J32799EN

Laboratory Information System (LIS) Guide

VITROS® 5600 Integrated System
VITROS® 4600 Chemistry System
VITROS® 3600 Immunodiagnostic System
VITROS® XT 7600 Integrated System
VITROS® XT 3400 Chemistry System

integrity by intelli check®

Ortho Clinical Diagnostics

VITROS®

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Laboratory Information System (LIS) Guide

1. Introduction

Laboratory Information System (LIS) refers to the subsystems that support the capability to program patient samples remotely on the system, transfer data regarding the patient and physician demographics, quality control data and query another system for previously programmed samples. The LIS includes the VITROS® 5600 Integrated System (VITROS® 5600), the VITROS® XT 7600 Integrated System (VITROS® XT 7600), the VITROS® 4600 Chemistry System (VITROS ®4600), the VITROS® XT 3400 Chemistry System (VITROS® XT 3400), or the VITROS® 3600 Immunodiagnostic System (VITROS® 3600); the Laboratory Computer system; and the hardware that connects the systems.

Note: Not all products and systems are available in all countries.

1.1 Scope

This document contains all specifications to aid in developing communications between the VITROS® 5600 Integrated System, the VITROS® XT 7600 Integrated System, the VITROS® 4600 Chemistry System, the VITROS® XT 3400 Chemistry System, or the VITROS® 3600 Immunodiagnostic System and the Laboratory Computer. Supported communication protocols include ASTM and HL7.

1.2 Revision History

Change bars in the margins of the document pinpoint the exact locations of the most recent changes. Deletions are not noted.

Issued	Section Number	Section Title	Revision Details
2022-05-25	2.2.6.4	Instrument Status Record	Added System response to query of System/Subsystem status.
	2.2.7	Instrument Status Query	Added System response to query of System/Subsystem status.
	2.2.8	Test Completion Status	Added System response to query on time to result for sample.
	4.7.4	Status Messages	Added System response to query of System/Subsystem status.
	4.8	Test Completion Status Messages	Added System response to query on time to result for sample.
	4.9	Analyzer Status Mesages	Added System response to query of System/Subsystem status.
	5.2.11	Status Query Message Structure	Added message structure details.
	5.2.12	Status Query Response Message Structure	Added message structure details.
	5.2.13	Test Completion Status Query Message Structure	Added message structure details.

Issued	Section Number	Section Title	Revision Details
	5.2.14	Test Completion Status Response Message Structure	Added message structure details.
	5.3.16	ASTM Status Query Message Record	Added table with record details.
	5.3.17	ASTM M/S Instrument Status Record	Added table with record details.
	5.3.18	ASTM M/Q Assay Test-Completion Status Query Message Record	Added table with record details.
	5.3.19	ASTM M/T Assay Completion Status Message	Added table with record details.
	Appendix K	ASTM M/S Instrument Status Record Status Detail Mapping	Additional details for field 16 of 5.3.17.
2021-05-24	Appendix B	Analyte Codes	Added Analyte Code 100 CV2G, 101 CV2T, 102 CVG2, 103 CVT2, 104 IL-6, 105 CVGQN, 106 CV2TN, 107 BhCG2*, 108 CEA2*, 109 CKMB2*, 110 Prol2*, 111 Ferr2*, 359 A1C1*, 543 uCRP*, and 544 sCRP*.
	Appendix D	Result Classification	Added 100 CV2G, 101 CV2T, 102 CVG2, 103 CVT2, and 106 CV2TN to the Result Classification Table
	Appendix E	Standard and Conventional Units for Assays	Added A1C1*, BhCG2*, CEA2*, CKMB2*, CV2G, CV2T, CV2TN, CVG2, CVT2, CVGQN, Ferr2*, IL-6, Prol2*, sCRP*, and uCRP*.
	Appendix F	Result Codes	Added HL Hemoglobin Low code.
2020-10-17	5.3.11 5.5.3	ASTM M/R Reagent Inventory Record Inventory Detail (INV)	Updated from "reservedfluid3" to "SWAB"
	Appendix B	Analyte Codes	Added Analyte Code 091 CV2Ag. Removed “*” (Product in development) from aHTLV. Updated “Reserved Fluid 3” to “SWAB”.
	Apendix D	Result Classification	Added CV2Ag to the Result Classification Table. Remved “*” (Product in development) rom aHTLV.
	Appendix E	Standard and Conventional Units for Assays	Added CV2Ag. Removed “*” (Product in development) from aHTLV.

Issued	Section Number	Section Title	Revision Details
2020-04-24	Appendix B	Analyte Codes	Added Analyte Codes 087 CoV2G and 089 CoV2T. Updated the statement from “For all assays, assay availability is subject to local regulatory requirements.” to “The assays listed in the table are subject to local regulatory requirements and may not be available in all regions.”
	Appendix D	Result Classification	Added CoV2G and CoV2T to the Result Classification Table.
	Appendix E	Standard and Conventional Units for Assays	Added CoV2G and CoV2T.
2020-03-05	Appendix B	Analyte Codes	Updated the test code for PCT from 085 to 086.
2019-05-29	Appendix B	Analyte Codes	Added Analyte Codes 035 TSH3, 052 NT-proBNP II, 053 aHTLV and 085 PCT.
	Appendix D	Result Classification	Added aHTLV to the Result Classification Table.
	Appendix E	Standard and Conventional Units for Assays	Added aHTLV, NT-proBNP II, PCT and TSH3.
2019-03-28	Appendix B	Analyte Codes	Added Analyte Code 069 HIV Combo, 082 hs Troponin I and 083 Anti-T.cruzi.
	Appendix D	Result Classification	Added Anti-T.Cruzi and HIVc to the Result Classification Table.
	Appendix E	Standard and Conventional Units for Assays	Added aTCRU and hsTnI.
			Minor editorial updates.
2017-12-19	-	-	Added the VITROS® XT 3400 Chemistry System and VITROS® XT 7600 Integrated System to the title page and footers.
	1 and 1.1	Introduction and Scope	Added VITROS® XT 3400 Chemistry System and VITROS® XT 7600 Integrated System and added **Note:** Not all products and systems are available in all countries.
	5.3.13 and 5.5.3	ASTM M/B Bulk Consumables Inventory Record and Inventory Detail (INV)	Added VITROS® XT 3400
	5.5.13	Query Acknowledgment Details (QAK)	Corrected spelling of defined
	Appendix B, Appendix C, and Appendix E	Analyte Codes; Diluent Codes; Standard and Conventional Units for Assay	Added XT 3400 and XT 7600 to text above table and to table columns

Issued	Section Number	Section Title	Revision Details
	Appendix F	Result Codes	Added MF (Multiple Reagent Formats) to the table
	Appendix H	Download Messages	Removed mention of specific systems from the Condition column in the Code Number 14 row, as it applies to all systems; changed to say “target system” instead.
	Appendix I and Appendix J	Mechanical/Electrical Interfaces for Serial Communications; Network Connections through Ethernet	Added VITROS® XT 7600 System and VITROS® XT 3400 System to text above the table
	Appendix J	Network Communications through Ethernet	Added VITROS® XT 7600 and VITROS® XT 3400
2017-07-10	Appendix B Appendix E	Analyte Codes Standard and Conventional Units for Assays	Added: Analytes 42 INS (Insulin), 50 C-pep (C-peptide), 69 HIV c (HIV Combo), 357 ALTV (Alanine Aminotransferase), 358 ALT2 (Alanine Aminotransferase), 178 NCHEK (AKIRisk), 80 TIMP2 (TIMP-2), 81 IGFBP (IGFBP-7) and 307 Cl- (Chloride) - Urine Changed: Homocysteine 2 to Homocysteine Added: Assays ALT2, ALTV, Insulin, C-pep, NCHEK, TIMP2, IGFBP and HIV c
2014-10-20	Appendix B Appendix E	Analyte Codes Standard and Conventional Units for Assays	Added: Analytes 539 A1c (Hemoglobin A1c) and 540 Hb (Hemoglobin) Added: Derived Assays 927 %A1c (%Hemoglobin A1c) and 928 HbA1c (HbA1c)
2014-07-25	Appendix B Appendix E	Analyte Codes Standard and Conventional Units for Assays	Removed: 529 HCY Homocysteine (HCY). – A change bar marks where HCY was deleted in both tables.
2013-06-18	Appendix B Appendix E	Analyte Codes Standard and Conventional Units for Assays	Added: 542 HCY 2 Homocysteine 2 (HCY2).

Issued	Section Number	Section Title	Revision Details
2013-04-01	Appendix B	Analyte Codes	• Deleted: 035 Free B-hCG (FBhCG), 046 TSH30 (TSH30), and 332 Total Iron Binding Capacity (TIBC). • Added: 037 Free PSA (fPSA), 062 CMV IgG (CMV G), 063 CMV IgM (CMV M), 073 Syphilis TPA (Syph), 074 VITAMIN D TOTAL (tVitD), 075 Total PSA II (tPSA), and 174 % Free PSA (%fPSA). • Changed: 017 HBsAg ES (HBsAg), 018 anti-HBs (aHBs), 019 Anti-HBc (aHBc), 020 Anti-HBc IgM (HBc M), 022 Anti-HAV IgM (HAV M), 023 Anti-HVC (aHVC), 024 Anti HIV 1/2 (aHIV), 033 Folate (Fol), 038 CA 125 II (CA125), 039 CA 15-3 (CA153), 040 CA 19-9 (CA199), 044 NTx (NTx), 049 HBsAg Confirm (HBCon), 055 Free T3 II (FT3II), and 065 NT-proBNP (NTBNP).
2011-01-10	-	-	Added the VITROS® 4600 Chemistry System to the title page and footers.
	1 and 1.1	Introduction and Scope	Added the VITROS® 4600 Chemistry System.
	Appendix B and Appendix C	Analyte Codes and Diluent Codes	• Added the VITROS® 4600 Chemistry System. • Added User Defined for a body fluid choice. • Deleted 037 FPSA and 041 CA 72-4. • Corrected the spelling of Phenobarbital. • Marked HEM, ICT and TUR for VITROS® 3600. • Added User Defined Assays and User Defined Diluents.
	Appendix E	Standard and Conventional Units for Assays	• Removed %IFCC as an alternate unit for the d%A1c assay. • Added the VITROS® 4600 Chemistry System.
	Appendix F	Results Codes	Added the HC (High Concentration) code.
	Appendix I	Mechanical/Electrical Interfaces for Serial Communication	Added the VITROS® 4600 Chemistry System.

Issued	Section Number	Section Title	Revision Details
	Appendix J	Network Communications Through Ethernet	• Added the VITROS® 4600 Chemistry System • Updated the reference to the e-Connectivity® Network Connection Specifications and Network Form.
2010-11-10	2.2.2	Upload Patient Results	In the second bullet, added uploading results of tests in one group.
	4.4	Uploading Result Records	Used the term "Group" instead of "Technology" to describe this Upload Mode.
	Appendix B	Analyte Codes	Added analyte 070 iPTH and derived assay 925 mmA1c.
	Appendix E	Standard and Conventional Units for Assays	Added iPTH and derived assay mmA1c. Corrected the Conventional Units for dHb and the Conventional Units and Alternate Units for d%A1c.
2010-08-06	4.4	Uploading Result Records	Used the terms "Sample," "Result," and "Technology" to describe Upload Modes.
2010-03-12	All		Edited text, capitalization, and punctuation for clarity.
		Title page/Important information	Added copyright information.
	1.3	Definitions	Added definitions for In Process and Table. Redefined SI as Sample Indices and throughout the Guide.
	4.4	Uploading Result Records	Added information.
	5.1.7	Reprocessing Type Table	Added G for Reprocessed due to another reprocessing group component requiring reprocessing.
	5.1.8	Metering Point Type Table	Added this section.
	5.2.2.1	Result Upload Message Examples	Added examples of suppressed mean results.
	5.2.3.1	Host Query/Query Cancel Examples	Added metering point type in the examples.
	5.3.5	ASTM R Result Record	Added information in Notes column to field #s 4, 5, and 7.
	5.3.7	ASTM Q Request Record	Added metering reference point information to field #11, User Field 1, which is now supported.
	5.3.8	ASTM M/X Extended Result Record	For field #8, added "G" to the Notes column.

Issued	Section Number	Section Title	Revision Details
	5.4.4.1	HL7 OUL Unsolicited Observation Message Examples	Added two examples for suppressed mean result.
	5.4.5.1	HL7 QPB Host Query Message Example	Added metering point type in the QPD record example.
	5.4.6.1	HL7 RSP Host Query Response Message Example	Added metering point type in the QPD record example.
	5.4.6.2	HL7 RSP Host Query Response Message Example (No Program Found)	Added metering point type in the QPD record example.
	5.5.9	Observation Result (OBX)	For field #s 5,6, and 8, added information in the Notes column.
	5.5.15	Query Parameter Definition Details	Added metering reference point information to field #10 Location, which is now supported.
	5.5.19	Z-Segment Extended Results (ZER)	For field #5, added "G" to the Notes column.
	Appendix F	Result Codes	Updated the explanations of codes CE, EC, M2, and RE.
	Appendix G	Sample Indices Flags Sent to the LIS	Edited the name of this appendix and included only the 2-character flags sent to the LIS.

Previous Versions

Issued	Section	Revision Details
2008-08-29	4.3.2	Reworded: Explanation of attempt to edit a program in process (26).
	4.3.3	Reworded: Note regarding sample programs in process.
	4.3.3	Added: An explanation of a new sample program downloaded for a sample that already has a program in process.
	4.3.4	Changed: Reference to download message 27.
	4.4	Reworded: Explanation of results records and categorization.
	4.4	Added: Statement about qualitative text comments and result comment record.
	5.1.7	Added: Reprocessing Type table.
	5.2.2	Added: [C] Comment line in the Result Upload Message Structure.
	5.2.2.1	Added: A second Results Upload Message Example.
	5.3.6	Changed: #4 and #5 of ASTM C Comment Record.
	5.3.8	Added: #8 Reprocessing Type to the ASTM M/X Extended Result Record.
	5.4.4	Added: [NTE] line to HL7 OUL Unsolicited Observation Message Structure.
	5.4.4.1	Added: A second example of HL7 OUL Unsolicited Observation Message.
	5.5.7	Added: Information to #3 and #4 of Notes and Comments (NTE).
	5.5.19	Added: #5 Reprocessing Type to Z-Segment Extended Results (ZER).
2008-08-06	N/A	Initial release of the LIS Guide

1.3 Definitions

[ ]	In message formats, brackets indicate that the enclosed group of records/segments is optional.
{ }	In message formats, braces indicate that one or more of the enclosed group of records/segments may repeat.
ACK	Positive Acknowledgement. For ASTM - ASCII character 6. For HL7 - General acknowledgement message
Analyzer	An instrument and/or specimen processing and handling device that performs measurements on patient specimens of quantitative, clinically relevant analytes.
Assay Data Disk (ADD)	A CD that contains assay information.
ASCII	American Standard Code for Information Interchange
ASTM	American Society for Testing and Materials. In this guide, ASTM refers to the communication protocols defined by the E-1381 and E-1394 specifications noted in the references.
Baud rate	Speed of data communication between the System and the Lab Computer in bits per second.
Bi-directional	A communication protocol that supports both upload test results, download sample program (order) capabilities, and query requests
control characters	Non-printing ASCII characters in the range 0-31 and 127 decimal that effect actions to modify the processing of data.
data characters	Printable ASCII characters in the range 32-126 decimal that constitute the “text” of a message.
Data type	A data type restricts the contents and format of the data field. Data types are given a 2- or 3-letter code. Some data types are coded or composite types with several components. The applicable data type is listed and defined in each field definition. Chapter 2A of the HL7 v2.5 standard provides a complete listing of data types used in this guide and their definitions.
directly selected	Assay target that is depressed when the program is viewed on the Sample Programming screen.
download	Data sent from the Lab Computer to the System
DSR	“Data Set Ready” RS-232 control signal
DTE	Data Terminal Equipment. In common usage, DTE typically denotes the initiator of communications.
EAN	HL7 Automated Equipment Notification message
ENQ	ASTM Enquiry. ASCII character 5. This control character is used to establish communication between machines.
EOT	ASTM End of Transmission. ASCII character 4. A control character used to mark the end of a session.
EQU	HL7 Equipment Detail Segment
ERR	HL7 Error Segment

ETB	ASTM End of Transmission Block. ASCII character 23. This control character may be used in place of ETX to distinguish between the end of a data block at a different logical (abstraction) level.
ETX	ASTM End of Text. ASCII character 3. This control character denotes the end of the data (text) block.
Extended ASCII character set	ASCII characters in the range 128-255 decimal. Defined as in ISO 8859-1
Field	A string of characters within HL7 segments and ASTM records
frame	The basic unit of communication at the Data Link Layer for ASTM protocol (see also packet)
HL7	Health Level Seven.
Host Query	Requesting data from another system
In Process	In respect to Sample Programs – In Process refers to the time immediately following the completion of the tray scan in the Sample Handling subsystem all the way through either one of the following occurring: all work is completed (including reprocessing) all work is completed to the point where re-metering is required (tests waiting for reprocessing) and the sample has been removed from the Sample Handling subsystem
INR	HL7 Automated Equipment Inventory Request message
INU	HL7 Automated Equipment Inventory Update message
INV	HL7 Inventory Detail segment
ISO	International Standards Organization.
LCI	Lab Communication Interface. A System module that handles the Analyzer side of the interface to the Laboratory Information System.
LIS	Laboratory Information System. The Lab Computer together with the software that runs on it viewed as a logical unit.
LITT	Lab Interface Test Tool
Message	A text-based body of information comprised of a series of records (for ASTM) and segments (for HL7).
MLLP	Minimal Low-Level Protocol commonly used for HL7 communication over a TCP/IP network connection
MSA	HL7 message acknowledge segment
MSH	HL7 message header segment
NAK	ASTM Negative Acknowledgement. Can be ASCII character 21.
NDS	HL7 Notification Detail segment
NTE	HL7 Notes and Comments segment
OBR	HL7 Observation Request message
OBX	HL7 Observation Results segments

OML	HL7 Laboratory Order Request message
ORC	HL7 Common Order segment
Order	HL7 term for Sample Program download
ORL	HL7 Laboratory Order Response message
OSI	Open Systems Interconnection. The standard model for networking protocols and distributed applications. It defines seven network layers. Layer 1 - Physical Layer 2 - Data Link Layer 3 – Network Layer 4 – Transport Layer 5 – Session Layer 6 – Presentation Layer 7 - Application
OUL	HL7 Unsolicited Specimen Container Oriented Observation message. Message used for transmitting laboratory results supports a specimen-centric message for human, environmental and food testing of a biochemical nature including microbiology.
Packet	The basic unit of communication at the Data Link Layer
PID	HL7 Patient Information Segment
protocol	A set of rules for transmitting and receiving units of information at each level in a communication interface, where a given communication level corresponds to a logical level of data abstraction.
Protocol layer	The application of a layer paradigm to the definition of a protocol produces the concept of “protocol layers”. Each protocol layer handles discrete units of information pertaining to a particular communication or data abstraction level.
Protocol stack	A hierarchical organization of protocol layers, each handling a higher level of data abstraction that is used to provide a complete communications interface.
PSID Query	Positive Sample Identification query. A capability of the system to request test orders from the LIS given a sample ID, e.g., as automatically read from the sample/tray barcode reader on the system.
PV1	HL7 Patient Visit Segment
QAK	HL7 Query Acknowledgement segment
QBP_ZOS	HL7 Host Query Message. This is a proposed message format for the upcoming HL7 release.
QCN	HL7 Cancel Query Message
QID	HL7 Query Identification segment
QPD	HL7 Query Parameter definition segment
RCP	HL7 Response Control Parameter segment
Restricted Assay	A test requiring more stringent handling than other assays. Assays that have some parameters, defined on the Assay Data Disk (ADD), that cannot be changed.

RSP_ZOS	HL7 Host Query Response Message. This is a proposed message format for the upcoming HL7 release.
RTS	ASTM “Request To Send” RS-232 control signal
Rx	Receive(r).
SAC	HL7 Specimen Container Detail Segment
Sample	The discrete portion of a body fluid or tissue taken for examination, study, or analysis of one or more quantities or characteristics to determine the character of the whole
Sample Program	Test(s) requested on sample.
SI	Sample Indices (Sample Index)
Specimen	HL7 term for Sample.
Specimen ID	Sample ID. Can be manually entered from the GUI or Bar coded
SPM	HL7 Specimen segment
STX	ASTM Start of Text. ASCII character 2. This control character denotes the beginning of the data or “text” information block.
System	The software and hardware that together make up the Analyzer.
Table	The table attribute of the data field definition specifies the HL7 identifier for a set of coded values
TCP/IP	TCP/IP is a network protocol designed around a simple four-layer scheme. It does omit some features found under the OSI model. Also, it combines the features of some adjacent OSI layers and splits other layers apart. The four network layers defined by TCP/IP model are as follows. Layer 1 - Link Layer 2 - Network Layer 3 - Transport Layer 4 - Application
Trigger events	An event in the real world of healthcare creates the need for data to flow among systems. The real-world event is called the trigger event. This term is used in the context of HL7.
Tx	Transmit, Transmission, or Send(er).
Upload	Data sent from the System to the Lab Computer
UTF8	Multi byte character set
Z Segment	HL7 All message types trigger event codes, and segment ID codes beginning with Z are reserved for locally defined messages.
ZER	Custom HL7 segment representing the extended results

1.4 References

These documents form the basis for many of the specifications in this LIS Guide. The first two listed are particularly important.

NCCLS LIS1-A (Formerly ASTM E1381-02)	Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems

NCCLS LIS2-A (Formerly ASTM E1394-97)	Standard Specification for Transferring Information Between Clinical Laboratory Instruments and Computer Systems
N/A	HL7 2.5 Specifications, 2003
N/A	HL7 2.3 Implementation Guidelines
IEEE 802.3i	Ethernet Standard 10BaseT
IEEE 802.3u	Ethernet Standard 100BaseT

2. General Description

Laboratory Information System refers to the interface that communicates between the System and the Laboratory Computer System (Lab Computer). This communication can occur using either the HL7 or ASTM protocols.

With the ASTM protocol, communication can occur over either a serial line from the System to the Lab Computer or through the user's network. With the HL7 protocol, the communication only occurs over the user's network. The communications are bi-directional and include downloading sample programs from the Lab Computer to the System, uploading result records from the System to the Lab Computer, querying sample programs from the System to the Lab Computer, querying inventory from the Lab Computer to the System, and sending asynchronous notifications from the System to the Lab Computer. This document covers each of these aspects from the perspective of the System.

The specifications in this document are grouped into the following sections:

- Communications – This includes the physical interfaces and specific communications processing called for by the HL7 and ASTM protocols.
- Record Processing - This specifies the content of the messages (e.g., sample programs, results records patient information) and their components to be implemented in this application. The format and hierarchy are specified in Section 5.2 ASTM Messages and Section 5.4 HL7 Messages.

2.1 Functions

- Provide a method to receive remotely programmed patient and quality control sample programs from another system. (Download from Lab Computer)
- Provide a method to send patient results, quality control results, patient and physician demographics to another system. (Upload Results to Lab Computer)
- Provide the ability to request sample programs from another system in order to process sample. (Host Query)
- Provide indication to the operator the status of communication between the system and the Lab Computer. (Status)
- Provide the ability to process requests for onboard inventory levels. (Inventory Query)
- Provide a method to send Analyzer status information to another system. (Error Messages/Automation Status Updates/Download Messages)

2.2 Operational Overview

The following overview shows the general way the interactions occur between the LIS and System. There are other modes including error scenarios that are further detailed in the specifications.

2.2.1 Download Sample Programs

- Sample programs containing specimen ID, patient information, and tests to be run are entered into the Lab Computer.
- The Lab Computer transfers the sample program and patient information to the System.
- Information is entered in the System's Sample Database.
- The sample is presented at metering.
- The Sample Program database is queried for a sample program that matches the specimen ID or the tray cup position.
- The program is found and the sample is metered.

2.2.2 Upload Patient Results

- The sample is metered and processed.
- The last test completes, or any test completes if configured to upload individual results, or all tests in a group complete if configured to upload groups.
- The results from the System are transmitted to the Lab Computer.

2.2.3 Host Query

- The host query is configured to be on.
- A barcoded sample is scanned at the sample handling area.
- A request is sent from the System to the Lab Computer requesting information (sample program and patient demographics) for the Specimen ID on the barcode.
- The Lab Computer responds with the requested data.
- The sample program is entered into the database and the specimen is metered.

2.2.4 Error Handling

The System handles errors encountered during communication.

2.2.5 Inventory Query

- The Lab Computer requests onboard inventory information.
- The System responds with the requested data.

2.2.6 Asynchronous Messages

2.2.6.1 Error Messages

- The System posts a condition code (for some task other than LCI).
- The System transfers information about the condition code (severity, mod-err, short text).

2.2.6.2 Automation Status Updates

- The user saves changes to the Automation Configuration in Options.
- The System transfers the current state of the Automation Configuration.

2.2.6.3 Audit Messages (Download Messages)

- A sample program has invalid or missing contents.
- The System transfers a message indicating issues with the sample program.

2.2.6.4 Instrument Status Record

- The status of the analyzer changes.
- The system transfers a message indicating analyzer status details.

2.2.7 Instrument Status Query

- The Lab Computer requests the status of the analyzer.
- The system transfers a message indicating analyzer status details.

2.2.8 Test Completion Status

- The Lab Computer requests the status of a particular sample.
- The System responds with information about the sample and the status of each assay requested for it.

2.3 Design Constraints

The System software is compatible with ASTM specifications LIS1-A and LIS2-A.

The System software is compatible with HL7 v2.5 specifications, chapters 2, 3, 4, 7 and 13. This HL7 version does not include provisions for Host Query functionality so a custom Z segment is used.

2.4 Assumptions, Dependencies and Resulting Risks

- Only one LIS is connected at any one time to an Analyzer.
- The LIS provider complies with this specification.
- The specifications in this document apply to all protocols unless otherwise specified.
- The specifications of message processing are independent from those of communication. For example, where a protocol (e.g., ASTM) is mentioned in a processing specification, it applies to all communication methods supporting that protocol (e.g., Ethernet and Serial).
- This document will not describe the GUI itself, but only the functionality of the feature.
- No hardware requirements will be detailed in this document.
- An EIA RS-232 compatible serial communications port with a standard DB25 female connector is assumed for communication between the System and the Lab Computer when using the serial interface.
- A TCP/IP compatible network communications port with a standard Ethernet network is assumed for communication between the System and the Lab Computer when using the Ethernet interface.
- The security of network communications is the responsibility of the user.

- The system's firewall needs to be configured to allow communications to/from the LIS when using TCP/IP.

3. Communication Specifications

The following specifications are for the layers responsible for transporting messages between the System and the LIS. The content of these messages is not relevant for these layers, which only ensure that messages are transferred in an error-free manner between systems.

The System acts as a sender

- When a host query is initiated
- When results need to be uploaded to the Lab Computer
- When sending an asynchronous message
- When responding to an inventory query

The System acts as a receiver

- When the Lab Computer responds to a host query
- When sample programs are to be downloaded
- When sending an inventory query

Upon System startup, the LCI module tests communications.

If a connection to a LIS cannot be established, the LCI communicates an error condition to the operator.

3.1 Physical Interfaces

Note: See Appendix I Mechanical/Electrical Interfaces for details about these interfaces.

3.1.1 Physical Ethernet Interface

The ASTM and HL7 protocols support the use of TCP/IP communication for the physical transport layer. The two protocols share the same specifications for this layer.

The System establishes a connection to the Lab Computer at a configured IP address and port.

Note: This interface is bidirectional but only initiated by the System.

3.1.2 Physical Serial Interface

The System

- Uses 1 start bit
- Supports 1 or 2 stop bits
- Supports EVEN, ODD, and NONE parity
- Uses 8 data bits
- Supports the following baud rates:
    - 9600
    - 19200
    - 38400
    - 57600
    - 115200

3.2 ASTM Communications

Note: All referenced sections can be found in *Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems,* NCCLS LIS1-A (Formerly ASTM E1381-02).

The ASTM layers involved in transferring data from the System to the Lab Computer and the Lab Computer to the System are divided into these components:

- Physical Layer - Comprised of the actual hardware and software configuration used to communicate between the two systems. For serial communications, this corresponds to Section 5. For Ethernet communications, this corresponds to Section 7 and 8.2.1.1. For specifications, refer to the appropriate Interface (Ethernet or Serial).
- Datalink Layer - Responsible for the logical data frames comprised of the raw data exchanged with the physical layer. It ensures that packets can be transferred in an error-free manner between machines. For serial communications this corresponds to the Datalink layer specified in Section 6. For Ethernet communications, this corresponds to Section 8.

The System supports a configurable maximum frame size that supersedes values specified in *Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems,* NCCLS LIS1-A (Formerly ASTM E1381-02).

3.2.1 ASTM Datalink Serial Communications

Note: All referenced sections can be found in *Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems,* NCCLS LIS1-A (Formerly ASTM E1381-02).

The System supports the Establishment Phase (Link Connection) as specified in Section 6.2. This includes establishment and contention.

The System supports the Transfer Phase as specified in Section 6.3. This includes:

- Frame Format, Section 6.3.1
- Frame Numbering, Section 6.3.2
- Frame Checksums, Section 6.3.3
- Frame Acknowledgements, Section 6.3.4
- Frame Receiver Interrupts, Section 6.3.5

The System supports the Termination Phase (Link Release) as specified in, Section 6.4.

The System supports Error Recovery as specified in, Section 6.5. This includes:

- Detecting and handling defective frames, Section 6.5.1
- Timeouts, Section 6.5.2

The System supports the Restricted Message Characters requirement specified in Section 6.6.

3.2.2 ASTM Datalink Ethernet Communications

Note: All referenced sections can be found in *Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems, NCCLS LIS1-A* (Formerly ASTM E1381-02).

The System supports the Establishment Phase (Link Connection) as specified in Section 8.2. This includes establishment and contention.

The System supports the Transfer Phase as specified in Section 8.3. This includes:

- Frame Format, Section 8.3.1
- Frame Numbering, Section 8.3.2
- Frame Checksums, Section 8.3.3
- Frame Acknowledgements, Section 8.3.4
- Frame Receiver Interrupts, Section 8.3.5

The System supports the Termination Phase (Link Release) as specified in Section 8.4

The System supports Error Recovery as specified in Section 8.5. This includes:

- Detecting and handling defective frames, Section 8.5.1
- Timeouts, Section 8.5.2

The System supports the Restricted Message Characters requirement specified in Section 8.6.

3.3 HL7 Communications

3.3.1 HL7 MLLP Communications

This layer is responsible for implementing the MLLP protocol. This protocol, defined by HL7 2.3.1 standard, is essentially a half-duplex protocol, where a new message is sent only after receiving the acknowledgement for the previous message. The System implements MLLP as described in *HL7 2.3 Implementation Guidelines*. The System supports Error Recovery as specified in Section C.2.6. This includes Connect Retries, Section C.2.6.1; Connect Pause, Section C.2.6.3; and Receive Timeout Errors, Section C.2.6.2.

Every HL7 message is enclosed by special characters to form a block formatted as **<SB>dddd<EB><CR>**, where:

<**SB**> - start block character (1 byte), ASCII VT = 0x0B

dddd - Data (variable number of bytes). This is the HL7 data content of the block. The data can contain any single-byte values greater than 0x1F and the ASCII carriage return character, <CR>.

<**EB**> - end block character (1 byte), ASCII FS = 0x1C

<**CR**> - carriage return (1 byte) = 0x0D

Messages received with incorrect delimitation characters are ignored**.**

The System

- Supports a timeout of 30 seconds. This timeout is used by the connect and receive timeout.
- Supports a retry count of 5. The value is used by the connect retry.
- Supports a retry action pause of 0 seconds.
- Accepts messages up to the configured frame size (in bytes). Messages longer than this value are treated as a timeout and logged as a bad frame.
- Goes into a neutral state after attempting to reconnect to the LIS a configured number of times (5 times), pauses a configured amount of time (0 seconds), and then waits a configured timeout for each connection attempt (30 seconds).
- Requires a manual operation to restart the connection process after reaching the neutral state.

Note: The connection process is re-initiated by a reconfiguration, a new upload message, or an operator initiated request.

4. Processing Specifications

The following specifications apply to all protocols.

The transfer of data between the LIS and the System occurs when:

- The System is at least at ready state and configured to send and/or receive.
- The hardware required is connected.

The software supports the processing of samples while sample programs are downloaded to the System.

In the case of contention between the System sending or requesting data and the Lab Computer sending unsolicited data, the System activity takes priority.

4.1 HL7 Message Acknowledgements

For the HL7 protocol, the System expects to receive an ACK for each message it sends to the LIS. If the System does not receive an ACK before the send timeout expires, then the System assumes that the RSP^ZOS message is lost, reestablishes the connection, and sends the message again.

The System acknowledges all HL7 messages (except OML) received from a LIS by sending an ACK. See Section 5.4.1 HL7 ACK Acknowledgement Message.

If the protocol is set to HL7, the System produces an ORL - general laboratory order response for each OML (event O21) and each RSP^ZOS instead of an ACK message.

If the message cannot be acted upon, the System includes an error segment in the acknowledgement.

Messages that are not supported by the System result in an ACK message with an error condition code 200 – Unsupported message type.

ACK messages that are not expected by the System are discarded.

The System supports

- A timeout of 30 seconds. This timeout is used by the send.
- A retry count of 5. The value is used by the send retry.
- A retry action pause of 0 seconds

4.2 Downloading Sample Programs

The following specifications are for the download of sample program messages. See Section 4.3 LIS Append for a complete set of requirements regarding the subsequent processing that occurs when downloaded sample program is received.

The System uses the following format for the Universal Test ID: value=^^^LocalOrMfctrCode where LocalOrMfctrCode = ManualDilution + TestCode + TestDilution~TestCode + TestDilution~… where TestCode + TestDilution is repeated for each assay in the program.

If the protocol is set to ASTM, the System processes an Order Download message when received from a LIS. See Section 5.2.1 Order Download Message Structure for the structure.

If the protocol is set to ASTM, the System discards any comment records that appear after an Order Record on a download.

If the protocol is set to ASTM, the System accepts only General comments pertaining to patient demographics (those that appear after a Patient Record).

If the protocol is set to HL7, the System processes an OML message, Laboratory Order Request (event O21) when received from a LIS. See Section 5.4.2 HL7 OML Laboratory Order Message Structure.

Note: In relationship to triggers O21, O33, and O35, this message/trigger (O21) is used when an order with multiple samples and optionally multiple containers per order item are to be communicated.

If the protocol is set to HL7, the System sends the application acknowledgement (ORL) message indicating whether the order is accepted or rejected by the System. See Section 5.4.3 HL7 ORL Laboratory Order Response Message Structure.

Note: **1)** This ORL message indicates that the message was parsable and passed an initial set of edits. The order may still fail Sample Programming audits and return another message (Download Message) back to the LIS indicating the subsequent failure. **2)** Manually (on System) entered orders and updates to orders originally received from the LIS will not create an ORL. **3)** Other test requests (e.g., derived tests or their test components) may appear in the ORL when they were not requested by the LIS-OML. These do not need to be created by the LCI since they will be automatically generated by the System and associated with the order when the order (OML) is processed by the System.

If the protocol is set to HL7, the System only processes the first SAC segment for an SPM in each OML message while ignoring the remaining SAC segments if they are present.

If the protocol is set to HL7, the System accepts the first NTE segment that contains a comment type of "Generic" while ignoring the remaining NTE segments.

4.3 Auditing and Storing Sample Programs

4.3.1 Supported Fields

The System supports the following sample programming fields downloaded from a LIS.

- Sample ID (up to 15 printable characters)
- Tray ID (up to 2 alphanumeric characters)
- Cup Position (up to 2 numbers)
- (Test) Dilute (up to 4 numbers and a decimal point)
- Manual Dilution (4 numbers and a decimal point. Precision after the decimal is 4 numbers.)
- Test Code (3 numbers identify an Assay)
- Specimen Descriptor (1 number identifies a Body Fluid)

The System supports the following patient demographic fields downloaded from a LIS:

- Patient ID (up to 20 characters)
- Patient Last Name (up to 20 characters)
- Patient First Name (up to 15 characters)
- Patient Middle Initial (1 character)
- Patient Address (two input fields each with up to 20 characters)
- Patient Birth Date
- Range Attribute (1 character)
- Sex (1 character)
- Patient Room Number (up to 10 characters)
- Collection Date

- Collection Time
- Comments (up to 60 characters)
- Physician Last Name (up to 20 characters)
- Physician First Name (up to 15 characters)
- Physician Middle Initial (1 character)
- Physician ID (up to 15 characters)

4.3.1.1 Truncating Long Fields

After stripping any leading and trailing blanks, if any of the following fields in a downloaded program contains more than their maximum number of characters, the System truncates the fields and no download message is generated.

- The demographic “Physician Last Name” field
- The demographic “Physician First Name” field
- The demographic “Physician Middle Initial” field
- The demographic “Patient Address” field
- The demographic “Patient Room Number” field
- The demographic “Comments” field
- The demographic “Physician ID” field

After stripping any leading and trailing blanks, if any of the following fields in a downloaded program contains more than their maximum number of characters, download message #2 is generated and the program is rejected.

- The demographic “Patient ID” field
- The demographic “Patient Last Name” field (part of a key field)
- The demographic “Patient First Name” field (part of a key field)
- The demographic “Patient Middle Initial” field (part of a key field)
- The demographic “Patient Birth Date” field (System date audits apply)
- The demographic “Collection Date” field (System date audits apply)
- The demographic “Collection Time” field (System time audits apply)
- The sample program “Sample ID” field (other audits apply)
- The sample program “Tray” field (other audits apply)
- The sample program “Cup” field (other audits apply)
- The sample program “Dilute” field (other audits apply)
- The sample program “Manual Dilution” field (other audits apply)
- The demographic “Sex” field (other audits apply)
- The demographic “Demographic Attribute” field (other audits apply)

Note: For HL7 messages, violation of character counts in the above fields (with the exception of the two dilution fields) results in the rejection of the message at transmission time. As a result, no download message is generated. The ERR segment of the acknowledgment will indicate the error

4.3.2 LIS Sample Program Verification

Downloaded sample programs that contain errors can be dispositioned in a variety of ways. Serious errors result in the rejection of the entire sample program and cause a download message to be generated. Less serious errors could cause the rejection of a single assay but would also generate a download message. The least serious conditions result in processing the valid portion of the sample program while ignoring the invalid portion. For example, if a dilution factor is specified for a derived test, the test is performed but the dilution factor is not applied.

Download messages are generated to represent the detection of the following types of sample programming and validation errors. Except when explicitly noted, all the messages indicate the rejection of an entire sample program. (Code numbers are included in parenthesis. Item numbers displayed in brackets do not pertain to this System; they are included in this list for completeness.)

Note: See Appendix H Download Messages for a list of the messages and the recommended action for each message.

- Missing sample ID (1) – The sample program has a blank sample ID.
- Invalid data in field (2) – The sample program has problems with data in one or more fields. That could include invalid characters, fields that were too long, a body fluid mismatch for an append program, or an unsuccessful lookup of sex or range attribute.
- Tray name or cup missing (4)
    - 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.
- Sample/patient name mismatch (6) – The sample program has the same sample ID as a program already in the sample DataBase, but the patient names (last, first and MI) do not match.
- Sample program/cup mismatch (7) – The sample program has a position that has already been assigned to another sample program.
- Sample manually edited (12) – An attempt was made to edit the sample program from the Lab Computer after it had been edited using the Sample Programming screen.
- No assays requested (13) – The sample program was downloaded with no assay requests. This applies only if the sample program does not exist to begin with.
- Invalid assay requested (14) – An assay was requested which is currently not supported by the System. The program is accepted but the unsupported assay is deleted from the program.
- Derived test replicated (15) – The sample program included a request to replicate a derived test. The program is accepted and the requested derived test is calculated.
- Too many assays (16) – The sample program has more than the maximum assays or replicates requested. This includes volume checks.
- Sample/tray program changed (17) – The sample program has been assigned to another tray. The sample program is accepted as long as that tray is not currently in the metering area.
- Sample program taken off tray (18) – The sample program has become unassigned. The sample program is accepted. If the matching sample is in the buffer, automatic assignment will assign the unassigned program; therefore, this audit code may only be generated if the matching sample is not in the metering area.

- No assays: sample deleted (19) – The sample program did not include any assays and was deleted by the Lab Computer.
- Dilution out of range (20)
  - The manual dilution factor for this sample program is not between 0.0001 – 9999.0.
  - The product of Test Dilution factor (i.e., Operator Requested Dilution) and Standard Dilution factor is not a valid dilution factor.
  - The assay is not dilutable and the test dilution factor is not 1.0.
  - The assay is not configured for a diluent fluid and the Test Dilution factor (i.e., Operator Requested Dilution) is not 1.0
- Body fluid unknown (22) – The sample program included a body fluid that the System does not currently support.
- Program pretreated assays separately (23) – The sample program included pretreated and non-pretreated assays or included pretreated assays from multiple pretreatment groups. This restriction does not apply to QC programs.
- Assays in progress could not be deleted (25) – An attempt to delete the program was made. The sample program is accepted but not all tests could be deleted because they were already in process. These tests will be completed, but they will be prevented from reprocessing.
- Attempt to edit a program in process (26) – An attempt was made to append to a program while it was in process but program information was changed that cannot be changed when the program is in process. The program is rejected.
- An append program was downloaded but not all the assays could be added to the program (27). For example, a derived test was requested, but one of the components was already in the original program. The program is saved.

4.3.3 Storing Sample Programs

The System allows local sample programming to occur simultaneously with LIS downloaded sample programming or host query.

The System supports the ability to add a new sample program received from the LIS.

A sample program being downloaded from the LIS overwrites a saved sample program when all of the following conditions are met:

- The Sample ID of a saved sample program matches the ID of the downloaded sample program.
- The patient first name, last name, and middle initial on the saved program are the same as on the downloaded program.
- The saved sample program was previously downloaded from the LIS.
- The saved sample program has not been modified through the System's GUI.
- The saved sample program is not in process.

Note: Some sample program verification audits described above may prevent the program from being saved.

The downloaded sample program causes the deletion of a saved sample program when all of the following conditions are met:

- The Sample ID of a saved sample program matches the ID of downloaded sample program.

- The patient first name, last name, and middle initial on the saved program are the same as on the downloaded program.
- The downloaded sample program is marked for cancellation or there are no tests programmed.
- The saved sample program was previously downloaded from the LIS.
- The saved sample program has not been modified through the System's GUI.
- The sample program is not in process.

Note: For sample programs that are in process, assays in the program will be prevented from any possible reprocessing but not be deleted from the program.

If a new sample program (not an append) is downloaded from LIS for a sample that already has a program in process, the following shall occur:

- The program in process is deleted from the database.
- All tests of the program in process are allowed to complete, but no reprocessing occurs.
- The new program is saved to the database.

Discussion: Some sample program verification audits described above may prevent the program from being saved.

Discussion: The new program will be started when 1) the program in process is complete and the sample is re-scanned, or 2) when a new program is downloaded, and the program in process is complete, and the sample is still in the metering area.

When processing a downloaded sample program, the System applies an assay's default replicate count to the first downloaded test; each additional downloaded test shall not apply the replicate count.

Note: For example, if an assay's default replicate count was 3, and there were 2 requests for the assay in the download, a total of 4 reps would be performed.

Permanent sample programs cannot be created from a LIS download.

When a birth date is supplied by the LIS, the System determines and stores the age, in days, in the patient demographics.

4.3.3.1 Tests with Blanks (Na+ and K+ Urine)

The LIS can explicitly request an unequal number of Na+ or K+ tests in urine.

For each Na+ rep in the downloaded sample program, the System ensures there is an associated K+ rep to serve as a blank in the following manner:

- If there is the same number of K+ reps as Na+ reps in the download, the System adds the requested number of Na+ and K+ reps to the sample program. (There is no need to add blank K+ reps since K+ reps are already requested.)
- If there are more Na+ reps than K+ reps in the download, the System adds the appropriate number of "blank" K+ reps to the sample program, so that the number of Na+ and K+ reps are equal.

The dilution factor for an Na+ rep and its associated K+ rep is the same and is set to the dilution factor specified for the Na+ rep.

4.3.3.2 Assays that Share Slides (Bu and Bc)

Bu and Bc tests are performed using the same slide. Although the user can explicitly request an unequal number of Bu and Bc tests, the System programs and reports an equal number of Bu and Bc tests.

If there are more Bu reps than Bc reps in the downloaded sample program, the System adds enough Bc reps to make the rep counts equal. The added Bc reps are labeled "adjunct" and use the same dilution as the corresponding Bu rep.

If there are more Bc reps than Bu reps in the downloaded sample program, the System adds enough Bu reps to make the rep counts equal. The added Bu reps are labeled "adjunct" and use the same dilution as the corresponding Bc rep.

If the dilution factor for a Bu rep and matching Bc rep is not the same, the sample program is rejected with an audit code 2.

4.3.3.3 Derived Tests

If a downloaded program contains a derived test and the program already includes one or more assays that are components of the derived test, additional replicates for the included assays are not programmed.

If a downloaded program contains a derived test and a dilution factor is requested, the dilution factor is not applied to the test. No download message is generated.

Note: The screen Options and Configuration – Configure Assays allows users to specify whether or not a derived test result should be calculated and reported if that derived test's components have been programmed.

If the user requests the results for a derived test reported when all the components are requested in a downloaded program, the derived test is added (and considered directly selected) only if all components are directly selected to the sample program to the sample program.

Note: For example, if only Bc is requested in a program, Bu will be added but will not be considered directly selected. In this case, the derived test NBIL (which has two components, Bu and Bc) will not be added.

If a downloaded program contains a derived test but not any of the derived test's components, when the components are added, they shall be considered directly selected.

4.3.4 LIS Append

The LIS may request to add tests to an existing program. This section outlines the behavior for dealing with these append programs.

An append program being downloaded from the LIS finds a match with an existing saved program to modify when all of the following conditions are met:

- The Sample ID of a saved sample program matches the ID of append program.
- The patient first name, last name, and middle initial on the saved program are the same as on the append program.
- The body fluid of the saved program is the same as on the append program.
- The saved sample program was previously downloaded from the LIS.
- The saved sample program has not been modified through the System's GUI.

An append program is treated as a regular downloaded program if no match is found.

Not In Process: An append program is composed with the matching saved program that is **not in process** in the following ways to create a resultant program:

- Any tests specified in the append program not existing in the saved program are added along with any related tests (derived, blanks, two-result, components).
- Any tests specified in the append program that exist in the saved are added, overwriting the existing tests. Any non-existing related tests will also be added (derived, blanks, components).
- Non-test program information from the append program will overwrite existing information.

Note: Assays in the saved program but not in the append program remain in the resultant program.

In Process: An append program is composed with the matching saved program that is **in process** in the following ways to create a resultant program:

- Any tests specified in the append program not existing in the saved program are added along with any related tests (derived, blanks, two-results, components) provided that all related tests also do not exist in the saved program.

Note: Derived tests will not be automatically added if one of the components is already in the program and the second component is appended

- Any tests specified in the append program that exist in the saved program are ignored.
- All other non-test program information and patient demographics from the append program overwrite existing information.

Note: Assays in the saved program but not in the append program remain in the resultant program.

The following audits are performed on the resultant program as well as the append program:

- Remove Sample Indices (SI) assays for programs with mixed SI and non-SI assays.
    - If the program does not exist in the database, SI tests will be removed from the resultant program and no download message will be generated.
    - If the program exists in the database, and has not started, SI tests will be removed from the resultant program and no download message will be generated.
    - If the program exists in the database, and is in process:
        - If the original program was SI only, all Non-SI assays will be ignored and download message 27 will be generated. (Refer to Appendix H Download Messages.)
        - If the original program was not SI only, all SI assays will be ignored and no download message will be generated.
- Program pretreated assays separately. (Download message 23. Refer to Appendix H Download Messages.)
- Too many assays. (Download message 16. Refer to Appendix H Download Messages.)An append program with no tests indicated updates non-test program information and patient demographics only.

4.4 Uploading Result Records

The System provides a method to upload test results, patient, and physician demographics.

The System uploads result records to the Lab Computer provided all of the following conditions are met:

- The Lab Computer is able to accept transmissions.
- No downloads are occurring at the time. (Not Applicable for HL7)
- No host queries are in process.
- Result records exist and are ready to be uploaded.
- No inventory queries are in process.

If the System is configured for the ASTM protocol, results are sent to the LIS with the Result Upload message. See Section 5.2.2 for the message structure.

If the System is configured for the HL7 protocol, results are sent to the LIS with an OUL message, Unsolicited Specimen Container Oriented Observation, (event R23). See Section 5.4.4 HL7 OUL Unsolicited Observation Message Structure.

Note: The OUL^R23 message event is relatively new in HL7, specifically for lab automation equipment container-oriented test results. Even though the message is titled Unsolicited Specimen Container Oriented Observation, there is very little that distinguishes a solicited result from an unsolicited result so there is only one result type message for both. See Chapter 7.3.8 of the *HL7 2.5 Specification, 2003*.

Results with multiple replicates have each replicate uploaded along with the mean of the replicates. Mean results are indicated by an MN code in the abnormal flags field.

For results records where the mean concentration is suppressed, the numerical value and units are suppressed for a mean result record.

For semi-quantitative/qualitative assays the numerical value and units are suppressed in a result record if the assay is not configured to display value with the result.

Results with 0 (e.g., Derived Tests) or 1 replicate record have only the test record sent.

For results records that have the following:

- a qualitative categorization
- a numerical result outside the reportable range

the categorization takes priority and the following occurs:

- the numerical value and units are suppressed if the system is not configured to include reportable range flags in the result
- above/below reportable range flag are suppressed.

The System uploads an extended result record for each replicate result record only when configured to send extended result information. The following extended results information will be sent:

- Reagents
- Calibration
- Quality Control (for quality control samples)
- Diluents

If an attempt to upload results occurs during the download of sample programs, the current sample program being downloaded is allowed to complete.

Once the sample program currently being downloaded is complete, the upload of results occurs.

The system waits for all tests in a sample to complete until results are uploaded when the upload mode is configured to "Sample." The system uploads results as each test completes when upload mode is configured to "Result."

When the system is configured with an upload mode of "Group," results are uploaded using the following rules:

- Measured tests are eligible for upload if they are complete and all the other tests in the result record that share the same upload group are also complete.
- Derived tests are eligible for upload if all of their components are eligible for send or have already been sent.

Sample Indices tests have their own result records like any other assay. These result records will be uploaded with the first result message for a sample regardless of the upload mode.

The Sample Indices result records contain any Hemolysis, Icterus or Turbidity codes specific to the sample.

The Sample Indices results are created whether Sample Indices is enabled or not.

If the System is configured to include reportable range flags in the result field, the System includes:

- A ">" in front of the result value when the result is above the reportable range
- A "<" in front of the result value when the result is below the reportable range

QC samples always upload the numerical result and units for semi-quantitative/qualitative assays.

Note: This overrides the “Display value with result” selection on the "Review/Edit Configuration" screen in Options & Configuration.

If configured to include qualitative text comments, the system uploads a result comment record containing the qualitative text for result records with a qualitative categorization.

4.5 Host Query

4.5.1 Basic Functionality

The user can configure the Host Query feature to be either on or off.

If the System is configured for the ASTM protocol, a host query is sent to the LIS with a Host Query message. See Section 5.2.3 Host Query/Query Cancel Message Structure for the message structure.

If the System is configured for the HL7 protocol, a host query is sent to the LIS with a QBP_ZOS message, Host Query Message. See Section 5.4.5 HL7 QBP_ZOS Host Query Message Structure.

The System requests sample program information based on the barcode of the sample.

The System processes all downloaded sample programs (either requested or unsolicited) while a query is pending.

If the System is configured for the HL7 protocol, a host query response is received from the LIS with a RSP_ZOS message, Host Query Response. See Section 5.4.6 HL7 RSP_ZOS Host Query Response Message Structure.

If the System is configured for the ASTM protocol, a host query response is received from the LIS with an Order Download message for successful queries and a Failed Host Query Response message for unsuccessful queries. See Sections 5.2.1 Order Download Message Structure and 5.2.4 Failed Host Query Response Message Structure.

4.5.2 Host Query Timer

The user sets a timer that determines how long the System waits for a response to a query. The default timer value is 2.4 seconds, but this can be changed to values between 1.9 and 9.9 seconds.

After a configuration change, a timer change goes into effect with the next query.

The Host Query timer starts when the query record/segment is sent to the LIS.

The Host Query timer stops when any one of the following conditions occurs:

- A matching specimen ID with sample program is downloaded.
- No sample program is available for the query. (For ASTM, the indication is an “I” in the termination code field of the Message Termination Record. For HL7, the indication is the Query Response Status value of “NF” that is returned in the QAK segment of the RSP^ZOS.)
- An error has occurred. (For ASTM, the indication is a “Q” in the termination code field of the Message Termination Record. For HL7, the indication is the Query Response Status value of “AE” or “AR” that is returned in the QAK segment of the RSP^ZOS.)
- The timer has expired.

Note: An append program can satisfy a Host Query.

If a query is requested and the timer expires before a response to the query, an attention error is posted with text substitution displaying the timer value and the sample ID.

Once a query has been requested and a response is pending, no results are uploaded.

If a query request is sent and the timer expires, a query cancel message is sent. For HL7 protocol, a QCN message is sent. See Section 5.4.7 HL7 QCN Host Query Cancel Message Structure. For ASTM protocol, a Host Query Cancel message is sent. See Section 5.2.3 Host Query/Query Cancel Message Structure.

4.5.3 Sending and Receiving Messages

Each query that is sent is a separate message.

The priority of requests from highest to lowest shall be:

- Canceling a query request
- Requesting a query
- Responding to an inventory query
- Uploading asynchronous notifications
- Uploading results

The termination code field of the termination record is ignored unless it contains a Q (Error in the last request) or an I (no information available). For HL7 Query Response Status, a value of “AR”, “AE” or “NF” is returned in the QAK segment of the RSP^ZOS.

The specimen ID field of the Order record is ignored when there is an I in the termination code field of the Message Termination Record. For HL7-Query Response Status, a value of “NF” is returned in the QAK segment of the RSP^ZOS.

If a Q (error in the last request) or an I (no information available) is in the termination code field of the Message Termination record, a condition code is posted. For HL7 Query Response Status, a value of “AR”, “AE” or “NF” is returned in the QAK segment of the RSP^ZOS.

If Host Query is turned off, no further queries are sent.

If Host Query is turned off while a request is in process, the request will finish.

Note: If Host Query is turned off while there are pending queries, those queries waiting to be sent are purged.

4.5.4 Host Query Priority

If the protocol is set to ASTM and a Host Query request needs to be sent to the LIS while messages are being downloaded, the download of the current message is allowed to complete.

The query is allowed to start and end (including cancel) before the System initiates any other requests.

If the protocol is set to ASTM, messages are being uploaded, and a query is requested; the upload stops on a frame boundary unless the next frame to send is the last.

If the protocol is set to ASTM and an upload is interrupted due to a query request, the System sends a T (sender cancel) in the Termination Code field of the Message Termination record.

If the protocol is set to HL7, messages are being uploaded, and a query is requested; the upload stops on a message boundary.

If the protocol is set to ASTM and the upload of results for a patient record was interrupted due to a host query request, all previously transmitted results for that patient (ASMT Patient record) are resent along with those results not sent once the upload resumes.

Note: Downloaded messages include sample programs and inventory queries. Uploaded messages include results, inventory replies, and asynchronous notifications.

The messages upload when no additional queries are pending.

4.6 Inventory Query

The System accepts incoming inventory queries when no inventory queries are in process.

If the System is configured for the ASTM protocol, an inventory query is received by the LIS with an Inventory Query message. See Section 5.2.5 Inventory Query Message Structure.

If the System is configured for the HL7 protocol, an inventory query is received from the LIS with an INR Equipment Inventory Request message. See Section 5.4.8 HL7 INR Equipment Inventory Request Message Structure.

The System sends an inventory response message when:

- No downloads are occurring at the time (Not Applicable to HL7)
- No host queries are in process
- An inventory query was received from the Lab Computer

If the System is configured for the HL7 protocol, an inventory update is sent to the LIS with an INU Equipment Inventory Update message. See Section 5.4.9 HL7 INU Equipment Inventory Update Message Structure.

If the System is configured for the ASTM protocol, an inventory update is sent to the LIS with an Inventory Response message. See Section 5.2.7 Inventory Response Message Structure.

An inventory response message contains Reagent Inventory Records if the Inventory Type code in the Inventory Query record is either R (Reagents) or A (All inventory types).

An inventory response message shall contain Diluent Inventory Records if the Inventory Type code in the Inventory Query record is either D (Diluents) or A (All inventory types).

An inventory response message contains a Bulk Consumables Inventory Record if the Inventory Type code in the Inventory Query record is either B (Bulk Consumables) or A (All inventory types).

If the protocol is set to ASTM and an inventory query cannot be processed, the System responds with a message containing only a Header and Trailer record. The Termination Code of the Trailer record is Q (Error In Last Request). See Section 5.2.6 Failed Inventory Query Response Message Structure.

If the protocol is set to HL7 and an inventory query cannot be processed, the System responds with an Acknowledgement with an error segment in it.

If the protocol is set to ASTM and inventory is not on board for the requested inventory type, the System responds with a message containing only a Header and Trailer record. The Termination Code of the Trailer record is I (No Information Available). See Section 5.2.6 Failed Inventory Query Response Message Structure.

If the protocol is set to HL7 and inventory is not on board for the requested inventory type, the System responds with an INU Equipment Inventory Update message with no INV segments.

4.7 Asynchronous Notifications

4.7.1 Automation Status Updates

The System sends an automation status update message when all the following conditions are met:

- The System is configured to send asynchronous messages.
- No downloads are in process. (Not Applicable to HL7)
- No host queries are in process.
- No inventory queries are in process.
- A user has changed automation configuration settings.

If the System is configured for the HL7 protocol, an automation status update is sent to the LIS with an Automated Equipment Notification (EAN) message. See Section 5.4.10 HL7 EAN Equipment Notification Message Structure.

If the System is configured for the ASTM protocol, an automation status update is sent to the LIS with an Automation Configuration Notification message. See Section 5.2.8 Automation Configuration Notification Message Structure.

4.7.2 Error Messages

The System sends an error message when all the following conditions are met:

- The System is configured to send asynchronous messages.
- No downloads are in process. (Not Applicable to HL7)
- No host queries are in process.
- No inventory queries are in process.
- One or more condition codes have been posted.

If the System is configured for the HL7 protocol, an error message is sent to the LIS with an Automated Equipment Notification (EAN) message. See Section 5.4.10 HL7 EAN Equipment Notification Message Structure.

If the System is configured for the ASTM protocol, an error message is sent to the LIS with an Error Notification message. See Section 5.2.9 Error Notification Message Structure.

The System excludes the following types of condition codes from transmission:

- Condition codes with a Transient severity
- Condition codes posted by the LIS interface task

4.7.3 Download Messages

The System sends a message containing a Download Messages when all the following conditions are met:

- The System is configured to send asynchronous messages.
- No downloads are in process. (Not Applicable to HL7)
- No host queries are in process.
- No inventory queries are in process.
- One or more download messages have been posted.

If the System is configured for the HL7 protocol, Download Messages are sent to the LIS with an Automated Equipment Notification (EAN) message. See Section 5.4.10 HL7 EAN Equipment Notification Message Structure.

If the System is configured for the ASTM protocol, Download Messages are sent to the LIS with a Download Message Notification message. See Section 5.2.10 Download Message Notification Message Structure.

4.7.4 Status Messages

Note: This feature is only supported for the ASTM protocol.

When the System/Subsystem changes, the System sends the information to the Lab Computer via asynchronous messages:

- The System statuses communicated to the Lab Computer are “Ready”, “Equilibrating”, “Initializing”, etc. The Subsystem statuses are “Ready” or “Not Ready”.

  Note: The System status may be “Ready” while one of the Subsystems is “Not Ready” (for example, if the Subsystem is disabled in Options).

- If the System is “Not Ready”, “Equilibrating”, etc., the status message contains the reason why (for example, MicroSlide incubator temperature out of range, MicroSlide incubator humidity out of range, cuvette supply inoperative, etc.)

- The Analyzer status is sent to the LIS with an Instrument Status Message Notification message. See Section 5.2.12 Status Query Response Message Structure.

If the Analyzer status changes, the Analyzer will send an Analyzer Status message asynchronously.

The default configuration for the asynchronous Analyzer Status messages is disabled. It must be enabled by Ortho Care.

4.8 Test Completion Status Messages

Note: This feature is only supported for the ASTM protocol.

The System responds to a query (containing the Sample ID) from the Lab Computer with the time to result for all the assays that are being run on the sample:

- For all the assays that are complete, the System returns “sample completed”.
- For all the assays for which distribution has not occurred yet, the System returns “sample not started”.
- If the sample program does not exist, the System returns “sample not found”.
- For the assays that are in progress, the System returns the time to result expressed in minutes:seconds.
- A test completion query is received by the Lab Computer with a Test Completion Status Query message. See Section 5.2.13 Test Completion Status Query Message Structure. The System responds with a Test Completion Status message. See Section 5.2.14 Test Completion Status Query Message Structure.

4.9 Analyzer Status Messages

Note: This feature is only supported for the ASTM protocol.

When the System receives a status query message on the LIS interface, the System replies with the status information.

- Overall Analyzer status (Not Ready, Ready, Equilibrating, …)

- Testing State (Assays in Progress or Assays Completed)
- Sampling state (Sampling Off, Internal Sampling, …)
- Status of various subsystems
- Detailed subsystem status for any subsystems that are Not Ready (up to 5)
- Other information

An analyzer status query is received by the Lab Computer with a Status Query message. See Section 5.2.11 Status Query Message Structure.

An analyzer status message is sent to the Lab Computer with a Status Query Response message. See 5.2.12 Status Query Response Message Structure.

5. Message Specifications

The following specifications apply to all protocols.

In order to provide consistency with Sample Programming and to meet database storage requirements, the field size limits described in Section 4.3.1 Supported Fields are used.

Not supported fields for all records are ignored on a download.

The System uploads null values for any field listed as Not supported for all records.

The System transmits and receives data streams using Unicode/UTF-8.

The System transmits and receives data streams using the ISO8859/1 Extended ASCII character set.

The character encoding is configurable.

Note: Only one character encoding is supported at a given time.

The System logs an error if it receives a message using a character set different from its configured character set.

The System transmits unmappable characters as a tilde (~) for the ASTM protocol and a pound sign (#) for the HL7 protocol.

Note: Not all UTF-8 characters can be mapped to the Extended ASCII set.

The System does not allow the "+" character to be used as an encoding character. The "+" character is reserved as a separator for the Ortho-Clinical Diagnostic universal test identifier.

5.1 Common Record Specifications

5.1.1 General

The record and segment specifications in Sections 5.3 ASTM Records and 5.5 HL7 Message Segments include fields that are not be supported by the interface. These fields are shaded in the tables that follow and the words "Not Supported" appear in the Notes column for these fields.

5.1.2 Result Flags

Flag	Description
0	No error
1	Above Reference Range
2	Below Reference Range

Flag	Description
4	Above Measuring (Reportable) Range
5	Below Measuring (Reportable) Range
6	Prediction Failure Value Reported as “No Result”
7	Above supplemental Range
8	Below supplemental range
A	The value of the QC result is greater than two but less than or equal to three baseline standard deviations below the baseline mean. (-2S).
B	The value of the QC result is greater than two but less than or equal to three baseline standard deviations above the baseline mean. (+2S)
C	The value of the QC result is greater than three baseline standard deviations below the baseline mean. (-3S)
D	The value of the QC result is greater than three baseline standard deviations above the baseline mean. (+3S)
E	The values of two consecutive QC results are both greater than two standard deviations above or below the baseline mean. (22s)
F	The values of two consecutive QC results have a change of at least four standard deviations. (R4s)
G	The values of four consecutive QC results are all greater than one standard deviation above or below the baseline mean. (41s)
H	The values of ten consecutive QC results are all above or all below the baseline mean. (10x)
J	The result of this Sample Indices test exceeds the threshold for this assay.
Q	Qualitative (semi-quantitative) assay Result Classification 1
R	Qualitative (semi-quantitative) assay Result Classification 2
S	Qualitative (semi-quantitative) assay Result Classification 3
T	Qualitative (semi-quantitative) assay Result Classification 4
U	Qualitative (semi-quantitative) assay Result Classification 5

5.1.3 Calibration Status

Status	Description
N	Normal Calibration
U	User Calibrated

Status	Description
M	User Modified
B	User Modified/Calibrated

5.1.4 Fluid Reagent Status

Status	Description
U	Current: There is a passing “Current” calibration for this lot/fluid
C	Calibrated: There is a passing calibration for this lot/fluid
null	Not Supported / Not Calibrated: This fluid is not supported or there are no passing calibrations for this lot/fluid.

5.1.5 Severity Level

ASTM Severity	HL7 Severity	Description
A	N	Attention
N	W	Action
M	S	Malfunction
S	C	Shutdown

5.1.6 Inventory Type

Type	Description
R	Reagents (carts and packs)
D	Diluents
B	Bulk consumables (fluids, tips, cuvettes, waste)
A	All inventory types

5.1.7 Reprocessing Type

Type	Description
N	None, initial testing
R	Retesting

Type	Description
I	Retesting due to insufficient inventory
D	Reflex dilution/reduction
F	Reflex test; reflexed from same or different test
G	Reprocessed because another reprocessing group component requiring reprocessing

5.1.8 Metering Point Type

Type	Description
A	Specimen positioned at the MicroSlide/MicroTip Point of Reference
B	Specimen positioned at the MicroImmunoassay Point of Reference
	An empty string that identifies a specimen not positioned at an external metering point

5.2 ASTM Messages

Note: All referenced sections can be found in *Standard Specification for Transferring Information Between Clinical Laboratory Instruments and Computer Systems,* NCCLS LIS2-A (Formerly ASTM E1394-97) unless otherwise noted.

The LIS processes the record types and fields defined in *Standard Specification for Transferring Information between Clinical Laboratory Instruments and Computer Systems,* NCCLS LIS2-A (Formerly ASTM E1394-97) with the exception of Scientific (S) records. In the record field descriptions, all values are text and meet the ASTM Common Field Types specification, Section 6.6. If a field value has multiple components, they are differentiated by the "^" character. If the System protocol is set to ASTM, the following Messages are utilized.

The System supports the hierarchical message structure as defined in Sections 5.1.8 through 5.1.11.

The System supports the Logical Information Storage and Logical Transmission Error Recovery Requirements defined in Sections 5.2.1 and 5.2.2.

The System processes Receiver Interrupt requests from the LIS. The System re-establishes a session as sender at the end of the LIS message transmission or after the 15-second timeout. At that time, the System sends the records specified by the Logical Information Storage and Logical Transmission Error Recovery Requirements defined in Section 5.2.2

5.2.1 Order Download Message Structure

The ASTM Order Download message uses the following message structure:

```
H  -- HEADER (See Section 5.3.1 in this LIS Guide.)
{
P  -- PATIENT (See Section 5.3.3 in this LIS Guide.)
   [C]  -- COMMENT (See Section 5.3.6 in this LIS Guide.)
   {O}  -- ORDER (See Section 5.3.4 in this LIS Guide.)
```

```
}
L  -- TRAILER (See Section 5.3.2 in this LIS Guide.)
```

5.2.1.1 Order Download Message Example

```
H|\^&|||LITT||||||||LIS2-A|20061214093913
P|1|U000856|||ORR^ABIGAIL^G||19780407|F||843 TALL OAKS
DR^HAILVILLE, MD 45831|||RASHAMDRA^SANJAY^V|S||||||||||U7
C|1|N|Patient is complaining of shortness of breath and chest
pain.|G
O|1|S4331009704||^^^1.0+300+1.0\300+2.0\001+1.0|R||20061214093913
||||N||||5||||||||||O
O|2|U4331009704||^^^1.0+301+1.0|R||20061214093913||||N||||3||||||
||||O
L|1|N
```

5.2.2 Result Upload Message Structure

The ASTM Result Upload message uses the following message structure:

```
H  -- HEADER (See Section 5.3.1 in this LIS Guide.)
P  -- PATIENT (See Section 5.3.3 in this LIS Guide.)
   [C]  -- COMMENT (See Section 5.3.6 in this LIS Guide.)
    O  -- ORDER (See Section 5.3.4 in this LIS Guide.)
      {
      R -- RESULT (See Section 5.3.5 in this LIS Guide.)
            [C] – COMMENT (See Section 5.3.6 in this LIS Guide)
            [M/X]  -- EXTENDED RESULT
                  (See  Section 5.3.8 in this LIS Guide.)
      }
L  -- TRAILER (See Section 5.3.2 in this LIS Guide.)
```

5.2.2.1 Result Upload Message Examples

This example includes the optional extended results records:

```
H|\^&|||qnxa224|||||||LISH2-A|20061213141607

P|1|U000919|||SEAN^BOYD^M||19951227|M||123 MAIN STREET^ROCHESTER,
NY|||SMITH^JOHN^H|1||||||||||SWVV

C|1|I|Free form comment about a patient.|G

O|1|4331035404^5^3||^^^1.0000+301+1.0|S||20060731085403||||N||||5
|||||||||F

R|1|^^^1.0000+301+1.0|4.1|g/dL||^2^EP\^0^\^0^\^0^||V||BREDICK|200
60731090236|20060731090820|43000224

M|1|X|06446337^20071101185959^20060722064135^M6587^J6767^0|200607
20081750^N||8001011234\8002015678\8002010090

R|2|^^^1.0000+950+1.0|15|||^5^||V||BREDICK|20060731090236|2006073
1090258|43000224

R|3|^^^1.0000+951+1.0|2|||^5^||V||BREDICK|20060731090236|20060731
090258|43000224

R|4|^^^1.0000+952+1.0|24|||^0^||V||BREDICK|20060731090236|2006073
1090258|43000224

L|1|N
```

This example contains optional "<" or ">" signs in the result value field and also includes the optional result comment containing qualitative text:

```
H|\^&|||qnxa224|||||||LIS2-A|20080822100735

P|1|PID12345|||Doe^John^X||19850105|M||123<SP>Main<SP>St<SP>Apt<S
P>4^Anytown<SP>USA|||Jones^Robert^H|1||||||||||S8

C|1|I|This<SP>is<SP>a<SP>patient<SP>co|G

O|1|DAT12345^1^1||^^^1.0000+521+1.0\522+1.0\523+1.0\950+1.0\951+1
.0\952+1.0|R||20080822080000||||N||||3||||||||||F

R|1|^^^1.0000+521+1.0|<100|ng/mL||^Q^OREP\^0^NR\^0^NR\^0^NR||V|||
20080822093518|20080822093850|43000224

C|1|I|Negative|I

R|2|^^^1.0000+522+1.0|100|ng/mL||^Q^EP\^0^NR\^0^NR\^0^NR||V|||200
80822093518|20080822093814|43000224

C|1|I|Negative|I

R|3|^^^1.0000+523+1.0|500|ng/mL||^R^EP\^0^NR\^0^NR\^0^NR||V|||200
80822093518|20080822093936|43000224

C|1|I|Positive|I

R|4|^^^1.0000+525+1.0|>1000|ng/mL||^R^OREP\^0^NR\^0^NR\^0^NR||V||
|G20080822093518|20080822094001|43000224

C|1|I|Positive|I

R|5|^^^1.0000+950+1.0|No<SP>Result|||^0^NR||V|||20080822093518|20
080822093518|43000224
```

```
R|6|^^^1.0000+951+1.0|No<SP>Result|||^0^NR||V|||20080822093518|20
080822093518|43000224

R|7|^^^1.0000+952+1.0|No<SP>Result|||^0^NR||V|||20080822093518|20
080822093518|43000224

L|1|N
```

This is an example of a suppressed mean result when three replicates of the assay are run:

```
H|\^&|||qnxa152|||||||LIS2-A|20090402152556<CR>

P|1|PID12345|||Doe^John^X||19850105|M||123<SP>Main<SP>St<SP>Apt<S
P>4^Anytown<SP>USA|||Jones^Robert^H|1||||||||||S8

C|1|I|This<SP>is<SP>a<SP>patient<SP>co|G
O|1|test3^1^1||^^^1.0000+019+1.0\019+1.0\019+1.0\019+1.0\019+1.0\
019+1.0\950+1.0\951+1.0\952+1.0|R||||||N||||5||||||||||F<CR>

R|1|^^^1.0000+019+1.0||||^0^UCFRMN\^6^ES\^6^ES\^6^ES||V|||2009040
2073138|20090402074353|qnxa0152<CR>

C|1|I|See<SP>Replicates|I<CR>

R|2|^^^1.0000+019+1.0||||^S^REEMUC\^6^ES\^6^ES\^6^ES||V|||2009040
2073142|20090402074218|qnxa0152<CR>

C|1|I|Negative|I<CR>

R|3|^^^1.0000+019+1.0||||^S^REEMUC\^6^ES\^6^ES\^6^ES||V|||2009040
2073201|20090402074237|qnxa0152<CR>

C|1|I|Negative|I<CR>

R|4|^^^1.0000+019+1.0||||^S^REEMUC\^6^ES\^6^ES\^6^ES||V|||2009040
2073220|20090402074256|qnxa0152<CR>

C|1|I|Negative|I<CR>

R|5|^^^1.0000+019+1.0||||^S^REEMUC\^6^ES\^6^ES\^6^ES||V|||2009040
2073239|20090402074315|qnxa0152<CR>

C|1|I|Negative|I<CR>

R|6|^^^1.0000+019+1.0||||^S^REEMUC\^6^ES\^6^ES\^6^ES||V|||2009040
2073258|20090402074334|qnxa0152<CR>

C|1|I|Negative|I<CR>

R|7|^^^1.0000+019+1.0||||^S^REEMUC\^6^ES\^6^ES\^6^ES||V|||2009040
2073317|20090402074353|qnxa0152<CR>

C|1|I|Negative|I<CR>

R|8|^^^1.0000+950+1.0|No<SP>Result|||^6^ES||V|||20090402073138|20
090402073331|qnxa0152<CR>

R|9|^^^1.0000+951+1.0|No<SP>Result|||^6^ES||V|||20090402073138|20
090402073331|qnxa0152<CR>

R|10|^^^1.0000+952+1.0|No<SP>Result|||^6^ES||V|||20090402073138|2
0090402073331|qnxa0152<CR>

L|1|N<CR>
```

This is an example of a suppressed mean result when only one replicate of the assay is run:

```
H|\^&|||qnxa152|||||||LIS2-A|20090402152556<CR>

P|1|PID12345|||Doe^John^X||19850105|M||123<SP>Main<SP>St<SP>Apt<S
P>4^Anytown<SP>USA|||Jones^Robert^H|1||||||||||S8

C|1|I|This<SP>is<SP>a<SP>patient<SP>co|G

O|1|OneRepOnly^8^1||^^^1.0000+019+1.0\950+1.0\951+1.0\952+1.0|R||
||||N||||5|||||||||F<CR>

R|1|^^^1.0000+019+1.0|2.75|My<SP>Units||^S^REEMUC\^6^ES\^6^ES\^6^
ES||V|||20090402080046|20090402081126|qnxa0152<CR>

C|1|I|Negative|I<CR>

R|2|^^^1.0000+950+1.0|No<SP>Result|||^6^ES||V|||20090402080046|20
090402080104|qnxa0152<CR>

R|3|^^^1.0000+951+1.0|No<SP>Result|||^6^ES||V|||20090402080046|20
090402080104|qnxa0152<CR>

R|4|^^^1.0000+952+1.0|No<SP>Result|||^6^ES||V|||20090402080046|20
090402080104|qnxa0152<CR>

L|1|N<CR>
```

5.2.3 Host Query/Query Cancel Message Structure

The ASTM Host Query/Query Cancel message uses the following message structure:

```
H  -- HEADER (See Section 5.3.1 in this LIS Guide.)
      Q  -- REQUEST (See Section 5.3.7 in this LIS Guide.)
L  -- TRAILER (See Section 5.3.2 in this LIS Guide.)
```

5.2.3.1 Host Query/Query Cancel Example

Host Query

```
H|\^&|||qnxa224|||||||LIS2-A|20061214091313

Q|1|^100987654321||ALL||||||A||O

L|1|N
```

Host Query Cancel

```
H|\^&|||qnxa224|||||||LIS2-A|20061214091316

Q|1|^100987654321||ALL||||||A||A

L|1|T
```

5.2.4 Failed Host Query Response Message Structure

The ASTM Failed Host Query Response message uses the following message structure:

```
H  -- HEADER (See Section 5.3.1 in this LIS Guide.)
      [R] -- REQUEST (See Section 5.3.7 in this LIS Guide.)
L  -- TRAILER (See Section 5.3.2 in this LIS Guide.)
```

5.2.4.1 Failed Host Query Response Example

```
H|\^&|||LITT||||||||LIS2-A|20061214091313
L|1|I
```

5.2.5 Inventory Query Message Structure

The ASTM Inventory Query message uses the following message structure:

```
H  -- HEADER (See Section 5.3.1 in this LIS Guide.)
      M/I  -- INVENTORY QUERY (See Section 5.3.10 in this LIS
                  Guide.)
L  -- TRAILER (See Section 5.3.2 in this LIS Guide.)
```

5.2.5.1 Inventory Query Message Example

```
H|\^&|||LITT||||||||LISH2-A|20061213142107
M|1|I|A
L|1|N
```

5.2.6 Failed Inventory Query Response Message Structure

The ASTM Failed Inventory Query Response message uses the following message structure:

```
H  -- HEADER (See Section 5.3.1 in this LIS Guide.)
L  -- TRAILER (See Section 5.3.2 in this LIS Guide.)
```

5.2.6.1 Failed Inventory Query Response Message Example

```
H|\^&|||qnxa224||||||||LISH2-A|20061213093820
L|1|I
```

5.2.7 Inventory Response Message Structure

The ASTM Inventory Response message uses the following message structure:

```
H  -- HEADER (See Section 5.3.1 in this LIS Guide.)
      [{M/R}] -- REAGENT INVENTORY (See Section 5.3.11 in this
                  LIS Guide.)
      [{M/D}] -- DILUENT INVENTORY (See Section 5.3.12 in this
                  LIS Guide.)
      [{M/B}] -- BULK CONSUMABLES INVENTORY (See Section 5.3.13
                  in this LIS Guide.)
L  -- TRAILER (See Section 5.3.2 in this LIS Guide.)
```

5.2.7.1 Inventory Response Message Example

```
H|\^&|||qnxa224|||||||LISH2-A|20061213093820
M|1|R|001||1600^20071213093820^40^^^^^^^^^^
M|2|D|2601|0001||20071213093821|40
M|3|D|2603|0516||20071213093821|40
M|4|B|Lot1^125|Lot2^25|Infinite|45|10|3500|4|22|49|1^596000|2645
L|1|N
```

5.2.8 Automation Configuration Notification Message Structure

The ASTM Automation Configuration Notification message uses the following message structure:

```
H  -- HEADER (See Section 5.3.1 in this LIS Guide.)
      {M/A}  -- AUTOMATION CONFIGURATION (See Section 5.3.9 in
                this LIS Guide.)
L  -- TRAILER (See Section 5.3.2 in this LIS Guide.)
```

5.2.8.1 Automation Configuration Notification Message Example

```
H|\^&|||qnxa224|||||||LIS2-A|20061214091933
M|1|A|D\D
L|1|N
```

5.2.9 Error Notification Message Structure

The ASTM Error Notification message uses the following message structure:

```
H  -- HEADER (See Section 5.3.1 in this LIS Guide.)
      {M/E}  -- ERROR (See Section 5.3.14 in this LIS Guide.)
L  -- TRAILER (See Section 5.3.2 in this LIS Guide.)
```

5.2.9.1 Error Notification Message Example

```
H|\^&|||qnxa224|||||||LIS2-A|20061214091744
M|1|E|PWE|005|A|Hemolysis coded 'ES' - Turbidity may be
interfering|20061214091744
L|1|N
```

5.2.10 Download Message Notification Message Structure

The ASTM Download Message Notification uses the following message structure:

```
H  -- HEADER (See Section 5.3.1 in this LIS Guide.)
      {M/M}  -- DOWNLOAD MESSAGE (See Section 5.3.15 in this LIS
                Guide.)
L  -- TRAILER (See Section 5.3.2 in this LIS Guide.)
```

5.2.10.1 Download Message Notification Message Example

```
H|\^&|||qnxa224|||||||LIS2-A|20061214092212
M|1|M|13|13-No assays requested.|20060130044311|3705000004^2^1
L|1|N
```

5.2.11 Status Query Message Structure

The ASTM Status Query message uses the following message structure:

```
H - Header (see Section 5.3.1 in this LIS Guide.)
      M/S Status Query (see Section 5.3.16 in this LIS Guide.)
L - Trailer (see Section 5.3.2 in this LIS Guide.)
```

5.2.11.1 Status Query Message Structure Example

```
H|\^&|||qnxa224|||||||LIS2-A|20061214092212
M|1|S
L|1|N
```

5.2.12 Status Query Response Message Structure

The Status Query Response message uses the following message structure:

```
H - Header (see Section 5.3.1 in this LIS Guide.)
      M-M/S Instrument Status Record (see Section 5.3.17 in this
LIS Guide.)
L - Trailer (see Section 5.3.2 in this LIS Guide.)
```

5.2.12.1 Status Query Response Message Example

```
H|\^&|||qnxa224|||||||LIS2-A|20061214092212
M|1|S|1|1|1|1|1|1|1|1|1|1|1|1|1|1|1|1|1|2^3\4^5\6^7\8^9\10^11|3.8
|9158|2|
L|1|N
```

5.2.13 Test Completion Status Query Message Structure

The Test Completion Status Query Message uses the following message structure:

```
H - Header (see Section 5.3.1 in this LIS Guide.)
      M/Q Assay Test-Completion Status Query Message Record (see
Section 5.3.18 in this LIS Guide.)
L – Trailer (see Section 5.3.2 in this LIS Guide.)
```

5.2.13.1 Test Completion Status Query Message Example

```
H|\^&|||qnxa224|||||||LIS2-A|20061214092212
M|1|^SampleID|Q
L|1|N
```

5.2.14 Test Completion Status Message Structure

The Test Completion Status Record Message uses the following message structure:

```
H - Header (see Section 5.3.1 in this LIS Guide.)

      M/Q Assay Test-Completion Status Query Record Message (one
A message per assay) (see Section 5.3.19 in this LIS Guide.)

L - Trailer (see Section 5.3.2 in this LIS Guide.)
```

5.2.14.1 Test Completion Status Message Example

a. Normal Case:

```
H|\^&|||qnxa224|||||||LIS2-A|20061214092212
M|1|T|^SampleID|^^^300|complete|J34001234
M|2|T|^SampleID|^^^301|03:00|J34001234
M|3|T|^SampleID|^^^302|test not started|J34001234
L|1|N
```

b. No sample program or recent results found on analyzer:

```
H|\^&|||qnxa224|||||||LIS2-A|20061214092212
M|1|T|^SampleID||not found|J34001234
L|1|N
```

5.3 ASTM Records

ASTM Records are the components that make up ASTM Messages. In the tables that show the field sequences, shaded rows with Not Supported in the Notes column indicate fields that are not supported by the System. No data is sent in these field positions. The Column Headings of "D" and "U" indicate the optionality of the fields in the record when Downloading to the System (D) and Uploading to the LIS (U). The column Heading of "R" indicates the Repeatability. Use the table below as a key for the values in these columns:

D	U	R
R = Required Field	A = Always Sent	Y = Field can repeat.
O = Optional Field	S = Sometimes Sent	*Blank* = Field Does not repeat
N = Never Used	N = Never Sent	
- = not applicable	- = not applicable	

The System ignores incoming Result, Request Information, Scientific, and Manufacturer Information record types with the exception of Manufacturer Information records defined in this document.

The software accepts and ignores the following escape sequences:

- &H& Start highlighting text
- &N& Normal text (end highlighting)
- &Zcccc& Local (manufacturer) defined escape sequence

The software accepts and supports the following escape sequences:

- &F& Embedded field delimiter character

- &S& Embedded component field delimiter character
- &R& Embedded repeat field delimiter character
- &E& Embedded escape delimiter character
- &Xhhhh& hexadecimal data (e.g., &XA& is a linefeed character)

All date fields are formatted as specified by Dates and Times defined in Section 6.6.2 of *Standard Specification for Transferring Information Between Clinical Laboratory Instruments and Computer Systems,* NCCLS LIS2-A (Formerly ASTM E1394-97).

5.3.1 ASTM H Header Record

The System supports the following unshaded fields of the ASTM Header (H) Record as defined in Section 7.1 of *Standard Specification for Transferring Information Between Clinical Laboratory Instruments and Computer Systems,* NCCLS LIS2-A (Formerly ASTM E1394-97).

#	D	U	R	Field	Length	Notes
1	R	A		Record Type ID	1	= “H” or “h”
2	R	A		Field Delimiters	4	= “|\\^&” These are the Field, Repeat, Component and Escape Delimiters. All delimiters are fixed on upload. All delimiters can be variable on download. Not allowed to use a “+”” sign.
3	N	N		Message Control ID		Not supported
4	N	N		Access Password		Not supported
5	N	A		Sender Name/ID	7	System Name field from System configuration
6	N	N		Sender Street Address		Not supported
7	N	N		Reserved Field		Not supported
8	N	N		Sender Telephone Number		Not supported
9	N	N		Characteristics of Sender		Not supported
10	N	N		Receiver ID		Not supported
11	N	N		Comment		Not supported
12	N	N		Processing ID		Not supported
13	N	A		Version Number	8	ASTM protocol version “LIS2-A”
14	N	A		Date and Time of Message	14	Date and Time of transmission

5.3.2 ASTM L Trailer Record

The System supports the following fields of the ASTM Trailer (T) Record as defined in Section 13.1 of *Standard Specification for Transferring Information Between Clinical Laboratory Instruments and Computer Systems,* NCCLS LIS2-A (Formerly ASTM E1394-97).

#	D	U	R	Field	Length	Notes
1	R	A		Record Type ID	1	= “L” or “l”
2	R	A		Sequence number	1	= 1
3	R	A		Termination Code	1	Values other than N, T, Q, or I not supported

5.3.3 ASTM P Patient Record

The System supports the following unshaded fields of the ASTM Patient (P) Record as defined in Section 8.1 of *Standard Specification for Transferring Information Between Clinical Laboratory Instruments and Computer Systems,* NCCLS LIS2-A (Formerly ASTM E1394-97).

#	D	U	R	Field	Length	Notes
1	R	A		Record Type ID	1	= “P” or “p”
2	R	A		Sequence number	1	reset for each new message
3	O	S		Practice Assigned Patient ID	20	= Patient ID
4	N	N		Lab Assigned Patient ID		Not supported
5	N	N		Patient ID No. 3		Not supported
6	O	S		Patient Name	20^15^1	= Last^First^Middle. Suffix and title not supported
7	N	N		Mother's Maiden Name		Not supported
8	O	S		Birthdate	8	= actual birthdate
9	O	S		Patient Sex	1	Must match one of the configured demographic sex characters on the System.
10	N	N		Patient Race/Ethnic Origin		Not supported
11	O	S		Patient Address	20^20	Component1^Component2
12	N	N		Reserved Field		Not supported
13	N	N		Patient Telephone Number		Not supported
14	O	S		Attending Physician ID	20^15^1	= Last^First^Middle. The System only allows the ID of one physician.

#	D	U	R	Field	Length	Notes
15	O	S		Special Field 1	1	= Range Attribute. Must match one of the configured demographic attribute characters on the System.
16	N	N		Special Field 2		Not supported
17	N	N		Patient Height		Not supported
18	N	N		Patient Weight		Not supported
19	N	N		Patient's Diagnosis		Not supported
20	N	N		Patient Active Medications		Not supported
21	N	N		Patient's Diet		Not supported
22	N	N		Practice Field 1		Not supported
23	N	N		Practice Field 2		Not supported
24	N	N		Admission and Discharge Dates		Not supported
25	N	N		Admission Status		Not supported
26	O	S		Location	10	= patient room number
27	N	N		Nature of Alternative Diagnosis Code		Not supported
28	N	N		Alternative Diagnosis Code		Not supported
29	N	N		Patient Religion		Not supported
30	N	N		Marital Status		Not supported
31	N	N		Isolation Status		Not supported
32	N	N		Language		Not supported
33	N	N		Hospital Service		Not supported
34	N	N		Hospital Institution		Not supported
35	N	N		Dosage Category		Not supported

5.3.4 ASTM O Order Record

The System supports the following unshaded fields of the ASTM Order (O) Record as defined in Section 9.4 of *Standard Specification for Transferring Information Between Clinical Laboratory Instruments and Computer Systems,* NCCLS LIS2-A (Formerly ASTM E1394-97).

#	D	U	R	Field	Length	Notes
1	R	A		Record Type ID	1	= “O” or “o”
2	R	A		Sequence Number	1	Starts at 1. Sequence number increases by one for each result within an order. Reset for new message
3	R	A		Specimen ID	15^2^2	= SampleID^Tray ID^Cup. Assigned by the LIS (if download) and returned by the Analyzer. Made up of three components. The Sample ID or the Tray and Cup are required on download
4	N	N		Instrument Specimen ID		Not supported
5	R	A	Y	Universal Test ID	Variable	= ^^^LocalOrMfctrCode. See Specification LISH153 It is empty if Action Code is C.
6	R	A		Priority	1	= S, A, R, C, P S and A considered STAT priority
7	N	N		Requested/Order Date and Time		Not supported
8	O	S		Specimen Collection Date and Time	14	= date and time specimen was collected
9	N	N		Collection End Time		Not supported
10	N	N		Collection Volume		Not supported
11	N	N		Collector ID		Not supported

#	D	U	R	Field	Length	Notes
12	O	A		Action Code	1	= C, N, A, P, L, X, Q P, L, X, and Q are treated as N. On Download: N (normal) adds a program for this order A (append) adds tests to the matching program overwriting any existing tests and demographics. For orders with no tests, only demographics will be updated. See Section 4.3.4 LIS Append for details. C (cancel) deletes the matching program. On upload System always sends “N”
13	N	N		Danger Code		Not supported
14	N	N		Relevant Clinical Info		Not supported
15	N	N		Date/Time Specimen Received		Not supported
16	R	A		Specimen Descriptor	1	= body fluid
17	N	N		Ordering Physician		Not supported
18	N	N		Physician's Phone Number		Not supported
19	N	N		User Field 1		Not supported
20	N	N		User Field 2		Not supported
21	N	N		Laboratory Field 1		Not supported
22	N	N		Laboratory Field 2		Not supported
23	N	N		Date/Time Results Reported or Last Modified		Not supported
24	N	N		Instrument Charge		Not supported
25	N	N		Instrument Section ID		Not supported

#	D	U	R	Field	Length	Notes
26	N	A		Report Types	1	= O, P, F O for downloading P for uploading when some tests are still in progress F for uploading when all tests in sample are complete Other values not supported
27	N	N		Reserved Field		Not supported
28	N	N		Location or Ward of Specimen Collection		Not supported
29	N	N		Nosocomial Infection Flag		Not supported
30	N	N		Specimen Service		Not supported
31	N	N		Specimen Institution		Not supported

5.3.5 ASTM R Result Record

The System supports the following unshaded fields of the ASTM Result (R) Record as defined in Section 10.1 of *Standard Specification for Transferring Information Between Clinical Laboratory Instruments and Computer Systems,* NCCLS LIS2-A (Formerly ASTM E1394-97).

#	D	U	R	Field	Length	Notes
1	-	A		Record Type ID	1	= “R” or “r”
2	-	A		Sequence number	unlimited	Initial value is 1, reset for each new order; maximum length is unlimited
3	-	A	Y	Universal Test ID	^^^13	= ^^^LocalOrMfctrCode See 4.2 Downloading Sample Programs in this LIS Guide.

#	D	U	R	Field	Length	Notes
4	-	A		Data or Measurement Value	9	Floating Point Numeric Result converted to configured units. "No Result" will appear when System cannot report numeric value. If configured to include the measuring (reportable) range flag in the result field, for results that are outside of measuring range (Result Flag of 4 or 5), a ">" or "<" will be prepended to the value; the value will represent the extreme of the measuring (reportable) range. If not configured to include the measuring (reportable) range flag in the result field, for results that are outside of measuring range (Result Flag of 4 or 5), the value will represent the extreme of the measuring (reportable) range. If not configured to include the measuring (reportable) range flag in the result field, for results that are outside of measuring range (Result Flag of 4 or 5) and also have a qualitative result classification (Result Flag Q, R, S, T, or U), the value will be left blank. For semi-quantitative/qualitative assays the value is blank if the assay is not configured to display the value with the result. If this is a mean record and the result record indicates that the mean concentration should be suppressed, the value will be left blank.
5	-	A		Units of Measurement Value	12	Actual Value (e.g., mg/dL). Units are configured via O&C – Configure Assays. For semi-quantitative/qualitative assays the value is blank if the assay is not configured to display the value with the result. If this is a mean record and the result record indicates that the mean concentration should be suppressed, the value will be left blank
6	-	N		Reference Ranges		Not supported

#	D	U	R	Field	Length	Notes
7	-	S	Y	Result Abnormal Flags	^1^10	= ^ResultFlag (See 5.1.2 Result Flags in this LIS Guide.)^Code\; maximum length = ^1^10 This field shall be repeated 3 times (for a total of 4 repetitions). The first is for any flag/codes specific to the assay, the second is for any specific to Hemolysis, the third for Icterus and the fourth for Turbidity. Component 1 of this field is always an empty string. Component 3 of this field will contain up to 5 non-delimited two-character codes as specified in Appendix F Result Codes and Appendix G Sample Indices Flags in this LIS Guide.
8	-	N		Nature of Abnormality Testing		Not supported
9	-	A		Result Status	1	= “V”. Values other than V not supported
10	-	N		Date of Change in Instrument Normative Values or Units		Not supported
11	-	S		Operator Identification	15	= OperatorID. Operator that started to run the test
12	-	A		Date/Time Test Started	14	= RepStartTime in format of YYYYMMDDHHMMSS
13	-	A		Date/Time Test Completed	14	= RepEndTime in format of YYYYMMDDHHMMSS
14	-	A		Instrument Identification	12	= JNumber

5.3.6 ASTM C Comment Record

The System supports the following fields of the Comment (C) Record as defined in Section 11.1 of *Standard Specification for Transferring Information Between Clinical Laboratory Instruments and Computer Systems,* NCCLS LIS2-A (Formerly ASTM E1394-97).

#	D	U	R	Field	Length	Notes
1	R	A		Record Type ID	1	= “C” or “c”
2	R	A		Sequence number	1	Initial value is 1; reset for each new record type
3	N	A		Comment Source	1	= “I” Values other than I not supported
4	R	A		Comment Text	60	Value is free text for patient comments. Value is the qualitative result for result comments.
5	R	A		Comment Type	1	= “G”, “I” G (generic/free text) used for patient comments. I (instrument flags) used for result comments to report qualitative results. Values other than G are not supported for patient comments.

5.3.7 ASTM Q Request Record

The System supports the following unshaded fields of the Request (Q) Record as defined in Section 12.1 of *Standard Specification for Transferring Information Between Clinical Laboratory Instruments and Computer Systems,* NCCLS LIS2-A (Formerly ASTM E1394-97).

#	D	U	R	Field	Length	Notes
1	-	A		Record Type ID	1	= “Q” or “q”
2	-	A		Sequence number	1	Initial value is 1; reset for each new message
3	-	A		Starting Range ID Number	^15	= ^Computer System Specimen ID. The specimen ID of interest, only one allowed per record.
4	-	N		Ending Range ID Number		Not supported
5	-	A		Universal Test ID	3	= “ALL” Values other than “ALL” are not supported
6	-	N		Nature of Request Time Limits		Not supported
7	-	N		Beginning Request Results Date and Time		Not supported
8	-	N		Ending Request Results Date and Time		Not supported
9	-	N		Requesting Physician Name		Not supported
10	-	N		Requesting Physician Phone Number		Not supported
11	-	S		User Field 1	1	=”A”, “B”, or “”. A = Specimen positioned at the MicroSlide/MicroTip Point of Reference. B = Specimen positioned at the MicroImmunoassay Point of Reference. “” = An empty string identifies a specimen not positioned at an external metering point.
12	-	N		User Field 2		Not supported
13	-	A		Request Information Status Codes	1	= “A”, “O”. A = Abort/Cancel request. O = requesting test orders and demographics only

5.3.8 ASTM M/X Extended Result Record

The System supports the following fields of the Extended Result (M/X) Record as defined in Section 15.1 of *Standard Specification for Transferring Information Between Clinical Laboratory Instruments and Computer Systems,* NCCLS LIS2-A (Formerly ASTM E1394-97).

#	D	U	R	Field	Length	Notes
1	-	A		Record Type ID	1	= “M” or “m”
2	-	A		Sequence number	1	= 1
3	-	A		SubType Id	1	= “X” or “x”
4	-	A		Reagents	12^14^14^5^5^4	= ReagentLot^ReagentExpDate^ReagentLoadDate^ ERFLot^IWFLot^SRLot Note: SRLot is left blank if no SR was used for this result.
5	-	S		Calibration	14^1^14	= CalibrationDate^CalibrationStatus^CalExpDate (See 5.1.3 Calibration Status in this LIS Guide.) Only included if the associated calibration record still exists in the database.
6	-	S		Quality Control	10^14^14	= ControlLot^ControlCreationDate^ControlExpDate. Only if result is for a QC test.
7	-	S	Y	Diluents	12	= DiluentLot. Repeated for all diluent lots used.
8	-	A		Reprocessing Type	1	= “N”, “R”, “I”, “D”, “F” or "G" See 5.1.7, Reprocessing Type Table

5.3.9 ASTM M/A Automation Configuration Record

The System supports the following fields of the Automation Configuration (M/A) Record as defined in Section 15.1 of *Standard Specification for Transferring Information Between Clinical Laboratory Instruments and Computer Systems,* NCCLS LIS2-A (Formerly ASTM E1394-97).

#	D	U	R	Field	Length	Notes
1	-	A		Record Type ID	1	= “M” or “m”
2	-	A		Sequence number	1	= 1
3	-	A		Sub Type Id	1	= “A” or “a”
4	-	A	Y	Automation Enabled	1	= “E”, “D”. Indicates whether automation is enabled/disabled: E = Enabled D = Disabled This field is repeated for each external metering position. The first occurrence is for the MicroSlide metering arm; the second occurrence is for the µIA metering arm.

5.3.10 ASTM M/I Inventory Query Record

The System supports the following fields of the Inventory Query (M/I) Record as defined in Section 15.1 of *Standard Specification for Transferring Information Between Clinical Laboratory Instruments and Computer Systems,* NCCLS LIS2-A (Formerly ASTM E1394-97).

#	D	U	R	Field	Length	Notes
1	R	-		Record Type ID	1	= “M” or “m”
2	R	-		Sequence number	1	= 1
3	R	-		Sub Type Id	1	= “I” or “i”
4	R	-		Inventory Type	1	= “R”, “D”, “B”, “A” Indicates the type of inventory requested. See Section 5.1.6 Inventory Type in this LIS Guide.

5.3.11 ASTM M/R Reagent Inventory Record

The System supports the following fields of the Reagent Inventory (M/R) Record as defined in Section 15.1 of *Standard Specification for Transferring Information Between Clinical Laboratory Instruments and Computer Systems,* NCCLS LIS2-A (Formerly ASTM E1394-97).

#	D	U	R	Field	Length	Notes
1	-	A		Record Type ID	1	= “M” or “m”
2	-	A		Sequence number	1	= 1
3	-	A		Sub Type Id	1	= “R” or “r”
4	-	A		Analyte Code	3	= TestCode
5	-	S	Y	Shared Analyte Code	3	= TestCode of other assays that share this reagent (i.e., Fe/TIBC). This field is repeated for each shared assay.
6	-	A	Y	Reagent Info	=12^14^3^1^1^1^1^1^1^1^1^1^1	= ReagentLot^ExpirationDate^RemainingTestCount^SerumReagentStatus^CSFReagentStatus^UrineReagentStatus^WholeBloodReagentStatus^PlasmaReagentStatus^AmnioReagentStatus^reservedfluid1status^reservedfluid2status^SWABstatus. See 5.1.4 Fluid Reagent Status in this LIS Guide for fluid reagent statuses. This field is repeated for each cart/pack on board for this assay.

5.3.12 ASTM M/D Diluent Inventory Record

The System supports the following fields of the Diluent (M/D) Inventory Record as defined in Section 15.1 of *Standard Specification for Transferring Information Between Clinical Laboratory Instruments and Computer Systems,* NCCLS LIS2-A (Formerly ASTM E1394-97).

#	D	U	R	Field	Length	Notes
1	-	A		Record Type ID	1	= “M” or “m”
2	-	A		Sequence number	1	= 1
3	-	A		Sub Type Id	1	= “D” or “d”
4	-	A		Diluent	4	= DiluentCode. Bottle fluid code of diluent.
5	-	A		Lot Number	10 (12 for XT 3400)	= LotNumber. In CCPPPPGGLLLL format 12 alphanumeric characters for 3400.
6	-	S		Remaining Volume	8	= Volume. Remaining volume of diluent in mL. Will be null for diluents tracked by count (MicroWell diluents)
7	-	A		Date and Time of Expiration	14	= ExpDate. Expiration date of the diluent in YYYYMMDDHHMMSS format
8	-	S		Remaining Count	5	= Count. Remaining count of diluent will be null for diluents tracked by volume (MicroSlide/MicroTip diluents).

5.3.13 ASTM M/B Bulk Consumables Inventory Record

The System supports the following fields of the Bulk Consumables Inventory (M/B) Record as defined in Section 15.1 of *Standard Specification for Transferring Information Between Clinical Laboratory Instruments and Computer Systems,* NCCLS LIS2-A (Formerly ASTM E1394-97).

Note: Values for any items that are not present on VITROS® 3600 or VITROS® XT 3400 are set to 0.

#	D	U	R	Field	Length	Notes
1	-	A		Record Type ID	1	= “M” or “m”
2	-	A		Sequence number	1	= 1
3	-	A		Sub Type Id	1	= “B” or “b”
4	-	S		ERF	5^3	= Lot^RemainingTests
5	-	S		IWF	5^3	= Lot^RemainingTests
6	-	A		VersaTips	8	= NumberRemaining. The string “Infinite” is reported in this field if the VersaTip hopper sensor is blocked indicating there are at least 300 tips remaining.
7	-	A		MicroTips	3	= NumberRemaining
8	-	A		Cuvettes	3	= NumberRemaining
9	-	A		Slide Waste	4	= SpaceAvailable. Indicates the number of tests that can be performed before the waste container is full.
10	-	A		ImmunoAssay (IA) Waste	5	= PercentFull. Indicates how full the container is in percentage. This container is used for tips, cuvettes, wells, and MicroTip trays.
11	-	A		ImmunoAssay Reagent (IAR) Waste	3	= PercentFull. Indicates how full the container is in percentage. This container is used for tips. On the 3400, this container is used for VTip trays, Vtips, Mixing Cupt Trays and carts and is referred to was Waste Container D
12	-	A		Liquid Waste	4	= PercentFull. Indicates how full the container is in percentage.
13	-	A		Signal Reagent	5^4	= CurrentLot^RemainingTests. Indicates the current lot of SR being used. Staged SR packs may be from a different lot.

#	D	U	R	Field	Length	Notes
14	-	A		UWR	4	= VolumeRemaining. Remaining volume in mL.
15				Mixing Cup Array	1	=Number Remaining (For the 3400: 1 or 0 – system only knows when there is not a tray blocking the second tray sensor)

5.3.14 ASTM M/E Error Record

The System supports the following fields of the Error (M/E) Record as defined in Section 15.1 of *Standard Specification for Transferring Information Between Clinical Laboratory Instruments and Computer Systems,* NCCLS LIS2-A (Formerly ASTM E1394-97).

#	D	U	R	Field	Length	Notes
1	-	A		Record Type ID	1	= “M” or “m”
2	-	A		Sequence number	1	= 1
3	-	A		Sub Type Id	1	= “E” or “e’
4	-	A		Error Module	3	= ModuleNumber. Module number of condition code
5	-	A		Error Number	3	= ErrorNumber. Error number of condition code
6	-	A		Severity	1	= “A”, “N”, “M’, “S”. See 5.1.5 Severity Level in this LIS Guide.
7	-	A		Short Error Text	80	= ShortText. Short error text with substitution, the same that appears in Condition Review
8	-	A		Date and Time Of Error	14	= TimeOfError. In YYYYMMDDHHMMSS format
9	-	S		Specimen ID	15^2^2	= SampleID^Tray^Cup. Will only be filled if this error applies to a sample. Sample ID^Tray^Cup

Note: For automation samples at the MicroSlide POR, the tray is “A#” and cup will be 1.

Note: For automation samples at the MicroIA POR, the tray is “B#” and cup will be 1.

5.3.15 ASTM M/M Download Message Record

The System supports the following fields of the Error (M/M) Record as defined in Section 15.1 of *Standard Specification for Transferring Information Between Clinical Laboratory Instruments and Computer Systems,* NCCLS LIS2-A (Formerly ASTM E1394-97).

#	D	U	R	Field	Length	Notes
1	-	A		Record Type ID	1	= “M” or “m”
2	-	A		Sequence number	1	= 1
3	-	A		Sub Type Id	1	= “M” or “m”
4	-	A		Audit Code	2	= AuditCode. See LIS Sample Program Verification in this LIS Guide for a list.
5	-	A		Message	80	= Message. Text description of audit is the same that appears in Sample Programming.
6	-	A		Date and Time	14	= TimeofAudit. In YYYYMMDDHHMMSS format
7	-	S		Specimen ID	15^2^2	= SampleID^Tray^Cup. Will only be filled if this error applies to a sample.

5.3.16 ASTM Status Query Record

The System supports the following fields of the Status Query Record:

#	D	U	R	Field	Length	Notes
1	R	-		Record Type ID	1	= “M” or “m”
2	R	-		Sequence number	1	= 1
3	R	-		Sub Type Id	1	= “S” or “s”

5.3.17 ASTM M/S Instrument Status Record

The System supports the following fields of the Instrument Status (M/S) Record.

For Field 16, Status Details, see Appendix K for a listing of possible values for SubsystemID and ReasonID.

#	D	U	R	Field	Length	Notes
1	-	A		Record Type ID	1	= “M” or “m”
2	-	A		Sequence number	1	= 1
3	-	A		Sub Type Id	1	= “S” or “s”

#	D	U	R	Field	Length	Notes
4	-	A		Overall Analyzer Status	1	= “0”, “1”, “2”, “3”, “4”, etc. Indicates overall analyzer status. 0 = Not Ready 1 = Ready 2 = Equilibrating 3 = Initializing 4 = Diagnostics mode
5	-	A		Testing State	1	= “0” or “1” 0 = Assays in Progress 1 = Assays Completed
6	-	A		Sampling State	1	= empty, “0”, “1”, “2”, “3”, “4”, etc. Sampling State reflects whether the system is actively performing primary metering, or potentially restarting primary metering on its own in the future. Empty = “Sampling State” field is disabled. 0 = Sampling Off 1 = Internal Sampling 2 = External Sampling 3 = Internal and External Sampling (5600/3600/7600) 4 = Reflex Sampling (4600) 5 = Sample Pending Only generated if the “Sampling State” field is enabled via the Shell command.
7	-	A		MicroWell Assay Processing Status	1	= empty, “0”, “1”, “2”, “3” or “4” Empty = subsystem is not available on the analyzer model (for example, the XT3400 cannot process µWells) 0 = Inoperative/Not Ready 1 = Ready/Operative 2 = Out of Range 3 = Environment Disabled 4 = Disabled

#	D	U	R	Field	Length	Notes
8	-	A		Dilution and MicroTip Assay Processing Status	1	= empty, “0”, “1”, “2”, “3” or “4” Empty = subsystem is not available on the analyzer model (for example, the XT3400 cannot process µWells) 0 = Inoperative/Not Ready 1 = Ready/Operative 2 = Out of Range 3 = Environment Disabled 4 = Disabled Note: Values 2 and 3 N/A to 3400 which does dilutions but does not process MicroTips.
9	-	A		PM MicroSlide Processing Status	1	= empty, “0”, “1”, “2”, “3” or “4” Empty = subsystem is not available on the analyzer model (for example, the XT3400 cannot process µWells) 0 = Inoperative/Not Ready 1 = Ready/Operative 2 = Out of Range 3 = Environment Disabled 4 = Disabled
10	-	A		Rate/CM MicroSlide Processing Status	1	= empty, “0”, “1”, “2”, “3” or “4” Empty = subsystem is not available on the analyzer model (for example, the XT3400 cannot process µWells) 0 = Inoperative/Not Ready 1 = Ready/Operative 2 = Out of Range 3 = Environment Disabled 4 = Disabled

#	D	U	R	Field	Length	Notes
11	-	A		IR MicroSlide Processing Status	1	= “0”, “1”, “2”, “3” or “4” Empty = subsystem is not available on the analyzer model (for example, the XT3400 cannot process µWells) 0 = Inoperative/Not Ready 1 = Ready/Operative 2 = Out of Range 3 = Environment Disabled 4 = Disabled
12	-	A		MicroSensor Processing Status	1	= “0”, “1”, “2”, “3” or “4” 0 = Inoperative/Not Ready 1 = Ready/Operative 2 = Out of Range 3 = Environment Disabled 4 = Disabled
13	-	A		STAT Lane Metering Position Status	1	= empty, “0”, “1” or “2” Empty = subsystem is not available on the analyzer model (for example, the XT3400 cannot process µWells) 0 = Inoperative/Not Ready 1 = Ready/Operative 2 = N/A 3 = N/A 4 = Disabled
14	-	A		Routine Metering Position Status	1	= empty, “0”, “1” or “2” Empty = subsystem is not available on the analyzer model (for example, the XT3400 cannot process µWells) 0 = Inoperative/Not Ready 1 = Ready/Operative 2 = N/A 3 = N/A 4 = Disabled

#	D	U	R	Field	Length	Notes
15	-	A		VersaTip Supply Status	1	= empty, “0”, “1” or “2” Empty = subsystem is not available on the analyzer model (for example, the XT3400 cannot process µWells) 0 = Inoperative/Not Ready 1 = Ready/Operative 2 = N/A 3 = N/A 4 = Disabled
16	-	A		Status Details	3^1\3^1\ 3^1\3^1\ 3^1\	=SubsystemID/ReasonID\ SubsystemID/ReasonID\ SubsystemID/ReasonID\ SubsystemID/ReasonID\ SubsystemID/ReasonID\ Indicates main reasons (up to 5) for overall analyzer status associated with Inoperative or Out of Range subsystems. Empty means no conditions, i.e., analyzer is “Ready”. This is the information that can be seen in the analyzer’s Main status screen > View Subsystems screen. Reason ID encoding: 0 = Inoperative/Not Ready 1 = Ready (N/A) 2 = Out of Range 3 = Environmentally Disabled 4 = Disabled
17	-	A		Analyzer SW Version	10	Analyzer SW Version (e.g., 3.8)
18	-	A		Analyzer ADD Version	10	= ADD version
19	-	A		e-Connectivity Status	1	= e-Connectivity status 0 = disconnected 1 = connecting 2 = connected

5.3.18 ASTM M/Q Assay Test-Completion Status Query Message Record

The System supports the following fields of the Assay Test-Completion Status Query (M/Q) Record.

#	D	U	R	Field	Length	Notes
1	A	N		Record Type ID	1	= “M” or “m”
2	A	N		Sequence number	1	= 1
3	A	N		Sub Type Id	1	= Q
4	A	N		Starting Range ID Number	15	=^Computer system Specimen ID. The specimen ID of interest, only one allowed per record.

5.3.19 ASTM M/T Assay Test Completion Status Message

The System supports the following fields of the Assay Test Completion (M/T) Record.

#	D	U	R	Field	Length	Notes
1		A		Record Type ID	1	= “M” or “m”
2		A		Sequence number	unlimited	Initial value is 1, reset for each new order, maximum length is unlimited.
3		A		Sub Type Id	1	= “T” or “t”
4		A		Specimen ID	15	=^Computer system Specimen ID. The specimen ID of interest, only one allowed per record.
5		A		Universal Test ID	13	= ^^^LocalOrMfrctrCode See Downloading Sample Programs (Section 4.2) in this LIS Guide.
6		S		Data or Measurement Value	20	Will contain the status of the assay. = “complete” if the assay has already been resulted. = “test not started” if the sample program is available but the assay has not been started. = “mm:ss” if the assay is in progress. Time to result is expressed in minutes:seconds left. = “not found” if there is no sample program associated with the sample ID.
7		A		Instrument Identification	12	= J Number

5.4 HL7 Messages

The System supports the HL7 Version 2.5 messaging protocol specifications. The System implements HL7 message structures and formats as described in *HL7 2.5 Specifications, 2003,* specifically Clinical Laboratory Automation messaging as detailed and referenced in Chapter 13 and all referenced chapters of the HL7 messaging document. If the System protocol is set to HL7, the following messages are utilized.

In defining the HL7 message structures, the optional HL7 segments that are not relevant to the System are not included in the requirements for the HL7 interface.

Note: All referenced sections can be found in *HL7 2.5 Specifications, 2003* unless otherwise noted.

5.4.1 HL7 ACK Acknowledgement Message

The HL7 ACK message uses the following message structure as defined in Section 13.3 of *HL7 2.5 Specifications, 2003.*

```
MSH    -- Message Header (See Section 5.5.5 in this LIS Guide.)
MSA    -- Message Acknowledgment (See Section 5.5.4 in this LIS
                Guide.)
[{ERR}]      -- Error (See Section 5.5.1 in this LIS Guide.)
```

5.4.1.1 HL7 ACK Acknowledgement Message Example

```
MSH|^&~\|||||20080128111742.315||ORL^O22^ORL_O22|20080128111742.3
15|P|2.5||||||UNICODE<SP>UTF-8|||

MSA|AR|tBTTPzcded||||

ERR||PID^^5^^2^|102|E|||Field<SP>exceeds<SP>maximum<SP>number<SP>
of<SP>characters,<SP>chars=16,<SP>max=15|||||
```

5.4.2 HL7 OML Laboratory Order Message Structure

The HL7 OML message uses the following message structure:

```
MSH   -- Message Header (See Section 5.5.5 in this LIS Guide.)

[                 -- PATIENT begin

   PID -- Patient Identification (See Section 5.5.11 in this LIS
                  Guide.)

   [{NTE}] -- Notes and Comments (for Patient) (See Section 5.5.7
                  in this LIS Guide.)

   [PV1] -- Patient Visit (See Section 5.5.12 in this LIS Guide.)

]           -- PATIENT end

ORC    -- Common Order (See Section 5.5.10 in this LIS Guide.)

OBR   -- Observation Request (See Section Section 5.5.8 in this
                  LIS Guide.)

SPM   -- Specimen (See Section 5.5.18 in this LIS Guide.)

{           -- CONTAINER begin

   SAC -- Specimen Container (See Section 5.5.17 in this LIS
                  Guide.)

}           -- CONTAINER end
```

5.4.2.1 HL7 OML Laboratory Order Message Example

```
MSH|^&~\|LITT||||20071022093057||OML^O21^OML_O21|tWcKE<SP>QBK5|P|
2.5||||||UNICODE<SP>UTF-8|||

PID|||1234567890||Doe^John^M||19791203000000|M|||100<SP>Indigo<SP
>Creek<SP>Dr^Rochester,<SP>NY<SP>14626||||||||||||||||||||||||||
|

NTE||L|Comment<SP>about<SP>patient|G

PV1||N|^RM<SP>2MS7||||8651847^Robert^Smith^M||||||||||S|||||||||
|||||||||||||||||||||||

ORC|NW|||||||||||||||||||||||||||

OBR||||^^^1.0+001+1.0|R||20071022092920||||S|||||||||||||F||||||
|||||||||||||||||

SPM||||5|||||||||||||||||||||||||

SAC|||SID54981||||||||||1|1|||||||||||||||||||||||||||||
```

5.4.3 HL7 ORL Laboratory Order Response Message Structure

The HL7 ORL message uses the following message structure as defined in Section 4.4.7 of *HL7 2.5 Specifications, 2003.*

```
MSH   -- Message Header (See Section 5.5.5 in this LIS Guide.)
MSA   -- Message Acknowledgment (See Section 5.5.4 in this LIS
                 Guide.)
[{ERR}]     -- Error (See Section 5.5.1 in this LIS Guide.)
[           -- RESPONSE begin
   [        -- PATIENT begin
      PID -- Patient Identification (See Section 5.5.11 in this
                 LIS Guide.)
      [{          -- ORDER begin
         ORC -- Common Order (See Section 5.5.10 in this LIS
                 Guide.)
         [        -- OBSERVATION_REQUEST begin
            OBR   -- Observation Request (See Section Section
                  5.5.8 in this LIS Guide.)
            [{    -- SPECIMEN begin
               SPM      -- Specimen (See Section 5.5.18 in this
                  LIS Guide.)
               [{SAC}]  -- Specimen Container Details (See
                  Section 5.5.17 in this LIS Guide.)
            }]    -- SPECIMEN end
         ]        -- end OBSERVATION_REQUEST
      }]          -- ORDER end
   ]        -- PATIENT end
]           -- RESPONSE end
```

5.4.3.1 ORL Laboratory Order Response Message Example

```
MSH|^&~\|||||20071022093016.332||ORL^O22^ORL_O22|20071022093016.3
32|P|2.5||||||UNICODE<SP>UTF-8|||

MSA|AA|tWcKE<SP>QBK5||||

PID|||1234567890||Doe^John^M||19791203000000|M|||100<SP>Indigo<SP
>Creek<SP>Dr^Rochester,<SP>NY<SP>14626||||||||||||||||||||||||||
|

ORC|NW|||||||||||||||||||||||||||||

OBR||||^^^1.0+001+1.0|R||20071022092920||||S|||||||||||||F||||||
||||||||||||||||

SPM||||5|||||||||||||||||||||||||

SAC|||SID54981||||||||||1|1|||||||||||||||||||||||||||||
```

5.4.4 HL7 OUL Unsolicited Observation Message Structure

The HL7 OUL message uses the following message structure as defined in Section 7.3.8 of *HL7 2.5 Specifications, 2003.*

Note: The ZER, Extended Results segment appears when Extended Results upload is enabled.

```
MSH   -- Message Header (See Section 5.5.5 in this LIS Guide.)
[ PID ] -- Patient Identification (See Section 5.5.11 in this LIS
                Guide.)
[{NTE}] -- Notes and Comments for Patient ID (See Section 5.5.7
                in this LIS Guide.)
[ PV1 ] -- Patient Visit (See Section 5.5.12 in this LIS Guide.)
{ -- SPECIMEN BEGIN
   SPM -- Specimen information (See Section 5.5.18 in this LIS
                Guide.)
   {SAC} -- Container information (See Section 5.5.17 in this LIS
                Guide.)
   { -- ORDER begin
      OBR (See Section 5.5.8 in this LIS Guide.)
      [ORC] (See Section 5.5.10 in this LIS Guide.)
      [{ -- RESULT Begin
         OBX (See Section 5.5.9 in this LIS Guide.)
         [NTE] – Notes and Comments for Observation (See Section
                5.5.7 in this LIS Guide.)
         [ZER] – Extended Results (See Section 5.5.19 in this LIS
                Guide.)
      }] -- RESULT End
   } -- ORDER end
} -- SPECIMEN end
```

5.4.4.1 HL7 OUL Unsolicited Observation Message Examples

The following example includes the extended results record.

```
MSH|^&~\|||||20071022100010.136||OUL^R23^OUL_R23|20071022100010.1
36|P|2.5||||||UNICODE<SP>UTF-8|||

PID|||PATID15||Doe^John^Q||20060105|M|||Address1^Address2||||||||
||||||||||||||||||||

NTE||I|Patient<SP>comments|G

PV1||N|^RM15||||DOCID15^Smith^John<SP>^X||||||||||2||||||||||||
||||||||||||||||||||

SPM||||5|||||||||||||||||||||||||

SAC|||LCITest-15|||||||||||2|5|||||||||||||||||31||24||6||||||||

OBR|||bredick|^^^1.0000+300+1.0~950+1.0~951+1.0~952+1.0|R||200702
05131723|||||||||||||||||F|||||||||||||||||||||||

ORC|NW|||||||||||||||||||||||||||||

OBX|||^^^1.0000+300+0.0||57|mg/dL||^0^EP~^0^~^0^~^0^|||F||||bredi
ck|||00000000|20070205181718

ZER|00000000^^19691231190001^E1234^I1234^0|20070205124344^B^20070
305124344|^^|

OBX|||^^^1.0000+950+1.0||31|||^0^~^^~^^~^^|||F||||bredick|||00000
000|20070205131723

OBX|||^^^1.0000+951+1.0||6|||^0^~^^~^^~^^|||F||||bredick|||000000
00|20070205131723

OBX|||^^^1.0000+952+1.0||24|||^0^~^^~^^~^^|||F||||bredick|||00000
000|20070205131723
```

This example contains optional "<" or ">" signs in the result value field and also includes the optional result comment containing qualitative text:

```
MSH|^&~\|43000224||||20080826104459.259||OUL^R23^OUL_R23|20080826
104459.259|P|2.5||||||UNICODE<SP>UTF-8|||

PID|||PID12345||Doe^John^X||19850105|M|||123<SP>Main<SP>St<SP>Apt
<SP>4^Anytown<SP>USA|||||||||||||||||||||||||||

NTE||I|This<SP>is<SP>a<SP>patient<SP>comment|G

PV1||N|^S8||||DOC12345^Jones^Robert^H||||||||||1|||||||||||||||
||||||||||||||||

SPM||||3|||||||||||||||||||||||||

SAC|||DAT12345|||||||||1|1|||||||||||||||||||||||||||

OBR||||^^^1.0000+521+1.0~522+1.0~523+1.0~950+1.0~951+1.0~952+1.0|
R||20080822080000|||||||||||||||||F|||||||||||||||||||||||

ORC|NW|||||||||||||||||||||||||||||

OBX|||^^^1.0000+521+1.0||<100|ng/mL||^Q^OREP~^0^NR~^0^NR~^0^NR|||
F|||||||43000224|20080822093850

NTE||I|Negative|I
```

```
OBX|||^^^1.0000+522+1.0||100|ng/mL||^Q^EP~^0^NR~^0^NR~^0^NR|||F||
|||||43000224|20080822093814

NTE||I|Negative|I

OBX|||^^^1.0000+523+1.0||500|ng/mL||^R^EP~^0^NR~^0^NR~^0^NR|||F||
|||||43000224|20080822093936

NTE||I|Positive|I

OBX|||^^^1.0000+525+1.0||>1000|ng/mL||^R^OREP~^0^NR~^0^NR~^0^NR||
|F|||||||43000224|20080822094001

NTE||I|Positive|I

OBX|||^^^1.0000+950+1.0||No<SP>Result|||^0^NR~^^~^^~^^|||F|||||||
43000224|20080822093518

OBX|||^^^1.0000+951+1.0||No<SP>Result|||^0^NR~^^~^^~^^|||F|||||||
43000224|20080822093518

OBX|||^^^1.0000+952+1.0||No<SP>Result|||^0^NR~^^~^^~^^|||F|||||||
43000224|20080822093518
```

This is an example of a suppressed mean result when six replicates of the assay are run:

```
MSH|^&~\|qnxa0152||||20090402151403.275||OUL^R23^OUL_R23|20090402
151403.275|P|2.5||||||UNICODE<SP>UTF-8|||<CR>

PID|||||^^|||||||^|||||||||||||||||||||||||||<CR>

NTE||||<CR>

PV1|||^||||^^^|||||||||||||||||||||||||||||||||||||||||||<CR>

SPM||||5|||||||||||||||||||||||||<CR>

SAC|||test3||||||||||1|1|||||||||||||||||||||||||||||<CR>

OBR||||^^^1.0000+019+1.0~019+1.0~019+1.0~019+1.0~019+1.0~019+1.0~
950+1.0~951+1.0~952+1.0|R|||||||||||||||||||F|||||||||||||||||||
|||||<CR>

ORC|NW|||||||||||||||||||||||||||||<CR>

OBX|||^^^1.0000+019+1.0|||||^0^UCFRMN~^6^ES~^6^ES~^6^ES|||F||||||
|qnxa0152|20090402074353<CR>

NTE||I|See<SP>Replicates|I<CR>

OBX|||^^^1.0000+019+1.0|||||^S^REEMUC~^6^ES~^6^ES~^6^ES|||F||||||
|qnxa0152|20090402074218<CR>

NTE||I|Negative|I<CR>

OBX|||^^^1.0000+019+1.0|||||^S^REEMUC~^6^ES~^6^ES~^6^ES|||F||||||
|qnxa0152|20090402074237<CR>

NTE||I|Negative|I<CR>

OBX|||^^^1.0000+019+1.0|||||^S^REEMUC~^6^ES~^6^ES~^6^ES|||F||||||
|qnxa0152|20090402074256<CR>

NTE||I|Negative|I<CR>

OBX|||^^^1.0000+019+1.0|||||^S^REEMUC~^6^ES~^6^ES~^6^ES|||F||||||
|qnxa0152|20090402074315<CR>
```

```
NTE||I|Negative|I<CR>

OBX|||^^^1.0000+019+1.0|||||^S^REEMUC~^6^ES~^6^ES~^6^ES|||F||||||
|qnxa0152|20090402074334<CR>

NTE||I|Negative|I<CR>

OBX|||^^^1.0000+019+1.0|||||^S^REEMUC~^6^ES~^6^ES~^6^ES|||F||||||
|qnxa0152|20090402074353<CR>

NTE||I|Negative|I<CR>

OBX|||^^^1.0000+950+1.0||No<SP>Result|||^6^ES~^^~^^~^^|||F|||||||
qnxa0152|20090402073331<CR>

OBX|||^^^1.0000+951+1.0||No<SP>Result|||^6^ES~^^~^^~^^|||F|||||||
qnxa0152|20090402073331<CR>

OBX|||^^^1.0000+952+1.0||No<SP>Result|||^6^ES~^^~^^~^^|||F|||||||
qnxa0152|20090402073331<CR>
```

This is an example of a suppressed mean result when only one replicate of the assay is run:

```
MSH|^&~\|qnxa0152||||20090402151404.343||OUL^R23^OUL_R23|20090402
151404.343|P|2.5||||||UNICODE<SP>UTF-8|||<CR>

PID|||||^^|||||||^|||||||||||||||||||||||||||<CR>

NTE||||<CR>

PV1|||^||||^^^|||||||||||||||||||||||||||||||||||||||||||||<CR>

SPM||||5|||||||||||||||||||||||||<CR>

SAC|||OneRepOnly|||||||||||8|1|||||||||||||||||||||||||||||<CR>

OBR||||^^^1.0000+019+1.0~950+1.0~951+1.0~952+1.0|R|||||||||||||
|||||F|||||||||||||||||||||||<CR>

ORC|NW|||||||||||||||||||||||||||<CR>

OBX|||^^^1.0000+019+1.0||2.75|My<SP>Units||^S^REEMUC~^6^ES~^6^ES~
^6^ES|||F|||||||qnxa0152|20090402081126<CR>

NTE||I|Negative|I<CR>

OBX|||^^^1.0000+950+1.0||No<SP>Result|||^6^ES~^^~^^~^^|||F|||||||
qnxa0152|20090402080104<CR>

OBX|||^^^1.0000+951+1.0||No<SP>Result|||^6^ES~^^~^^~^^|||F|||||||
qnxa0152|20090402080104<CR>

OBX|||^^^1.0000+952+1.0||No<SP>Result|||^6^ES~^^~^^~^^|||F|||||||
qnxa0152|20090402080104<CR>
```

5.4.5 HL7 QBP_ZOS Host Query Message Structure

The HL7 QBP message uses the following message structure:

```
MSH   -- Message Header Segment (See Section 5.5.5 in this LIS
                 Guide.)

QPD   -- Parameter Definition (Section 5.5.15 in this LIS Guide.)
```

```
RCP    -- Response Control Parameter Segment (See Section 5.5.16
                  in this LIS Guide.)
```

5.4.5.1 HL7 QBP Host Query Message Example

```
MSH|^&~\|||||20071022103351.228||QBP^ZOS^QBP_ZOS|20071022103351.2
28|P|2.5||||||UNICODE<SP>UTF-8|||

QPD|ZOS^Lab<SP>Order<SP>Specimen<SP>Query|20071022103351.228|SID1
2345|||||||A||

RCP|I||R||||
```

5.4.6 HL7 RSP_ZOS Host Query Response Message Structure

The HL7 RSP message uses the following message structure:

```
MSH   Message Header (Section 5.5.5 in this LIS Guide)

QAK   Query Acknowledgement (Section 5.5.13 in this LIS Guide)

QPD   Query Parameter Definition
           (Section 5.5.15 in this LIS Guide)

[     --- RESPONSE DATA Begin

   [  --- PATIENT Begin

      PID         Patient Identification
         (Section 5.5.11 in this LIS Guide)

      [{ NTE }]   Notes and Comments (for Patient ID)
         (Section 5.5.7 in this LIS Guide)

      [PV1]       Patient Visit (Section 5.5.12 in this LIS
Guide)

   ]  --- PATIENT end

   SPM      Specimen (Section 5.5.18 in this LIS Guide)

   SAC      Specimen Container (Section 5.5.17 in this LIS Guide)

   ORC      Common Order (Section 5.5.10 in this LIS Guide)

   [OBR]    Observation Request
         (Section Section 5.5.8 in this LIS Guide)

]     --- RESPONSE DATA End
```

5.4.6.1 HL7 RSP Host Query Response Message Example

```
MSH|^&~\|LITT||||20071022104336||RSP^ZOS^RSP_ZOS|LJMnnU1ZIY|P|2.5
||||||UNICODE<SP>UTF-8|||

QAK|20071022104255.318|OK|ZOS^Lab<SP>Order<SP>Specimen<SP>Query|1
||

QPD|ZOS^Lab<SP>Order<SP>Specimen<SP>Query|20071022104255.318|SID1
2345|||||||A||

PID|||PID123456||Doe^John^M||20071203000000|M|||100<SP>Indigo<SP>
Creek<SP>Dr^Rochester,<SP>NY<SP>14626|||||||||||||||||||||||||||

NTE||P|patient<SP>comments|G

PV1||N|^2M<SP>S7||||8651847^Robert^Smith^M||||||||||S||||||||||
|||||||||||||||||||||

SPM||||5|||||||||||||||||||||||

SAC|||SID12345|||||||||||||||||||||||||||||||||||||

ORC|NW|||||||||||||||||||||||||||

OBR|||qTY7a|^^^1.000+300+1.0|R||20060609000000||||S|||||||||||||
F|||||||||||||||||||||||
```

5.4.6.2 HL7 RSP Host Query Response Message Example (No Program Found)

```
MSH|^&~\|LITT||||20071022103433||RSP^ZOS^RSP_ZOS|gpyLLEG<SP>vz|P|
2.5|||||||||

QAK|20071022103351.228|NF|ZOS^Lab<SP>Order<SP>Specimen<SP>Query|0
||

QPD|ZOS^Lab<SP>Order<SP>Specimen<SP>Query|20071022103351.228|SID1
2345|||||||A||
```

5.4.7 HL7 QCN Host Query Cancel Message Structure

The HL7 QCN message uses the following message structure:

```
MSH   Message Header (See Section 5.5.4 in this LIS Guide.)

QID   Query Identification (See Section 5.5.14 in this LIS
Guide.)
```

5.4.7.1 HL7 QCN Host Query Cancel Message Example

```
MSH|^&~\|||||20071022103354.230||QCN^J01^QCN_J01|20071022103354.2
30|P|2.5|||||UNICODE<SP>UTF-8|||

QID|20071022103351.228|ZOS^Lab<SP>Order<SP>Specimen<SP>Query
```

5.4.8 HL7 INR Equipment Inventory Request Message Structure

The HL7 INR message uses the following message structure as defined in Section 13.3.6 in *HL7 2.5 Specifications, 2003.*

```
MSH   -- Message Header (See Section 5.5.5 in this LIS Guide.)

EQU   -- Equipment Detail (See Section 5.5.2 in this LIS Guide.)

INV   -- Inventory Detail (See Section 5.5.3 in this LIS Guide.)
```

5.4.8.1 HL7 INR Equipment Inventory Request Message Example

The LIS queries the chemistry analyzer 0001 for status of all packages of the substance (id=MF01239)

```
MSH|^&~\|LITT||||20071022093918||INR^U06^INR_U06|6Js5<SP>CHv7A|P|
2.5||||||UNICODE<SP>UTF-8|||

EQU|J43000001|20071022093918|||

INV|A|~~~~~~~~|||||||||||||||||
```

5.4.9 HL7 INU Equipment Inventory Update Message Structure

The HL7 INU message uses the following message structure:

```
MSH   -- Message Header (See Section 5.5.5 in this LIS Guide.)

EQU   -- Equipment Detail (See Section 5.5.2 in this LIS Guide.)

      [{INV}] -- Inventory Detail (See Section 5.5.3 in this LIS
                 Guide.)
```

5.4.9.1 HL7 INU Equipment Inventory Update Message Example

```
MSH|^&~\|||||20071022093836.369||INU^U05^INU_U05|20071022093836.3
69|P|2.5||||||UNICODE<SP>UTF-8|||

EQU|00000000|20071022093836|||

INV|001|~~~~~~~~|SR||||||100||COUNT|20071211075549|||001|2050||||

INV|300|~~~~~~~~|SR||||||60||COUNT|20071029092641|||300|00492619|
|||

INV|317|~~~~~~~~|MR||||||60||COUNT|20071105082644|||317~327|02365
912||||

INV|327|~~~~~~~~|MR||||||60||COUNT|20071105082644|||327~317|02365
912||||

INV|500|~~~~~~~~|SR||||||50||COUNT|20071114075505|||500|150004000
1||||

INV|1001|~~~~~~~~|DI||||||63||mL|20071212075505||||8000010001||||

INV|2601|~~~~~~~~|DI||||||100||COUNT|20071211075549||||9998||||

INV|ERF|~~~~~~~~|LI||||||800||COUNT|||||100||||

INV|IWF|~~~~~~~~|LI||||||300||COUNT|||||100||||

INV|VT|~~~~~~~~|SC||||||Infinite||COUNT|||||||||

INV|MT|~~~~~~~~|SC||||||384||COUNT|||||||||

INV|CUV|~~~~~~~~|SC||||||300||COUNT|||||||||

INV|SW|~~~~~~~~|SW||||||3780||COUNT|||||||||

INV|CW|~~~~~~~~|SW||||||0||%|||||||||

INV|TW|~~~~~~~~|SW||||||0||%|||||||||

INV|LW|~~~~~~~~|LW||||||96||%|||||||||

INV|SR|~~~~~~~~|LI||||||393||COUNT|||||1||||

INV|UWR|~~~~~~~~|LI||||||5198||mL|||||||||
```

```
INV|MCA|~~~~~~~~|SC||||||1|COUNT|||||||||
```

5.4.10 HL7 EAN Equipment Notification Message Structure

The HL7 EAN message uses the following message structure as defined in Section 13.3.9 in *HL7 2.5 Specifications, 2003.*

```
MSH   -- Message Header (See Section 5.5.5 in this LIS Guide.)
EQU   -- Equipment Detail (See Section 5.5.2 in this LIS Guide.)
{           -- Notification Begin
   NDS -- Notification Detail (See Section 5.5.6 in this LIS
                Guide.)
}           -- Notification End
```

5.4.10.1 HL7 EAN Equipment Notification Message Example (Error)

```
MSH|^&~\|||||20071022094305.929||EAN^U09^EAN_U09|20071022094305.9
29|P|2.5||||||UNICODE<SP>UTF-8|||
EQU|00000000|20071022094305|||
NDS|329|20071022093708|N|PWE-107^MicroSensor<SP>Ref<SP>and<SP>Dar
k<SP>readings<SP>have<SP>same<SP>value:<SP>ID<SP>SID54981,<SP>Ind
ex<SP>&SID54981&1&1
```

5.4.10.2 HL7 EAN Equipment Notification Message Example (Automation Configuration)

```
MSH|^&~\|||||20071022094437.945||EAN^U09^EAN_U09|20071022094437.9
45|P|2.5||||||UNICODE<SP>UTF-8|||
EQU|00000000|20071022094437|||
NDS|0|20071022094437|N|AutoConfig-0^Disabled
NDS|1|20071022094437|N|AutoConfig-1^Enabled
```

5.4.10.3 HL7 EAN Equipment Notification Message Example (Download Message)

```
MSH|^&~\|||||20071022101519.271||EAN^U09^EAN_U09|20071022101519.2
71|P|2.5||||||UNICODE<SP>UTF-8|||
EQU|00000000|20071022101519|||
NDS|4|20071022100658|N|Audit-17^17-Sample/tray<SP>program<SP>chan
ged.&SID54981&2&1
```

5.5 HL7 Message Segments

The following section defines the HL7 message segments that are used. All segments are terminated with a Carriage Return <CR> (hex 0D0A). This designation cannot be changed.

The delimiter values are given in MSH-1 and MSH-2 and used throughout the message. Applications must use agreed-upon delimiters to parse the message segments. The recommended delimiters for laboratory messages are listed in the first two fields of the MSH segment. The System employs the delimiters for all upload message segments. This is not configurable.

Escape sequences for field separator, component separator, subcomponent separator, repetition separator, and escape character are also valid within an ST (String) data field. No escape sequence may contain a nested escape sequence.

The following escape sequences are used in the System:

\F\ field separator

\S\ component separator

\T\ subcomponent separator

\R\ repetition separator

\E\ escape character

\Xdddd...\ hexadecimal data

The following message segments are used for HL7 messages. In the tables that show the field sequences, shaded rows with Not Supported in the Notes column indicate fields that are not supported by the System. No data is sent in these field positions. The Column Headings of “D” and “U” indicate the optionality of the fields in the record when Downloading to the System (D) and Uploading to the LIS (U). The column Heading of “R” indicates the Repeatability. The System uses only the first repetition when it expects a single value. All other repetitions are ignored. Use the table below as a key for the values in these columns:

D	**U**	**R**
R = Required Field	A = Always Sent	Y = Field can repeat.
O = Optional Field	S = Sometimes Sent	*Blank* = Field Does not repeat
N = Never Used	N = Never Sent	*9* = Integer for max # of repetitions
- = not applicable	- = not applicable	

The “DT” column indicates the HL7 Datatype.

5.5.1 Error (ERR)

The System supports the following unshaded fields of the Error (ERR) Segment as defined in Section 2.15.5 of *HL7 2.5 Specifications, 2003*.

#	D	U	R	Field	Length	Notes
1	N	N		Error Code and Location		N/A – Not supported
2	N	S	Y	Error Location	10	Location of error in message SegmentID^^FieldPosition^^ComponentNumber^Sub-ComponentNumber
3	R	A		HL7 Error Code	3^^3^^2^2	Error Number, Mapped to a subset of HL7 Chapter 2, table 0357 Error condition code. For example, required field missing, unsupported message type, etc. The supported subset is: 0 – Message Accepted; 100 – Segment sequence error; 101 – Required field missing; 102 – Data type error; 103 – Table value not found; 200 – Unsupported message type; 201 – Unsupported event code; 202 – Unsupported processing id; 203 – Unsupported version id; Application related errors are handled in other messages sent to the LIS.
4	R	A		Severity	1	W or E
5	N	N		Application Error Code		N/A – Not supported
6	N	N		Application Error Parameter		N/A – Not supported
7	N	S		Diagnostic Information	2048	Additional details about the error.
8	N	N		User Message		N/A – Not supported
9	N	N	Y	Inform Person Indicator		N/A – Not supported
10	N	N		Override Type		N/A – Not supported
11	N	N	Y	Override Reason Code		N/A – Not supported
12	N	N	Y	Help Desk Contact Point		N/A – Not supported

5.5.2 Equipment Detail (EQU)

The System supports the following unshaded fields of the Equipment Detail (EQU) Segment as defined in Section 13.4.1 of *HL7 2.5 Specifications, 2003*.

#	D	U	R	Field	Length	Notes
1	R	A		Equipment Instance Identifier	12	J Number (Serial number).
2	R	A		Event Date/Time	14	Date/Time in format of YYYYMMDDHHMMSS
3	N	N		Equipment State		Not supported
4	N	N		Local/Remote Control State		Not supported
5	N	N		Alert Level		Not supported

5.5.3 Inventory Detail (INV)

The System supports the following unshaded fields of the Inventory Detail (INV) Segment as defined in Section 13.4.4 of *HL7 2.5 Specifications, 2003.*

Note: Values for any items that are not present on VITROS® 3600 or VITROS® XT 3400 are set to 0.

#	D	U	R	Field	Length	Notes
1	R	A		Substance Identifier	3	When requesting inventory: “A”=All, “R”=Reagents, “D”=Diluents, “B”=Bulks. See 5.1.6 Inventory Type in this LIS Guide. When replying analyte code, diluent code, “ERF”=Electrolyte Reference Fluid, “IWF”=Immuno-Wash Fluid, “SR”=Signal Reagent, “UWR”=Universal Wash Reagent, “VT”=VersaTip, “MT”=MicroTip, “CUV”=Cuvette, "MCA"=Mixing Cup Tray, “SW”=Slide Waste, “CW”= ImmunoAssay (IA) Waste, “TW”= ImmunoAssay Reagent (IAR) Waste, “LW”=Liquid Waste
2	N	A	Y/ 9	Substance Status	1	For reagents this is the Fluid Reagent Status See 5.1.4 Fluid Reagent Status in this LIS Guide. Repeated for all fluids (serum, CSF, urine, whole blood, plasma, amniotic, reservedfluid1, reservedfluid2, SWAB).

#	D	U	R	Field	Length	Notes
3	N	A		Substance Type	2	"SR" for reagents without any shared analyte, "MR" for reagents with shared analyte(s), "DI" for diluents, "LW" for liquid waste, "SW" for solid waste (or Waste D on 3400), "SC" for tips and cuvettes and mixing cup trays, "LI" for ERF, IWF, SR and UWR.
4	N	N		Inventory Container Identifier		Not supported
5	N	N		Container Carrier Identifier		Not supported
6	N	N		Position on Carrier		Not supported
7	N	N		Initial Quantity		Not supported
8	N	N		Current Quantity		Not supported
9	N	A		Available Quantity	8	MicroWell Diluents – Remaining Count Non-MicroWell Diluents – Remaining Count Reagents – Remaining Test Count ERF/IWF/SR – Remaining Test Count UWR – Remaining Volume Tips/Cuvettes/Mixing Cup Tray – Remaining Count Slide Waste – Remaining Test Count Non-Slide Waste – % Remaining Space **Note:** When the system is not actively counting Vtips, "Infinite" is used.
10	N	N		Consumption Quantity		Not supported
11	N	A		Quantity Units	5	COUNT – When reporting a count % – When reporting a percentage remaining mL – When reporting a volume.
12	N	S		Expiration Date/Time	14	Date/Time of Expiration in format of YYYYMMDDHHMMSS Applies to reagents and diluents.
13	N	N		First Used Date/Time		Not supported
14	N	N		On Board Stability Duration		Not supported

#	D	U	R	Field	Length	Notes
15	N	S	Y	Test/Fluid Identifier(s)	3	= TestCode of assay + test code of other assays that share this reagent (ex. Fe/TIBC). This field is repeated for each shared assay.
16	N	S		Manufacturer Lot Number	12	Lot Number Applies to reagents, diluents, ERF, IWF and SR. (On the 3400, diluents do not require Lot Numbers to be entered.)
	N	N		Manufacturer Identifier		Not supported
	N	N		Supplier Identifier		Not supported
	N	N		On Board Stability Time		Not supported
	N	N		Target Value		Not supported

5.5.4 Message Acknowledgement (MSA)

The System supports the following unshaded fields of the Message Acknowledgement (MSA) Segment as defined in Section 2.15.8 of *HL7 2.5 Specifications, 2003.*

#	D	U	R	Field	Length	Notes
1	R	A		Acknowledgement Code	2	AA – Application Accept AE – Application Error AR – Application Reject
2	R	A		Message Control Id	unlimited	The message control ID of the message sent by the sending system. On upload this will be a Time stamp (down to millisec).
3	N	N		Text Message		Not supported
4	N	N		Expected Sequence Number		Not supported
5	N	N		Delayed Acknowledgement Type		Not supported
6	N	N		Error Condition		Not supported

5.5.5 Message Header (MSH)

The System supports the following unshaded fields of the Message Header (MSH) Segment as defined in Section 2.15.9 of *HL7 2.5 Specifications, 2003.*

#	D	U	R	Field	Length	Notes
1	R	R		Field Separator	1	"|"
2	R	R		Encoding Characters	4	"^" = Component Separator "&" = Sub-Component Separator "~" = Repetition Separator "\" = Escape Character All delimiters are fixed on upload. All delimiters can be variable on download. Not allowed to use a "+" sign.
3	N	A		Sending Application	12	J Number when uploading
4	N	N		Sending Facility		Not supported
5	N	N		Receiving Application		Not supported
6	N	N		Receiving Facility		Not supported
7	R	A		Date/Time Of Message	18	Date/Time of Message with millisecond accuracy in format of YYYYMMDDHHMMSS.000
8	N	N		Security		Not supported
9	R	A		Message Type	3^3^7	Type^Event^Structure, i.e., OUL^R23^OUL_R23
10	R	A		Message Control ID	18	This is a date time stamp with millisecond accuracy in format of YYYYMMDDHHMMSS.000
11	R	A		Processing ID	1	"P"
12	R	A		Version ID	3	"2.5"
13	N	N		Sequence Number		Not supported
14	N	N		Continuation Pointer		Not supported
15	N	N		Accept Acknowledgment Type		Not supported
16	N	N		Application Acknowledgment Type		Not supported
17	N	N		Country Code		Not supported
18	O	A		Character Set	13	UNICODE UTF-8 or 8859/1 based configured value. Log an error if they are different from the configured setting.

#	D	U	R	Field	Length	Notes
19	N	N		Principal Language Of Message		Not supported
20	N	N		Alternate Character Set Handling Scheme		Not supported
21	N	N	Y	Message Profile Identifier		Not supported

5.5.6 Notification Detail (NDS)

The System supports the following fields of the Notification Detail (NDS) Segment as defined in Section 13.4.7 of *HL7 2.5 Specifications, 2003.*

#	D	U	R	Field	Length	Notes
1	-	A		Notification Reference Number	10	Error Messages: Condition ID from the condition database. Auto Config Messages: Interface ID Download Messages: Audit ID from the sample database
2	-	A		Notification Date/Time	14	= TimeofError or = TimeofConfigChange or = TimeofAudit in the format of YYYYMMDDHHMMSS
3	-	A		Notification Alert Severity	1	Error Messages use condition code severity levels. See Section 5.1.5 Severity Level in this LIS Guide. Auto Config Messages Use: N = Attention Download Messages Use: N = Passing audits W = Failing audits
4	-	A		Notification Code	Error: 7^80&15&2&2 AutoConfig: 12^8 DL Msg: 8^80&15&2&2	Error Messages Use: <Mod>-<Err>^ShortText &SampleID&Tray&Cup Auto Config Message Use: AutoConfig-<If>^Enabled or AutoConfig-<If>^Disabled Download Messages Use: Audit-<AuditCode>^ AuditText &SampleID&Tray&Cup

5.5.7 Notes and Comments (NTE)

The System supports the following unshaded fields of the Notes and Comments (NTE) Segment as defined in Section 2.15.10 of *HL7 2.5 Specifications, 2003.*

#	D	U	R	Field	Length	Notes
1	N	N		Not used		Not supported
2	O	A		Source of Comment	1	Comment source – "P" – Practice, "L" – Lab Computer, "I" – Instrument – This is optional and may be blank. The Analyzer will always set this value to "I".
3	O	S	Y	Comment	60	For patient comments: comment lines 1-3 are "glued" together. On uploading one comment will exist in this sequence. On the download, we are using the first repetition only. For result comments: Contains the qualitative result.
4	O	A		Comment Type	1	Comment type – "G" – Generic, "T" – Test Name, "P" – Positive, "N" – Negative, "I" – Instrument – This is optional and may be blank. The Analyzer will always set this value to "G" for patient comments and "I" for result comments.

5.5.8 Observation Request (OBR)

The System supports the following unshaded fields of the Observation Request (OBR) Segment as defined in Section 7.4.1 of *HL7 2.5 Specifications, 2003.*

#	D	U	R	Field	Length	Notes
1	N	N		Set ID – OBR		Not supported
2	N	N		Placer Order Number		Not supported
3	N	S		Filler Order Number	15	= OperatorID (On upload only when operator logged in at test start)
4	R	A		Universal Service Identifier	Variable	= Universal Test Id See 4.2 Downloading Sample Programs
5	R	A		Priority – OBR	7	= "STAT" or "Routine"
6	N	N		Requested Date/Time		Not supported

#	D	U	R	Field	Length	Notes
7	N	A		Observation Date/Time #	14	= Specimen Collection Date/Time in the format of YYYYMMDDHHMMSS
8	N	N		Observation End Date/Time #		Not supported
9	N	N		Collection Volume *		Not supported
10	N	N		Collector Identifier *		Not supported
11	R	N		Specimen Action Code *	1	“A” for append; all else is new.
12	N	N		Danger Code		Not supported
13	N	N		Relevant Clinical Information		Not supported
14	N	N		Specimen Received Date/Time *		Not supported
15	N	N		Specimen Source		Not supported
16	N	N		Ordering Provider		Not supported
17	N	N		Order Callback Phone Number		Not supported
18	N	N		Placer Field 1		Not supported
19	N	N		Placer Field 2		Not supported
20	N	N		Filler Field 1		Not supported
21	N	N		Filler Field 2		Not supported
22	N	N		Results Rpt/Status Chng - Date/Time +		Not supported
23	N	N		Charge to Practice +		Not supported
24	N	N		Diagnostic Serv Sect ID		Not supported
25	N	A		Result Status	1	“A” when partial/individual upload; “F” for final upload
26	N	N		Parent Result		Not supported
27	N	N		Quantity/Timing		Not supported
28	N	N		Result Copies To		Not supported
29	N	N		Parent		Not supported
30	N	N		Transportation Mode		Not supported
31	N	N		Reason for Study		Not supported
32	N	N		Principal Result Interpreter		Not supported

#	D	U	R	Field	Length	Notes
33	N	N		Assistant Result Interpreter		Not supported
34	N	N		Technician		Not supported
35	N	N		Transcriptionist		Not supported
36	N	N		Scheduled Date/Time		Not supported
37	N	N		Number of Sample Containers		Not supported
38	N	N		Transport Logistics of Collected Sample		Not supported
39	N	N		Collector's Comment		Not supported
40	N	N		Transport Arrangement Responsibility		Not supported
41	N	N		Transport Arranged		Not supported
42	N	N		Escort Required		Not supported
43	N	N		Planned Patient Transport Comment		Not supported
44	N	N		Procedure Code		Not supported
45	N	N		Procedure Code Modifier		Not supported
46	N	N		Placer Supplemental Service Information		Not supported
47	N	N		Filler Supplemental Service Information		Not supported
48	N	N		Medically Necessary Duplicate Procedure Reason.		Not supported
49	N	N		Result Handling		Not supported

5.5.9 Observation Result (OBX)

The System supports the following unshaded fields of the Observation Result (OBX) Segment as defined in Section 7.4.2 of *HL7 2.5 Specifications, 2003.*

#	D	U	R	Field	Length	Notes
1	-	N		Set ID – OBX		Not supported
2	-	N		Value Type		Not supported
3	-	A		Observation Identifier	^^^13	= ^^^LocalOrMfctrCode See 4.2 Downloading Sample Programs
4	-	N		Observation Sub-ID		Not supported

#	D	U	R	Field	Length	Notes
5	-	A		Observation Value	9	Data or Measurement Value. Floating point numeric value converted to configured units. “No Result” will appear when System cannot report numeric result. If configured to include the measuring (reportable) range flag in the result field, for results that are outside of measuring range (Result Flag of 4 or 5), a ">" or "<" will be prepended to the value; the value will represent the extreme of the measuring (reportable) range. If not configured to include the measuring (reportable) range flag in the result field, for results that are outside of measuring range (Result Flag of 4 or 5), the value will represent the extreme of the measuring (reportable) range. If not configured to include the measuring (reportable) range flag in the result field, for results that are outside of measuring range (Result Flag of 4 or 5) and also have a qualitative result classification (Result Flag Q, R, S, T, or U), the value will be left blank. For semi-quantitative/qualitative assays, the value is blank if the assay is not configured to display the value with the result, If this is a mean record and the result record indicates that the mean concentration should be suppressed, the value is blank.
6	-	S		Units	12	Units of Measurement Value (e.g., mg/dL) For semi-quantitative/qualitative assays, the value is blank if the assay is not configured to display the value with the result, If this is a mean record and the result record indicates that the mean concentration should be suppressed, the value is blank
7	-	N		References Range		Not supported

#	D	U	R	Field	Length	Notes
8	-	S	Y	s	^1^10	= ^ResultFlag (see 5.1.2 Result Flags in this LIS Guide.)^Code. (Code will contain up to 5 non-delimited two-character codes.) This field shall be repeated 3 times (for a total of 4 repetitions). The first is for any flag/codes specific to the assay; the second is for any specific to Hemolysis; the third, for Icterus; and the fourth, for Turbidity. Component 1 of this field is always an empty string. Component 3 of this field will contain up to 5 non-delimited two-character codes as specified in as specified in Appendix F Result Codes and Appendix G Sample Indices Flags in this LIS Guide.
9	-	N		Probability		Not supported
10	-	N		Nature of Abnormal Test		Not supported
11	-	A		Observation Result Status	1	“S” for partial/individual upload, “F” for final
12	-	N		Effective Date of Reference Range		Not supported
13	-	N		User Defined Access Checks		Not supported
14	-	N		Date/Time of the Observation		Not supported
15	-	S		Producer's ID	15	= Operator ID (only when operator logged in at test start)
16	-	N		Responsible Observer		Not supported
17	-	N		Observation Method		Not supported
18	-	S		Equipment Instance Identifier	12	Instrument ID – J Number (Serial number)
19	-	A		Date/Time of the Analysis	14	= RepEndTime in format of YYYYMMDDHHMMSS

5.5.10 Common Order (ORC)

The System supports the following unshaded fields of the Common Order (ORC) Segment as defined in Section 4.5.1 of *HL7 2.5 Specifications, 2003.*

#	D	U	R	Field	Length	Notes
1	R	N		Order Control	2	Order Record, Action Code.

#	D	U	R	Field	Length	Notes
						The values supported are: NW – New Order; CA – Cancel Order; XO – Change Order A value of 'XO' should be used in conjunction with an 'A' for the Specimen Action Code in the Observation Request segment (Section 5.5.8).
2	N	N		Placer Order Number		Not supported
3	N	N		Filler Order Number		Not supported
4	N	N		Placer Group Number		Not supported
5	N	N		Order Status		Not supported
6	N	N		Response Flag		Not supported
7	N	N		Quantity / Timing		Not supported
8	N	N		Parent		Not supported
9	N	N		Date/Time of Transaction		Not supported
10	N	N		Entered by		Not supported
11	N	N		Verified by		Not supported
12	N	N		Ordering Provider		Not supported
13	N	N		Enterer's Location		Not supported
14	N	N		Call back phone number		Not supported
15	N	N		Order effective date/time		Not supported
16	N	N		Order control code reason		Not supported
17	N	N		Entering Organization		Not supported
18	N	N		Entering Device		Not supported
19	N	N		Action By		Not supported
20	N	N		Advanced Beneficiary Notice Code		Not supported
21	N	N		Ordering Facility Name		Not supported

#	D	U	R	Field	Length	Notes
22	N	N		Ordering Facility Address		Not supported
23	N	N		Ordering Facility Phone Number		Not supported
24	N	N		Ordering Provider Address		Not supported
25	N	N		Order Status Modifier		Not supported
26	N	N		Advanced Beneficiary Notice Override reason		Not supported
27	N	N		Filler's Expected Availability Date/Time		Not supported
28	N	N		Confidentiality Code		Not supported
29	N	N		Order Type		Not supported
30	N	N		Enterer Authorization Mode		Not supported

5.5.11 Patient ID (PID)

The System supports the following unshaded fields of the Patient ID (PID) Segment as defined in Section 3.4.2 of *HL7 2.5 Specifications, 2003.*

#	D	U	R	Field	Length	Notes
1	N	N		Set ID – PID		Not supported
2	N	N		Patient ID		Not supported
3	O	S	Y	Patient Identifier List	20	= Patient ID – The first component of the first repetition is used as the patient id. All other ids are ignored. – The System supports a blank in this field.
4	N	N		Alternate Patient ID - PID		Not supported
5	O	S	Y	Patient Name	20^15^1	= Last^First^MI – The first repetition is used. – The System supports a blank in this field.
6	N	N		Mother’s Maiden Name		N/A – Not supported
7	O	S		Date/Time of Birth	8	= Birth date – The System supports a blank in this field. If not blank, the expected format is YYYYMMDD
8	O	S		Sex	1	Must match one of the configured demographic sex characters on the system.
9	N	N		Patient Alias		N/A – Not supported

#	D	U	R	Field	Length	Notes
10	N	N		Race		N/A – Not supported
11	O	S	Y	Patient Address	20^20	= Address1^Address2. Patient Address in two components as defined in the Analyzer. – The first repetition is used. – The System supports a blank in this field.
12	N	N		County Code		N/A – Not supported
13	N	N		Phone Number - Home		N/A – Not supported
14	N	N		Phone Number - Business		N/A – Not supported
15	N	N		Primary Language		N/A – Not supported
16	N	N		Marital Status		N/A – Not supported
17	N	N		Religion		N/A – Not supported
18	N	N		Patient Account Number		N/A – Not supported
19	N	N		SSN Number - Patient		N/A – Not supported
20	N	N		Driver's License Number - Patient		N/A – Not supported
21	N	N		Mother's Identifier		N/A – Not supported
22	N	N		Ethnic Group		N/A – Not supported
23	N	N		Birthplace		N/A – Not supported
24	N	N		Multiple Birth Indicator		N/A – Not supported
25	N	N		Birth Order		N/A – Not supported
26	N	N		Citizenship		N/A – Not supported
27	N	N		Veterans Military Status		N/A – Not supported
28	N	N		Nationality		N/A – Not supported
29	N	N		Patient Death Date and Time		N/A – Not supported
30	N	N		Patient Death Indicator		N/A – Not supported
31	N	N		Identity Unknown Indicator		N/A – Not supported
32	N	N		Identity Reliability Code		N/A – Not supported
33	N	N		Last Update Date/Time		N/A – Not supported
34	N	N		Last Update Facility		N/A – Not supported

#	D	U	R	Field	Length	Notes
35	N	N		Species Code		N/A – Not supported
36	N	N		Breed Code		N/A – Not supported
37	N	N		Strain		N/A – Not supported
38	N	N		Production Class Code		N/A – Not supported
39	N	N		Tribal Citizenship		N/A – Not supported

5.5.12 Patient Visit (PV1)

The System supports the following unshaded fields of the Patient Visit (PV1) Segment as defined in Section 3.4.3 of *HL7 2.5 Specifications, 2003.*

#	D	U	R	Field	Length	Notes
1	N	N		Set ID - PV1		
2	O	S		Patient Class	1	= "N" – The System supports a blank in this field.
3	O	S		Assigned Patient Location	^10	= ^room – The System supports a blank in this field.
4		O		Admission Type		Not supported
5		O		Pre-admit Number		Not supported
6		O		Prior Patient Location		Not supported
7	O	S		Attending Doctor	15^20 ^15^1	= DoctorID^Last^First^MI – The System supports a blank in this field.
8	N	N		Referring Doctor		Not supported
9	N	N		Consulting Doctor		Not supported
10	N	N		Hospital Service		Not supported
11	N	N		Temporary Location		Not supported
12	N	N		Pre-admit Test Indicator		Not supported
13	N	N		Re-admission Indicator		Not supported
14	N	N		Admit Source		Not supported
15	N	N		Ambulatory Status		Not supported
16	N	N		VIP Indicator		Not supported
17	N	N		Admitting Doctor		Not supported
18	O	S		Patient Type	1	= RangeAttribute. Must match one of the configured demographic attribute characters on the System. These are user-defined in Options & Configuration – Configure Demographics screen.
19	N	N		Visit Number		Not supported
20	N	N		Financial Class		Not supported
21	N	N		Charge Price Indicator		Not supported
22	N	N		Courtesy Code		Not supported

#	D	U	R	Field	Length	Notes
23	N	N		Credit Rating		Not supported
24	N	N		Contract Code		Not supported
25	N	N		Contract Effective Date		Not supported
26	N	N		Contract Amount		Not supported
27	N	N		Contract Period		Not supported
28	N	N		Interest Code		Not supported
29	N	N		Transfer to Bad Debt Code		Not supported
30	N	N		Transfer to Bad Debt Date		Not supported
31	N	N		Bad Debt Agency Code		Not supported
32	N	N		Bad Debt Transfer Amount		Not supported
33	N	N		Bad Debt Recovery Amount		Not supported
34	N	N		Delete Account Indicator		Not supported
35	N	N		Delete Account Date		Not supported
36	N	N		Discharge Disposition		Not supported
37	N	N		Discharged to Location		Not supported
38	N	N		Diet Type		Not supported
39	N	N		Servicing Facility		Not supported
40	N	N		Bed Status		Not supported
41	N	N		Account Status		Not supported
42	N	N		Pending Location		Not supported
43	N	N		Prior Temporary Location		Not supported
44	N	N		Admit Date/Time		Not supported
45	N	N		Discharge Date/Time		Not supported
46	N	N		Current Patient Balance		Not supported
47	N	N		Total Charges		Not supported
48	N	N		Total Adjustments		Not supported
49	N	N		Total Payments		Not supported

#	D	U	R	Field	Length	Notes
50	N	N		Alternate Visit ID		Not supported
51	N	N		Visit Indicator		Not supported
52	N	N		Other Healthcare Provider		Not supported

5.5.13 Query Acknowledgement Details (QAK)

The System supports the following unshaded fields of the Query Acknowledgement Details (QAK) Segment as defined in Section 5.5.2 of *HL7 2.5 Specifications, 2003.*

#	D	U	R	Field	Length	Notes
1	R	-		Query Tag	5	Unique query ID
2	R	-		Query Response Status	2	OK – Data Found, no errors NF – No data found, no errors AE – Application error AR – Application reject
3	R	-		Message Query Name	28	= “ZOS^Lab Order Specimen Query”
4	R	-		Hit Count	1	0 for NF, AE, or AR 1 for OK
5	N	-		This payload		Not supported
6	N	-		Hits remaining		Not supported

5.5.14 Query Identification Details (QID)

The System supports the following fields of the Query Identification Details (QID) Segment as defined in Section 5.5.3 of *HL7 2.5 Specifications, 2003.*

#	D	U	R	Field	Length	Notes
1	-	A		Query Tag	5	Unique query ID
2	-	A		Message Query Name	28	= “ZOS^Lab Order Specimen Query”

5.5.15 Query Parameter Definition Details (QPD)

The System supports the following unshaded fields of the Query Parameter Definition Details (QPD) Segment as defined in Section 5.5.4 of *HL7 2.5 Specifications, 2003*.

#	D	U	R	Field	Length	Notes
1	R	A		Message Query Name	28	= “ZOS^Lab Order Specimen Query”
2	R	A		Query Tag	18	Unique query ID (this tag is a date time stamp with millisecond accuracy in the format of YYYYMMDDHHMMSS.000)
3	O	A		Container Identifier	15	Specimen ID
4	N	N		Carrier Type		Not supported
5	N	N		Carrier ID		Not supported
6	N	N		Position in Carrier		Not supported
7	N	N		Tray Type		Not supported
8	N	N		Tray ID		Not supported
9	N	N		Position in Tray		Not supported
10	N	S		Location	1	=”A”, “B”, or “”. A = Specimen positioned at the MicroSlide/MicroTip Point of Reference. B = Specimen positioned at the MicroImmunoassay Point of Reference. “” = An empty string identifies a specimen not positioned at an external metering point.
11	N	N		Requested Date LL		Not supported
12	N	N		Requested Date UL		Not supported

5.5.16 Response Control Parameter Details (RCP)

The System supports the following unshaded fields of the Response Control Parameter Details (RCP) Segment as defined in Section 5.5.6 of *HL7 2.5 Specifications, 2003.*

#	D	U	R	Field	Length	Notes
1	-	A		Query Priority	1	I – immediate
2	-			Quantity Limited Request		Not supported
3	-	A		Response Modality	1	R – realtime
4	-	N		Execution and Delivery Time		Not supported
5	-	N		Modify Indicator		Not supported
6	-	N		Sort-by Field		Not supported
7	-	N		Segment group inclusion		Not supported

5.5.17 Specimen Container Details (SAC)

The System supports the following unshaded fields of the Specimen Container Details (SAC) Segment as defined in Section 13.4.3 of *HL7 2.5 Specifications, 2003.*

#	D	U	R	Field	Length	Notes
1		O		External Accession Identifier		N/A – Not supported
2		O		Accession Identifier		N/A – Not supported
3	R	S		Container Identifier	15	= SampleID. SampleID or Tray and Cup are required on download.
4		C		Primary (parent) Container Identifier		N/A – Not supported
5		O		Equipment Container Identifier		N/A – Not supported
6		C		Specimen Source		N/A – Not supported
7		O		Registration Date/Time		N/A – Not supported
8		O		Container Status		N/A – Not supported
9		O		Carrier Type		N/A – Not supported
10		O		Carrier Identifier		N/A – Not supported
11		O		Position in Carrier		N/A – Not supported
12		O		Tray Type - SAC		N/A – Not supported
13	O	A		Tray Identifier	2	Tray.

#	D	U	R	Field	Length	Notes
14	O	A		Position in Tray	2	Cup position.
15		O		Location		N/A – Not supported
16		O		Container Height		N/A – Not supported
17		O		Container Diameter		N/A – Not supported
18		O		Barrier Delta		N/A – Not supported
19		O		Bottom Delta		N/A – Not supported
20		O		Container Height/Diameter/Delta Units		N/A – Not supported
21		O		Container Volume		N/A – Not supported
22		O		Available Specimen Volume		N/A – Not supported
23		O		Initial Specimen Volume		N/A – Not supported
24		O		Volume Units		N/A – Not supported
25		O		Separator Type		N/A – Not supported
26		O		Cap Type		N/A – Not supported
27		O		Additive		N/A – Not supported
28		O		Specimen Component		N/A – Not supported
29		O		Dilution Factor		N/A – Not supported
30		O		Treatment		N/A – Not supported
31		O		Temperature		N/A – Not supported
32	N	S		Hemolysis Index	9	Hemolysis Value (upload only). Data or Measurement Value. If the value is “No result”, then the field will be null.
33		O		Hemolysis Index Units		N/A – Not supported
34	N	S		Lipemia Index	9	Turbidity Value (upload only). If the value is “No result”, then the field will be null.
35		O		Lipemia Index Units		N/A – Not supported
36	N	S		Icterus Index	9	Icterus Value (upload only). Data or Measurement Value. If the value is “No result”, then the field will be null.
37		O		Icterus Index Units		N/A – Not supported

#	D	U	R	Field	Length	Notes
38		O		Fibrin Index		N/A – Not supported
39		O		Fibrin Index Units		N/A – Not supported
40		O		System Induced Contaminants		N/A – Not supported
41		O		Drug Interference		N/A – Not supported
42		O		Artificial Blood		N/A – Not supported
43		O		Special Handling Code		N/A – Not supported
44		O		Other Environmental Factors		N/A – Not supported

5.5.18 Specimen (SPM)

The System supports the following unshaded fields of the Specimen (SPM) Segment as defined in Section 7.4.3 of *HL7 2.5 Specifications, 2003.*

#	D	U	R	Field	Length	Notes
1	N	N		Set ID – SPM		Not supported
2	N	N		Specimen ID		Not supported
3	N	N	Y	Specimen Parent IDs		Not supported
4	R	A		Specimen Type	1	Body fluid (use OCD values)
5	N	N		Specimen Type Modifier		Not supported
6	N	N		Specimen Additives		Not supported
7	N	N		Specimen Collection Method		Not supported
8	N	N		Specimen Source Site		Not supported
9	N	N		Specimen Source Site Modifier		Not supported
10	N	N		Specimen Collection Site		Not supported
11	N	N		Specimen Role		Not supported
12	N	N		Specimen Collection Amount		Not supported
13	N	N		Grouped Specimen Count		Not supported
14	N	N		Specimen Description		Not supported
15	N	N		Specimen Handling Code		Not supported
16	N	N		Specimen Risk Code		Not supported

#	D	U	R	Field	Length	Notes
17	N	N		Specimen Collection Date/Time		Not supported
18	N	N		Specimen Received Date/Time		Not supported
19	N	N		Specimen Expiration Date/Time		Not supported
20	N	N		Specimen Availability		Not supported
21	N	N		Specimen Reject Reason		Not supported
22	N	N		Specimen Quality		Not supported
23	N	N		Specimen Appropriateness		Not supported
24	N	N		Specimen Condition		Not supported
25	N	N		Specimen Current Quantity		Not supported
26	N	N		Number of Specimen Containers		Not supported
27	N	N		Container Type		Not supported
28	N	N		Container Condition		Not supported
29	N	N		Specimen Child Role		Not supported

5.5.19 Z-Segment Extended Results (ZER)

The System supports the following fields of the Z Segment Extended Results (ZER) Segment.

#	D	U	R	Field	Length	Notes
1	-	A		Reagents	12^14^14^5^5^4	= ReagentLot^ReagentExpDate^ReagentLoadDate^ERFLot^IWFLot^SRLot Note: SRLot is left blank if no SR was used for this result.
2	-	S		Calibration	14^1^14	= CalibrationDate^CalibrationStatus^CalExpDate (See 5.1.3 Calibration Status in this LIS Guide.) Sent only if calibration info still in database. Date in the format of YYYYMMDDHHMMSS
3	-	S		Quality Control	10^14^14	= ControlLot^ControlCreationDate^ControlExpDate. Sent only if Quality Control sample. Date in the format of YYYYMMDDHHMMSS
4	-	S	Y	Diluents	12	= DiluentLot Repeated for each diluent lot used
5	-	A		Reprocessing Type		= “N”, “R”, “I”, “D”, “F” or "G" See 5.1.7, Reprocessing Type Table

Appendix A Notes

Delayed Response

When an Assay Data Disk (ADD) is being loaded onto the System (about 10 minutes), the System cannot process any incoming requests from the LIS. This delayed response in the communications between the LIS and the System may cause the LIS to time out. Communication is reestablished automatically when the ADD load has been completed.

Example: If the LIS sends an Inventory Query to the System during an ADD load, the query cannot be completed and the LIS may time out. The Inventory Query takes approximately 1 minute to process.

Appendix B Analyte Codes

The assays listed in the table are subject to local regulatory requirements and may not be available in all regions.

VITROS® 5600 refers to the VITROS® 5600 Integrated System; VITROS® XT 7600 refers to the VITROS® XT 7600 Integrated System; VITROS® 3600 refers to the VITROS® 3600 Immunodiagnostic System; VITROS® 4600 refers to the VITROS® 4600 Chemistry System; and VITROS® XT 3400 refers to the VITROS® XT 3400 Chemistry System.

NA in the VITROS® 3600, VITROS® 4600, or VITROS® XT 3400 columns indicates the assay is not available for that System.

An * indicates that the product is in development.

MicroSlide, MicroTip, and MicroWell Assays

Analyte Code	Report Name	Assay Name	Body Fluid	VITROS® 5600	VITROS® XT 7600	VITROS® 3600	VITROS® 4600	VITROS® XT 3400
	Body Fluid Key: 2 CSF, 3 Urine, 4 Whole Blood, 5 Serum, 6 Plasma, 7 Amniotic Fluid, 8 Reserved Fluid 1, 9 Reserved Fluid 2, 10 SWAB, UD User Defined							
001	TSH	TSH	5	√	√	√	NA	NA
001	TSH	TSH	6	√	√	√	NA	NA
002	TT4	Total T4	5	√	√	√	NA	NA
002	TT4	Total T4	6	√	√	√	NA	NA
003	TT3	Total T3	5	√	√	√	NA	NA
003	TT3	Total T3	6	√	√	√	NA	NA
004	FT4	Free T4	5	√	√	√	NA	NA
005	FT3	Free T3	5	√	√	√	NA	NA
005	FT3	Free T3	6	√	√	√	NA	NA
006	T3U	T3 Uptake	5	√	√	√	NA	NA
006	T3U	T3 Uptake	6	√	√	√	NA	NA
008	E2	Estradiol	5	√	√	√	NA	NA
008	E2	Estradiol	6	√	√	√	NA	NA
009	LH	LH	5	√	√	√	NA	NA
009	LH	LH	6	√	√	√	NA	NA
010	FSH	FSH	5	√	√	√	NA	NA
010	FSH	FSH	6	√	√	√	NA	NA
011	Prol	Prolactin	5	√	√	√	NA	NA
011	Prol	Prolactin	6	√	√	√	NA	NA
012	Prog	Progesterone	5	√	√	√	NA	NA
012	Prog	Progesterone	6	√	√	√	NA	NA
013	B-hCG	Total B-hCG	5	√	√	√	NA	NA
013	B-hCG	Total B-hCG	6	√	√	√	NA	NA

Analyte Code	Report Name	Assay Name	Body Fluid	VITROS® 5600	VITROS® XT 7600	VITROS® 3600	VITROS® 4600	VITROS® XT 3400
	Body Fluid Key: 2 CSF, 3 Urine, 4 Whole Blood, 5 Serum, 6 Plasma, 7 Amniotic Fluid, 8 Reserved Fluid 1, 9 Reserved Fluid 2, 10 SWAB, UD User Defined							
013	B-hCG	Total B-hCG II	5	√	√	√	NA	NA
013	B-hCG	Total B-hCG II	6	√	√	√	NA	NA
014	Testo	Testosterone	5	√	√	√	NA	NA
014	Testo	Testosterone	6	√	√	√	NA	NA
015	AFP	AFP	5	√	√	√	NA	NA
015	AFP	AFP	6	√	√	√	NA	NA
015	AFP	AFP	7	√	√	√	NA	NA
016	CEA	CEA	5	√	√	√	NA	NA
016	CEA	CEA	6	√	√	√	NA	NA
017	HBsAg	HBsAg	5	√	√	√	NA	NA
017	HBsAg	HBsAg	6	√	√	√	NA	NA
017	HBsAg	HBsAg ES	5	√	√	√	NA	NA
017	HBsAg	HBsAg ES	6	√	√	√	NA	NA
018	aHBs	anti-HBs	5	√	√	√	NA	NA
018	aHBs	anti-HBs	6	√	√	√	NA	NA
019	aHBc	Anti-HBc	5	√	√	√	NA	NA
019	aHBc	Anti-HBc	6	√	√	√	NA	NA
020	HBc M	Anti-HBc IgM	5	√	√	√	NA	NA
020	HBc M	Anti-HBc IgM	6	√	√	√	NA	NA
021	HBeAg	HBeAg	5	√	√	√	NA	NA
022	HAV M	Anti-HAV IgM	5	√	√	√	NA	NA
022	HAV M	Anti-HAV IgM	6	√	√	√	NA	NA
023	aHCV	Anti-HCV	5	√	√	√	NA	NA
023	aHCV	Anti-HCV	6	√	√	√	NA	NA
024	aHIV	Anti HIV 1/2	5	√	√	√	NA	NA
024	aHIV	Anti HIV 1/2	6	√	√	√	NA	NA
025	Rub G	Rubella IgG	5	√	√	√	NA	NA
025	Rub G	Rubella IgG	6	√	√	√	NA	NA
026	Rub M	Rubella IgM	5	√	√	√	NA	NA
026	Rub M	Rubella IgM	6	√	√	√	NA	NA
027	Tox G	Toxoplasma IgG	5	√	√	√	NA	NA
027	Tox G	Toxoplasma IgG	6	√	√	√	NA	NA
028	Tox M	Toxoplasma IgM	5	√	√	√	NA	NA
028	Tox M	Toxoplasma IgM	6	√	√	√	NA	NA
029	CK-MB	CK-MB	5	√	√	√	NA	NA

Analyte Code	Report Name	Assay Name	Body Fluid	VITROS® 5600	VITROS® XT 7600	VITROS® 3600	VITROS® 4600	VITROS® XT 3400
	Body Fluid Key: 2 CSF, 3 Urine, 4 Whole Blood, 5 Serum, 6 Plasma, 7 Amniotic Fluid, 8 Reserved Fluid 1, 9 Reserved Fluid 2, 10 SWAB, UD User Defined							
029	CK-MB	CK-MB	6	√	√	√	NA	NA
030	TropI	Troponin I ES	5	√	√	√	NA	NA
030	TropI	Troponin I ES	6	√	√	√	NA	NA
031	Ferr	Ferritin	5	√	√	√	NA	NA
031	Ferr	Ferritin	6	√	√	√	NA	NA
032	B12	Vitamin B12	5	√	√	√	NA	NA
032	B12	Vitamin B12	6	√	√	√	NA	NA
033	Fol	Red Cell Folate	4	√	√	√	NA	NA
033	Fol	Folate	5	√	√	√	NA	NA
033	Fol	Folate	6	√	√	√	NA	NA
034	Cort	Cortisol	3	√	√	√	NA	NA
034	Cort	Cortisol	5	√	√	√	NA	NA
034	Cort	Cortisol	6	√	√	√	NA	NA
035	TSH3	TSH3	5	√	√	√	NA	NA
035	TSH3	TSH3	6	√	√	√	NA	NA
036	PSA	PSA	5	√	√	√	NA	NA
036	PSA	PSA	6	√	√	√	NA	NA
037	fPSA	Free PSA	5	√	√	√	NA	NA
037	fPSA	Free PSA	6	√	√	√	NA	NA
038	CA125	CA 125 II	5	√	√	√	NA	NA
038	CA125	CA 125 II	6	√	√	√	NA	NA
039	CA153	CA 15-3	5	√	√	√	NA	NA
039	CA153	CA 15-3	6	v	√	√	NA	NA
040	CA199	CA 19-9	5	√	√	√	NA	NA
040	CA199	CA 19-9	6	√	√	√	NA	NA
042	INS	Insulin	5	√	√	√	NA	NA
042	INS	Insulin	6	√	√	√	NA	NA
043	aHBe	Anti-HBe	5	√	√	√	NA	NA
044	NTx	NTx	3	√	√	√	NA	NA
045	-	(Reserved for Internal Use)		√	√	√	NA	NA
049	HBCon	HBsAg Confirm	5	√	√	√	NA	NA
049	HBCon	HBsAg Confirm	6	√	√	√	NA	NA
050	C-pep	C-peptide	5	√	√	√	NA	NA
050	C-pep	C-peptide	6	√	√	√	NA	NA

Analyte Code	Report Name	Assay Name	Body Fluid	VITROS® 5600	VITROS® XT 7600	VITROS® 3600	VITROS® 4600	VITROS® XT 3400
	Body Fluid Key: 2 CSF, 3 Urine, 4 Whole Blood, 5 Serum, 6 Plasma, 7 Amniotic Fluid, 8 Reserved Fluid 1, 9 Reserved Fluid 2, 10 SWAB, UD User Defined							
051	Myog	Myoglobin	5	√	√	√	NA	NA
051	Myog	Myoglobin	6	√	√	√	NA	NA
052	NBNP2	NT-proBNP II	5	√	√	√	NA	NA
052	NBNP2	NT-proBNP II	6	√	√	√	NA	NA
053	aHTLV	Anti-HTLV I/II	5	√	√	√	NA	NA
053	aHTLV	Anti-HTLV I/II	6	√	√	√	NA	NA
055	FT3II	Free T3 II	5	√	√	√	NA	NA
055	FT3II	Free T3 II	6	√	√	√	NA	NA
058	-	(Reserved for Internal Use)		√	√	√	NA	NA
061	HAV T	Anti-HAV Total	5	√	√	√	NA	NA
061	HAV T	Anti-HAV Total	6	√	√	√	NA	NA
062	CMV G	CMV IgG	5	√	√	√	NA	NA
062	CMV G	CMV IgG	6	√	√	√	NA	NA
063	CMV M	CMV IgM	5	√	√	√	NA	NA
063	CMV M	CMV IgM	6	√	√	√	NA	NA
064	aHBs	Anti-HBs	5	√	√	√	NA	NA
065	NTBNP	NT-proBNP	5	√	√	√	NA	NA
065	NTBNP	NT-proBNP	6	√	√	√	NA	NA
069	HIVc	HIV Combo	5	√	√	√	NA	NA
069	HIVc	HIV Combo	6	√	√	√	NA	NA
070	iPTH	Intact PTH	5	√	√	√	NA	NA
070	iPTH	Intact PTH	6	√	√	√	NA	NA
073	Syph	Syphilis TPA	5	√	√	√	NA	NA
073	Syph	Syphilis TPA	6	√	√	√	NA	NA
074	tVitD	VITAMIN D TOTAL	5	√	√	√	NA	NA
075	tPSA	Total PSA II	5	√	√	√	NA	NA
075	tPSA	Total PSA II	6	√	√	√	NA	NA
080	TIMP2	TIMP-2	3	√	√	√	NA	NA
081	IGFBP	IGFBP-7	3	√	√	√	NA	NA
082	hsTnI	hs Troponin I	5	√	√	√	NA	NA
082	hsTnI	hs Troponin I	6	√	√	√	NA	NA
083	aTCRU	Anti-T.cruzi	5	√	√	√	NA	NA
083	aTCRU	Anti-T.cruzi	6	√	√	√	NA	NA
086	PCT	Procalcitonin	5	√	√	√	NA	NA

Analyte Code	Report Name	Assay Name	Body Fluid	VITROS® 5600	VITROS® XT 7600	VITROS® 3600	VITROS® 4600	VITROS® XT 3400
	Body Fluid Key: 2 CSF, 3 Urine, 4 Whole Blood, 5 Serum, 6 Plasma, 7 Amniotic Fluid, 8 Reserved Fluid 1, 9 Reserved Fluid 2, 10 SWAB, UD User Defined							
086	PCT	Procalcitonin	6	√	√	√	NA	NA
087	CoV2G	SARS-CoV-2 IgG	5	√	√	√	NA	NA
089	CoV2T	SARS-CoV-2 Tot	5	√	√	√	NA	NA
089	CoV2T	SARS-CoV-2 Tot	6	√	√	√	NA	NA
091	CV2Ag	SARS-CoV-2 Ag	10	√	√	√	NA	NA
100	CV2G	SARS-CoV-2 IgG	5	√	√	√	NA	NA
101	CV2T	SARS-CoV-2 Tot	5	√	√	√	NA	NA
101	CV2T	SARS-CoV-2 Tot	6	√	√	√	NA	NA
102	CVG2	SARS-CoV2 IgG 2	5	√	√	√	NA	NA
103	CVT2	SARS-CoV2 Tot 2	5	√	√	√	NA	NA
103	CVT2	SARS-CoV2 Tot 2	6	√	√	√	NA	NA
104	IL-6	IL-6	5	√	√	√	NA	NA
105	CVGQN	SARS CV2 IgG QN	5	√	√	√	NA	NA
105	CVGQN	SARS CV2 IgG QN	6	√	√	√	NA	NA
106	CV2TN	SARS-CoV2 Tot N	5	√	√	√	NA	NA
106	CV2TN	SARS-CoV2 Tot N	6	√	√	√	NA	NA
107	BhCG2*	Total B-hCG II	5	√	√	√	NA	NA
107	BhCG2*	Total B-hCG II	6	√	√	√	NA	NA
108	CEA2*	CEA 2	5	√	√	√	NA	NA
108	CEA2*	CEA 2	6	√	√	√	NA	NA
109	CKMB2*	CK-MB 2	5	√	√	√	NA	NA
109	CKMB2*	CK-MB 2	6	√	√	√	NA	NA
110	Prol2*	Prolactin 2	5	√	√	√	NA	NA
110	Prol2*	Prolactin 2	6	√	√	√	NA	NA
111	Ferr2*	Ferritin 2	5	√	√	√	NA	NA
111	Ferr2*	Ferritin 2	6	√	√	√	NA	NA
300	GLU	Glucose	2	√	√	NA	√	√
300	GLU	Glucose	3	√	√	NA	√	√
300	GLU	Glucose	5	√	√	NA	√	√
300	GLU	Glucose	6	√	√	NA	√	√

Analyte Code	Report Name	Assay Name	Body Fluid	VITROS® 5600	VITROS® XT 7600	VITROS® 3600	VITROS® 4600	VITROS® XT 3400
	Body Fluid Key: 2 CSF, 3 Urine, 4 Whole Blood, 5 Serum, 6 Plasma, 7 Amniotic Fluid, 8 Reserved Fluid 1, 9 Reserved Fluid 2, 10 SWAB, UD User Defined							
301	TP	Total Protein	5	√	√	NA	√	√
301	TP	Total Protein	6	√	√	NA	√	√
302	URIC	Uric Acid	3	√	√	NA	√	√
302	URIC	Uric Acid	5	√	√	NA	√	√
302	URIC	Uric Acid	6	√	√	NA	√	√
303	ALB	Albumin	5	√	√	NA	√	√
303	ALB	Albumin	6	√	√	NA	√	√
304	TRIG	Triglycerides	5	√	√	NA	√	√
304	TRIG	Triglycerides	6	√	√	NA	√	√
305	CHOL	Cholesterol	5	√	√	NA	√	√
305	CHOL	Cholesterol	6	√	√	NA	√	√
306	AMYL	Amylase	3	√	√	NA	√	√
306	AMYL	Amylase	5	√	√	NA	√	√
306	AMYL	Amylase	6	√	√	NA	√	√
307	Cl-	Chloride	3	√	√	NA	√	√
307	Cl-	Chloride	5	√	√	NA	√	√
307	Cl-	Chloride	6	√	√	NA	√	√
308	K+	Potassium	3	√	√	NA	√	√
308	K+	Potassium	5	√	√	NA	√	√
308	K+	Potassium	6	√	√	NA	√	√
309	Na+	Sodium	3	√	√	NA	√	√
309	Na+	Sodium	5	√	√	NA	√	√
309	Na+	Sodium	6	√	√	NA	√	√
310	ECO2	Enzymatic CO2	5	√	√	NA	√	√
310	ECO2	Enzymatic CO2	6	√	√	NA	√	√
311	PHOS	Phosphorus	3	√	√	NA	√	√
311	PHOS	Phosphorus	5	√	√	NA	√	√
311	PHOS	Phosphorus	6	√	√	NA	√	√
312	LAC	Lactate	6	√	√	NA	√	√
314	CREA	Creatinine	3	√	√	NA	√	√
314	CREA	Creatinine	5	√	√	NA	√	√
314	CREA	Creatinine	6	√	√	NA	√	√
315	UREA	Urea Nitrogen	3	√	√	NA	√	√
315	UREA	Urea Nitrogen	5	√	√	NA	√	√
315	UREA	Urea Nitrogen	6	√	√	NA	√	√

Analyte Code	Report Name	Assay Name	Body Fluid	VITROS® 5600	VITROS® XT 7600	VITROS® 3600	VITROS® 4600	VITROS® XT 3400
	Body Fluid Key: 2 CSF, 3 Urine, 4 Whole Blood, 5 Serum, 6 Plasma, 7 Amniotic Fluid, 8 Reserved Fluid 1, 9 Reserved Fluid 2, 10 SWAB, UD User Defined							
317	Bu	Unconjugated Bilirubin	5	√	√	NA	√	√
317	Bu	Unconjugated Bilirubin	6	√	√	NA	√	√
318	Ca	Calcium	3	√	√	NA	√	√
318	Ca	Calcium	5	√	√	NA	√	√
318	Ca	Calcium	6	√	√	NA	√	√
319	TBIL	Total Bilirubin	5	√	√	NA	√	√
319	TBIL	Total Bilirubin	6	√	√	NA	√	√
320	AST	Aspartate Aminotransferase	5	√	√	NA	√	√
320	AST	Aspartate Aminotransferase	6	√	√	NA	√	√
321	ALKP	Alkaline Phosphatase	5	√	√	NA	√	√
321	ALKP	Alkaline Phosphatase	6	√	√	NA	√	√
322	ALT	Alanine Aminotransferase	5	√	√	NA	√	√
322	ALT	Alanine Aminotransferase	6	√	√	NA	√	√
323	LDH	Lactate Dehydrogenase	5	√	√	NA	√	√
323	LDH	Lactate Dehydrogenase	6	√	√	NA	√	√
324	CK	Creatine Kinase	5	√	√	NA	√	√
324	CK	Creatine Kinase	6	√	√	NA	√	√
325	LIPA	Lipase	5	√	√	NA	√	√
325	LIPA	Lipase	6	√	√	NA	√	√
326	GGT	Gamma Glutamyltransferase	5	√	√	NA	√	√
326	GGT	Gamma Glutamyltransferase	6	√	√	NA	√	√
327	Bc	Conjugated Bilirubin	5	√	√	NA	√	√
327	Bc	Conjugated Bilirubin	6	√	√	NA	√	√
328	THEO	Theophylline	5	√	√	NA	√	√
328	THEO	Theophylline	6	√	√	NA	√	√

Analyte Code	Report Name	Assay Name	Body Fluid	VITROS® 5600	VITROS® XT 7600	VITROS® 3600	VITROS® 4600	VITROS® XT 3400
	Body Fluid Key: 2 CSF, 3 Urine, 4 Whole Blood, 5 Serum, 6 Plasma, 7 Amniotic Fluid, 8 Reserved Fluid 1, 9 Reserved Fluid 2, 10 SWAB, UD User Defined							
329	CKMB	CKMB	5	√	√	NA	√	√
330	Mg	Magnesium	3	√	√	NA	√	√
330	Mg	Magnesium	5	√	√	NA	√	√
330	Mg	Magnesium	6	√	√	NA	√	√
331	Fe	Iron	5	√	√	NA	√	√
331	Fe	Iron	6	√	√	NA	√	√
333	PROT	CSF Protein	2	√	√	NA	√	√
334	SALI	Salicylate	5	√	√	NA	√	√
334	SALI	Salicylate	6	√	√	NA	√	√
335	ALC	Alcohol	5	√	√	NA	√	√
335	ALC	Alcohol	6	√	√	NA	√	√
336	AMON	Ammonia	6	√	√	NA	√	√
337	CHE	Cholinesterase	5	√	√	NA	√	√
337	CHE	Cholinesterase	6	√	√	NA	√	√
338	AcP	Acid Phosphatase	5	√	√	NA	√	√
338	AcP	Acid Phosphatase	6	√	√	NA	√	√
340	Li	Lithium	5	√	√	NA	√	√
340	Li	Lithium	6	√	√	NA	√	√
341	DGXN	Digoxin	5	√	√	NA	√	√
341	DGXN	Digoxin	6	√	√	NA	√	√
342	PHBR	Phenobarbital	5	√	√	NA	√	√
342	PHBR	Phenobarbital	6	√	√	NA	√	√
343	PHYT	Phenytoin	5	√	√	NA	√	√
343	PHYT	Phenytoin	6	√	√	NA	√	√
344	CRP	C Reactive Protein	5	√	√	NA	√	√
344	CRP	C Reactive Protein	6	√	√	NA	√	√
345	CRBM	Carbamazepine	5	√	√	NA	√	√
345	CRBM	Carbamazepine	6	√	√	NA	√	√
347	ACET	Acetominophen	5	√	√	NA	√	√
347	ACET	Acetominophen	6	√	√	NA	√	√
348	UPRO	Urine Protein	3	√	√	NA	√	√
353	CRPJ	CRPJ	5	√	√	NA	√	√

Analyte Code	Report Name	Assay Name	Body Fluid	VITROS® 5600	VITROS® XT 7600	VITROS® 3600	VITROS® 4600	VITROS® XT 3400
	Body Fluid Key: 2 CSF, 3 Urine, 4 Whole Blood, 5 Serum, 6 Plasma, 7 Amniotic Fluid, 8 Reserved Fluid 1, 9 Reserved Fluid 2, 10 SWAB, UD User Defined							
353	CRPJ	CRPJ	6	√	√	NA	√	√
354	ALTJ	ALTJ	5	√	√	NA	√	√
354	ALTJ	ALTJ	6	√	√	NA	√	√
355	ASTJ	ASTJ	5	√	√	NA	√	√
355	ASTJ	ASTJ	6	√	√	NA	√	√
356	dHDL	Direct HDLC	5	√	√	NA	√	√
356	dHDL	Direct HDLC	6	√	√	NA	√	√
357	ALTV	Alanine Aminotransferase	5	√	√	NA	√	√
357	ALTV	Alanine Aminotransferase	6	√	√	NA	√	√
358	ALT2	Alanine Aminotransferase	5	√	√	NA	√	√
358	ALT2	Alanine Aminotransferase	6	√	√	NA	√	√
359	A1C1*	Hemoglobin A1c	4	√	√	NA	√	√
500	TRFRN	Transferrin	5	√	√	NA	√	NA
500	TRFRN	Transferrin	6	√	√	NA	√	NA
501	IgG	IgG	5	√	√	NA	√	NA
501	IgG	IgG	6	√	√	NA	√	NA
502	IgM	IgM	5	√	√	NA	√	NA
502	IgM	IgM	6	√	√	NA	√	NA
503	IgA	IgA	5	√	√	NA	√	NA
503	IgA	IgA	6	√	√	NA	√	NA
504	PALB	Prealbumin	5	√	√	NA	√	NA
504	PALB	Prealbumin	6	√	√	NA	√	NA
505	mALB	Microalbumin	3	√	√	NA	√	NA
506	ApoA1	ApoA1	5	√	√	NA	√	NA
506	ApoA1	ApoA1	6	√	√	NA	√	NA
507	ApoB	ApoB	5	√	√	NA	√	NA
507	ApoB	ApoB	6	√	√	NA	√	NA
508	hsCRP	high sensitivity CRP	5	√	√	NA	√	NA
508	hsCRP	high sensitivity CRP	6	√	√	NA	√	NA
509	C3	C3	5	√	√	NA	√	NA
509	C3	C3	6	√	√	NA	√	NA

Analyte Code	Report Name	Assay Name	Body Fluid	VITROS® 5600	VITROS® XT 7600	VITROS® 3600	VITROS® 4600	VITROS® XT 3400
	Body Fluid Key: 2 CSF, 3 Urine, 4 Whole Blood, 5 Serum, 6 Plasma, 7 Amniotic Fluid, 8 Reserved Fluid 1, 9 Reserved Fluid 2, 10 SWAB, UD User Defined							
510	C4	C4	5	√	√	NA	√	NA
510	C4	C4	6	√	√	NA	√	NA
511	VALP	Valproic Acid	5	√	√	NA	√	NA
511	VALP	Valproic Acid	6	√	√	NA	√	NA
512	GENT	Gentamicin	5	√	√	NA	√	NA
512	GENT	Gentamicin	6	√	√	NA	√	NA
513	TOBRA	Tobramycin	5	√	√	NA	√	NA
513	TOBRA	Tobramycin	6	√	√	NA	√	NA
514	VANC	Vancomycin	5	√	√	NA	√	NA
514	VANC	Vancomycin	6	√	√	NA	√	NA
515	CAFFN	Caffeine	5	√	√	NA	√	NA
515	CAFFN	Caffeine	6	√	√	NA	√	NA
517	dLDL	direct LDL	5	√	√	NA	√	NA
517	dLDL	direct LDL	6	√	√	NA	√	NA
520	RF	Rheumatoid Factor	5	√	√	NA	√	NA
520	RF	Rheumatoid Factor	6	√	√	NA	√	NA
521	AMPH	Amphetamines	3	√	√	NA	√	NA
522	BARB	Barbiturates	3	√	√	NA	√	NA
523	BENZ	Benzodiazepines	3	√	√	NA	√	NA
524	THC	Cannabinoids	3	√	√	NA	√	NA
525	COCM	Cocaine Metabolite	3	√	√	NA	√	NA
526	METD	Methadone	3	√	√	NA	√	NA
527	OP-LO	Opiates-Low Cutoff	3	√	√	NA	√	NA
528	PCP	Phencyclidine	3	√	√	NA	√	NA
530	dTIBC	Direct TIBC	5	√	√	NA	√	NA
531	ASO	Anti-streptolysin O	5	√	√	NA	√	NA
531	ASO	Anti-streptolysin O	6	√	√	NA	√	NA
533	HPT	Haptoglobin	5	√	√	NA	√	NA
533	HPT	Haptoglobin	6	√	√	NA	√	NA
534	AAT	Alpha-1-antitrypsin	5	√	√	NA	√	NA

Analyte Code	Report Name	Assay Name	Body Fluid	VITROS® 5600	VITROS® XT 7600	VITROS® 3600	VITROS® 4600	VITROS® XT 3400
	Body Fluid Key: 2 CSF, 3 Urine, 4 Whole Blood, 5 Serum, 6 Plasma, 7 Amniotic Fluid, 8 Reserved Fluid 1, 9 Reserved Fluid 2, 10 SWAB, UD User Defined							
535	dHA1c	Hemoglobin A1c	4	√	√	NA	√	NA
536	dHb	Hemoglobin	4	√	√	NA	√	NA
537	OP-HI	Opiates-High Cutoff	3	√	√	NA	√	NA
539	A1c	Hemoglobin A1c	4	√	√	NA	√	NA
540	Hb	Hemoglobin	4	√	√	NA	√	NA
542	HCY2	Homocysteine	5	√	√	NA	√	NA
542	HCY2	Homocysteine	6	√	√	NA	√	NA
543	uCRP*	Ultrasensitive CRP	5	√	√	NA	√	NA
543	uCRP*	Ultrasensitive CRP	6	√	√	NA	√	NA
544	sCRP*	Standard CRP	5	√	√	NA	√	NA
544	sCRP*	Standard CRP	6	√	√	NA	√	NA
911	LDLmt	Derived LDL	5	√	√	NA	√	NA
911	LDLmt	Derived LDL	6	√	√	NA	√	NA
950	HEM	Hemolysis	2	√	√	√	√	√
950	HEM	Hemolysis	5	√	√	√	√	√
950	HEM	Hemolysis	6	√	√	√	√	√
951	ICT	Icterus	2	√	√	√	√	√
951	ICT	Icterus	5	√	√	√	√	√
951	ICT	Icterus	6	√	√	√	√	√
952	TUR	Turbidity	2	√	√	√	√	√
952	TUR	Turbidity	5	√	√	√	√	√
952	TUR	Turbidity	6	√	√	√	√	√
980	UDA01	(User-Defined)	UD	√	√	NA	√	NA
981	UDA02	(User-Defined)	UD	√	√	NA	√	NA
982	UDA03	(User-Defined)	UD	√	√	NA	√	NA
983	UDA04	(User-Defined)	UD	√	√	NA	√	NA
984	UDA05	(User-Defined)	UD	√	√	NA	√	NA
985	UDA06	(User-Defined)	UD	√	√	NA	√	NA
986	UDA07	(User-Defined)	UD	√	√	NA	√	NA
987	UDA08	(User-Defined)	UD	√	√	NA	√	NA
988	UDA09	(User-Defined)	UD	√	√	NA	√	NA
989	UDA10	(User-Defined)	UD	√	√	NA	√	NA
990	UDA11	(User-Defined)	UD	√	√	NA	√	NA

Analyte Code	Report Name	Assay Name	Body Fluid	VITROS® 5600	VITROS® XT 7600	VITROS® 3600	VITROS® 4600	VITROS® XT 3400
	Body Fluid Key: 2 CSF, 3 Urine, 4 Whole Blood, 5 Serum, 6 Plasma, 7 Amniotic Fluid, 8 Reserved Fluid 1, 9 Reserved Fluid 2, 10 SWAB, UD User Defined							
991	UDA12	(User-Defined)	UD	√	√	NA	√	NA
992	UDA13	(User-Defined)	UD	√	√	NA	√	NA
993	UDA14	(User-Defined)	UD	√	√	NA	√	NA
994	UDA15	(User-Defined)	UD	√	√	NA	√	NA
995	UDA16	(User-Defined)	UD	√	√	NA	√	NA
996	UDA17	(User-Defined)	UD	√	√	NA	√	NA
997	UDA18	(User-Defined)	UD	√	√	NA	√	NA
998	UDA19	(User-Defined)	UD	√	√	NA	√	NA
999	UDA20	(User-Defined)	UD	√	√	NA	√	NA

*Product in development.

Derived Assays

Analyte Code	Report Name	Assay Name	Body Fluid	VITROS® 5600	VITROS® XT 7600	VITROS® 3600	VITROS® 4600	VITROS® XT 3400
	Body Fluid Key: 2 CSF, 3 Urine, 4 Whole Blood, 5 Serum, 6 Plasma, 7 Amniotic Fluid, 8 Reserved Fluid 1, 9 Reserved Fluid 2, 10 SWAB							
165	T3/T4	TT3/TT4 Ratio	5	√	√	√	NA	NA
165	T3/T4	TT3/TT4 Ratio	6	√	√	√	NA	NA
168	FT4I	FT4 Index	5	√	√	√	NA	NA
168	FT4I	FT4 Index	6	√	√	√	NA	NA
169	FT3I	FT3 Index	5	√	√	√	NA	NA
169	FT3I	FT3 Index	6	√	√	√	NA	NA
171	L/F	LH/FSH Ratio	5	√	√	√	NA	NA
171	L/F	LH/FSH Ratio	6	√	√	√	NA	NA
174	%fPSA	% Free PSA	5	√	√	√	NA	NA
174	%fPSA	% Free PSA	6	√	√	√	NA	NA
178	NCHEK	AKIRisk	3	√	√	√	NA	NA
900	U/CR	UR/Creatinine Ratio	5	√	√	NA	√	√
900	U/CR	UR/Creatinine Ratio	6	√	√	NA	√	√
901	AGPK	Anion Gap (K+)	5	√	√	NA	√	√
901	AGPK	Anion Gap (K+)	6	√	√	NA	√	√
902	AGP	Anion Gap	5	√	√	NA	√	√
902	AGP	Anion Gap	6	√	√	NA	√	√
903	A/G	A/G Ratio	5	√	√	NA	√	√
903	A/G	A/G Ratio	6	√	√	NA	√	√
904	NBIL	Neonatal Bilirubin	5	√	√	NA	√	√
904	NBIL	Neonatal Bilirubin	6	√	√	NA	√	√
905	DBIL	Direct Bilirubin	5	√	√	NA	√	√
905	DBIL	Direct Bilirubin	6	√	√	NA	√	√
906	DELB	Delta Bilirubin	5	√	√	NA	√	√
906	DELB	Delta Bilirubin	6	√	√	NA	√	√
907	%MB	% CKMB	5	√	√	NA	√	√
908	OSMO	Osmolality	5	√	√	NA	√	√
908	OSMO	Osmolality	6	√	√	NA	√	√
910	GLOB	Globulin	5	√	√	NA	√	√
910	GLOB	Globulin	6	√	√	NA	√	√

Analyte Code	Report Name	Assay Name	Body Fluid	VITROS® 5600	VITROS® XT 7600	VITROS® 3600	VITROS® 4600	VITROS® XT 3400
	Body Fluid Key: 2 CSF, 3 Urine, 4 Whole Blood, 5 Serum, 6 Plasma, 7 Amniotic Fluid, 8 Reserved Fluid 1, 9 Reserved Fluid 2, 10 SWAB							
912	VLDL	VLDL	5	√	√	NA	√	√
912	VLDL	VLDL	6	√	√	NA	√	√
916	LDL	LDL	5	√	√	NA	√	√
916	LDL	LDL	6	√	√	NA	√	√
917	C/H	CHOL/dHDL	5	√	√	NA	√	√
917	C/H	CHOL/dHDL	6	√	√	NA	√	√
918	d%A1c	%Hemoglobin A1c	4	√	√	NA	√	NA
919	%SAT	% Iron Saturation	5	√	√	NA	√	NA
919	%SAT	% Iron Saturation	6	√	√	NA	√	NA
925	mmA1c	HbA1c	4	√	√	NA	√	NA
927	%A1c	%Hemoglobin A1c	4	√	√	NA	√	NA
928	HbA1c	HbA1c	4	√	√	NA	√	NA

Appendix C Diluent Codes

VITROS® 5600 refers to the VITROS® 5600 Integrated System; VITROS® XT 7600 to the VITROS® XT 7600 Integrated System; VITROS® 3600 to the VITROS® 3600 Immunodiagnostic System; VITROS® 4600 to the VITROS® 4600 Chemistry System; and VITROS® XT 3400 to the VITROS® XT 3400 Chemistry System.

NA in the VITROS® 3600, VITROS® 4600, or VITROS® XT 3400 columns indicates the diluent is not needed for that System.

Diluent Code	Diluent Name	VITROS® 5600	VITROS® XT 7600	VITROS® 3600	VITROS® 4600	VITROS® XT 3400
1001	Saline	√	√	NA	√	√
1002	BSA	√	√	NA	√	√
1003	Water	√	√	NA	√	√
1004	Specialty	√	√	NA	√	√
1005	UED	√	√	NA	√	√
1006	ApoDiluent	√	√	NA	√	√
1007	DATDil2	√	√	NA	√	NA
1008	DATDil	√	√	NA	√	NA
1020	Lysis Buff	√	√	NA	√	NA
1301	(User Defined)	√	√	NA	√	√
1302	(User Defined)	√	√	NA	√	√
1303	(User Defined)	√	√	NA	√	√
1304	(User Defined)	√	√	NA	√	√
2601	HSDA	√	√	√	NA	NA
2603	HSDB	√	√	√	NA	NA

Appendix D Result Classification

Analyte Code	Assay Name	Result Class 1 (Q)	Result Class 2 (R)	Result Class 3 (S)	Result Class 4 (T)
017	HBsAg (International)	Negative	Borderline	Reactive	
017	HBsAg (US)	Negative	Retest?	Positive	
018	aHBs (International)	Antibody Negative	Borderline	Antibody Positive	
019	aHBc (International)	Reactive	Borderline	Negative	Retest?
019	aHBc (US)	Reactive	Retest?	Negative	Equivocal
020	HBc M (International)	Negative	Borderline	Reactive	
020	HBc M (US)	Negative	Retest?	Reactive	
021	HbeAg (International)	Negative	Borderline	Reactive	
022	HAV M	Negative	Borderline	Reactive	
023	aHCV (International)	Negative	Borderline	Reactive	
023	aHCV (US)	Negative	Retest?	Reactive	
023	aHCVS	Negative	Borderline	Reactive	
024	aHIV (International)	Negative	Borderline	Reactive	
024	aHIV (US)	Negative	Retest?	Reactive	
025	Rub G	Negative	Low Positive	Positive	
026	Rub M (International)	Negative	Borderline	Reactive	
027	Tox G (International)	Negative	Borderline	Reactive	
028	Tox M (International)	Negative	Borderline	Reactive	
043	aHBe (International)	Negative	Borderline	Reactive	
053	aHTLV	Non-reactive	Reactive		
061	HAV T	Antibody Positive	Borderline	Antibody Negative	Retest?
062	CMV G (International)	Negative	Borderline	Reactive	
063	CMV M (International)	Negative	Borderline	Reactive	
064	aHBs (US)	Negative	Indeterminate	Positive	
069	HIV c (US)	Negative	Reactive		

Analyte Code	Assay Name	Result Class 1 (Q)	Result Class 2 (R)	Result Class 3 (S)	Result Class 4 (T)
069	HIV c (International)	Negative	Retest?	Reactive	
083	aTCRU	Non-Reactive	Reactive		
087	CoV2G	Non-Reactive	Reactive		
089	CoV2T	Non-Reactive	Reactive		
091	CV2Ag	Non-Reactive	Reactive		
100	CV2G	Non-Reactive	Reactive		
101	CV2T	Non-Reactive	Reactive		
102	CVG2	Non-Reactive	Reactive		
103	CVT2	Non-Reactive	Reactive		
105	CVGQN	Non-Reactive	Reactive		
106	CV2TN	Non-Reactive	Reactive		
521	AMPH	Negative	Positive		
522	BARB	Negative	Positive		
523	BENZ	Negative	Positive		
524	THC	Negative	Positive		
525	COCM	Negative	Positive		
526	METD	Negative	Positive		
527	OP-LO	Negative	Positive		
528	PCP	Negative	Positive		
537	OP-HI	Negative	Positive		

*Product in development.

Appendix E Standard and Conventional Units for Assays

A hyphen (-) in a unit column indicates that either the assay is qualitative and does not require units or the unit type is not needed for the assay.

VITROS® 5600 refers to the VITROS® 5600 Integrated System; VITROS® XT 7600 to the VITROS® XT 7600 Integrated System; VITROS® 3600 to the VITROS® 3600 Immunodiagnostic System; VITROS® 4600 to the VITROS® 4600 Chemistry System; and VITROS® XT 3400 to the VITROS® XT 3400 Chemistry System.

NA in the VITROS® 3600, VITROS® 4600, or VITROS® XT 3400 columns indicates the assay is not available on that System.

MicroSlide, MicroTip, and MicroWell Assays

Assay	Conventional Units	Alternate Units	International Units	VITROS® 5600	VITROS® XT 7600	VITROS® 3600	VITROS® 4600	VITROS® XT 3400
A1c	g/dL	-	-	√	√	NA	√	NA
A1C1*	%NGSP	-	mmol/mol	√	√	NA	√	√
AAT	mg/dL	-	g/L	√	√	NA	√	NA
ACET	µg/mL	mg/dL	µmol/L	√	√	NA	√	√
AcP	U/L	ηkat/L	U/L	√	√	NA	√	√
AFP	IU/mL	ng/mL	-	√	√	√	NA	NA
aHBc	-	-	-	√	√	√	NA	NA
aHBs	IU/L	mIU/mL	-	√	√	√	NA	NA
aHCV	-	-	-	√	√	√	NA	NA
aHIV	-	-	-	√	√	√	NA	NA
aHTL	-	-	-	√	√	√	NA	NA
ALB	g/dL	µmol/L	g/L	√	√	NA	√	√
ALC	mg/dL	g/L	mmol/L	√	√	NA	√	√
ALKP	U/L	µkat/L	U/L	√	√	NA	√	√
ALT	U/L	µkat/L	U/L	√	√	NA	√	√
ALTV	U/L	µkat/L	U/L	√	√	NA	√	√
ALTJ	U/L	µkat/L	U/L	√	√	NA	√	√
ALT2	U/L	µkat/L	U/L	√	√	NA	√	√
AMON	µmol/L	µg/dL	µmol/L	√	√	NA	√	√
AMPH	ng/mL	-	ug/L	√	√	NA	√	√
AMYL	U/L	µkat/L	U/L	√	√	NA	√	√
ApoA1	mg/dL	-	g/L	√	√	NA	√	NA
ApoB	mg/dL	-	g/L	√	√	NA	√	NA
ASO	IU/mL	KIU/L	IU/mL	√	√	NA	√	NA
AST	U/L	µkat/L	U/L	√	√	NA	√	√
ASTJ	U/L	µkat/L	U/L	√	√	NA	√	√

Assay	Conventional Units	Alternate Units	International Units	VITROS® 5600	VITROS® XT 7600	VITROS® 3600	VITROS® 4600	VITROS® XT 3400
aTCRU	-	-	-	√	√	√	NA	NA
B12	pg/mL	-	-	√	√	√	NA	NA
BARB	ng/mL	-	ug/L	√	√	NA	√	NA
Bc	mg/dL	mg/L	µmol/L	√	√	NA	√	√
BENZ	ng/mL	-	ug/L	√	√	NA	√	NA
B-hCG	IU/L	mIU/mL	-	√	√	√	NA	NA
BhCG2*	IU/L	mIU/mL	-	√	√	√	NA	NA
Bu	mg/dL	mg/L	µmol/L	√	√	NA	√	√
BUN	mg/dL	mg/dL	mmol/L	√	√	NA	√	√
C3	mg/dL	-	mg/L	√	√	NA	√	NA
C4	mg/dL	-	mg/L	√	√	NA	√	NA
Ca	mg/dL	mg/L	mmol/L	√	√	NA	√	√
CA 125	U/mL	-	-	√	√	√	NA	NA
CA 15-3	U/mL	-	-	√	√	√	NA	NA
CA 19-9	U/mL	-	-	√	√	√	NA	NA
CAFFN	µg/mL	mg/L	µmol/L	√	√	NA	√	NA
CEA	ng/mL	-	-	√	√	√	NA	NA
CEA2*	ng/mL	-	-	√	√	√	NA	NA
CHE	U/mL	kU/L	U/L	√	√	NA	√	√
CHOL	mg/dL	g/L	mmol/L	√	√	NA	√	√
Cl-	mmol/L	-	mmol/L	√	√	NA	√	√
CK	U/L	µkat/L	U/L	√	√	NA	√	√
CKMB	U/L	µkat/L	U/L	√	√	NA	√	√
CKMB2*	µg/L	ng/mL	-	√	√	√	NA	NA
CK-MB	µg/L	ng/mL	-	√	√	√	NA	NA
COCM	ng/mL	-	ug/L	√	√	NA	√	NA
Cort	nmol/L	µg/dL	-	√	√	√	NA	NA
CoV2G	-	-	-	√	√	√	NA	NA
CoV2T	-	-	-	√	√	√	NA	NA
CV2Ag	-	-	-	√	√	√	NA	NA
CV2G	-	-	-	√	√	√	NA	NA
CV2T	-	-	-	√	√	√	NA	NA
CV2TN	-	-	-	√	√	√	NA	NA
CVG2	-	-	-	√	√	√	NA	NA
CVT2	-	-	-	√	√	√	NA	NA
CVGQN	BAU/mL	-	-	√	√	√	NA	NA

Assay	Conventional Units	Alternate Units	International Units	VITROS® 5600	VITROS® XT 7600	VITROS® 3600	VITROS® 4600	VITROS® XT 3400
C-pep	ng/mL	pmol/L	-	√	√	√	NA	NA
CRBM	µg/mL	mg/L	µmol/L	√	√	NA	√	√
CREA	mg/dL	mg/L	µmol/L	√	√	NA	v	V
CRP	mg/L	µg/dL	mg/dL	√	√	NA	√	√
CRPJ	mg/L	µg/dL	mg/dL	√	√	NA	√	√
DGXN	ng/mL	µg/L	nmol/L	√	√	NA	√	√
dHA1c	g/dL	-	g/L	√	√	NA	√	NA
dHb	g/dL	-	g/L	√	√	NA	√	NA
dHDL	mg/dL	g/L	mmol/L	√	√	NA	√	√
dLDL	mg/dL	-	mmol/L	√	√	NA	√	√
dTIBC	ug/dL	mg/L	umol/L	√	√	NA	√	NA
E2	pmol/L	pg/mL	-	√	√	√	NA	NA
ECO2	mmol/L	-	mmol/L	√	√	NA	√	√
FBhCG	mIU/mL	ng/mL	-	√	√	√	NA	NA
Fe	µg/dL	mg/L	µmol/L	√	√	NA	√	√
Ferr	ng/mL	-	-	√	√	√	NA	NA
Ferr2*	ng/mL	-	-	√	√	√	NA	NA
Folat	ng/mL	-	-	√	√	√	NA	NA
FSH	IU/L	mIU/mL	-	√	√	√	NA	NA
FT3	pmol/L	pg/mL	-	√	√	√	NA	NA
FT3 II	nmol/L	ng/mL	-	√	√	√	NA	NA
FT4	pmol/L	ng/dL	-	√	√	√	NA	NA
FT4 II	nmol/L	µg/dL	-	√	√	√	NA	NA
GENT	µg/mL	mg/L	µmol/L	√	√	NA	√	NA
GGT	U/L	µkat/L	U/L	√	√	NA	√	√
GLU	mg/dL	g/L	mmol/L	√	√	NA	√	√
HAV M	-	-	-	√	√	√	NA	NA
HAV T	-	-	-	√	√	√	NA	NA
Hb	g/dL	-	-	√	√	NA	√	NA
HBc M	-	-	-	√	√	√	NA	NA
HBCon	% reduction	-	-	√	√	√	NA	NA
HBeAg	-	-	-	√	√	√	NA	NA
HBsAg	-	-	-	√	√	√	NA	NA
HCY2	umol/L	-	-	√	√	NA	√	NA
HEM	-	-	-	√	√	√	√	√
HIV c	-	-	-	√	√	√	NA	NA

Assay	Conventional Units	Alternate Units	International Units	VITROS® 5600	VITROS® XT 7600	VITROS® 3600	VITROS® 4600	VITROS® XT 3400
HPT	mg/dL	-	g/L	√	√	NA	√	√
hsCRP	mg/L	-	mg/L	√	√	NA	√	NA
hsTnI	ng/L	pg/mL	-	√	√	√	NA	NA
ICT	-	-	-	√	√	√	√	√
IgA	mg/dL	-	mg/L	√	√	NA	√	NA
IGFBP	ng/ml	-	ug/L	√	√	√	NA	NA
IgG	mg/dL	-	g/L	√	√	NA	√	NA
IgM	mg/dL	-	mg/L	√	√	NA	√	NA
IL-6	pg/mL	-	-	√	√	√	NA	NA
INS	uIU/mL	pmol/L	-	√	√	√	NA	NA
iPTH	pg/mL	pmol/L	-	√	√	√	NA	NA
K+	mmol/L	-	mmol/L	√	√	NA	√	√
LAC	mmol/L	mg/dL	mmol/L	√	√	NA	√	√
LDH	U/L	µkat/L	U/L	√	√	NA	√	√
LH	IU/L	mIU/mL	-	√	√	√	NA	NA
Li	mmol/L	mEq/L	mmol/L	√	√	NA	√	√
LIPA	U/L	µkat/L	U/L	√	√	NA	√	√
mALB	mg/L	-	-	√	√	NA	√	NA
METD	ng/mL	-	ug/L	√	√	NA	√	NA
Mg	mg/dL	mEq/L	mmol/L	√	√	NA	√	√
Na+	mmol/L	-	mmol/L	√	√	NA	√	√
NBNP2	pg/mL	pmol/L	-	√	√	√	NA	NA
NCHEK	-	-	-	√	√	√	NA	NA
NTx	nM BCE	-	-	√	√	√	NA	NA
OP-HI	ng/mL	-	ug/L	√	√	NA	√	NA
OP-LO	ng/mL	-	ug/L	√	√	NA	√	NA
PALB	mg/dL	-	mg/L	√	√	NA	√	NA
PCP	ng/mL	-	ug/L	√	√	NA	√	NA
PCT	ng/mL	µg/L	-	√	√	√	NA	NA
PHBR	µg/mL	mg/L	µmol/L	√	√	NA	√	√
PHOS	mg/dL	mg/L	mmol/L	√	√	NA	√	√
PHYT	µg/mL	mg/L	µmol/L	√	√	NA	√	√
Prog	nmol/L	ng/mL	-	√	√	√	NA	NA
Prol	mIU/mL	ng/mL	-	√	√	√	NA	NA
Prol2*	mIU/mL	ng/mL	-	√	√	√	NA	NA
PROT	mg/dL	g/L	mg/L	√	√	NA	√	√

Assay	Conventional Units	Alternate Units	International Units	VITROS® 5600	VITROS® XT 7600	VITROS® 3600	VITROS® 4600	VITROS® XT 3400
PSA	ng/mL	µg/L	-	√	√	√	NA	NA
RF	IU/mL	-	kU/L	√	√	NA	√	NA
RUB G	IU/mL	-	-	√	√	√	NA	NA
RUB M	-	-	-	√	√	√	NA	NA
SALI	mg/dL	mg/L	mmol/L	√	√	NA	√	√
sCRP*	mg/L	mg/dL	mg/L	√	√	NA	√	NA
T3U	% uptake	Unit value	-	√	√	√	NA	NA
TBIL	mg/dL	mg/L	µmol/L	√	√	NA	√	√
Testo	nmol/L	ng/mL	-	√	√	√	NA	NA
THC	ng/mL	-	ug/L	√	√	NA	√	NA
THEO	µg/mL	-	µmol/L	√	√	NA	√	√
TIBC	µg/dL	mg/L	µmol/L	NA	NA	NA	√	√
TIMP2	ng/ml	-	ug/L	√	√	√	NA	NA
TOBRA	µg/mL	mg/L	µmol/L	√	√	NA	√	NA
Tox G	IU/mL	-	-	√	√	√	NA	NA
Tox M	-	-	-	√	√	√	NA	NA
TP	g/dL	-	g/L	√	√	NA	√	√
TRFRN	mg/dL	-	g/L	√	√	NA	√	NA
TRIG	mg/dL	g/L	mmol/L	√	√	NA	√	√
Trop	ng/mL	µg/L	-	√	√	√	NA	NA
TSH	mIU/L	µIU/mL	-	√	√	√	NA	NA
TSH3	µIU/mL	mIU/L	-	√	√	√	NA	NA
TT3	nmol/L	ng/mL	-	√	√	√	NA	NA
TT4	nmol/L	µg/dL	-	√	√	√	NA	NA
TUR	-	-	-	√	√	√	√	√
uCRP*	mg/L	mg/dL	mg/L	√	√	NA	√	NA
UPRO	mg/dL	mg/L	g/L	√	√	NA	√	√
UREA	mg/dL	mg/dL(A)	mmol/L	√	√	NA	√	√
URIC	mg/dL	mg/L	µmol/L	√	√	NA	√	√
VALP	µg/mL	mg/L	µmol/L	√	√	NA	√	√
VANC	µg/mL	mg/L	µmol/L	√	√	NA	√	√

*Product in development.

Derived Assays

Assay	Conventional Units	Alternate Units	International Units	VITROS® 5600	VITROS® XT 7600	VITROS® 3600	VITROS® 4600	VITROS® XT 3400
%A1c	%NGSP	-	-	√	√	NA	√	NA
%MB	%	%	%	√	√	NA	√	√
%SAT	%	-	-	√	√	NA	√	NA
A/G	-	-	-	√	√	NA	√	√
AGP	mmol/L	-	mmol/L	√	√	NA	√	√
AGPK	mmol/L	-	mmol/L	√	√	NA	√	√
C/H	-	-	-	√	√	NA	√	√
d%A1c	%NGSP	-	-	√	√	NA	√	NA
DBIL	mg/dL	mg/L	µmol/L	√	√	NA	√	√
DELB	mg/dL	mg/L	µmol/L	√	√	NA	√	√
FT3I	-	-	-	√	√	√	NA	NA
FT4I	-	-	-	√	√	√	NA	NA
GLOB	g/dL	-	g/L	√	√	NA	√	√
HbA1c	mmol/mol	-	-	√	√	NA	√	NA
L/F	-	-	-	√	√	√	NA	NA
LDL	mg/dL	g/L	mmol/L	√	√	NA	√	√
mmA1c	mmol/mol	-	-	√	√	NA	√	NA
NBIL	mg/dL	mg/L	µmol/L	√	√	NA	√	√
OSMO	mosm/kg	-	mosm/kg	√	√	NA	√	√
T3/T4	-	-	-	√	√	√	NA	NA
U/CR	-	-	-	√	√	NA	√	√
VLDL	mg/dL	g/L	mmol/L	√	√	NA	√	√

Appendix F Result Codes

When two or more codes are generated, they are displayed on the screen and in printed reports in the order of importance.

With some codes, **No result** is often reported. Frequently the System retests the sample automatically depending on the situation.

Result Code	Description	Condition	System and Operator Actions
AF	Air Filter Failure	The filtered air operation did not occur during the reading of the well. **No result** is reported.	The test is automatically retested. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions.
AR	Adjusted Result	A user adjustment parameter was applied to the result.	No action is necessary. User adjustment parameters are defined on the Options & Configuration - Review/Edit Assay Data screen.
BP	Blank Prediction	The System was unable to compute the result for the blank slide. **No result** is reported.	The test is automatically retested along with the blank assay. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions.
CB	Cuvette Blank	The associated baseline transmittance reading of the test result is above or below configurable limits that are loaded from the Assay Data Disk. **No result** is reported.	The test is automatically retested. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions. Check for an optical problem with the CUVETTE row or with the sample.
CC	Configuration Conflict	A configurable parameter prevented a result from being fully evaluated.	Check the configuration for the affected assay. **Example 1:** An assay with qualitative reporting has one end of its reportable range set so that one of the qualitative categories could never be reached. No qualitative categorization is performed. **Example 2:** A sample program contains a demographic character that is not a valid character at the time of processing. The default reference range will be used instead of a demographic range.

Result Code	Description	Condition	System and Operator Actions
CE	Calibration Expired	The calibration used for result prediction was expired at the time of the result prediction. The setting “Use expired calibration” can be configured to allow using expired calibrations. However, the setting does not apply to restricted assays. (Expired calibrators are never allowed for restricted assays.) **No result** is reported for restricted assays. Note: If “Use expired calibration” is not enabled, result code II is displayed.	For a restricted assay, calibrate it and repeat the test.
DE	Drop Error	The proboscis was unable to dispense the correct amount of fluid. **No result** is reported.	The test is automatically retested. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions. Check for fibrin in the sample or in the METERING system.
DP	Substrate Depleted	Substrate depletion has occurred in a rate or IR test. **No result** is reported.	The test is automatically reflex diluted if enabled and configured for that assay. Refer to the appropriate Instructions for Use for more information.
EA	Expired Aliquot	The CuveTip in the Disposable Tip Processing Center has expired. **No result** is reported	The test is automatically retested. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions.

Result Code	Description	Condition	System and Operator Actions
EC	Expired Calibrator	The result prediction was based on a calibration using expired calibrator fluids. The setting “Use expired reagent” can be configured to allow using expired calibrators. However, the setting does not apply to restricted assays. (Expired calibrators are never allowed for restricted assays.) **No result** is reported for restricted assays. Note: If “Use expired reagent” is not enabled, result code II is displayed.	For a restricted assay, calibrate it and repeat the test.
ED	Edited Result	The Operator edited the replicate result in Results Review. **No result** is reported for restricted assays. (Editing a result is not allowed for restricted assays.)	No action is necessary.
EM	Expired Maintenance Usage Interval	(Applies to MicroWell Assays only) The recommended interval for Subsystem Cleaning, using the Maintenance Pack, has expired. **No result** is reported for restricted assays.	Perform the Subsystem Cleaning procedure as described in V-Docs.
EP	Edited Demographics Data	The operator edited the demographics data value in the result record in Results Review.	No action is necessary.
ER	Computational Error	A computational error occurred, such as the log of a negative number or division by zero. **No result** is reported.	The test is automatically retested. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions.
FC	Flagged Component	At least one of the measured components of a derived test has a code, a flag, or a Sample Indices flag.	Examine the component test results for the actual cause of this code.
FR	Flagged Replicate	Applied to a test mean, at least one replicate was flagged.	Examine the replicate tests for the actual cause of this code.

Result Code	Description	Condition	System and Operator Actions
HC	High Concentration	Occurs if the concentration is too high to calculate a prediction. **No result** is reported	The test is automatically reflex diluted if enabled and configured for that assay.
HL	Hemoglobin Low	(Applies to patient sample test results for whole blood assays that support sampling from a primary draw tube.) Occurs if the sample viscosity or hemoglobin index predictions are below the thresholds specified for this assay on the ADD. **NOTE:** If the sample viscosity is below the threshold, an **ME** code will also occur and **No result** is reported.	Interpret result with caution. Evaluate sample for signs of settling. Ensure the whole blood sample is suspended and re-run the test. If the HL code repeats on a well-suspended sample, refer to the assay IFU “Other Limitations” section for more information.
HN	High Noise	(Applies to multiple point rate assays) The HN code usually occurs on high-activity samples that generate irregular kinetics. **No result** is reported.	The test is automatically reflex diluted if enabled and configured for that assay.
IC	Invalid Component	A derived test result was not computed because one or more component tests failed to predict a result or were outside the range of the System. **No result** is reported.	All component tests are automatically retested. Examine the component test results for the actual cause of this code.
ID	Invalid Dilution	The concentration of the diluted sample fluid is less than the minimum diluted concentration that is loaded from the Assay Data Disk. For Total βHCG, **No result** is reported.	The test is automatically retested. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions. Use the neat or undiluted sample with a lower dilution factor.
II	Insufficient Inventory	There was insufficient inventory of the required wells or reagents for the test before it was scheduled to be processed. **No result** is reported.	The test is retested after a set time interval to allow for replenishment. Check inventory levels using Reagent Management.

Result Code	Description	Condition	System and Operator Actions
IS	Insufficient Sample	The sample had insufficient volume to meter all of the tests programmed. **No result** is reported.	The test is automatically retested. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions. Check the sample for sufficient Fluid.
IT	Incubator Temperature	The incubator temperature was out of tolerance at some point while the test sample was being incubated. **No result** is reported for restricted assays.	Once the System displays "READY," repeat the test.
KE	Kinetic Error	The multiple point rate test has a high activity or has an interfering substance present. For immuno-rate tests, the analyte concentration is below the dynamic range or substrate depletion. **No result** is reported.	The test is automatically retested. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions. Refer to the appropriate Instructions for Use for more information.
LS	Lot Switch	A new reagent lot was used to process this test.	Verify that QC was performed before reporting results using the new lot.
LT	Luminometer Temperature	The luminometer temperature was out of tolerance when the sample was being measured. **No result** is reported for restricted assays.	Check the condition codes for potential causes and actions; check environmental monitoring for out-of-range temperatures.
M1	Category 1 Modified Values	The test data was modified. The new data does not affect the shape of the calibration curve.	Check the settings for the analyte on the Options & Configuration - Review/Edit Calibrations screen and on the Options & Configuration – Configure Assays screen.
M2	Category 2 Modified Values	The test data was modified that does affect the calculation of patient data. The new data is used to generate the calibration curve. **No result** is reported for restricted assays.	Check the settings for the analyte on the Options & Configuration - Review/Edit Calibrations screen. Consult a Lab Supervisor or a Key Operator to determine if the M2 code is valid.

Result Code	Description	Condition	System and Operator Actions
ME	Mechanical Error	A hardware- or operator-induced error may have occurred. **No result** is reported.	The test is automatically retested. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions. If the condition persists, initialize the System and/or correct the condition manually.
MF	Multiple Reagent Formats	Multiple Reagent Formats (MicroSlide and XT MicroSlide) were used for Quality Control and the mean was not calculated. **No result** is reported.	Manually calculate the mean, if required. Run multiple reagent formats separately for Quality Control.
MN	Mean	The test result is a mean of replicate results.	No action is necessary.
MW	Multiple Windows	(Applies to multiple point rate assays) Measurements show excessive irregularity and lack of smoothness.	No action is necessary.
NC	Not Calibrated	No calibration is currently in use for the requested test. **No result** is reported.	The test is retested after a set time interval. This allows time to restore a valid calibration or calibrate the assay.
NF	No Fluid	The System did not detect any fluid during aspiration. **No result** is reported.	Check for sufficient sample volume and for fibrin in the sample or in the metering subsystem.
NQ	No Quality Control	No baseline QC data exists for this control fluid.	Add the test to the control fluid definition using Quality Control - Define Controls. Initialize or check the Condition Review screen and perform the recommended procedures. Process the control fluid again.
OC	Operator Requested Concentration	The test was performed with a dilution that was lower than the configured value.	No action is necessary.
OD	Operator Requested Dilution; Out of Range Dilution	The out of range dilution has been selected in sample programming.	No action is necessary.

Result Code	Description	Condition	System and Operator Actions
OR	Outside of Measuring (Reportable) Range	The result is outside of the System's measuring (reportable) range. **No result** is reported.	The test is automatically reflex diluted if enabled. It is a high-concentration sample and configured for that assay and reflex dilution is configured for that assay. Check for measuring (reportable) range flags and follow the recommended actions.
OS	Outside Spline	The slide response is above or below the mathematical spline function for the required test. **No result** is reported.	The test is automatically reflex diluted if enabled. It is a high-concentration sample and configured for that assay and reflex dilution is configured for that assay. Refer to the other codes displayed in the report and the Condition Review screen for more information. A wash error might have occurred (Immuno-rate tests only). If so, follow the actions listed for the WE result code.
PF	Prediction Failure	The System detected an invalid response or no response during assay processing. **No result** is reported.	The test is automatically retested. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions. Also refer to the other codes listed in the report.
PI	Potential Interferent	There is a potential interfering substance to Bu in the sample. The code is reported with the Bc result. **No result** is reported.	If the PI code appears with the Bc result, do not dilute the sample. Repeat the sample using the TBIL slide. Refer to Instructions for Use for more information.

Result Code	Description	Condition	System and Operator Actions
PI	Potential Interferent	There is a potential interfering substance to Bu in the sample. The code is reported with the Bc result. **No result** is reported. The PI code can be reported with Bu. In this case, the code indicates that Bc is not readable by the System. As a result, the Bu cannot be reported. The PI code can also be reported with AcP. In this case, the code indicates a substrate depletion condition that shows the probable presence of bilirubin.	If the PI code appears with the Bu result, dilute the sample with a normal patient sample or 7% BSA. Then repeat the test on the BuBc slide. Refer to the appropriate Instructions for Use for more information for both conditions.
RC	Reference Check	The Photometer, Luminometer, or MicroWell Incubator reference readings are outside specifications. **No Result** may be reported. (**No result** is reported for restricted assays.)	If **No Result** is reported, the test is automatically retested. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions. Also check this screen for related Photometer, Luminometer, or MicroWell Incubator condition codes and perform the recommended procedures.
RD	Reflex Dilution (Out-of- Range)	The test was a reflex test using more sample dilution than was used in the original test.	No action is necessary.
RE	Reagent Expired	The test was processed with an expired reagent pack or expired signal reagent. The setting “Use expired reagent” can be configured to allow using expired reagents. However, this setting does not apply to restricted assays. (Expired reagents are never allowed for restricted assays.) **No result** is reported for restricted assays. Note: If “Use expired calibration” is enabled, result code II is displayed.	For restricted assays, load new reagents and repeat the test.

Result Code	Description	Condition	System and Operator Actions
RP	Reflex Test Processed	This result is from a derivative or repeat reflex test.	No action is necessary.
RR	Recalculated Result	The test results were recalculated because of an operator action in Results Review.	No action is necessary.
RS	Reduced Standard Dilution	The test was a reflex test using more sample than the original test.	No action is necessary.
SC	Spread Check Failure	A replicate result exceeded the percentage spread limit for the mean for the reagent lot specified on the ADD.	Check the Condition Review screen for additional condition codes and for codes that occurred at or near the time the replicates were processed. Repeat the assay, sample, or calibration.
SE	Sample Exited/Expired	The sample was removed or moved to the Load/Unload area after initial metering but before sample fluid for the affected test has been metered. This code also occurs if the COVER was opened or the sample expired before some tests could be metered. **No result** is reported.	The test is automatically retested if the sample progresses to the metering area within the expiration time. (This does not apply to LAS samples.) Repeat any expired tests with a fresh aliquot of sample.
SP	Multiple Spikes	More than one data spike occurred while reading a multiple point rate test. **No result** is reported.	The test is automatically retested. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions. Refer to the other codes displayed in the report and Condition Review screen for rate lamp condition codes.
TD	Test Deleted	The sample program is deleted before the sample fluid for the affected test has been metered. **No result** is reported.	No action is necessary.
TR	Trim Error	The System could not find a suitable area to read on the curve of a multiple point rate test due to noise or high activity sample. **No result** is reported.	The test is automatically reflex diluted if enabled and configured for that assay. Refer to the appropriate Instructions for Use for more information.

Result Code	Description	Condition	System and Operator Actions
UC	User Calibration	The calibration parameters for this test were input manually. **No result** is reported for restricted assays.	No action is necessary.
VS	Viscous Sample	The sample viscosity exceeds a value obtained from the Assay Data Disk. **No result** is reported for restricted assays.	Check for additional codes and flags. Note: Higher viscosities report **No result** with an ME flag.
WE	Wash Error	The Immuno-rate (IR) wash was invalid or the Well Wash was invalid. **No result** is reported.	The test is automatically retested. If the repeated result continues to generate a result code, check the Condition Review screen for potential causes and actions.
WT	Well Temperature	The well wash is outside specifications. **No result** is reported for restricted assays.	Check the Condition Review screen for potential causes and actions; check environmental monitoring for out-of-range temperatures.
ZS	Negative Derived Test Result	A derived test was computed by setting a negative component result to zero.	Check for additional codes and flags.

Appendix G Sample Indices Flags Sent to the LIS

Flag	Condition	Application	Occurrence
ES	Examine Sample	Patient test results for all samples where Sample Indices is run.	The Sample Indices result is outside the reportable range for that index.
ME	Mechanical Error	Patient sample test results for all samples where Sample Indices is run	There is a mechanical error in the Sample Indices system (MICROSENSOR).
NA	SI Globally Not Available	MicroSlide assays. MicroWell assays. MicroTip Special Chemistry assays.	The Sample Indices system (MICROSENSOR) is completely disabled.
NR	Not Run	MicroSlide assays. MicroWell assays. MicroTip Special Chemistry assays	- The Sample Indices system (MICROSENSOR) was universally enabled but disabled during sample programming for the sample. - The sample was diluted. - The sample was pretreated.
pi	Potential Interferent	MicroSlide assays. MicroWell assays. MicroTip Special Chemistry assays	A > code applies to the combination of sample and Sample Indices and the assay's threshold value for the index is greater than or equal to the index's reportable range upper limit.

Appendix H Download Messages

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 download the program again.
2	Invalid data field	The sample program cannot read data in one or more fields. The fields could be too long or could contain invalid characters.	Refer to the permitted field size for patient records. Refer to an ASCII Character Chart for a listing of valid characters. Correct any size or character errors and then download the sample program again.
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 download program again. Delete the sample position or add a tray name. Then download the sample program 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 (last, first, middle initial).	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 sample program or is attempting to edit the assays for a previously downloaded sample program.	Change the sample ID or sample position. Then download the sample program again.
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 required	The sample program was downloaded with no assay requests. This applies only if the sample program does not exist to begin with.	Add assays to the sample program and download the program again.

Code Number	Message	Condition	Action
14	Invalid assay requested	An assay was requested which is currently not supported by the target system. The program is accepted but the unsupported assay is deleted from the program.	Refer to Appendix B Analyte Codes for a list of supported assays. Edit assay requests and download the sample program again.
15	Derived test replicated	The sample program included a request to replicate a derived test. This program is accepted and the requested derived test is calculated.	Delete requests for the replicating of derived tests and download sample program again. (Derived tests cannot be replicated.)
16	Too many assays	The sample program has more than the maximum number of assays or replicates allowed, including volume checks.	Edit assay requests so that the sample program does not exceed 40 reps or 50 reportable results and download the program again.
17	Sample/tray program changed	The sample program has been assigned to another tray. The sample program is accepted.	Place the sample on the tray to which the sample program has been assigned.
18	Sample program taken off tray	The sample program is unassigned. The sample program is accepted.	Remove the sample from the tray specified in the download program.
19	No assays: sample deleted	The sample program did not include any assays and was deleted by the laboratory computer. This condition occurs only when the sample ID was previously downloaded with tests.	Remove the sample from the tray.
20	Dilution out of range	The Manual Dilution factor for this sample program is not between 0.0001 and 9999.0. The product of Test Dilution factor and Standard Dilution factor is not supported	Change the dilution factor and download the sample program again. Refer to the operator's manual and assay IFU's.
22	Body fluid unknown	The sample program included a body fluid that the Analyzer does not currently support.	Refer to Appendix B Analyte codes for supported assay body fluids.
23	Cannot program pretreated and non-pretreated assays	The sample program included both pretreated and non-pretreated assays.	Create one sample program including pretreated assays, and other program including non-pretreated assays. Run each program separately.
25	Assays in progress could not be deleted	An attempt to delete a sample program that was in progress was made.	No action required; the sample program continues.

Code Number	Message	Condition	Action
26	Attempt to overwrite in process program	An attempt to overwrite (not append) an in-process program was made.	No action required; the in-process program is not overwritten and the sample program continues.
27	An append program was downloaded but not all the assays could be added to the program.	For example, a derived test was requested, but one of the components was already in the original program.	No action required; the program is saved and the sample program continues.

Appendix I Mechanical/Electrical Interfaces for Serial Communications

Mechanical Interface

An EIA RS-232 (or CCIT V.24) compatible serial communications port with a standard DB25F female connector (such as AMP Inc., Part No. 2066 53-1) is used to connect the VITROS® 5600 System, the VITROS® XT 7600 System, the VITROS® 4600 System, the VITROS® 3600 System, or the VITROS® XT 3400 System to the laboratory computer. The VITROS® 5600 System, the VITROS® XT 7600, the VITROS® 4600 System, the VITROS® 3600 System, and the VITROS® XT 3400 System use chassis-mounted connectors rather than cable-mounted connectors. If the laboratory computer being connected to the System is EIA RS-449 (or other standard interface) compatible, you must install an interface adapter.

Data and Transmit Control Pins

The System is configured as Data Terminal Equipment (DTE).

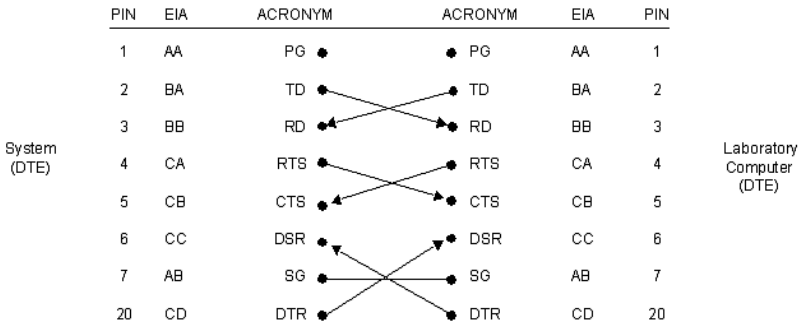
Pin 1	Protective ground (AA).
Pin 2	System - Transmitted data (BA) - Serial data from the System to the laboratory computer.
Pin 3	System - Received data (BB) - Serial data from the laboratory computer to the System.
Pin 4	Request to send (CA) - Control signal from the System that indicates the System is ready to transmit data.
Pin 5	Clear to send (CB) - Control signal to the System that indicates the laboratory computer is ready to receive data.
Pin 6	Data set ready (CC) - Control signal to the System 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 System to the laboratory computer that indicates the System is on-line.

Cable

The user supplies the standard interface cable. Cable configurations are determined by the interface to the laboratory computer. Most computer systems have an RS-232-compatible serial port and emulate DTE or DCE (Data Communications Equipment). 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 System's Clear to Send (CTS) input. On a System, 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.

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

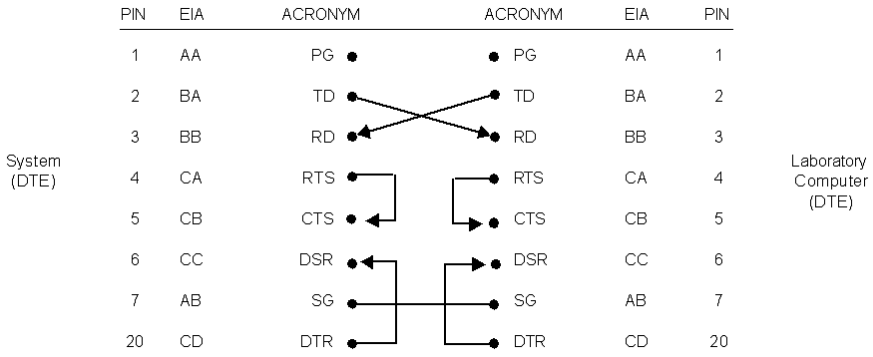
Applicable for Systems where CTS hardware flow control is required. Half duplex transmission is allowed. The laboratory computer requires on-line control. That is, the laboratory computer can go off-line or on-line, and the System is aware of the state of the laboratory computer.



Example: CTS Hardware Flow Control (DTE/DTE)

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

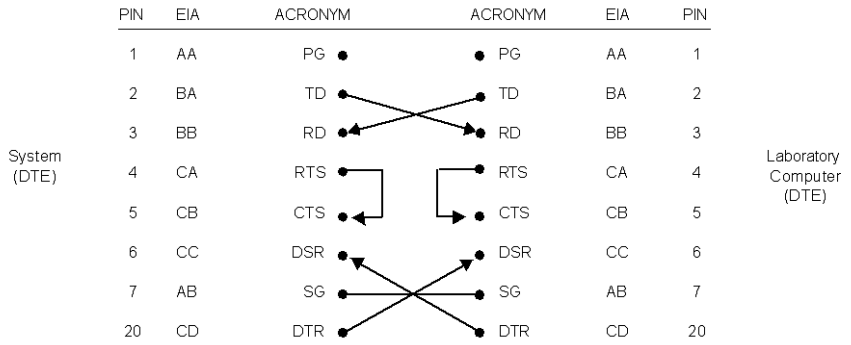
Applicable for installations with 3-wire cable already installed. Hardware CTS flow control is not possible. Each System interprets the other as being on-line when the System itself is on-line.



Example: Existing 3-Wire Cable (DTE-DTE)

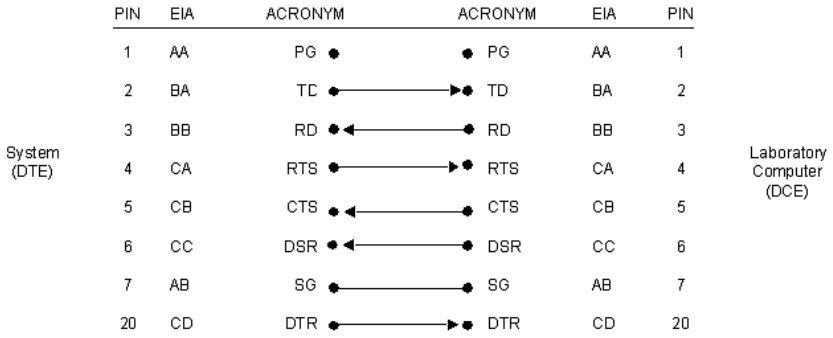
CTS Hardware Flow Not Functional (DTS/DSR Handshake and CTS/RTS Loopback)

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



Example: CTS Hardware Flow Not Functional (DTE-DTE)

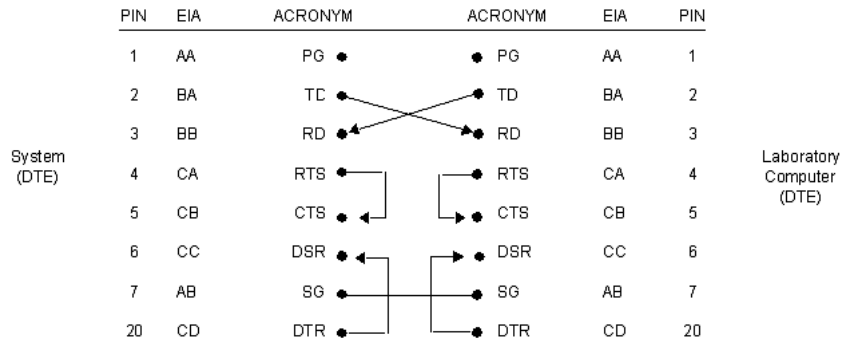
Hardware Flow Control Functional (DTS/DSR and CTS/RTS Handshake)



Example: Hardware Flow Control Functional (DTE-DCE)

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

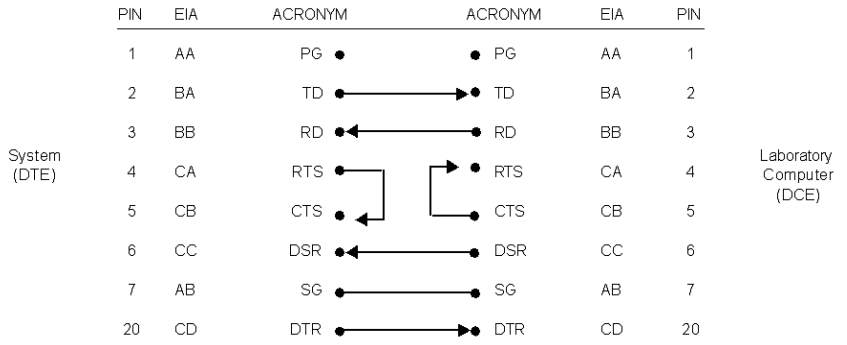
Hardware CTS flow control is not possible. Each System interprets the other as being on-line when the System itself is on-line.



Example: 3-Wire Capability (DTE-DTE)

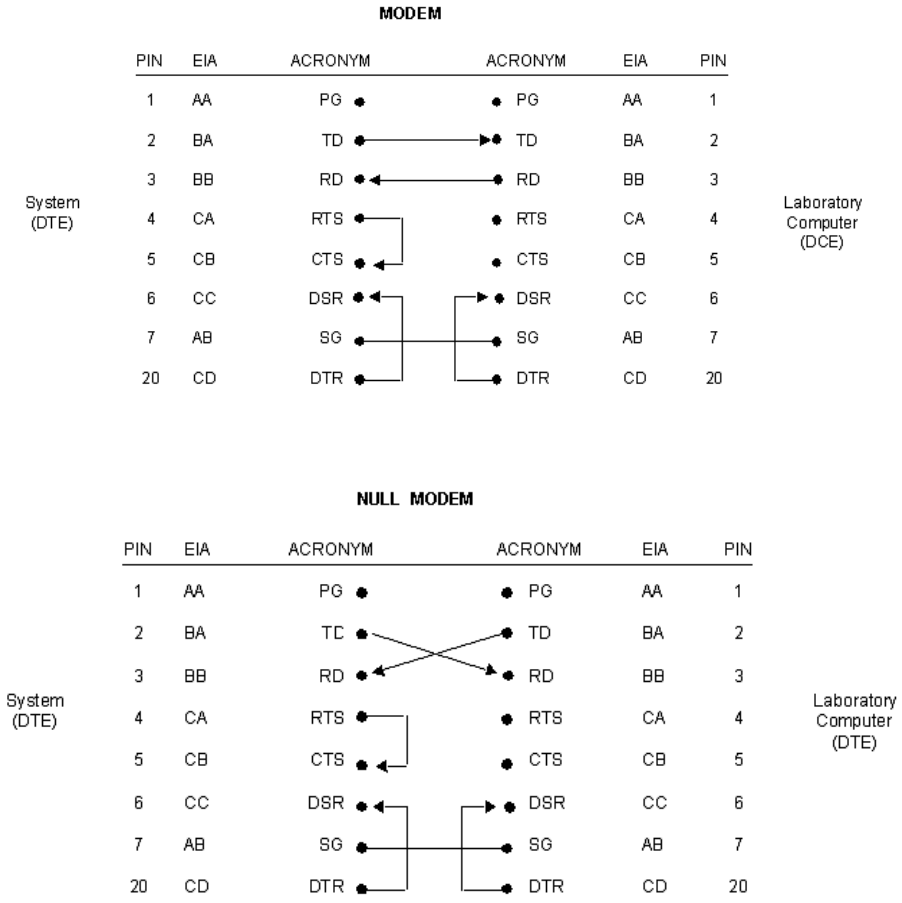
CTS Hardware Flow Control Not Functional (DTS/DSR Handshake and CTS/RTS Loopback)

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



Example: CTS Hardware Flow Control Not Functional (DTE-DCE)

ASTM Wire Cable Configuration



ASTM Wire Cable Configuration

Electrical Interface

The System operates interface signals according to the voltage levels and electrical characteristics defined by EIA Standard RS-232 (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 System uses 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 is attempted until the DSR signal is active. If DSR goes ON, the communication will resume with the Header Record. When DSR switches to OFF during communication, a single ATTENTION level condition is reported.

Appendix J Network Communications through Ethernet

Network communications between the LIS and the VITROS® 5600, the VITROS® XT 7600, the VITROS® 4600, the VITROS® 3600, or the VITROS® XT 3400 are established through an Ethernet connection. This network connection is the same as the one used for e-Connectivity® for the VITROS® 5,1 FS Chemistry System, the VITROS® ECiQ Immunodiagnostic System, and the VITROS® ECi Immunodiagnostic System.

The e-Connectivity Specifications: SSL only - e-Connectivity® Network Connection Specifications and Network Form (J56087 or J65347) explains this connection. This document is posted on www.orthoclinical.com; select Ortho Care™ > Technical Documents > Other Technical Documentation.

Additionally, the VITROS® XT 7600 and VITROS® XT 3400 systems support the use of separate Ethernet port connections to separate the e-Connectivity and LIS network traffic.

Appendix K ASTM M/S Instrument Status Record Status Detail Mapping

ID Name

170, "Dilution & MicroTip Assay Processing",
171, "PM MicroSlide Processing",
172, "Rate/CM MicroSlide Processing",
173, "IR MicroSlide Processing",
174, "MicroSensor Processing",
175, "STAT Lane Metering Position",
176, "Routine Metering Positions",
177, "TriFlex Metering Location",
178, "MicroSlide Incubator",
179, "MicroSlide Supply 1",
180, "MicroSlide Supply 2",
181, "Primary Tip Sealer",
182, "Secondary Tip Sealer",
183, "Cuvette Supply",
184, "Cuvette Incubator",
185, "Cuvette Incubator Evaporation Cover",
186, "MicroIA Reagent Supply 3",
187, "Cuvette Read Channel",
188, "Electrometer",
189, "CM/RT Incubator",
190, "PM Incubator",
191, "WF Metering",
192, "ERF Metering",
193, "Reflectometer",
194, "MicroSlide Supply 2",
195, "MicroSlide Supply 1",
196, "MicroSlide Metering",
197, "uIA Metering",
198, "CuveTip Ring",
199, "uIA VersaTip Ring",
200, "VersaTip Supply",
201, "MicroSensor",
202, "MicroTip Supply",
203, "Waste Container C",
204, "Waste Container B",
205, "Photometer",
206, "Cuvette Incubator",
207, "Cuvette Supply",
208, "Supply 3",
209, "Routine Lane",
210, "Reprocessing Metering Location",
211, "STAT Lane",
214, "SR Metering",
215, "Final Well Wash",
216, "Preliminary Well Wash",
217, "MicroWell Incubator",
218, "Luminometer",
219, "UWR",

255, "MicroWell Assay Processing",
257, "Final Well Wash",
258, "Preliminary Well Wash",
260, "Waste Container A",
261, "Liquid Waste",
262, "MicroIA Reagent Supply 4",
263, "MicroWell Reagent Metering",
264, "System Compressor",
265, "MicroWell Sample Metering",
266, "MicroIA Reagent Supply",
267, "Dilution Processing",
268, "Waste Container D"

Reasons
0, "Inoperative",
1, "Ready",
2, "Environment out of range",
3, "Environment disabled",
4, "Disabled"

IVD

EC REP

Ortho-Clinical Diagnostics
1500 Boulevard Sébastien Brant
B.P. 30335
67411 Illkirch
CEDEX, France

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14626
USA