded as 00 in bars. Stop characters are encoded as 10 in bars. The spaces included in both the stop and start characters are narrow. The start character includes a following narrow space. Interleaved 2 of 5 bar code is continuous because there are no intercharacter gaps. All of the spaces contain information. An Interleaved 2 of 5 symbol contains all numeric data characters and the check character if used. The reader does not transmit the start/stop characters.

- The minimum nominal narrow element width is 0.0075 inch (0.19 mm).
- The maximum nominal narrow element width is 0.020 inch (0.51 mm).
- The nominal ratio of the width of the wide elements to the width of the narrow elements is between 2.2:1 and 3:1.
- The nominal width of the various elements and the nominal ratio of wide to narrow elements must not change within a given bar code symbol.
- The maximum printing tolerances (T) on the element widths for an Interleaved 2 of 5 bar code can be determined as follows:

$$T = \pm((18N-21)/80)X$$

Where: N = The nominal wide to narrow element ratio.

X = The nominal narrow element width.

- The symbol length for Interleaved 2 of 5 can be calculated as follows:

$$L = P(4N+6)+6+N)X+2Q$$

Where: P = the number of data character pairs.

N = the nominal wide to narrow element ratio.

X = the nominal narrow element width.

Q = the width of the quiet zone.

- In a specific application, using Interleaved 2 of 5 bar code, the number of data characters in all Interleaved 2 of 5 bar code symbols is the same and the reading equipment is set for the selected length. Leading zeros should be added to shorter messages so that the resulting length is the same as all other Interleaved 2 of 5 bar code symbols being used.

IMPORTANT: Interleaved 2 of 5 symbology used with no check digit requires close attention to label placement and skew. If a label is skewed, offset, or extended beyond the end(s) of the tube, the sample ID could be misread as a short sample ID in autodiscrimination mode.

1.2 Code 39

Code 39 is also known as Standard Code 39, Code 3 of 9, or as Standard Code 3 of 9. Code 39 is a variable length, bidirectional, discrete, self-checking alphanumeric bar code. The data set for Code 39 contains 43 characters: 0 to 9, A to Z, -, ., /, +, %, and space. Each character is composed of nine elements, five bars, and four spaces. Three of the nine elements are wide (binary value 1) and six of the elements are narrow (binary value 0). A common character (*) is used for both the start and stop character. Each character in a Code 39 bar code symbol is separated by an intercharacter gap.

A message consists of any number of data characters enclosed between two start/stop characters. The character (*) is used with a leading quiet zone to indicate a stop character. Figure 4 (see page 9) shows the code symbology for the Code 39 characters. A Code 39 symbol contains all data alphanumeric data characters, the check character if used, and start/stop characters. The reader does not transmit the start/stop characters.

- The minimum nominal narrow element width is 0.0075 inch (0.19 mm).
- The maximum nominal narrow element width is 0.020 inch (0.51 mm).
- The nominal ratio of the width of the wide elements to the width of the narrow elements is between 2.2:1 and 3:1.
- The nominal width of the various elements and the nominal ratio of wide to narrow elements must not change within a given bar code symbol.

- The maximum printing tolerances (T) on the element widths for a Code 39 bar code can be determined as follows:

$$T = \pm (4/27)(N-2/3)X$$

Where: N = the nominal wide to narrow element ratio.

X = the nominal narrow element width.

- Within a given Code 39 symbol, the minimum nominal width of the intercharacter spaces is (X-T).
- Within a given Code 39 symbol, the maximum nominal width of the intercharacter spaces is 5.3X for values of X less than 0.01 inch (0.25 mm), and 3X or 0.053 inch (1.35 mm) whichever is greater for values of X greater than or equal to 0.01 inch (0.25 mm).
- The symbol length for Code 39 can be calculated as follows:

$$L = I(1 + C) + (C + 2)(6X + 3NX) + 2Q$$

Where: N = the nominal wide to narrow element ratio.

X = the nominal narrow element width.

Q = the width of the quiet zone.

I = the nominal width of intercharacter spaces.

C = the number of data characters (including check character if used).

1.3 Codabar

Codabar is also known as Rationalized Codabar.

Rationalized Codabar is printed primarily by on-demand printing systems. Codabar bar code is a discrete, variable length, bidirectional, self-checking, extended numeric bar code. The character set for Codabar contains 20 characters: 0 to 9, -, \$, :, /, ., +, and A to D. The characters A to D are used only as start and stop characters. Some users have chosen to designate these start and stop characters as lowercase a to d. Other users have also chosen to designate these same four symbols as T, N, *, and E, or t, n, *, and e, respectively, when they are used as stop characters. Each character consists of seven elements: four bars and three spaces. Two or three of these elements are wide (binary value 1), and the rest are narrow (binary value 0). The choice of any combination of start and stop characters can be used. Each character in a Codabar symbol is separated by an intercharacter space.

A message consists of any number of data characters enclosed between a start and stop character. Figure 5 (see page 10) shows the code symbology for Codabar characters. A Codabar symbol includes the start character, all data characters, the check character if used, and the stop character. The reader does not transmit the start/stop characters and check character (if used).

- The minimum nominal narrow element width is 0.0075 inch (0.19 mm).
- The maximum nominal narrow element width is 0.020 inch (0.51 mm).
- The nominal ratio of the width of the wide elements to the width of the narrow elements is between 2.2:1 and 3:1.
- The nominal width of the various elements and the nominal ratio of wide to narrow elements must not change within a given bar code symbol. Since some Codabar characters have

only 2 wide elements and others 3, a symbol will contain characters of two distinct widths.

- The maximum printing tolerances (T) on the element widths for a Codabar bar code can be determined as follows:

$$T = +/- ((5N-8)/20)X$$

Where: N = the nominal wide to narrow element ratio.

X = the nominal narrow element width.

- Within a given Codabar symbol, the minimum nominal width of the intercharacter spaces is (X-T).
- Within a given Codabar symbol, the maximum nominal width of the intercharacter spaces is 5.3X for values of X less than 0.01 inch (0.25 mm), and 3X or 0.053 inch (1.35 mm) whichever is greater for values of X greater than or equal to 0.01 inch (0.25 mm).
- The symbol length for Codabar can be calculated as follows:

$$L = ((2N + 5)C + (N-1)(W + 2))X + I(C-1) + 2Q$$

Where: N = the nominal wide to narrow element ratio.

X = the nominal narrow element width.

Q = the width of the quiet zone.

I = the nominal width of intercharacter spaces.

C = the total number of characters (including start and stop).

W = the number of wide data characters (occurrences of the symbols :, ., /, +).

Codabar supports the concatenation of two or more adjacent Codabar symbols into a single message. The reader will respond to symbols ending with the D stop character by waiting and looking for an adjacent symbol within 0.75 inch (19 mm) with a D start character. If the second symbol is found, the two data messages are concatenated into one with the D characters omitted. This procedure works bidirectionally and can concatenate any number of labels in a row up to the maximum message length allowed by the reader.

As an option for use with more traditional printing methods, Traditional Codabar can be used.

Traditional Codabar is completely compatible with Rationalized Codabar previously described. Figure 6 (found on page 10) shows the precise bar and space widths for each Codabar character when printed at a maximum density of 10 characters per inch. At this density, the allowable printed element width tolerance is:

$$T = \pm 0.0015 \text{ inch (0.038mm)}$$

When larger bar and space widths or printing tolerances are required, a lower print density can be achieved by applying a uniform magnification factor to all given dimensions including the tolerance. Within a given symbol, the density must be held constant.

1.4 Code 128

The characters in Code 128 are constructed of 11 modules arranged into three bars and three spaces. The bars have an even number of modules, and the spaces have an odd

number of modules. Bars are present at the exterior to facilitate the reading of high density symbols.

Bar code integrity is maintained by the presence of two self-checking features, via parity and a modulo 103 check character.

The series of the bar coded characters begins with a unique start character, followed by data and special characters, the check character, and the unique stop character. The stop character is unique in that it is composed of 13 modules of four bars and three spaces. The reader does not transmit start/stop characters.

- The minimum nominal narrow element width is 0.0075 inch (0.19 mm).
- The maximum nominal narrow element width is 0.020 inch (0.51 mm).
- The nominal ratio of the wide elements to the width of the narrow elements is between 2.2:1 and 3:1.
- The minimum height of the bar code is 0.375 inch (9.5 mm) or 15 percent of the symbol's length, whichever is greater.
- Three printing tolerances apply to a Code 128 symbol (see figure 1-1):

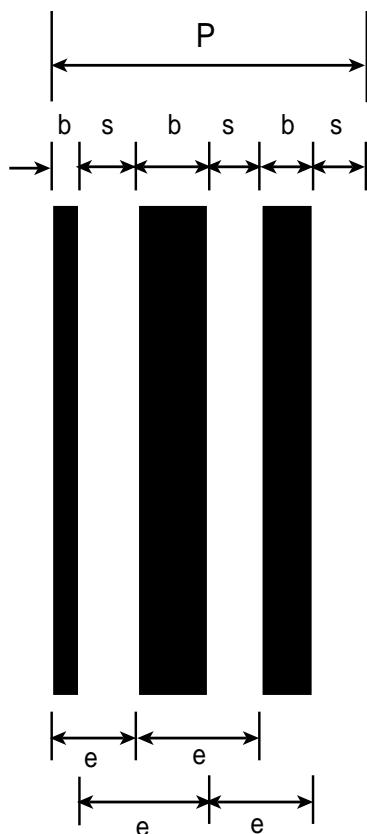


Figure 1-1. Code 128 Printing Tolerances

- b = deviation of individual bar or space width from the nominal dimension
- e = deviations from the nominal width between an edge of one bar and the similar edge of an adjacent bar
- p = deviations from nominal of the overall character width

The Code 128 printing tolerances are:

$$b = (\pm 0.40X - 0.0005) \text{ inch}$$

$$e = \pm 0.20X$$

$$p = \pm 0.20X$$

where X = the nominal narrow element width.

- The symbol length for Code 128 can be calculated as follows:

$$L = ((5.5D + 11C + 35) X) + 2Q$$

Where: L = length of symbol

D = the number of digits in the numeric fields
(note that one data character can encode two numeric digits if character subset C is used)

C = the number of ASCII characters not included in D, plus the number of function characters, plus the number of shift characters required

X = the nominal narrow element width

Q = the width of the quiet zone

1.5 ISBT 128

ISBT 128 bar code symbology uses a specific format for labels that contain the Donation Identification Number and is implemented using code 128 symbology. ISBT 128 bar codes contain the following 16 character format:

P αpppp yy nnnnnn ff

Where: P = is the primary data identifier ('=' or '&')

αpppp = designates the country/collection facility

yy = designates the year in which the donation was made

nnnnnn = is the serial number associated with the donation

ff = represent special flag characters

The VITROS ECi System Universal Sample Bar Code Reader will read the ISBT bar code. However, the ECi System Sample ID field has a maximum of 15 characters. Therefore, the ISBT 128 primary data identifier and special flag character fields will be removed after the Universal Sample Bar Code Reader scans the bar code. The ECi System Sample ID will contain 13 characters representing the country and collection facility, the year in which the donation was made, and the serial number associated with the donation.

The following 13 character format will be used by the ECi System for the ISBT 128 bar code:

αppppyy nnnnnn

Where: αpppp = designates the country/collection facility

yy = designates the year in which the donation was made

nnnnnn = is the serial number associated with the donation

Since the ECi System will interpret the ISBT 128 bar codes as 13 characters, Sample ID's manually programmed in Sample Programming and downloaded from a Laboratory Information System (LIS) must contain 13 characters to match the ISBT 128 bar code read by the Universal Sample Bar Code Reader.

IMPORTANT: If the donation serial number described above (nnnnnn) is less than six digits, leading zeros must be added to retain the 13 character Sample ID required by the ECi System.

If necessary, you should contact your LIS vendor for more information on configuring your Laboratory Information System to support ISBT 128 bar code symbology and proper communication protocol with the VITROS ECi System.

2.0 Check Characters

2.1 Interleaved 2 of 5

The added check character for Interleaved 2 of 5 symbols is calculated as a modulo 10 check digit based on alternate 1, 3 weightings of the data characters. The weighting is arranged so that the least significant digit is on the far right of the data stream and receives a 3 weight. For example:

Data Characters: 4 3 8 2 7

Weights: 3 1 3 1 3

$$\begin{aligned} \text{Weighted Sum} &= (3 \times 4) + (1 \times 3) + (3 \times 8) + (1 \times 2) + (3 \times 7) \\ &= 62 \end{aligned}$$

The check digit for the data characters is that which is added to the weighted sum producing a sum ending in 0. The check digit for the example is 8. The check digit is appended as the least significant digit to produce the result:

Data + Check Digit = 4 3 8 2 7 8

A leading zero will be required if an even number of data characters are to be appended with a check character to produce a result with an even number of characters.

2.2 Code 39 Check Character

The check character for Code 39 is positioned immediately following the final data character and before the stop character. Each data character is assigned a numerical value as shown in figure 2-1. The sum of the numerical values for all data characters of a symbol is calculated. The modulo 43 value of the calculated sum is used as the value for the check character. For example:

Symbol = TEST

T = 29

E = 14

S = 28

T = 29

$$29 + 14 + 28 + 29 = 100$$

$$100 \text{ Modulo } 43 = 14$$

14 = E

Symbol with Check Character = TESTE

Note: Code 39 Check Character Computation does not include start/stop characters.

Character	Value	Character	Value
0	0	M	22
1	1	N	23
2	2	O	24
3	3	P	25
4	4	Q	26
5	5	R	27
6	6	S	28
7	7	T	29
8	8	U	30
9	9	V	31
A	10	W	32
B	11	X	33
C	12	Y	34
D	13	Z	35
E	14	-	36
F	15	.	37
G	16	space	38
H	17	\$	39
I	18	/	40
J	19	+	41
K	20	%	42
L	21		

Figure 2-1. Code 39 Character Values.

2.3 Codabar Check Character

The check character for Codabar is positioned immediately following the final data character and before the stop character. Each Codabar character is assigned a numerical value as shown in figure 10. The sum of the numerical values for all the message characters (data characters + start/stop characters) is calculated. The modulo 16 value of the previously calculated sum is obtained. The check character value is that number which, when added to the sum of the numerical values of the message characters, produces a modulo 16 value of 0. In this way, the modulo 16 sum of the full symbol with the check character becomes 0. For example:

Symbol without check character = A37859B

$$A = 16$$

$$3 = 3$$

$$7 = 7$$

$$8 = 8$$

$$5 = 5$$

$$9 = 9$$

$$B = 17$$

$$16+3+7+8+5+9+17 = 65$$

$$65 \text{ modulo } 16 = 1$$

In this example, with a modulo 16 value of 1, 15 must be added to the sum of 65 to result in a modulo 16 value of 0; therefore, the check digit value is 15 which, from [figure 2-2](#) translates to “+,” resulting in a final symbol incorporating check character: A37859 + B.

Note: The Codabar Check Character computation includes start and stop characters.

Character	Value	Character	Value
0	0	-	10
1	1	\$	11
2	2	:	12
3	3	/	13
4	4	.	14
5	5	+	15
6	6	A/a/T/t	16
7	7	B/b/N/n	17
8	8	C/c/*	18
9	9	D/d/E/e	19

Figure 2-2. Codabar Character Numerical Values.

2.4 Code 128 Check Character

The Code 128 check character verifies the accuracy of the bar code. The value of the check character is equal to the modulo 103 sum of the start character and the weighted values of the data or special characters. The check character value is calculated as follows:

Symbol without check character = Start B 9710

Weights = 1234

$$\begin{aligned} \text{Weighted Sum} &= 104 + (25 \times 1) + (23 \times 2) + \\ &\quad (17 \times 3) + (16 \times 4) \\ &= 290 \end{aligned}$$

Divide 290 by 103, resulting in 2 with a remainder of 84. Refer to “Code 128 Bar Code Symbology.” [figure 5-5, on page 3](#). The check character is “t”, which has a value of 84 in the Code B column of that figure.

Note: The Code 128 check character computation includes the start character, but not the stop character.

3.0 Optical Parameters

3.1 Bar Code Reflectance

- Reflectance variations may be caused by spots, voids, smudges, or other defects that may interfere with decoding since scanners respond to reflectivity differences. The following reflectance measurements are not independent and must be considered simultaneously. [Figure 3-1](#), Bar Code Symbol Reflectance Measurement Techniques shows the bar code reflectance measurement process and shows the main measurement parameters.

- Minimum Space Reflectance ($R_s(\min)$)

The minimum reflectance within each space is equal to or greater than 37.5 percent.

- Maximum Bar Reflectance ($R_b(\max)$)

The maximum reflectance within each bar is 30 percent.

- Minimum Reflectivity Difference (MRD)

The measure of the reflectivity difference is MRD.

Figure 3-1 shows what the MRD is, as a scanning aperture.

passes through a bar code symbol.

$$\text{MRD} = \text{Rs(min)} - \text{Rb(max)}$$

The minimum reflectivity difference (MRD) is equal to or greater than 37.5 percent.

- **Element Reflectance Uniformity of a Single Element (ERU)**

Element reflectance uniformity is limited in proportion of the value of MRD. Each element of the symbol must meet the following requirement:

ERU ≤ 0.25 MRD.

- **Symbol Reflectance Uniformity of Bars Across Entire Symbol (SRUB)**

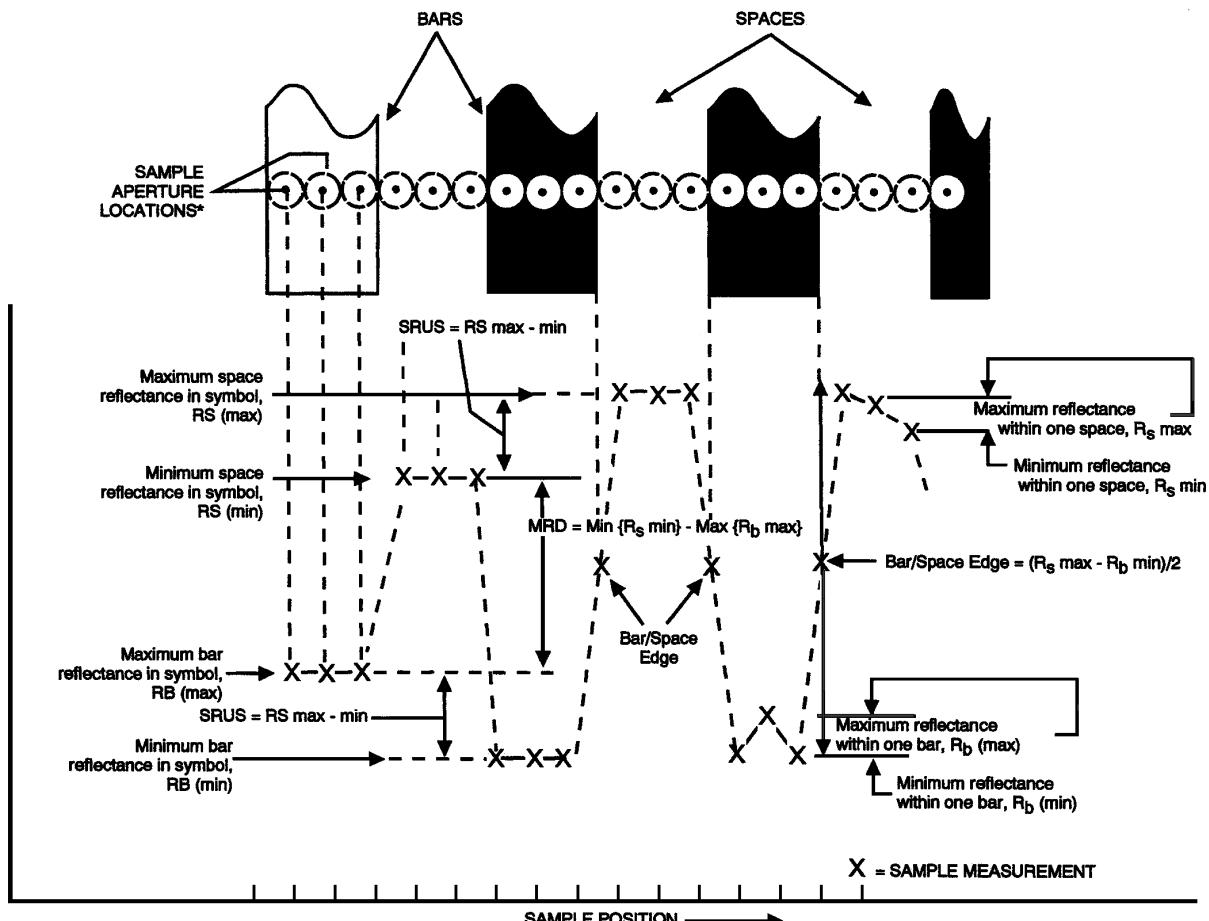
Symbol reflectance uniformity of bars is limited in proportion to MRD:

SRUB \leq 0.5 MRD.

- **Symbol Reflectance Uniformity of Spaces Across Entire Symbol**

Symbol reflectance uniformity of spaces is limited in proportion to MRD:

SRUS ≤ 0.5 MRD.



***Note:** For illustration purposes the aperture position is shown in discrete steps, in actuality the aperture is moving continuously.

Figure 3-1. Bar Code Symbol Reflectance Measurement Techniques

3.2 Print Contrast Signal (PCS)

As an alternative to using the bar code reflectance measurement methodology that makes use of MRD, bar code reflectance may also be checked using the Print Contrast Signal (PCS).

- The minimum print contrast signal (PCS) is 0.75, where:

$$\text{PCS} = \frac{\text{space reflectance (RL)} - \text{bar reflectance (RD)}}{\text{space reflectance}}$$

- The minimum space reflectance (RL) is 50 percent.

3.3 Spots and Voids

When PCS is used to check bar code reflectance, spots and voids must also be checked using the following method. Spots and voids that meet either of the following criteria are permitted:

- The spot or void can be contained within a circle, the diameter of which is 0.4 times the nominal narrow element width.
- The spot or void occupies no more than 25 percent of the area of a circle, the diameter of which is 0.8 times the nominal narrow element width. Larger spots and voids can be expected to degrade symbol readability.

4.0 Measurement Methodologies

4.1 Reflectivity

All bar code measurements are made with a reader having its peak response at 633 nanometers \pm 5 percent and having a half power band width no greater than 120 nanometers (in which there are no secondary peaks).

Reflectivity measurements are made with a source of incident irradiation of 45 degrees from a normal to the surface and in a plane containing the source irradiation element that is both normal to the surface and parallel to the bars. The reflected flux shall be collected within a 15 degree angle center about the normal. A measuring aperture of 0.006 inches (0.152 mm) is used. Reflectivity is measured with diffuse light relative to barium sulfate or magnesium oxide which shall be 100 percent.

4.2 Opacity

Opacity is the ratio of diffuse reflectance (R2) of a sample sheet of substrate, backed with a black surface of not more than 5 percent reflectance, to the diffuse reflectance (R1) of the same sheet backed with a white surface that has a minimum reflectance of 89 percent. Opacity is calculated as follows:

$$\text{Opacity} = R2/R1.$$

The concern is limiting the see-through problem.

4.3 Reflectance

The infinite pad method, as defined in the glossary, is used for measuring reflectance.

4.4 Element Width Measurement

The element width is the distance between its two edges. The element edge is defined as the location of the center of the measuring aperture when the aperture is in a position such that the observed reflectance is midway between the maximum reflectance of the adjacent space and the minimum reflectance of the adjacent bar.

5.0 Determination of Conformance

5.1 Verification Techniques

Verification of printed bar code conformance to specification can be done using manual and automatic inspection techniques with instruments having optical characteristics described in the Measurement Methodologies section.

5.2 Scan Criteria

A minimum of three scans are made through the bar code symbol as shown in figure 5-1. These scans are made parallel to the length of the bar code symbol. The scans are approximately to the length of the bar code symbol. The scans are considered conforming to the specification if it meets the following criteria:

- Dimensions
- Reflectance
- Correct character encodation

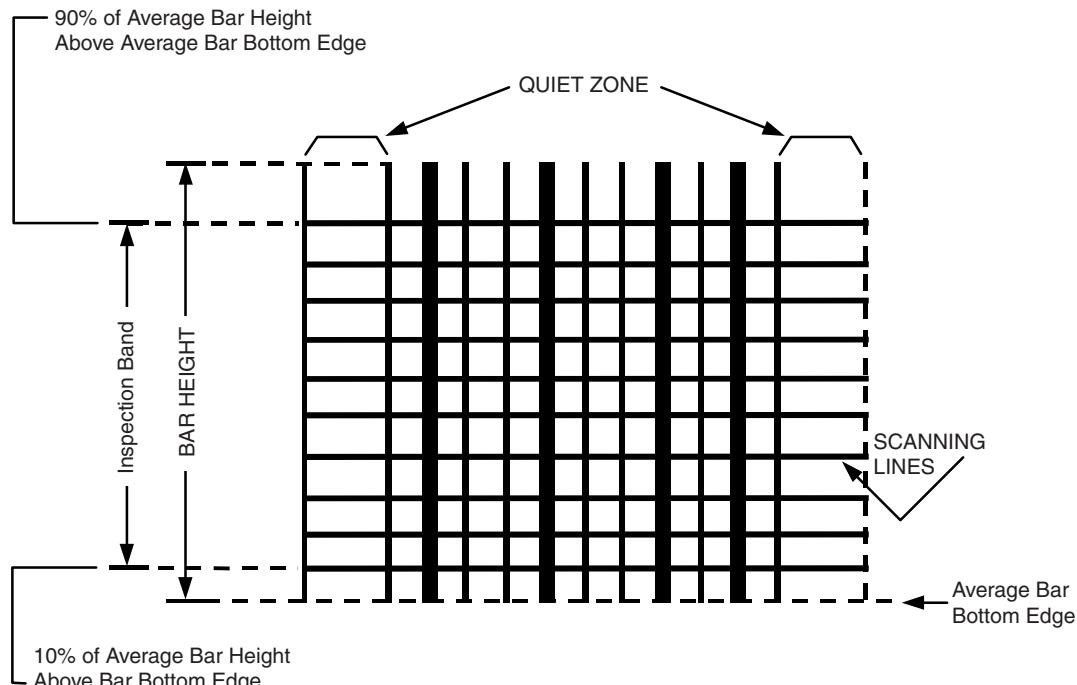


Figure 5-1. Scan Criteria.

5.3 Symbol Acceptance Criteria

The symbol is considered in conformance to its specification if 2/3 of the scans pass the criteria specified in the Appendix, section 5.2.

5.4 Sampling Methods and Levels

The sample size is sufficiently large to be statistically valid within the size of the lot or batch being inspected.

Automatic Tip Loader (ATL) Guide



Revision History

Revision Date	Description
9/01	Logo change on page 3-3.
2/01	New or revised information: <ul style="list-style-type: none">• New information regarding discarded sample tips.
2/98	Reflects support of <i>Vitros 250AT Chemistry System</i> .
3/97	First release of manual.

List of Revised Pages

Each page in your manual should be at the date listed below:

Publication Date	Chapter	Page
9/01	Chapter 3	Page 3-3
2/01	Chapter 1	Page xi
	Chapter 2	Page 2-7
	Chapter 5	Page 5-1
2/98	All chapters	All pages
3/97	All chapters	All pages

Table of Contents

Safety and Precautions

Bloodborne Pathogens	v
Precautions Regarding Maintenance	xi
Cleaning the Automatic Tip Loader.....	xi

1 Introduction

Intended Use	1–1
Automatic Tip Loader Components	1–2

2 Startup and Initialization

Pneumatic Tubing Routing	2–1
Physical Connection of the ATL to the Vitros AT System	2–2
Tube Connection to the ATL	2–2
Tube Connection to the Vitros 950AT Chemistry System	2–2
Tube Connection to the Vitros 250AT Chemistry System	2–3
Startup and Shutdown	2–4
Startup	2–4
Shutdown	2–5
Priming Sequence	2–6
Loading Tips	2–7

3 User Interface

General Information	3–1
Keypad Functionality	3–3
Menu Features	3–4
Configuration	3–4
Diagnostics	3–5
Historical Data	3–9
Status	3–11

4 Troubleshooting

Troubleshooting Procedure	4-2
Recovery Procedures	4-3
Status Codes	4-5
Clearing Analyzer Tip Jams on the Vitros 950AT System	4-6
Clearing Analyzer Tip Jams on the Vitros 250AT System	4-8

5 Maintenance

Cleaning ATL Components	5-1
Cleaning the Bowl	5-1
Cleaning the Linear Rail	5-1
Air Filter Maintenance	5-2
Replacing the filter	5-2

Safety and Precautions

Proper Use of Equipment

If this equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired. Only authorized Ortho-Clinical Diagnostics, Inc. service personnel are allowed to move the unit from one power supply receptacle to another. Equipment operators should follow OSHA/CDC/NIH/WHO guidelines and wear safety glasses.

Electrical Hazards

Potential electrical hazards exist behind the side, front and back panels of the *Vitros* Automatic Tip Loader. Keep doors, covers and panels closed during normal operation.

Bloodborne Pathogens

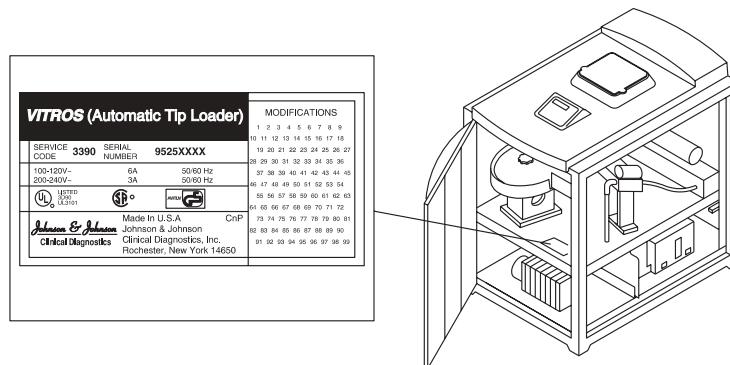
Universal Precautions following the OSHA Bloodborne Pathogens Standard and the CDC/NIH and WHO (World Health Organization) guidelines should be observed at all times when dealing with blood or body fluid and contaminated equipment.

Automatic Tip Loader Labels

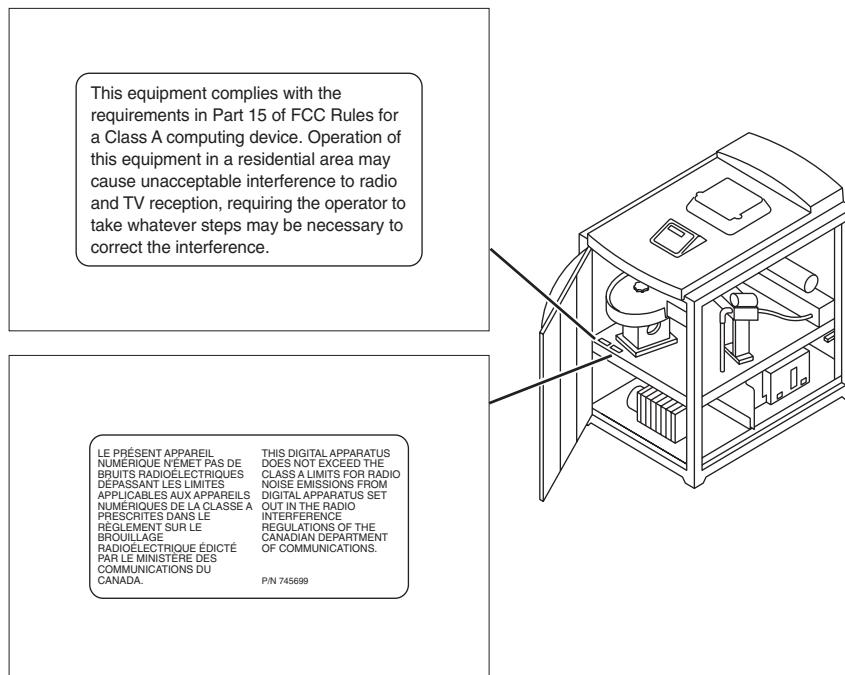
Listed below are the warning, safety, and miscellaneous labels on the tip loader. Illustrations are contained on the following pages.

- *Vitros* Automatic Tip Loader Dataplate/Hardware Modifications
- FCC /CDOC
- I/O Ports
- AC Fuse Label
- Hot Surface
- Mechanical Pinch Point
- Static Sensitive Icon
- Caution: Static Sensitive Components
- High Voltage
- Main Power Ground

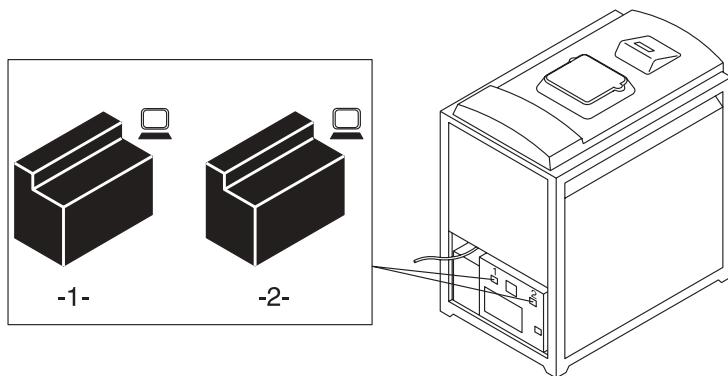
Vitros Automatic Tip Loader Dataplate/Hardware Modifications



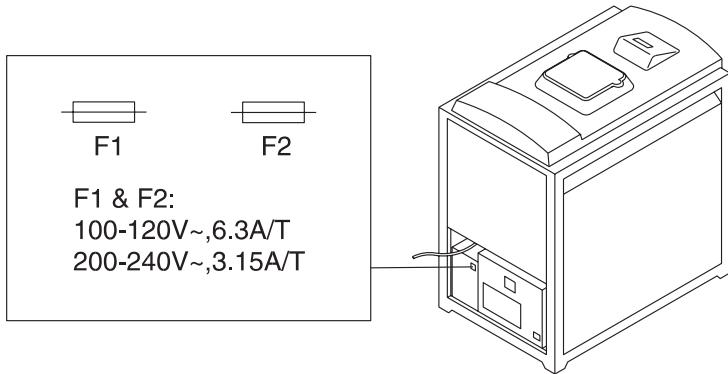
FCC/CDOC



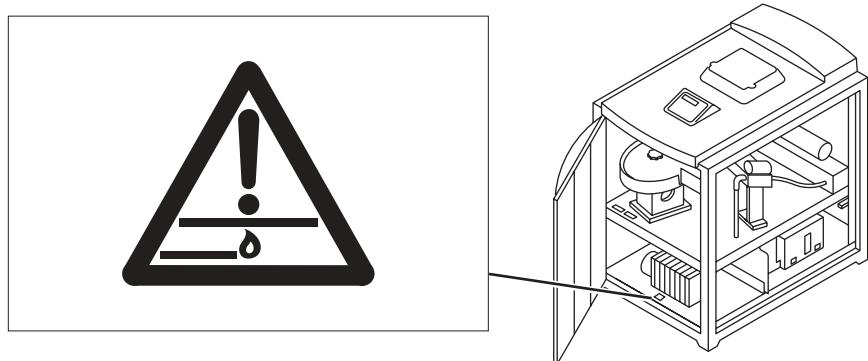
I/O Ports



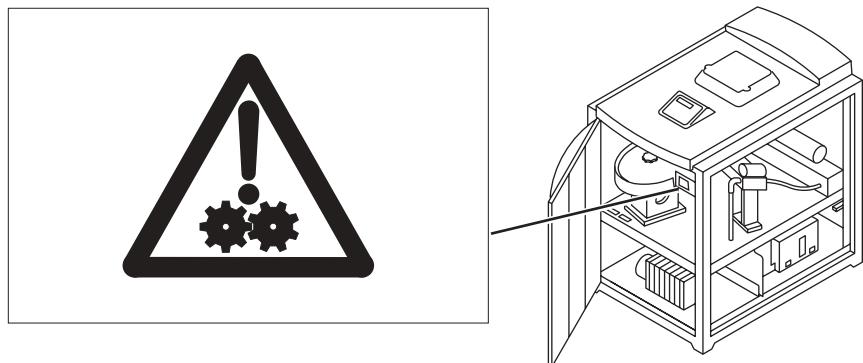
AC Fuse Label



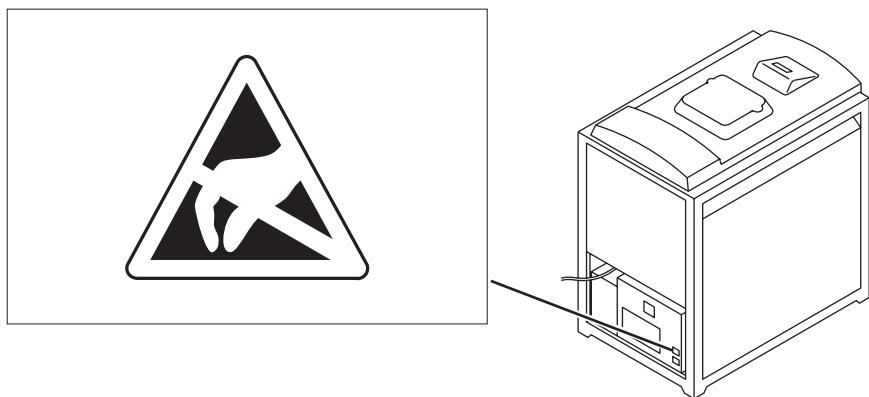
Hot Surface



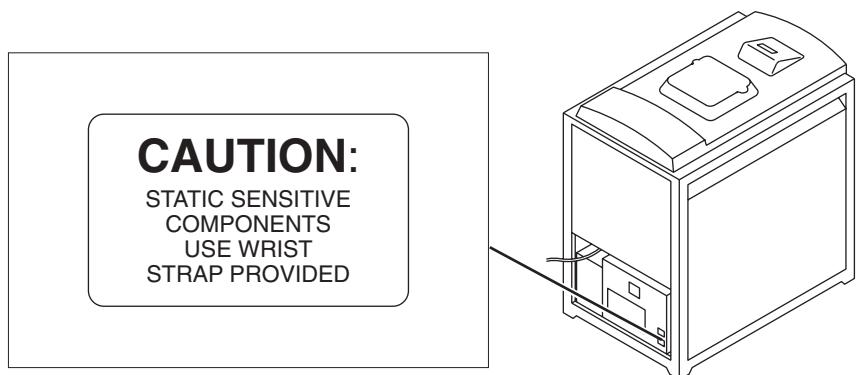
Mechanical Pinch Point



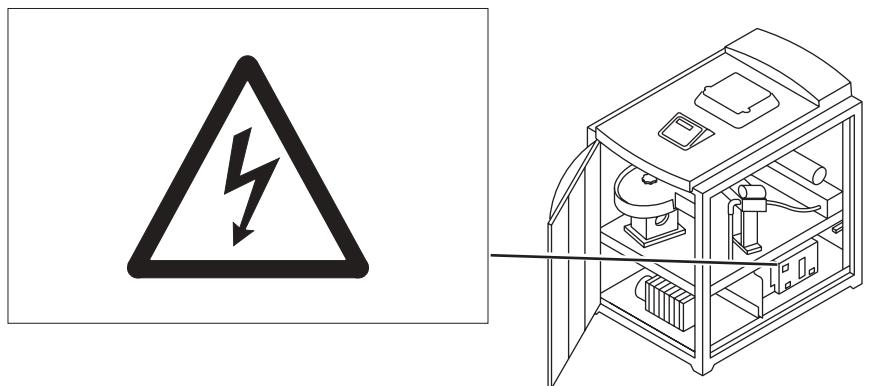
Static Sensitive Icon



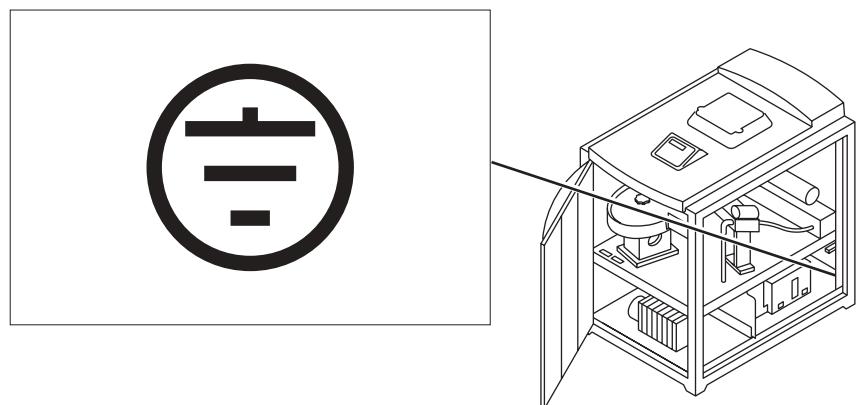
Caution: Static Sensitive Components



High Voltage



Main Power Ground



General Precautions

Moving Parts

Wherever there are moving parts, such as the hopper belt drive, bowl, and escapement, use caution when correcting malfunctions.

Precautions Regarding Maintenance

We recommend that the key operator perform all periodic maintenance procedures.

The *Vitros* Automatic Tip Loader should be powered off during any electrical or mechanical maintenance.

WARNING: *When removing pneumatic tubing from the analyzer, do not point the end of the tubing toward your face.*

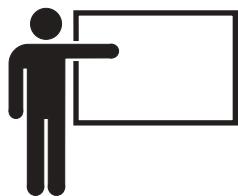
IMPORTANT: Do not re-load discarded sample tips found outside the hopper or bowl area. They may be damaged or contaminated.

Cleaning the Automatic Tip Loader

Cleaning Solvents

Do not use any solvents or cleaning solutions other than distilled or deionized water. See Chapter 5, Maintenance, for further instructions. Never use ammonia cleaners on or near the ATL.

CAUTION: *Do not use solvents, isopropyl alcohol, ammonia, or cleaning agents containing abrasives to clean the user interface screen. These items will damage the touch screen and impair your ability to interact with the tip loader computer. Use only non-ammonia glass cleaner.*



Introduction

Intended Use

The *Vitros* Automatic Tip Loader (ATL) is a free-standing apparatus that automates the manual process of loading tips on the *Vitros* 250AT and *Vitros* 950AT Chemistry Systems. The ATL delivers tips to the tip shuttle of a single analyzer through pneumatic tubing. The tip shuttle then positions the tip for pickup by the proboscis. The tip shuttle is equipped with a tip-present sensor to verify that a tip has been received from the *Vitros* Automatic Tip Loader.



Introduction

Automatic Tip Loader Components

Automatic Tip Loader Components

The *Vitros* Automatic Tip Loader (ATL) consists of the following components:

Actuation Counter A counter attached to the front frame of the ATL that keeps a continuous count of the sample tips dispensed.

Air Filter A filter on the air pump that cleans the air used to deliver the tips to the analyzer.

Air Pump A pump that provides a low pressure volume of air to move disposable tips through a predetermined length of tubing.

Bowl A housing for the rotating disk used to sort, orient, and transport tips from the hopper to the linear rail on an as needed basis.

Escapement A cylindrical device that captures and positions tips for delivery.

Hopper A stainless steel tip storage container that holds up to 2000 disposable tips. The hopper also includes a belt drive used to transport tips from the hopper to the bowl on an as needed basis.

Return Tray A tray that diverts nested tips away from the linear rail back to the bowl.

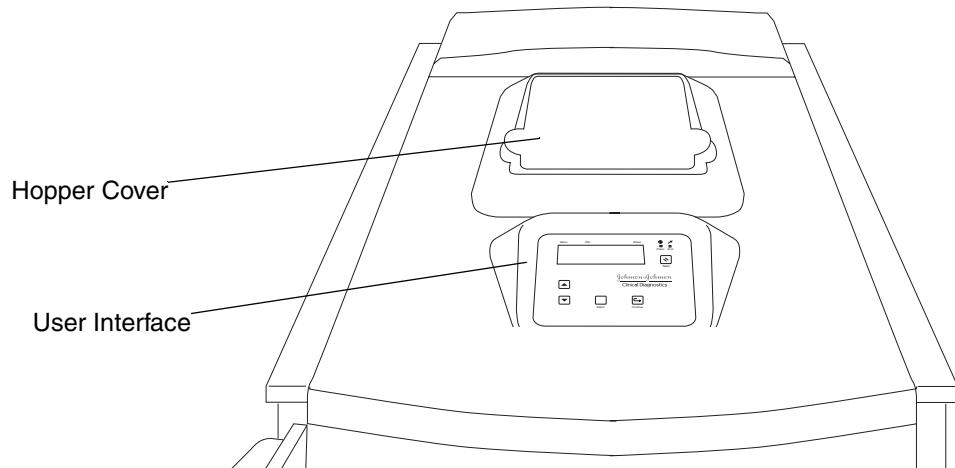
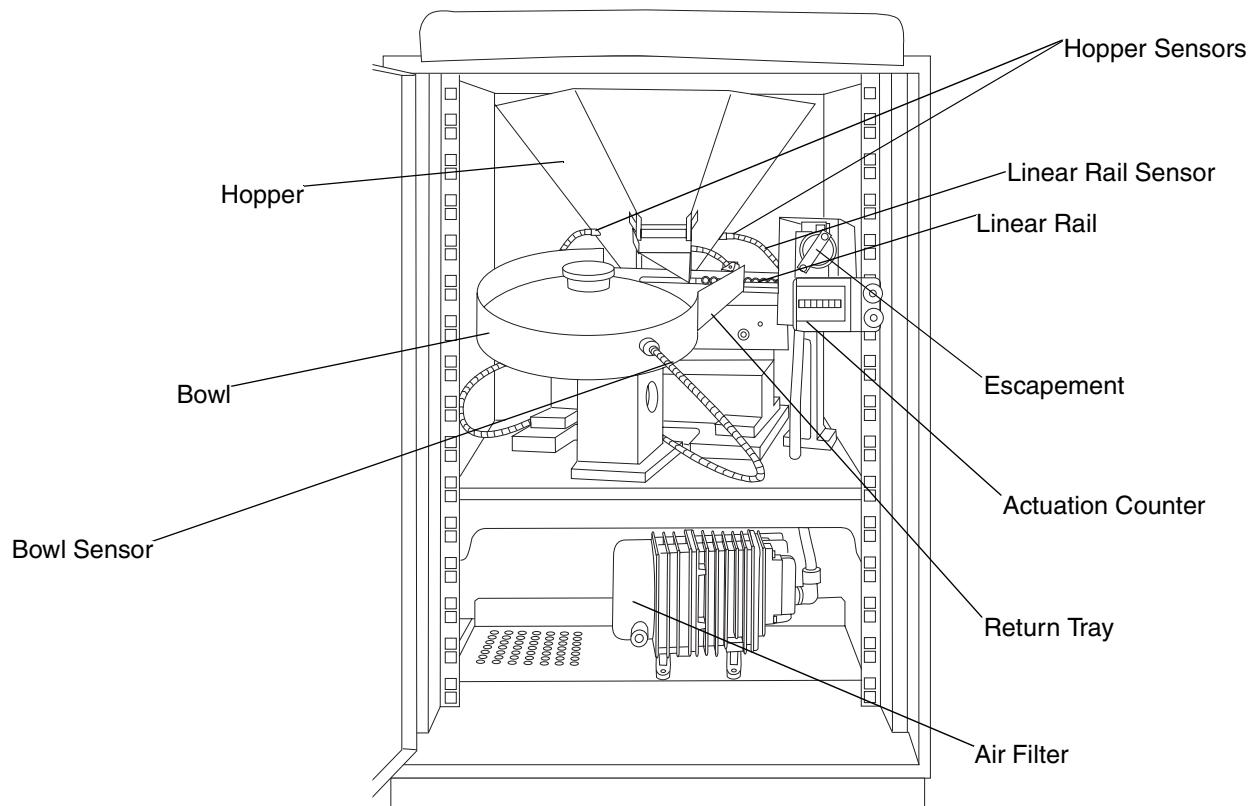
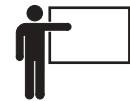
Sensors Fiber optic sensors that monitor the quantity of tips in the hopper, bowl, and linear rail.

Linear Rail A vibrating track consisting of two parallel plates. The rail consistently orients disposable tips and transports them to the escapement.

User Interface A screen and keypad that allows the operator to monitor tip loader status.

Introduction

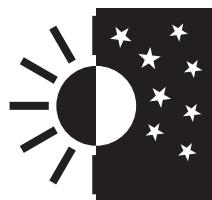
Automatic Tip Loader Components





Introduction

Automatic Tip Loader Components



Startup and Initialization

Pneumatic Tubing Routing

The *Vitros* Automatic Tip Loader (ATL) delivers tips to one *Vitros* 250AT or *Vitros* 950AT Chemistry System through pneumatic tubing. The ATL must be located within 50 feet of the analyzer.

Tubing routed from the ATL to the *Vitros* AT System must adhere to the following criteria:

- Length must be between 10 and 50 feet
- No tubing routed on the floor surface
- Anchored properly with devices that do not deform the cross-section geometry of the tubing
- No bends in the tubing tighter than a radius of 6.5 inches
- No loops along the entire length



Startup and Initialization

Physical Connection of the ATL to the Vitros AT System

Physical Connection of the ATL to the *Vitros AT System*

Before connecting the pneumatic tubing to the ATL or the *Vitros AT System*, be sure the ends of the tubing are clean and square. **Re-trim to achieve a clean, square cut if necessary.**

Tube Connection to the ATL

1. To connect the tubing to the escapement you must first feed one end of the tubing into the guide tube located on the back of the ATL. This guide tube protects the tubing as it exits the ATL frame.
2. Remove the right side panel of the ATL to gain access to the escapement.
3. Loosen the Allen head screws located on the rear of the escapement and carefully seat the tubing in the escapement so it is flush with the exit chamber.
4. Open the escapement and visually verify that the tubing is aligned with the escapement exit chamber such that a smooth tip transition can be made. Close the escapement when done.
5. Tighten the Allen head screws.
6. The guide tube will rotate 360 degrees to allow the tubing to be routed in any direction.

Tube Connection to the *Vitros 950AT Chemistry System*

1. To provide access to the *Vitros 950AT* tube pathway, remove the front and rear Sample Metering covers.
2. Route the tubing in through the back of the *Vitros 950AT* System. Use the brackets provided to guide the tubing to the tip shuttle housing.
3. Remove the brass fitting from the tip shuttle housing.
4. Loosen the fitting and insert the tubing. Tighten the fitting.
5. Place the fitting, with the tubing attached, into the tip shuttle housing.
6. Replace the front and back Sample Metering covers.

Startup and Initialization

Physical Connection of the ATL to the Vitros AT System



Tube Connection to the *Vitros 250AT Chemistry System*

1. To provide access to the *Vitros 250AT* tube pathway, remove the side Sample Metering cover.
2. Route the tubing in through the back of the *Vitros 250AT* System. Use the metal elbow provided to guide the tubing to the tip shuttle housing.
3. Loosen the brass fitting and insert the tubing. Tighten the fitting.
4. Replace the side Sample Metering cover.



Startup and Initialization

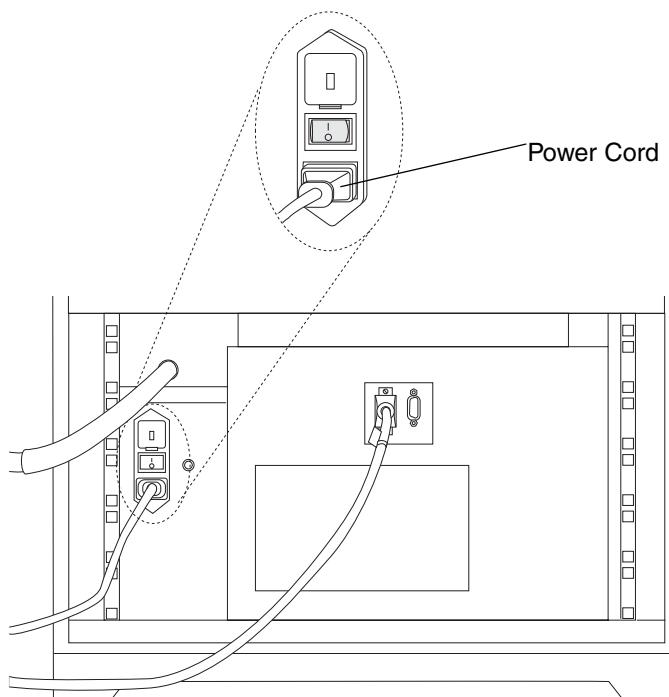
Startup and Shutdown

Startup and Shutdown

Startup

Follow these steps to start the ATL:

1. Connect the ATL power cord to a 115 vac outlet.

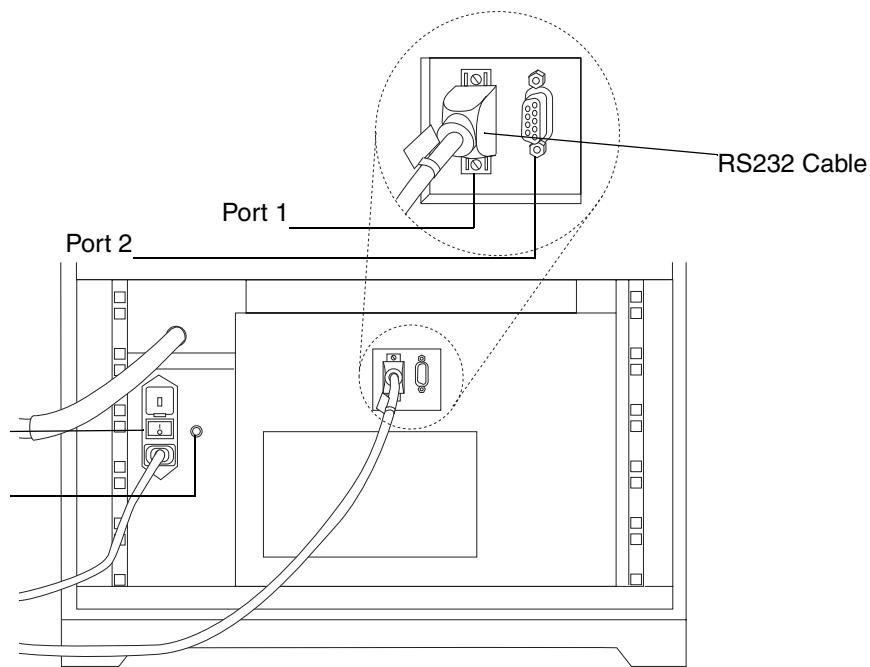


Startup and Initialization

Startup and Shutdown



2. Connect the RS232 cable to the analyzer -1- port (Port 1) of the electronics module located on the rear of the ATL.



3. Plug the opposite end of the RS232 cable into the ATL port of the IAC board of the Vitros AT System.
4. Flip the black power switch located on the back panel to the ON position. The green light located near the power switch will illuminate.

At startup, no mechanical movement should occur. The user interface will be blank for 3-4 seconds and then a “HEALTH CHECKS PASSED, WAITING FOR ANALYZER” message appears.

NOTE: Software will initially be downloaded from the Vitros AT System to the ATL the first time they are powered up together as a system.

Shutdown

Whenever the Vitros AT System is shut down, the ATL should also be shut down. This is accomplished by simply flipping the power switch to the OFF position. When restarting, start up the ATL first. The analyzer should be restarted when the “HEALTH CHECKS PASSED...” message appears on the ATL user interface.



Startup and Initialization

Priming Sequence

Priming Sequence

Once the “HEALTH CHECKS PASSED, WAITING FOR ANALYZER” message appears on the ATL user interface, communication can be established with the *Vitros* AT System.

NOTE: If the hopper is empty, place 4 boxes of *Vitros* Clinical Chemistry Disposable Tips (2,000 tips) in the hopper before the REINITIALIZE target is selected. Once communication has been established, refer to the procedure for loading tips later in this section to update the tip inventory.

To establish communication, select the REINITIALIZE target on the *Vitros* AT System Error Log screen (ER01A). Once this is done, the user interface on the ATL will display the Main Menu, and once communication is established, the ATL priming sequence will begin.

NOTE: The sequence described above applies if the ATL has been powered up or down *independent* of the *Vitros* AT System. If the ATL and analyzer are powered up together, the menu on the ATL will automatically display the Main Menu during analyzer initialization, and communication should also be established at this time.

The priming sequence is as follows:

- Tips are transported from the hopper to the bowl via the motor driven belt drive.
- Tips transported to the bowl will then be transported to the linear rail by the clockwise rotation of the bowl.
- Any tips that do not enter the linear rail will be rerouted back to the bowl.
- Tips that enter the linear rail will be transported to the escapement. When the sensor indicates that the linear rail is full, the ATL will go into an idle mode until more tips are required.

The *Vitros* Automatic Tip Loader is now operational.

Startup and Initialization

Loading Tips



Loading Tips

During normal operation the *Vitros* Automatic Tip Loader will continuously supply tips to a *Vitros* 250AT or *Vitros* 950AT Chemistry System. Sample tips can be loaded at any time without interrupting operations. The tip count appears on the user interface Main Menu. The tip count must be updated every time tips are loaded into the ATL.

NOTE: In most cases, an entire box of sample tips should be loaded into the ATL. All partially used boxes should remain closed between uses.

IMPORTANT: **Do not** load *Vitros* Microtips (used with the *Vitros* DT60 II Chemistry System and the *Vitros* 250 Chemistry System reference fluid) in the ATL. Using *Vitros* Microtips will cause the ATL to jam.

To update the tip inventory at any time follow these steps:

Menu	Title	Status
M00-MAIN MENU	OK	

Tip Inventory: 294
SELECT for submenu,
DOWN-ARROW to load.

1. From the Main Menu (M00), press the down ARROW key to enter the Load Tips screen (M01).

Menu	Title	Status
M01-LOAD TIPS	OK	

Fill hopper with
proper tips and
press UP-ARROW key.

2. Load 4 boxes of sample tips into the hopper and close the hopper cover.

NOTE: To reduce the chances of damaging sample tips, do not fill the hopper above the lower lip of the top cover.

IMPORTANT: Do not re-load discarded sample tips found outside the hopper or bowl area. They may be damaged or contaminated.

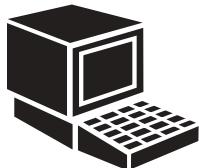


Startup and Initialization

Loading Tips

3. Press the up ARROW key to update the inventory to 2,000.
 - a. If 4 boxes were added, this will satisfy the hopper sensors and the Main Menu screen will be updated to 2,000.
 - b. If fewer than 4 boxes were added, and the hopper sensors are not satisfied, the Main Menu screen (M00) will not be updated and the tip count will remain 0.
 - c. During normal operation, an audible low tip warning will sound on the ATL when the tip count reaches 300 and a message will be posted on the analyzer. No other low tip warning alarm will be given on the ATL; however, periodic messages will be posted on the analyzer until the tip count reaches 0.
4. Press the CONTINUE key once to return to the Main Menu (M00).

User Interface



The *Vitros* Automatic Tip Loader user interface is composed of the keyboard input, menu system, LED indicators, and audible alarm. This chapter describes keypad functionality and menu usage. LED indicators and audible indicators are discussed in Chapter 4, Troubleshooting.

General Information

The user interface allows you to monitor *Vitros* Automatic Tip Loader operation and status through a menu system. Three levels within the menu system provide you with the necessary information. The Main Menu is displayed during normal operation. Other menus provide configuration, diagnostics, historical data, and status details.

Each menu within the system is identified by an alphanumeric screen designator that is displayed in the upper left corner of the screen. Also displayed in the right corner of each screen is the tip loader system status. This status will be one of the following:

OK ATL is operational.

INIT ATL hardware is initializing and unavailable.



User Interface

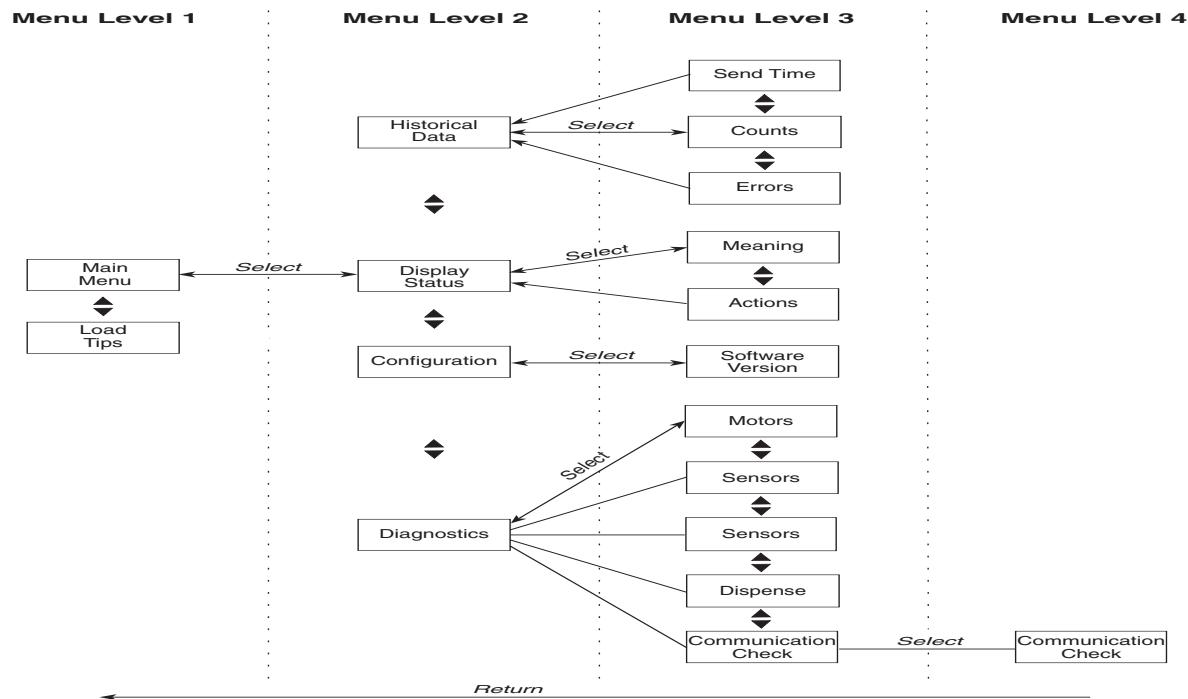
General Information

INOP ATL is reduced as a result of running out of tips or a hardware failure.

LOW ATL is operational, but has less than 300 tips.

AIR Tip delivery times are approaching the maximum allowable.

FULL Tip supply is operational but there are too many tips in the bowl.



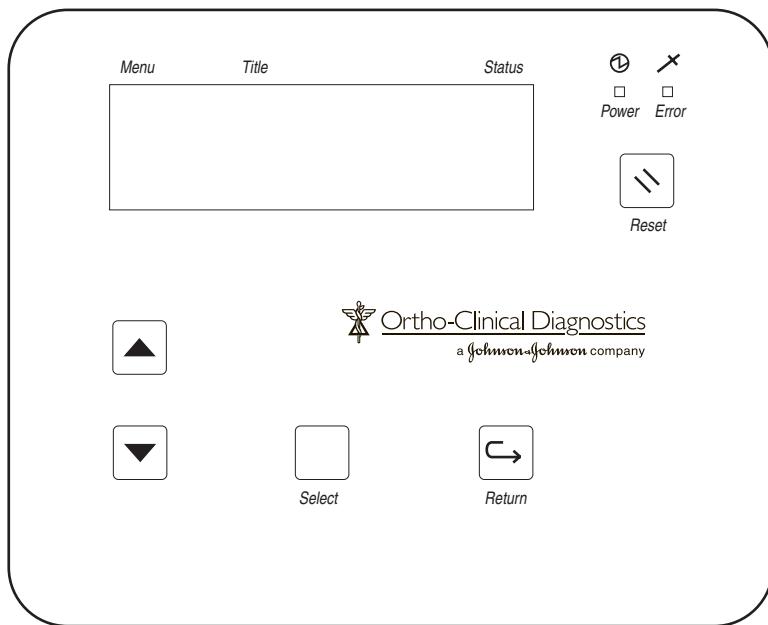
User Interface

Keypad Functionality



Keypad Functionality

The user interface keypad allows you to navigate through the menu system. The illustration below shows the menu screen and keypad.



SELECT This key allows you to move down through the levels of the user interface menu system. For example, to move from the Main Menu to the Display Status screen, use the SELECT key.

ARROW keys The up and down arrow keys allow you to scroll through the screens within a menu level. Both the up or down arrow keys scroll through the screens within the level in a continuous loop. For example, either the up or down arrow key will allow you to scroll to the Counts, Errors, or Send Time subfunctions under Historical Data.

RETURN This key allows you to move to a previous level within the menu system. For example, to move from the Counts screen to the Historical Data screen, and then from the Historical Data screen to the Main Menu, use the RETURN key.

RESET When pressed after an error condition, RESET puts the escapement in the home position, and delivers tips to the bowl or linear rail as required. Further troubleshooting may also be required to correct an error condition.



User Interface

Menu Features

Menu Features

This section describes the purpose and use of each menu within the *Vitros* Automatic Tip Loader user interface.

Configuration

This screen allows you to view the current software version of the ATL.

1. From the Main Menu (M00), press the SELECT key.
2. Use the up or down ARROW key to scroll within the screen level until you find the Configuration screen (C00).
3. Press the SELECT key. This allows you to view the current software loaded on the ATL.

Menu	Title	Status
C01-SW VERSION	OK	

Software Version
Number: V29

4. Press the RETURN key two times to return to the Main Menu (M00).

User Interface

Menu Features



Diagnostics

This screen allows you to monitor hardware functions. From the main Diagnostics screen you can access the Motors, Sensors, Dispense, and Communication Check screens.

IMPORTANT: Do not enter the Diagnostics screen while tips are being dispensed to an analyzer.

1. From the Main Menu (M00), press the SELECT key.
2. Use the up or down ARROW key to scroll within the screen level until you find the Diagnostics screen (D00).
3. Press the SELECT key to move to the next level of subfunctions.
4. Use the up or down ARROW key to scroll through these Diagnostic functions:
 - Motors (D01)
 - Sensors(D11, D12)
 - Dispense (D21)
 - Communication Check (D31, D32)

Motors

This screen allows you to exercise the ATL motors:

- Hopper belt drive
- Bowl
- Escapement
- Linear rail (TipQ)
- Air pump

The linear rail uses two vibrating blocks to induce movement.

1. On the Motors screen (D01), press the SELECT key until the cursor is at the desired motor.

Menu	Title	Status
D01-MOTORS		OK
Hopper:OFF	TipQ:OFF	
Bowl:OFF	Air:OFF	
Escap:OFF		

2. Change the motor state to ON or OFF:
 - a. Press the up or down ARROW key to change the user interface display to reflect the desired motor state.
 - b. Press the SELECT key to implement that state.



User Interface

Menu Features

3. If additional motors need exercising, press the SELECT key until the cursor is at the desired motor and repeat step 2.
4. Return all motor functionality to **off** before leaving the Motors screen (D01) by pressing the up or down ARROW key.
5. Press the RETURN key twice (if motors were exercised) to return to the Diagnostics screen (D00), or three times to return to the Main Menu (M00).

Sensors

From the Diagnostics screen, you can access two Sensors screens with the designators D11 and D12.

D11 This screen allows you to view the operational state of the hopper, bowl, linear rail, and escapement flag sensors.

Menu	Title	Status
	D11-SENSORS Hopper: OFF Escap: ON Bowl: OFF TipQ: ON	OK

The sensor state indicates if an object, such as a tip, is in the sensor path. States for the bowl and linear rail will be ON (blocked) or OFF (unblocked). Hopper sensor states will be ON (unblocked) or OFF (blocked). Escapement Flag sensor states will be ON (home) or OFF (not home).

Press the RETURN key once to return to the Diagnostic Menu (D00), or twice to return to the Main Menu (M00).

D12 This screen indicates if tips are present in the bowl or linear rail.

Menu	Title	Status
	D12-SENSORS TipQ Filling: YES Bowl Full: NO Tips in Bowl: YES	OK

Press the RETURN key once to return to the Diagnostic Menu (D00), or twice to return to the Main Menu (M00).

User Interface

Menu Features



Dispense

The Dispense screen (D21) allows you to dispense tips in a continuous incremental mode, or choose a quantity of tips less than or equal to 25 to be decrementally dispensed. Tips dispensed in the incremental mode will be delivered at a varying rate to mimic the demands of the *Vitros* 250AT or *Vitros* 950AT Chemistry System, while tips delivered in the decremental mode are delivered at a constant rate.

CAUTION: The *Vitros* Automatic Tip Loader pneumatic tubing must be disconnected from the analyzer prior to operation. If this is not done tips will be dispensed and nest together inside the tubing creating a jam. Once the tubing has been disconnected, place it above a receptacle which will collect the dispensed tips. Do not reuse dispensed tips.

To operate in a continuous incremental mode:

1. From the Dispense screen (D21), press the SELECT key two times. Initially the tip count indicator on the user interface will display a dispense value of zero and will then increment by one tip per delivery.

NOTE: Dispensing will continue until the ATL runs out of tips or an error condition occurs.

Menu	Title	Status
	D21 -DISPENSE	DIAG
	Dispense: 0	tips

2. Press the RETURN key once to stop dispensing, twice to return to the Diagnostics Menu (D00), or three times to return to the Main Menu (M00).



User Interface

Menu Features

To operate in a decremental mode:

1. From the Dispense screen (D21), press the SELECT key once.

Menu	Title	Status
D21 -DISPENSE	DIAG	
Dispense: 0	tips	

2. Use the up or down ARROW key to select a quantity of tips less than or equal to 25 to be dispensed, then press SELECT.

NOTE: Once the specified number of tips has been delivered the dispense operation will stop.

3. Press the RETURN key twice to return to the Diagnostics Menu (D00), or three times to return to the Main Menu (M00).

Communication Check

From the Diagnostics screen, you can access two Communication Check screens. The first, with the designator D31, provides the means to run a communication loopback test on the ATL. From this first screen you access screen D32 to monitor the results of the loopback test.

D31 1. This screen instructs you to insert a loopback connector to start running the communication loopback test on the ATL.

Menu	Title	Status
D31-COMM CHECK	OK	

Insert loopback
connector and press
SELECT to start.

1. To begin running the communication loopback test press the SELECT key. This will automatically move you to screen D32.
2. To exit screen D31 without running the test, press the RETURN key once to return to the Diagnostics Menu (D00) or twice to return to the Main Menu (M00).

User Interface

Menu Features



D32 This screen indicates the running status of the communications loopback test. Each time the test is run, the TESTS RUN field is updated. If a test fails, the TESTS FAILED field is updated. The communication loopback test will run continuously until this menu is exited.

Menu	Title	Status
	D32-COMM CHECK COMM LOOPBACK TEST Tests Run: 100 Tests Failed: 0	OK

To exit this screen press the RETURN key twice to return to the Diagnostics Menu (D00), and three times to return to the Main Menu (M00).

Historical Data

The Historical Data screens allow you to view various types of stored information.

1. From the Main Menu (M00), press the SELECT key.
2. Use the up or down ARROW key to scroll within the screen level until you find the Historical Data screen (H00).
3. Press the SELECT key to move into the Historical Data subfunctions.
4. Use the up or down ARROW key to scroll through the following subfunctions:
 - Counts (H01)
 - Errors (H11)
 - Send Time (H21)



User Interface

Menu Features

Counts

The Counts screen (H01) allows you to view the number of tips sent to the analyzer since the last analyzer reboot, and the number of resets that have occurred.

Menu	Title	Status
H01-COUNTS	OK	

Tips sent since last reboot: 1850
Resets: 9

Press the RETURN key once to return to the Historical Data screen (H00), or twice to return to the Main Menu (M00).

Errors

The Errors screen (H11) allows you to view the last 15 status codes. Only those errors that render the system inoperable are stored in the error history. Warning codes such as low tip count are not stored. The latest status code is displayed in the upper left corner, and the oldest status code is in the lower right corner. To display the meaning of the codes, refer to the Status portion of this chapter.

Menu	Title	Status
H11-ERRORS	OK	

I35 I36 I35 I36 I35
I36 I35 I31

Press the RETURN key once to return to the Historical Data screen (H00), or twice to return to the Main Menu (M00).

User Interface

Menu Features



Send Time

The Send Time screen (H21) allows you to view a running average of the last 10 tip delivery times (in milliseconds). The running average is updated and displayed on the screen each time a tip is delivered.

NOTE: The maximum allowable send time is 6000 milliseconds.

Menu	Title	Status
H21-SEND TIME	OK	

Average tip delivery
time: 137 msec

Press the RETURN key once to return to the Historical Data screen (H00), and twice to return to the Main Menu (M00).

Display Status

The Display Status screens allow you to display the current status of the *Vitros* Automatic Tip Loader, as well as view all of the possible status codes including the meaning and corrective action for each.

1. From the Main Menu (M00), press the SELECT key.
2. Use the up and down ARROW key to scroll within the screen level until you find the Display Status screen (S00).
Press the SELECT key to enter the Status subfunctions.
3. Use the up or down ARROW key to select either:
 - Meaning (S01)
 - Action (S11)



User Interface

Menu Features

Meaning

The Meaning screen (S01) allows the operator to display a message indicating the *current* ATL status, as well as *all* possible status codes and their definitions. From the Meaning screen (S01) you can view the current status of the ATL.

To view the definition of all status codes:

1. Press the SELECT key. Note the cursor that appears in the status code on the left of the user interface.

Menu	Title	Status
S01-MEANING	OK	

000: Tip loader is operational.

2. Use the up or down ARROW key to scroll through the entire list of status codes and their meanings.
3. Press the RETURN key two times to return to the Display Status screen (S00), or three times to return to the Main Menu (M00).

Action

The Action screen (S11) displays corrective actions for each status code which, when followed, should restore the *Vitros Automatic Tip Loader* to operation.

1. On the Action screen (S11), press the SELECT key and note the cursor that appears in the status code on the left of the user interface.

Menu	Title	Status
S11-ACTIONS	OK	

000: No Action Required.

2. Use the up or down ARROW key to scroll through the entire list of corrective actions for each status code.
3. Press the RETURN key two times to return to the Status screen (S00), three times to return to the Main Menu (M00).



Troubleshooting

The following features indicate that the *Vitros* Automatic Tip Loader is inoperative:

- An audible alarm on the ATL sounds
- An error indicator light on the user interface is illuminated
- An “INOP” message is posted in the upper right-hand corner of the user interface
- The status console displays the message “ATL INOP” or “TIPS INOP” with corresponding action codes



Troubleshooting

Troubleshooting Procedure

Troubleshooting Procedure

When an audible alarm occurs on the ATL, or the message “ATL INOP” or “TIPS INOP” appears on the *Vitros* AT System:

1. Record the error number from the ATL user interface and from the *Vitros* AT System status screen.
2. Touch RESET on the ATL user interface.
3. If the reset is successful, that is no alarm occurs, go to step 12. If another alarm occurs, or another “ATL INOP” or “TIPS INOP” message appears on the *Vitros* AT System, continue to step 4.
4. Record the errors from the ATL and *Vitros* AT System.
5. Troubleshoot the cause of the ATL error:
 - Visually inspect the ATL components
 - Check the length of the tubing for jammed tips
 - Check the ATL tip inventory
 - Check the *Vitros* AT System tip shuttle for jams
6. Touch RESET on the ATL user interface.
7. Touch REINITIALIZE on the *Vitros* 950AT System, or INITIALIZE on the *Vitros* 250AT System.
8. If the *Vitros* AT status is READY, and there is no ATL alarm, go to step 13. If another alarm occurs, or another “ATL INOP” or “TIPS INOP” message appears on the *Vitros* AT System, continue to step 9.
9. Record the error number from the ATL user interface, and from the *Vitros* AT System status screen.
10. Troubleshoot the ATL error (refer to Recovery Procedures in this chapter):
 - Inspect the Analyzer tip shuttle area
 - Check the length of the tubing for jammed tips
 - Check the ATL tip escapement
 - Check for nested tips in the *Vitros* AT System and ATL
11. Touch RESET on the ATL user interface.
12. Touch REINITIALIZE on the *Vitros* 950AT System, or INITIALIZE on the *Vitros* 250AT System.
13. The *Vitros* AT System status is READY; continue operation.



Recovery Procedures

On the Vitros Automatic Tip Loader:

1. Identify the Status condition and action (refer to Chapter 3, User Interface):
 - a. Enter the Status meaning screen (S01) to identify the status condition including status code and meaning.
 - b. Enter the Status action screen (S11) to identify the corrective action to be taken.
2. You can eliminate the audible alarm by pressing the RESET key on the ATL user interface. If the RESET key was pressed prior to viewing the Status Meaning screen (S01), view the most recent status code by entering the Historical Data Error screen (H11).
3. The corrective action specified for many of the status codes require the operator to “clear the system.”

To “clear the system:”

- a. Open the front door to gain access to the inside of the ATL.
- b. Observe the placement of all tips and identify the location of the failure mode.
- c. If necessary, remove tips from one or more of the ATL subsystems, such as the hopper, bowl, return tray, linear rail, and escapement.
- d. If tips are jammed in the escapement, remove tips from the linear rail then pivot the escapement housing back and remove any sample tips caught in the chamber. Removing or pushing the tips in the rail away from the escapement will avoid tips falling into the escapement chamber when its open. Remember to keep the linear rail sensor satisfied. If you don’t, tips will continue to feed into the rail while you are troubleshooting. Close the escapement housing before resuming operation.

NOTE: Make sure when closing the escapement housing that it is fully seated in its locating nest.



Troubleshooting

Recovery Procedures

4. If a condition requires the operator to verify operation of specific subsystems, the Diagnostic screen (D00) can be used (refer to Chapter 3, User Interface)

On the Vitros 250 AT or Vitros 950AT Chemistry System:

1. Once the condition has been corrected, press the REINITIALIZE target on the analyzer error log screen to restore communication with the ATL. If the previous steps have eliminated the error condition, the ATL status will state that the system is operational, and the analyzer Tips INOP message on the status console will disappear.

Troubleshooting

Status Codes



Status Codes

Status Code	Meaning	Automatic Tip Loader System Status
000	Tip supply	System operational
I22	Low on tips	System OK
I23	Delivery time too long	System OK
I24	Bowl over full	System OK
I25	Initializing	System unavailable
I26	Diagnostics mode	System unavailable
I27	Deliver diagnostic	System unavailable
I28	Undefined error	System unavailable
I29	Communications error	System unavailable
I30	Initialization error	System unavailable
I31	Bowl fill time-out	System unavailable
I32	Escapement not moving; time-out	System unavailable
I33	Escapement not home; time-out	System unavailable
I34	Escapement not home	System unavailable
I35	Tip arrival time-out	System unavailable
I36	Tip queue fill time-out	System unavailable

Figure 4–1. Status Codes and Meanings



Troubleshooting

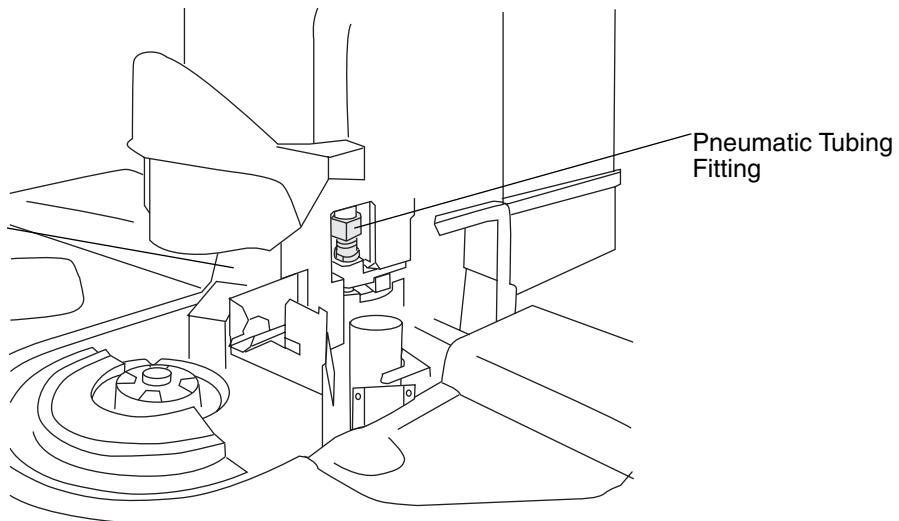
Clearing Analyzer Tip Jams on the Vitros 950AT System

Clearing Analyzer Tip Jams on the Vitros 950AT System

Follow these steps to clear a jam in the analyzer tip shuttle:

IMPORTANT: *Turn SAMPLING off before you clear the jam.*

1. Raise the metering safety shield on the 950AT Chemistry System.
2. Pull the service interlock switch out to remove power from the analyzer motors.
3. Raise the cover of the 950AT analyzer.
4. From the right front of the analyzer, lift the pneumatic tubing and fitting from the tip shuttle housing.

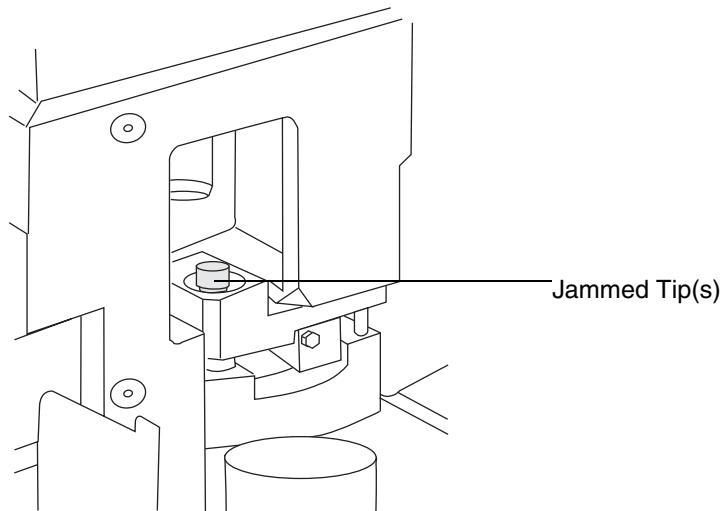


Troubleshooting

Clearing Analyzer Tip Jams on the Vitros 950AT System



5. Lift the tips (in the tip shuttle) up through the housing and remove.



6. Replace the pneumatic tubing and housing in the tip shuttle housing.
7. Close the cover of the 950AT analyzer.
8. Push in the service interlock switch to restore power to the analyzer motors.
9. Close the metering safety shield.



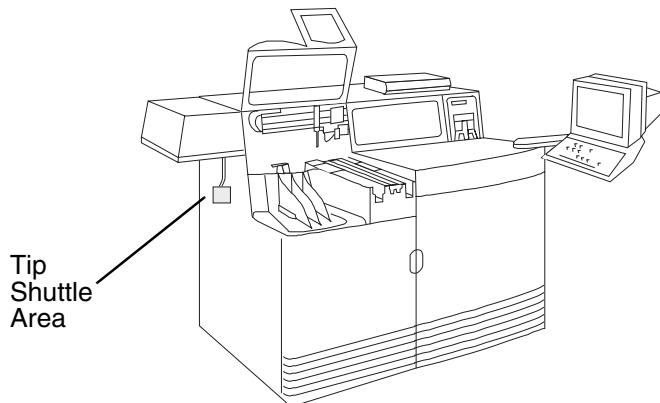
Troubleshooting

Clearing Analyzer Tip Jams on the Vitros 250AT System

Clearing Analyzer Tip Jams on the Vitros 250AT System

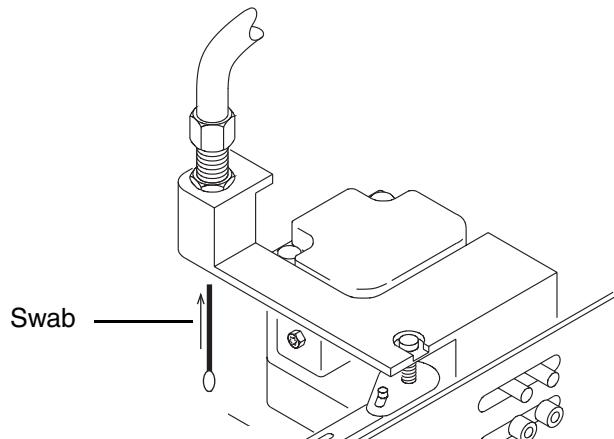
Follow these steps to clear a jam in the Vitros 250AT System tip shuttle:

1. Raise the top left cover of the 250AT Chemistry System.



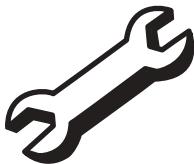
The service interlock system will remove power from the analyzer motors.

2. Using the wooden end of a cotton swab, gently push the jammed tip(s) upward until the tip shuttle is freed.



3. Rotate the tip shuttle toward the front of the analyzer.
4. Pull the jammed tips downward to remove them, and discard them.
5. Close the analyzer cover.
6. Touch the REINITIALIZE target to continue operation.

Maintenance



Cleaning ATL Components

Only two areas of the *Vitros* Automatic Tip Loader require periodic cleaning to remove paper dust or other debris.

CAUTION: DO NOT spray water directly onto any portion of the ATL.

Cleaning the Bowl

Once each week, wipe the disk with a clean lint-free cloth that has been dampened with distilled water.

NOTE: Do not loosen or tighten the black knob in the middle of the bowl.

Cleaning the Linear Rail

At least every 6 months, or as necessary, use a cotton swab that has been dampened with distilled water to wipe the inside walls of the linear rail track.

IMPORTANT: Do not re-load discarded sample tips found outside the hopper or bowl area. They may be damaged or contaminated.



Maintenance

Air Filter Maintenance

Air Filter Maintenance

The interval for the cleaning or replacement of the air pump filter will depend on the conditions at the site in which the *Vitros Automatic Tip Loader* is placed. The following check should be performed a minimum of every 6 months.

1. Access the Tip Time screen (H21) in Historical Data which displays the time it takes for the pump to deliver a requested sample tip to the analyzer.

Menu	Title	Status
H21-SEND TIME	OK	

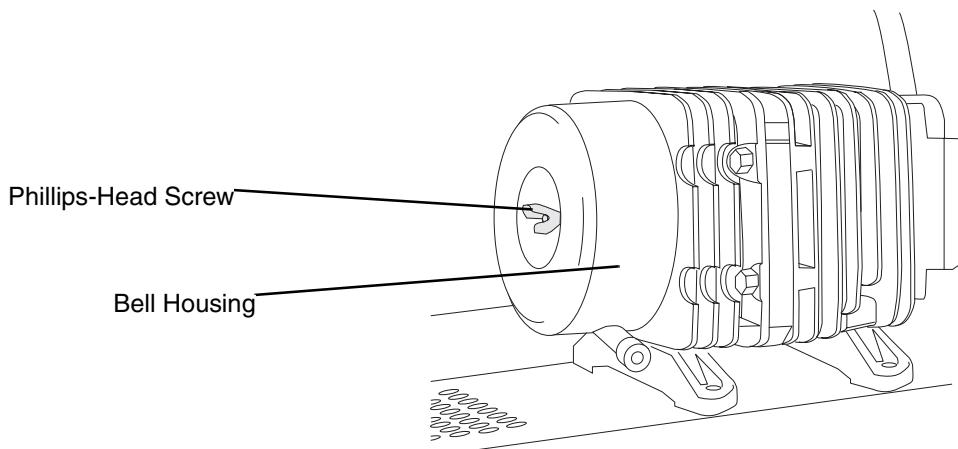
Average tip delivery
time: 137 msec

2. If this time is greater than 5750 msec. (5.75 seconds) replace the filter.

Replacing the filter

Open the front door of the ATL. The air filter is located within a white bell housing on the left side of the pump at the bottom of the ATL. The housing is held in place by one fastener.

1. Remove the Phillips-head screw to take off the white bell housing holding the filter.

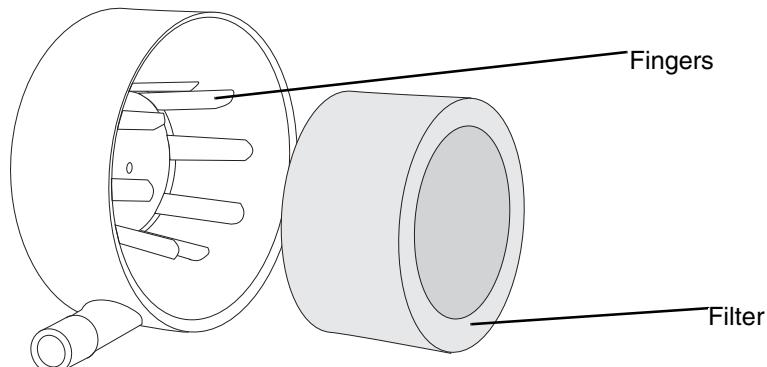


Maintenance

Air Filter Maintenance



2. The filter is held in place by a ring of plastic fingers. Pull the filter off these fingers and replace it with a new filter.



3. Replace the bell housing on the air pump with the arrow pointing up, and tighten the fastener.

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626



Ortho-Clinical Diagnostics
Mandeville House
62 The Broadway
Amersham
Buckinghamshire HP7 0HJ
England