VITROS® 5,1 FS Chemistry System ,Specification for Laboratory Computer Interface

Version 6.7 2017-07-21

Introduction

Laboratory Information System (LIS) refers to the subsystems that support the capability to program patient samples and test requests remotely on the analyzer, to transfer data regarding the patient and physician demographics, assay quality control data, and to query the laboratory computer system for test requests. The LIS includes VITROS® 5,1 FS Chemistry System software, the laboratory computer system, and the hardware that connects the two systems.

LIS Functions

- Provides a method to receive remotely programmed patient and quality control sample programs (test requests) from a lab computer (download from lab computer)
- Provides a method to send patient results and quality control results to a lab computer (upload results to lab computer)

- Provides the ability to request sample programs from a lab computer in order to process sample (host query)
- Provides indication to the operator the status of communication between the analyzer and the lab computer (status)
    - The LIS status: Idle, Upload, and download.
    - The Query status is: True, False.
- 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)

LIS Communications Protocol

The communications protocol used on the VITROS 5,1 FS Chemistry System was created by the American Society for Testing and Materials (ASTM). It is designed specifically for medical devices and supports the transfer of an array of medical data. It enables speedy communication while using a number of data protection mechanisms, such as, acknowledgments, timing mechanism, and data recovery procedures. It also establishes a national standard for communication among medical facilities and may eventually become an international standard. The ASTM protocol promotes data integrity while handling a great volume of data.
Information about this protocol can be found in a publication produced by ASTM: Annual Book of ASTM Standards. Designation: E 1394-97: “Standard Specification for Transferring Information Between Clinical Laboratory Instruments and Computer Systems” and Designation: 1381-95: “Specification for Low Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems.” It is recommended that these publications be obtained and used as supplements to this guide.

Operational Overview

Communication occurs over the serial lines from the analyzer to the lab computer using the ASTM protocol. The communications are bi-directional and include: downloading of sample programs from the lab computer to the analyzer, uploading of result records from the analyzer to the lab computer, and querying of sample programs from the analyzer to the lab computer.

Download Sample Programs

- Sample programs (containing specimen ID, patient information, and tests to be run) are entered into the lab computer
- The lab computer initiates communication to the analyzer
- The analyzer acknowledges requests for communication
- The lab computer transfers the sample program and patient information to the analyzer

- Information is entered in the appropriate 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 sample program is found and the sample is metered

Upload Patient Results

- Sample is metered and processed to completion; all tests are complete
- The analyzer initiates communication with the lab computer
- The lab computer acknowledges request
- Results from the analyzer are transmitted to the lab computer

  Note: The results can be uploaded individually.

Host Query

- Host query is configured to be ON
- A barcoded sample is scanned at the sample handling area
- A request is sent from the analyzer to the lab computer requesting information (sample program and patient demographics)
- The analyzer initiates communications, through the serial line, to the lab computer
- The lab computer responds with a message indicating that communication lines are available
- A request for all tests is issued from the analyzer to the lab computer using the specimen ID as the unique identifier
- The lab computer responds with the requested data
- The sample program is entered into the database and the specimen is metered

Error Handling

- The analyzer handles errors encountered during communication

Inventory Query

- Allows the laboratory to request inventory information from the analyzer

Asynchronous Messages

- A message containing an Automation Configuration Record

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Mechanical and Electrical Interfaces

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 5,1 FS Chemistry System to the laboratory computer. The VITROS 5,1 FS Chemistry System uses chassis mounted connectors rather than cable mounted connectors. If the laboratory computer being connected to the analyzers is EIA RS-449 (or other standard interface) compatible, you must install an interface adapter.

Data and Transmit Control Pins

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

Pin 1 Protective ground (AA).

Pin 2 Analyzer-transmitted data (BA) - Serial data from the analyzer to the laboratory computer.

Pin 3 Analyzer-received data (BB) - Serial data from the laboratory computer to the analyzer.

Pin 4 Request to send (CA) - Control signal from the analyzer that indicates the analyzer is ready to transmit data.

Pin 5 Clear to send (CB) - Control signal to the analyzer that indicates the laboratory computer is ready to receive data.

Pin 6 Data set ready (CC) - Control signal to the analyzer that indicates the laboratory computer is on-line.

Pin 7 Signal ground (AB) - Common ground reference point for all circuits except AA.

Pin 8 Carrier Detect (CF) - Optional.

Pin 20 Data terminal ready (CD) - Control signal from the analyzer to the laboratory computer that indicates the analyzer is on-line.

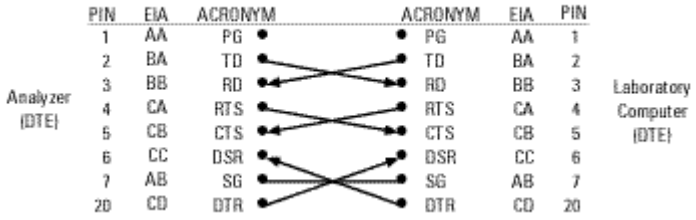
Cable

The standard interface cable is supplied by the user. Cable configurations are determined by the interface to the laboratory computer. Most computer analyzers 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 analyzer's Clear to Send (CTS) input.
On an analyzer a cable length of no more than 50 feet (5.24 meters) is recommended to maintain electrical signal characteristics defined by standard EIA RS-232C.

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

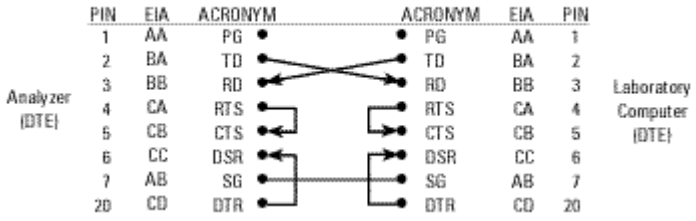
Applicable for analyzers where CTS hardware flow control is required. Half duplex transmission is allowed. On-line control is required by the laboratory computer (that is, the laboratory computer can go off-line or on-line, and it is noticed by the analyzer).



Example: CTS Hardware Flow Control (DTE/DTE).

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

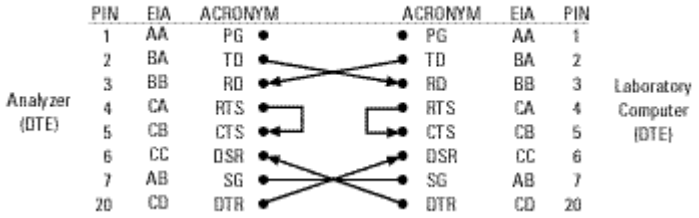
Applicable for installations with 3-wire cable already installed. Hardware CTS flow control is not possible. Each analyzer interprets the other as being on-line when the analyzer itself is on-line.



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

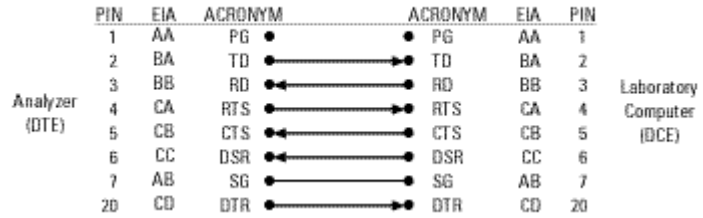
CTS Hardware Flow Not Functional (DTS/DSR Handshake and CTS/RTS Loopback)

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



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

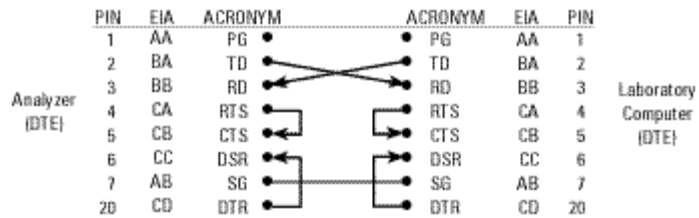
Hardware Flow Control Functional (DTS/DSR and CTS/RTS Handshake)



Example: Hardware Flow Control Functional (DTE-DCE).

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

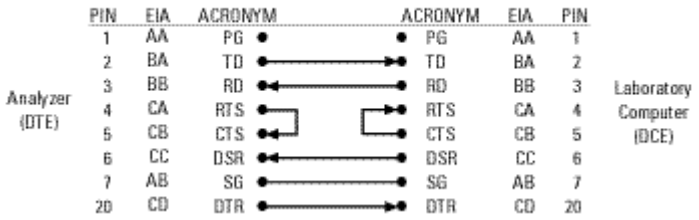
Hardware CTS flow control is not possible. Each analyzer interprets the other as being on-line when the analyzer itself is on-line.



Example: 3-Wire Capability (DTE-DCE).

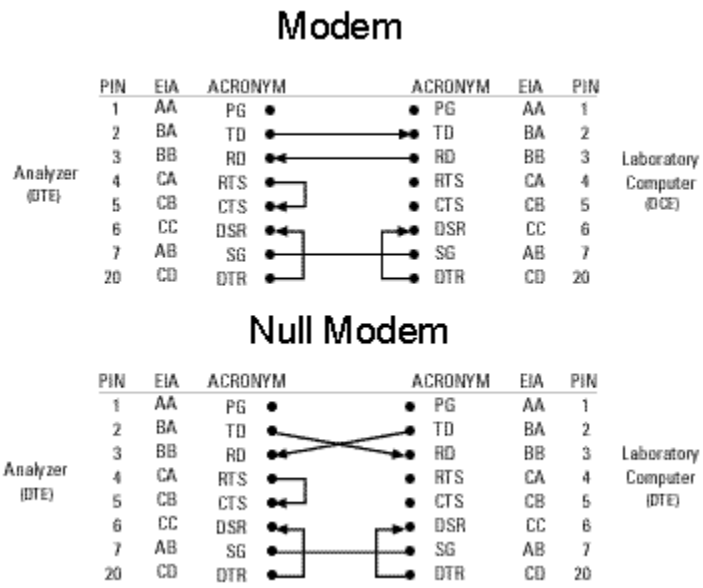
Hardware CTS Flow Control Not Functional (DTS/DSR Handshake and CTS/RTS Loopback)

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



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

ASTM Wire Cable Configuration



ASTM Wire Cable Configuration.

Electrical Interface

The analyzer 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 analyzer 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.

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Communications Interface: Bidirectional Mode ASTM Protocol

The bidirectional mode of communication allows you to download patient information and sample programs from the laboratory computer and upload patient test results from your analyzer.

Method of Transmission/ Reception

The ASTM protocol uses an asynchronous method of data transmission and reception (that is, serial by bit, start/stop). All bit sequencing, structure, and parity conform to ANSI standard X3.15-1976 and X3.16-1976. The ASTM protocol specifies 1 stop bit. The setting is user configurable for 1 or 2 bits.

Default Configuration: 1 stop bit

Parity

In ASTM character parity can be of three types:

1. ODD for odd parity
2. EVEN for even parity
3. NONE if parity checking is not desired

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

Default Configuration in the VITROS 5,1 FS Chemistry System: NONE

Character Transmission and Reception

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

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

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

Default Configuration in the VITROS 5,1 FS Chemistry System: 9600 baud rate, 8 data bits, no parity, 1 stop bit; the analyzer does not support 300, 600, 1200, 2400, and 4800 baud rate.

Transferring Data

The functions involved in transferring data from the analyzer to the lab computer and the lab computer to the analyzer are divided into these three components:

1. **Physical Layer** - This layer is comprised of the actual hardware and software configuration used to communicate between the two analyzers. This corresponds to the ASTM E 1381-95 Specification for Low Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems Section 5.

- The analyzer uses 1 start bit.
- The analyzer supports 1 or 2 stop bits.
- The analyzer supports EVEN, ODD, and NONE parity.
- The analyzer supports baud rates 9600, 19200, 38400, 57000, and 115200.
- The analyzer uses 8 data bits.

2. **Datalink Layer** - This layer handles the establishment of communication, error detection and error recovery in the sending and receiving of messages. This corresponds to the ASTM Datalink layer specified in ASTM E 1381-95 Specification for Low Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems Section 6.

- The Datalink layer is responsible for the logical data frames comprising the raw data exchanged with the physical layer. It ensures that packets can be transferred in an error-free manner between machines. See Section 6.1, of the ASTM E 1381-95 specification, for detailed specifications of this layer.

- The analyzer acts as a sender when a query is requested or when results need to be uploaded to the lab computer. The analyzer acts as a receiver when the lab computer responds to the query with information and when sample programs are to be downloaded.
- The analyzer supports the Establishment Phase (Link Connection) as specified in Section 6.2 of the ASTM E 1381-95 specification. This includes establishment and contention.
- The analyzer supports the Transfer Phase as specified in Section 6.3 of the ASTM E 1381-95 specification. This includes:
    - Frame Format - Section 6.3.1
    - Frame Numbering - Section 6.3.2
    - Frame Checksums - Section 6.3.3
    - Frame Acknowledgments - Section 6.3.4
    - Frame Receiver Interrupts - Section 6.3.5
- The analyzer supports the Termination Phase (Link Release) as specified in Section 6.4 of the ASTM E 1381-95 specification.
- The analyzer supports Error Recovery as specified in Section 6.5 of the ASTM E 1381-95 specification. This includes:
    - Detecting and handling defective frames - Section 6.5.1
    - Time-outs - Section 6.5.2
- The analyzer supports the restricted Message Characters requirement specified in Section 6.6 of the ASTM E 1381-95 specification.

3. **Record Processing** - This layer specifies the content of the records (sample programs, results records and patient information) to be implemented in this application. The format and hierarchy are specified in the ASTM E 1394-97 Standard Specification for Transferring Information Between Clinical Laboratory Instruments and Computers Systems but the content is unique to the application.

- The LIS processes the record types and fields defined in the ASTM E 1394-97 specification, with the exception of Scientific (S) records. All record field descriptions meet the ASTM Common Field Types specification (refer to Section 6.6). If the field value has multiple components, they are differentiated by the '^' character.
- The analyzer supports the hierarchical message structure as defined in Sections 5.1.8 through 5.1.11 in the ASTM E 1394-97 specification.
- The analyzer supports the Logical Information Storage and Logical Transmission Error Recovery Requirements defined in Sections 5.2.1 and 5.2.2 of the ASTM E 1394-97 specification.
- The analyzer processes Receiver Interrupt requests from the LIS. The analyzer reestablishes a session as sender at the end of the LIS message transmission or after the 15 second time-out. At that time, the analyzer sends the records specified by the Logical Information Storage and Logical Transmission Error Recovery Requirements defined in Section 5.2.2 of the ASTM E 1394-97 specification.

- In order to provide consistency with Sample Programming and to meet database storage requirements, the field size limits (described below) are used.
- Fields not supported by the analyzer are ignored on a download.
- The analyzer uploads null values for any field that is "Not Supported" for all records. See Record Processing for fields that are supported.
- The analyzer 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 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)

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Application Interface: Bidirectional Mode ASTM Protocol

The ASTM application layer enables the laboratory computer to automatically download patient data and sample programs to the VITROS 5,1 FS Chemistry System. It also enables the analyzer to automatically upload corresponding test results.

Terminology

ASTM uses the following terms to indicate the way it groups data:

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

	requests are transmitted in repeat fields within their related records.
Component Field	Part of a data field that might contain more than one piece of data. Address is a common example of a data field that has more than one component: street number, street name, city, and other location data are all component fields of address.

Record Types

ASTM uses common record types. Each record begins with a field identifying the record type, shown in parentheses below, and ends with a carriage return.

Header Record (H)	Contains identifying information about the sending station, conventions that the device uses for field recognition, and the date and time of send station transmission.
Patient Record (P)	Contains patient-related information like patient identification number, patient name, patient demographic information, and the name of the patient's attending physician.
Order Record (O)	Stores information about the assay or requests themselves and includes data about specimens, the time of collection, action requested, and the assay priority.
Result Record (R)	Contains information about the outcome of individual tests for individual patients and always follows a sample program record. (Note: In VITROS Chemistry System documentation, "sample program" is used where ASTM uses the term "test order." The term "test order" is used only when referring to the order record itself.) In an upload transmission, a single result for a given patient is coupled with the specific sample program to which it corresponds. The result contains the actual measurements derived from the test and provides a comparison of the individual result to certain ranges specified as norms for the laboratory.
Comments Record (C)	Allows the laboratory to enter free-form patient information.
Request Record (Q)	Allows the analyzer to request sample program information based on the barcode of the sample.
Extended Result Record (M)	Contains information about the reagents, calibrators, and/or control fluids used in the test.
Trailer Record (L)	Ends the session.

Automation Configuration Record (M)	Allows the analyzer to notify the laboratory when automation is turned on or off.
Inventory Query Record (M)	Allows the laboratory to request inventory information from the analyzer.
Reagent Inventory Record (M)	Contains information about carts or reagent packs associated with an analyte. It is sent in response to an inventory query.
Diluent Inventory Record (M)	Contains information about a single diluent onboard. It is sent in response to an inventory query.
Bulk Consumables Inventory Record (M)	Contains information about the bulk fluids, tips, cuvettes, and waste. It is sent in response to an inventory query.
Error Record (M)	Allows the analyzer to notify the laboratory when an error occurs. This corresponds to a condition code on the analyzer.

Conventions

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

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

Hierarchy

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

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

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

Comments always relate to the records immediately preceding them. Wherever they occur, comments take on the same level of the next higher record in the structure. If more than one comment record occurs, the last one is kept and the others are discarded. For VITROS Chemistry Systems, only comment records that pertain to the patient records are accepted; all others are discarded.

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

Record Sequencing and Numbering

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

Logical Storage

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

Transmission Conditions and Recovery

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

If there is a problem with transmission at the data link and a frame is not acknowledged (<NAK>), the protocol will retransmit a frame up to six times. If the frame is not acknowledged six times, the message cancels and the line returns to a neutral state.

The sending station remembers the frame that was canceled. When it begins to transmit again, it recognizes the canceled frame's position in the hierarchy. Recovery occurs at patient boundaries and begins with a new header record; the sending station:

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

Character Codes and Delimiters

Both the application and the communication layer, as implemented by the VITROS 5,1 FS Chemistry System, use a range of ASCII character codes to do the following tasks:

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

Field Length and ASTM Delimiters

ASTM assumes a variable length record. A blank or null value occupies no space and is only indicated by a field delimiter to hold the field's place within the record. ASTM does not assign any maximum lengths for fields; rather, it depends on buffering capabilities and the communication layer to parse and transmit messages efficiently.

ASTM uses several printable characters as special delimiters to assist in determining record layout. Although it can accept other delimiters as defined in a download session, the VITROS 5,1 FS Chemistry System uses only the ASTM default delimiters:

Field Delimiters (|)	Define the end of a new field and the beginning of another field.
Repeat Delimiters (\)	Indicate when a type of field occurs more than once in the same record. For example, if more than one test is requested for the same patient from the same sample, then a repeat delimiter will indicate where that additional test field begins.
Component Delimiters (^)	Separate each part of a field having more than one part. In an address field, component delimiters may separate street from city or city from state.
Escape Delimiters (&)	Optional indicators that can be used or ignored by the manufacturer.

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

The VITROS 5,1 FS Chemistry System uses the universal test ID in the order record to specify the assays to run for a given sample. The universal test ID has four components: the test ID code, test ID name, test ID type, and the manufacturer's code. However, of the four components, the VITROS 5,1 FS Chemistry System uses only the last one, the manufacturer's code, which ASTM allows the manufacturer to define. In the VITROS 5,1 FS Chemistry System the manufacturer's code contains these elements:

Manual Dilution Factor	Dilution for the entire sample program.
Plus sign (+)	Links a dilution factor with either whole series of tests or with a particular test.
Analyte (test) code (1–3 characters)	Decimal notation to represent the specific test being performed.
Test Dilution Factor (TDF)	Dilution associated with a particular assay or test within a sample program.

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

N.N+ddd+n.n\ddd+n.n\ddd+n.n\ddd+n.n\ddd+n.n...

Where:

N.N Dilution for the test to the left of the preceding manufacturer deliminater (+).

+ Links the dilution factors to the sample program or an individual test.

ddd Analyte code (e.g., 300 for glucose).

Note that there will be one ddd+n.n for each rep of each test. The range of n.n is from 1.0 to 100.0 in 0.1 increments.

n.n Test dilution factor.

**** Repeat delimiter; indicates that another test request follows. It separates one individual assay or test from the next.

Field Delimiters and Null Values

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

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

A field could have a null value for any number of reasons: the field is not implemented by either the laboratory computer or the particular analyzer, the field is used on one device and not the other so there is no purpose in transferring the data. In the VITROS 5,1 FS Chemistry System null values will overwrite, essentially erase, any existing data previously sent for a particular field. If you do not want to overwrite values on a particular record, you must resend those same values when you send a record.

Record Processing

The tables illustrated below list the fields that are supported by the analyzer. All other fields are ignored on a download, and a null value assigned to all fields not supported by the analyzer during an upload (reference the ASTM E 1394-7 Specification).

Header Record	Patient Record	Order Record	Result Record	Extended Result Record	Comment Record	Request Record
Trailer Record	Automation Configuration Record	Inventory Query Record	Reagent Inventory Record	Diluent Inventory Record	Bulk Consumables Record	Error Record

Downloading Sample Programs

The transfer of data will occur when:

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

The software will support the processing of samples while sample programs are downloaded to the analyzer.

In the case of contention between the analyzer sending or requesting data and the lab computer sending unsolicited data, the analyzer takes priority.

Header Record

Field	Field Type	Direction		Max Len	Description and Valid Values
		D	U		
1	Record Type ID	R	A	1	Required field containing an H or h identifying a header record.
2	Delimiters	R	A	4	The VITROS 5,1 FS Chemistry System transmits only the four default values shown below. Delimiters may not be duplicated. Field Delimiter I Repeat Delimiter \ Component Delimiter ^ Escape Delimiter &
5	Sender Name/ID	I	A	7	Name of the device sending the data.
13	Version Number	R	A	8	ASTM Protocol Version (E1394-97)
14	Date and Time of Message	I	A	14	Date and time of transmission: formatted as YYYYMMDDHHMMSS. For example, 3:35 PM on March 1, 2004 would be represented as: 20040301153500.

Legend: D Download U Upload
R Required A Always
I Ignored

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Patient Record

Field	Field Type	Direction		Max Len	Description and Valid Values
		D	U		
1	Record Type ID	R	A	1	Required field containing a P or p identifying a patient record.
2	Sequence Number	R	A	1	Starts with a 1 for the patient and is incremented by 1 for each additional patient within the transmission.
3	Practice Assign Patient ID	O	S	20	Can be assigned by the laboratory computer initially, stored in the patient ID of the sample program on the analyzer, and uploaded. Can also be assigned by an analyzer as part of an upload with no corresponding download.
6	Patient Name	O	S	20^15^1	Contains three components: Last Name (up to 20 characters) First Name (up to 15 characters) Middle Initial (up to 1 character) The suffix and title are not supported.
8	Birth Date	O	S	8	Formatted as YYYYMMDD. For example, a birth date of December 1, 2002 would be represented as: 20021201.
9	Patient's Sex	O	S	1	Default values: M - male F - female U - unassigned

					Other user defined single character values must be supported by both analyzer and lab computer.
11	Patient Address	O	S	20^20	Contains two components: Component 1 (up to 20 characters) Component 2 (up to 20 characters)
14	Attending Physician ID	O	S	20^15^1	Contains three components: Last Name (up to 20 characters) First Name (up to 15 characters) Middle Initial (up to 1 character) This field will only allow ID of one physician.
26	Location	O	S	10	First 10 characters of the patient room number, ward, etc.

Legend:

D	Download	U	Upload
R	Required	A	Always
O	Optional	S	Sometimes

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Order Record

Field	Field Type	Direction		Max Len	Description and Valid Values
		D	U		
1	Record Type ID	R	A	1	Required field that containing an O or o identifying an order.
2	Sequence Number	R	A	1	Starts with 1 for the first order record and is incremented by 1 for each additional order record for a Patient. This field resets to 1 when a new

					patient record is transmitted.
3	Specimen ID			15^2^2	Contains three components:
		R	A		Sample ID (up to 15 characters)
		O	S		Tray ID (up to 2 characters, 0–9, A–Z)
		O	S		Cup (up to 2 characters, 0–10)
					The value of this three component field is usually assigned by the laboratory computer before downloading. The analyzer uses and reports its results based on the assigned specimen ID.
5	Universal Test ID	R	A	Variable	Contains four components. The first three components (test ID code, test ID name and test ID type) are not used. The fourth component is:
					Local Manufacturer's Code: This component contains multiple analyte codes indicating all the assays to be processed for the sample program.
					The general structure of the Local Manufacturer's Code is:
					^^^ManualDilution + Test Code + TestDilution\ Test Code + TestDilution\ Test Code + TestDilution
					If the action code = C, this field is empty and only marked by a field delimiter.
6	Priority	R	A	1	Indicates the time frame in which the result is needed. In a download session, the following codes are valid for this field:
					A - STAT (ASAP)
					S - STAT
					R - Routine
8	Specimen Collect	O	S	14	Indicates the date and time when the specimen was collected, expressed as

	Date/Time				YYYYMMDDHHMMSS. For example, March 1, 2004 collection at 10 seconds after 3:35 PM would be: 20040301153510.
12	Action Code	O	S	1	Indicates whether the order record is new or there is a request to cancel: A - Append C - Cancel N - New P, L, Q, and X are treated as a new order record.
16	Specimen Type/Specimen Source	R	A	1	Indicates the type of specimen: 1 = Serum / Plasma 2 = CSF 3 = Urine 4 = Whole Blood 5 = Reserved 6 = Reserved
26	Record Types	I	A	2	Indicates the direction of the transmission: O - Downloading F - Uploading

Legend:

D	Download	U	Upload
R	Required	A	Always
O	Optional	S	Sometimes
I	Ignored		

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Uploading Result Records

The analyzer uploads result records to the lab computer provided all of the following are met:

- The analyzer is configured to upload results.
- The lab computer is configured to accept transmissions.
- The hardware connections are in place.
- No downloads are occurring at the time.
- No host queries are in process.
- Result records exist and are ready to be uploaded.
- No inventory queries are in process.

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 takes place.

Result Records will be uploaded for all replicates as well as the mean result. The mean can be identified by the "MN" code.

Result Record

Field	Field Type	Direction		Max Len	Description and Valid Values
		D	U		
1	Record Type ID		A	1	Required field containing an R or r identifying a result.
2	Sequence Number		A	Unlimited	Starts with 1 for the first result and increments by 1 for each additional result within the order. Resets to 1 when the results from another order record are being transmitted to the laboratory computer.
3	Universal Test ID		A	13	Contains four components. The first three components (test ID code, test ID name and test ID type) are not used. The fourth component is: Local Manufacturer's Code: this field contains the description of the

				replicate result being sent to the LIS. The field holds the manual dilution factor, analyte code, and test dilution factor for individual test to which the result applies. The general structure of the Local Manufacturer's Code is: ^^^ManualDilution + TestCode + TestDilution\ TestCode + TestDilution\ TestCode + TestDilution
4	Data or Measurement Data	A	9	9 character floating point that includes the decimal point and a negative sign when applicable. The number of precision point digits will vary by test and is configurable on the analyzer. Note: The string "No Result" is reported in this field if any type of condition exists, such as a numerical processing error.
5	Units of Measure	A	12	Up to 12 characters that the operator defines for analyte measurement through the Options & Configuration function.
7	Results Abnormal Flags	S	^1^10	Three-component field. The first component is empty. The second component is the Flag field. • Results Flag (in ASCII characters) 0 No Flag 1 Above Reference Range 2 Below Reference Range 4 Above Reportable Range 5 Below Reportable Range 6 Prediction failure, with value

reported as NO RESULT

7 Above Supplemental Range

8 Below Supplemental Range

A The value of the QC result is at least two but less than three baseline standard deviations below the baseline mean. (-2S)

B The value of the QC result is at least two but less than three baseline standard deviations above the baseline mean. (+2S)

C The value of the QC result is at least three baseline standard deviations below the baseline mean. (-3S)

D The value of the QC result is at least 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 Integrity Index exceeds the threshold for this assay.

- Result classification

				(qualitative) 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 Component 3 of this field contains up to five non-delimited two-character codes. It indicates operational problems causing abnormal results - Codes. See Result Flags Table for valid Result Flags. This field is repeated three times (for a total of four repetitions). The first is for any Flag & Code specific to the assay, the second is specific to Hemolysis, the third for Icterus, and the fourth for Turbidity.
9	Result Status	A	1	Valid value: V - operator verified/approved result.
11	Operator Identification	A	12	ID of the operator running the test.
12	Date/Time Test Started	A	14	Indicates the date and time when the specimen was collected, expressed as YYYYMMDDHHMMSS. For example, March 1, 2004 collection at

				10 seconds after 3:35 PM would be: 20040301153510.
13	Date/Time Test Completed	A	14	Indicates the date and time when the test was started, expressed as YYYYMMDDHHMMSS. For example, March 1, 2004 3:35 PM would be: 20040301153500.
14	Instrument Identification	A	12	ID of the device that actually ran the test.

Legend: D Download U Upload
A Always
S Sometimes

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Sample Integrity Flags

Flag	Condition	Application	Occurrence
NA	SI Globally Not Available	• MicroSlide assays. • MicroTip Special Chemistry assays.	If the Sample Integrity system (MICROSENSOR) is completely disabled.
ES	Examine Sample	Patient test results for all samples where sample integrity is run.	When the Sample Integrity Index is outside the reportable range for that index.
H	Hemolysis	Patient test results for all samples where sample integrity is run.	The level of hemolysis in the sample may interfere with the accuracy of the assay.
I	Icterus	Patient sample test results for all samples where sample integrity is run.	The level of icterus in the sample may interfere with the accuracy of the assay.
T	Turbidity	Patient sample test results for all samples where sample integrity is run.	The level of turbidity in the sample may interfere with the accuracy of the assay
ME	Mechanical Error	Patient sample test results for all samples where	If there is a mechanical error in the Sample

		sample integrity is run.	Integrity system (MICROSENSOR).
NR	Not Run	• MicroSlide assays. • MicroTip Special Chemistry assays.	• If the Sample Integrity system (MICROSENSOR) was universally enabled but disabled during sample programming for the sample. • If the sample was diluted. • If the sample was pretreated.
pi	Potential Interferent	• MicroSlide assays. • MicroTip Special Chemistry assays.	A > code applies to the combination of sample and Sample Integrity index **and** the assay's threshold value for the index is greater than or equal to the index's reportable range upper limit.

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Result Codes

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

Code	Description	Condition	Actions
VS	Viscous Sample	Occurs if the sample viscosity exceeds a value obtained either from software or the Assay Data Disk. All reps and tests for the sample will be coded VS.	Check for additional codes and flags. Note: Higher viscosities report **No Result** with an ME flag.

Code	Description	Condition	Actions
PI	Potential Interferent	There is a potential interfering substance to Bu in the sample. The code is reported with the Bc result.	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.
		The Pl code can be reported with Bu. In this case, the code indicates that Bc is not readable by the analyzer. As a result, the Bu cannot be reported.	If the PI code is with the Bu result, dilute the sample with a normal patient sample or 7% BSA. Then repeat on BuBc slide. Refer to the appropriate Instructions for Use for more information.
NC	Not Calibrated	No calibration is currently in use for the requested test.	Calibrate the test.
ME	Mechanical Error	A hardware or operator induced error might have occurred.	Initialize the analyzer and/or correct the condition manually.
II	Insufficient Inventory	There was not sufficient inventory of the required wells or reagents for the test before it was scheduled to be processed.	Check inventory levels using Reagent Management.
NI	No Inventory	There was no inventory of the required reagents for the test after it was scheduled to be processed.	Check inventory levels using Reagent Management.
RE	Reagent Expired	The test was processed from an expired reagent pack or signal reagent.	Load new reagents.
NF	No Fluid	The analyzer did not detect any fluid during aspiration.	Check for sufficient sample volume and for fibrin in the sample or the PRIMARY and/or SECONDARY METERING subsystem.
IS	Insufficient Sample	The sample had insufficient volume to meter all of the tests programmed.	Check the sample for sufficient fluid.

Code	Description	Condition	Actions
EA	Expired Aliquot	The CuveTip in the Disposable Tip Processing Center has expired.	Repeat the test with fresh sample
EI	Expired Dilution	The dilution cuvette in the CuveTip Ring has expired.	Repeat the test with fresh sample.
DE	Drop Error	The proboscis was unable to dispense the correct amount of fluid.	Check for fibrin in the sample or in the PRIMARY and/or SECONDARY METERING subsystem.
CB	Cuvette Blank	The test result's associated baseline transmittance reading is above or below configurable limits (loaded from the Assay Data Disk).	Check for an optical problem with the CUVETTE row or with the sample.
BP	Blank Prediction	The analyzer was unable to compute the result for the blank slide.	
SP	Multiple Spikes	More than one data spike was seen while reading a multiple point rate test.	Repeat the test. Refer to the other codes displayed in the report and condition code summary for rate lamp condition codes.
TR	Trim Error	The analyzer could not find a suitable area to read on the curve of a multiple point rate test due to noise or high activity sample.	Dilute the sample and repeat the test. Refer to the appropriate Instructions for Use for more information.
DP	Substrate Depleted	Substrate depletion has occurred in a rate or IR test.	Dilute the sample and repeat the test. Refer to the appropriate Instructions for Use for more information.
KE	Kinetic Error	The multiple point rate test has a high activity or has an interfering substance present.	Dilute the sample and repeat the test. Refer to the appropriate Instructions for Use for more information.

Code	Description	Condition	Actions
		On immuno-rate tests this is due to an analyte concentration below the dynamic range.	Refer to the appropriate Instructions for Use 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.	Dilute the sample.
IT	Incubator Temperature	The incubator temperature was out of tolerance at some point while the test sample was being incubated.	Once the analyzer displays "READY," repeat the test.
OR	Outside of Reportable Range	The result is outside of the system's reportable range.	Check for 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.	Refer to the other codes displayed in the report and condition code summary for more information.
		A wash error might have occurred (Immuno-rate tests only).	Follow the actions listed for the WE code.
PF	Prediction Failure	The master computer detected an invalid slide or no slide response.	Refer to the other codes displayed in the report and condition code summary for more information.
ER	Computational Error	A computational error occurred, such as the log of a negative number or division by zero.	Repeat the test.
IC	Invalid Component	A derived test result was not computed because one or more component tests failed to predict a result or were outside analyzer range.	Examine the component test results for the actual cause of this code.

Code	Description	Condition	Actions
FC	Flagged Component	At least one of the measured components of a derived test has a code, flag, or a HIT flag.	Examine the component test results for the actual cause of this code.
ZS	Negative Derived Test Result	A derived test was computed by setting a negative component result to zero.	Check for additional codes and flags.
WE	Wash Error	The Immuno-rate (IR) wash was invalid because one of the following occurred: • Insufficient wash fluid • Interfering substance in the sample • The IR wash module was not functioning properly • Incorrect calibration information • Calibration was not performed when a new lot of IWF was introduced • Sample might have a low total protein	Perform the following actions in the order given: 1. Repeat the test 2. Dilute the sample and repeat the test 3. Change the Wash Fluid Metering Tip 4. Change the IWF RESERVOIR 5. Verify that the IWF RESERVOIR is seated properly 6. Verify that the RESERVOIR LID ASSEMBLY is seated properly 7. Verify the analyte was calibrated using the new lot of IWF
M1	Category 1 Modified Values	The test data was modified. The new data does not affect the shape of the calibration curve.	Check the dynamic range for the analyte on the Options & Configuration - Review/User Calibrations screen and result text and ranges on the Options & Configuration - Review/Edit Assay Data screen.

Code	Description	Condition	Actions
M2	Category 2 Modified Values	The test data was modified. The new data is used to generate the calibration curve.	Check calibrator concentrations for the analyte on the Options & Configuration - Review/Edit Assay Data screen.
UC	User Calibration	The calibration parameters for this test were input manually.	No action necessary.
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.
MN	Mean	The test result is a mean of replicate results.	No action necessary.
MW	Multiple Windows	Applies to multiple point rate assays. Measurements show excessive irregularity and lack of smoothness.	No action necessary.
OD	Operator Requested Dilution	The out of range dilution has been selected in sample programming.	No action necessary.
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 necessary.
RP	Reflex Test Processed	This result is from a derivative or repeat reflex test.	No action necessary.
EP	Edited Demographics Data	The demographics data value in the result record was edited by the Operator in Results Review.	No action necessary.
RS	Reduced Standard Dilution	The test was a reflex test using more sample than the original test.	No action necessary.
ED	Edited Result	The replicate result was edited by the Operator in Results Review.	No action necessary.

Code	Description	Condition	Actions
RR	Recalculated Result	The test results were recalculated due to an Operator action in Results Review.	No action necessary.
AR	Adjusted Result	A user adjustment parameter was applied to the result.	No action necessary. User adjustment parameters are defined on the Options & Configuration - Review/Edit Assay Data screen.
OA	Operator Assay	The test was performed using open channel reagents.	No action necessary.
OC	Operator Requested Concentration	The test was performed with a dilution which was lower than the configured value.	No action necessary.
AT	Additional Test Result	The results were obtained from a source other than a VITROS analyzer, then manually entered to the report by the Operator.	No action necessary. The test result was manually entered by the operator.
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 codes and perform the recommended procedures. Process the control fluid again.
LS	Lot Switch	A new slide lot was used to process this test.	Verify that QC was performed before reporting results using the new slide lot.

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Comments Record

Field	Field Type	Direction		Max Len	Description and Valid Values
		D	U		
1	Record Type ID	R	A	1	Required field containing a C or c identifying a comment.
2	Sequence Number	R	A	1	Begins with 1 and is incremented by 1 for each additional comment record transmitted at that hierarchical level. Resets to 1 whenever a comment at another hierarchical record is sent.
3	Comment Source	I	A	1	Indicates the source of the comment. Used only on upload. Valid value: I - Instrument.
4	Comment Text	R	A	60	Free-form field of text that is user defined.
5	Comment Type	I	A	1	Indicates the nature of the comment. Used only on upload. Valid value: G - Generic.

Legend: D Download U Upload
R Required A Always
I Ignored

Return to Table List

Request Record

Field	Field Type	Direction		Max Len	Description and Valid Values
		D	U		
1	Record Type ID		A	1	Required field containing a Q or q identifying a request record.
2	Sequence Number		A	1	Begins with 1. Reset for each new message.
3	Starting Range ID Number		A	^15	Indicates the specimen ID of interest. Only one request per record is allowed.

Field	Field Type	Direction		Max Len	Description and Valid Values
		D	U		
5	Universal Test ID		A	3	Values other than "ALL" are not supported.
13	Request Information Status Codes		A	1	A = Abort/cancel last request criteria O = Requesting test orders and demographics only

Legend: D Download U Upload
R Required A Always

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Extended Result Record

Inclusion of the Extended Result Record in a message is a configurable option.

Field	Field Type	Direction		Max Len	Description and Valid Values
		D	U		
1	Record Type ID		A	1	Required field containing a M or m identifying it as a manufacturer record.
2	Sequence Number		A	1	Begins with 1. Reset for each new message.
3	Sub Type ID		A	1	Required field containing an X or x identifying an Extended Result Record.
4	Reagents		A	12^14^14^5^5	Contains five components: • Reagent lot (up to 12 characters) • Reagent Shelf Expiration Date (up to 14 characters) • Reagent Load Date (up to 14 characters) • Electrolyte Reference Fluid lot (up to 5 characters) • Wash Fluid lot (up to 5 characters)
5	Calibration		A	14^1	Contains two components: • Calibration Date (up to 14 characters) • Calibration Status (1 character) N = Normal Calibration

				U = User calibrated M = User modified This value is included only if the associated calibration exists in the database.
6	Quality Control	A	10^14^14	Contains three components: • Control Lot (up to 10 characters) • Control Creation Date (up to 14 characters) • Control Expiration Date (up to 14 characters) This value is included only if the result is for a Quality Control test.

Legend: D Download U Upload
R Required A Always
I Ignored

Return to Table List

Trailer Record

Field	Field Type	Direction		Max Len	Description and Valid Values
		D	U		
1	Record Type ID	R	A	1	Required field containing an L or l identifying it as a terminator record.
2	Sequence Number	R	A	1	Contains the value "1" indicating a message terminator.
3	Termination Code	R	A	1	Indicates the cause of termination. Valid values are: N or Null - Normal termination T - Sender cancel

Q - Error in last query

I - No information available from last query

Legend: D Download U Upload
R Required A Always

Return to Table List

Automation Configuration Record

Sending of this record is configurable.

Field	Field Type	Direction		Max Len	Description and Valid Values
		D	U		
1	Record Type ID		A	1	Required field containing a M or m identifying a request record.
2	Sequence Number		A	1	Begins with 1. Reset for each new message.
3	Sub Type ID		A	1	Required field containing an A or a identifying an Automation Configuration Record.
4	Automation Enabled		A	1	Indicated whether automation is enabled/disabled: E = Enabled D = Disabled

Legend: D Download U Upload
A Always

Return to Table List

Inventory Query Record

Field	Field Type	Direction		Max Len	Description and Valid Values
		D	U		
1	Record Type ID	R		1	Required field containing a M or m identifying a request record.
2	Sequence Number	R		1	Begins with 1. Reset for each new message.
3	Sub Type ID	R		1	Required field containing an I or i identifying an Automation Configuration Record.
4	Inventory Type	R		1	Indicated type of inventory requested: R = Reagents (carts and packs) D = Diluents B = Bulk consumables (fluids, tips, cuvettes, waste) A = All inventory types

Legend: D Download U Upload
R Required

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Reagent Inventory Record

In response to Inventory Query for reagents or all .

Field	Field Type	Direction		Max Len	Description and Valid Values
		D	U		
1	Record Type ID		A	1	Required field containing a M or m identifying it as a manufacturer record.
2	Sequence Number		A	1	Begins with 1. Reset for each new message.

3	Sub Type ID	A	1	Required field containing an R or r identifying a Reagent Inventory Record.
4	Analyte Code	A	3	Required field containing the Assay Number.
5	Shared Analyte Code	S	3	Required field containing the Assay Number, which may be repeated.
6	Reagent Info	A	12^14^3^1^1^1^1	Contains: • Reagent lot (up to 12 characters) • Expiration Date (up to 14 characters) • Remaining Test Count • Serum Plasma Reagent Status • CSF Reagent Status • Urine Reagent Status • Whole Blood Reagent Status • Fluid Reagent Status: 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 • This field will be repeated for each cart/reagent pack onboard.

Legend: D Download U Upload

S Sometimes A Always

Return to Table List

Diluent Inventory Record

In response to an Inventory Query for diluents or all.

Field	Field Type	Direction		Max Len	Description and Valid Values
		D	U		
1	Record Type ID		A	1	Required field containing a M or m identifying a request record.
2	Sequence Number		A	1	Begins with 1. Reset for each new message.
3	Sub Type ID		A	1	Required field containing an D or d identifying an Automation Configuration Record.
4	Diluent Code		A	4	Indicates bottle fluid code of diluent.
5	Lot Number		A	10	In CCPPPPGGLLLL format.
6	Remaining Volume		A	8	Remaining volume of diluent in mL.
7	Date and Time of Expiration		A	14	Expiration date of the diluent in YYYYMMDDHHMMSS format.

Legend: D Download U Upload
A Always

Return to Table List

Bulk Consumables Inventory Record

In response to an Inventory Query for bulks or all.

Field	Field Type	Direction		Max Len	Description and Valid Values
		D	U		
1	Record Type ID		A	1	Required field containing a M or m identifying a request record.
2	Sequence Number		A	1	Begins with 1. Reset for each new message.
3	Sub Type ID		A	1	Required field containing an B or b identifying an Automation Configuration Record.
4	ERF		S	5^3	Lot^Remaining Tests .
5	IWF		S	5^3	Lot^Remaining Tests.
6	VersaTips		A	8	The string "Infinite" is reported in this field if the VersaTip hopper sensor is blocked indicating there are at least 300 tips remaining.
7	MicroTips		A	3	Indicates the number of MicroTips remaining.
8	Cuvettes		A	3	Indicates the number of Cuvettes remaining.
9	Slide Waste		A	4	Indicates the number of tests that can be performed before the waste container is full.
10	Cuvette Waste		A	5	Indicates how full the container is in percentage. This container is used for tips, cuvettes, and MicroTip trays.

Legend: D Download U Upload
S Sometimes A Always

Return to Table List

Error Record

Sending of this record is configurable.

Field	Field Type	Direction		Max Len	Description and Valid Values
		D	U		
1	Record Type ID		A	1	Required field containing a M or m identifying a request record.
2	Sequence Number		A	1	Begins with 1. Reset for each new message.
3	Sub Type ID		A	1	Required field containing an E or e identifying an Automation Configuration Record.
4	Error Module		A	3	Module number of the condition code.
5	Error Number		A	3	Error number of the condition code.
6	Severity		A	1	A = Attention N = Action M = Malfunction S = Shutdown
7	Short Error Test		A	1	Short error test with substitution, the same that appears in Condition Review.
8	Date and Time of Error		A	14	In YYYYMMDDHHMMSS format.
9	Specimen ID		S	15^2^2	Will only be filled if an error applies to a sample.

Legend: D Download U Upload
S Sometimes A Always

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END OF TOPIC

Analyte Codes

Analyte Code	Report Name	Assay Name	Body Fluid
300	GLU	Glucose	1
300	GLU	Glucose	2
300	GLU	Glucose	3
301	TP	Total Protein	1
302	URIC	Uric Acid	1
302	URIC	Uric Acid	3
303	ALB	Albumin	1
304	TRIG	Triglycerides	1
305	CHOL	Cholesterol	1
306	AMYL	Amylase	1
306	AMYL	Amylase	3
307	Cl-	Chloride	1
307	Cl-	Chloride	3
308	K+	Potassium	1
308	K+	Potassium	3
309	Na+	Sodium	1
309	Na+	Sodium	3
310	ECO2	Enzymatic CO2	1
311	PHOS	Phosphorus	1
311	PHOS	Phosphorus	3
312	LAC	Lactate	1
314	CREA	Creatinine	1
314	CREA	Creatinine	3
315	UREA	Urea Nitrogen	1

315	UREA	Urea Nitrogen	3
317	Bu	Unconjugated Bilirubin	1
318	Ca	Calcium	1
318	Ca	Calcium	3
319	TBIL	Total Bilirubin	1
320	AST	Aspartate Aminotransferase	1
321	ALKP	Alkaline Phosphatase	1
322	ALT	Alanine Aminotransferase	1
323	LDH	Lactate Dehydrogenase	1
324	CK	Creatine Kinase	1
325	LIPA	Lipase	1
326	GGT	Gamma Glutamyltransferase	1
327	Bc	Conjugated Bilirubin	1
328	THEO	Theophylline	1
329	CKMB	CKMB	1
330	Mg	Magnesium	1
330	Mg	Magnesium	3
331	Fe	Iron	1
332	TIBC	Total Iron Binding Capacity	1
333	PROT	CSF Protein	2
334	SALI	Salicylate	1
335	ALC	Alcohol	1

336	AMON	Ammonia	1
337	CHE	Cholinesterase	1
338	AcP	Acid Phosphatase	1
340	Li	Lithium	1
341	DGXN	Digoxin	1
342	PHBR	Phenobarbitol	1
343	PHYT	Phenytoin	1
344	CRP	C Reactive Protein	1
345	CRBM	Carbamazepine	1
347	ACET	Acetominophen	1
348	UPRO	Urine Protein	3
353	CRPJ	CRPJ	1
354	ALTJ	ALTJ	1
355	ASTJ	ASTJ	1
356	dHDL	Direct HDLC	1
357	ALTV	Alanine Aminotransferase	1
358	ALT2	Alanine Aminotransferase	1
500	TRFRN	Transferrin	1
501	IgG	IgG	1
502	IgM	IgM	1
503	IgA	IgA	1
504	PALB	Prealbumin	1
505	mALB	Microalbumin	3
506	ApoA1	ApoA1	1
507	ApoB	ApoB	1
508	hsCRP	high sensitivity CRP	1

509	C3	C3	1
510	C4	C4	1
511	VALP	Valproic Acid	1
512	GENT	Gentamicin	1
513	TOBRA	Tobramycin	1
514	VANC	Vancomycin	1
515	CAFFN	Caffeine	1
516	HDLmt	direct HDL	1
517	dLDL	direct LDL	1
520	RF	Rhematoid Factor	1
521	AMPH	Amphetamines	3
522	BARB	Barbiturates	3
523	BENZ	Benzodiazepines	3
524	THC	Cannabinoids	3
525	COCM	Cocaine Metabolite	3
526	METD	Methoadone	3
527	OP-LO	Opiates-Low Cutoff	3
528	PCP	Phencyclidine	3
530	dTIBC	Direct TIBC	1
531	ASO	Anti-streptolysin O	1
533	HPT	Haptoglobin	1
534	AAT	Alpha-1-antitrypsin	1
535	dHA1c	Hemoglobin A1c	4
536	dHb	Hemoglobin	4
537	OP-HI	Opiates-High Cutoff	3
539	A1c	Hemoglobin A1c	4
540	Hb	Hemoglobin	4

542	HCY2	Homocysteine	1
900	U/CR	UR/Creatinine Ratio	1
901	AGPK	Anion Gap (K+)	1
902	AGP	Anion Gap	1
903	A/G	A/G Ratio	1
904	NBIL	Neonatal Bilirubin	1
905	DBIL	Direct Bilirubin	1
906	DELB	Delta Bilirubin	1
907	%MB	% CKMB	1
908	OSMO	Osmolality	1
910	GLOB	Globulin	1
911	LDLmt	Derived LDL	1
912	VLDL	VLDL	1
913	C/Hmt	CHOL/dHDL ratio	1
916	LDL	LDL	1
917	C/H	CHOL/dHDL	1
918	d%A1c	%Hemoglobin A1c	4
919	%SAT	% Iron Saturation	1
925	mmA1c	HbA1c	4
927	%A1c	%Hemoglobin A1c	4
928	HbA1c	HbA1c	4
950	HEM	Hemolysis	1
950	HEM	Hemolysis	2
951	ICT	Icterus	1
951	ICT	Icterus	2
952	TUR	Turbidity	1
952	TUR	Turbidity	2

Legend: Body Fluid
0 Unused
1 Serum/Plasma
2 CSF
3 Urine
4 Whole Blood
5 Fluid 1
6 Fluid 2

Diluent Codes

Diluent Code	Diluent Name
1001	Saline
1002	BSA
1003	Water
1004	Specialty
1005	UED
1006	ApoDiluent
1007	DATDil2
1008	DATDil
1020	Lysis Buff

Standard and Conventional Units for Assays

Assay	Conventional	Alternate	International
GLU	mg/dL	g/L	mmol/L
TP	g/dL	-	g/L
URIC	mg/dL	mg/L	µmol/L
ALB	g/dL	µmol/L	g/L

TRIG	mg/dL	g/L	mmol/L
CHOL	mg/dL	g/L	mmol/L
AMYL	U/L	µkat/L	U/L
CI^-	mmol/L	-	mmol/L
K^+	mmol/L	-	mmol/L
Na^+	mmol/L	-	mmol/L
ECO_2	mmol/L	-	mmol/L
PHOS	mg/dL	mg/L	mmol/L
LAC	mmol/L	mg/dL	mmol/L
CREA	mg/dL	mg/L	µmol/L
UREA	mg/dL	mg/dL(A)	mmol/L
BUN	mg/dL	mg/dL	mmol/L
Bu	mg/dL	mg/L	µmol/L
Ca	mg/dL	mg/L	mmol/L
TBIL	mg/dL	mg/L	µmol/L
AST	U/L	µkat/L	U/L
ALKP	U/L	µkat/L	U/L
ALT	U/L	µkat/L	U/L
ALTV	U/L	µkat/L	U/L
LDH	U/L	µkat/L	U/L
CK	U/L	µkat/L	U/L
LIPA	U/L	µkat/L	U/L
GGT	U/L	µkat/L	U/L
Bc	mg/dL	mg/L	µmol/L
THEO	µg/mL	-	µmol/L
CKMB	U/L	µkat/L	U/L
Mg	mg/dL	mEq/L	mmol/L

Fe	µg/dL	mg/L	µmol/L
TIBC	µg/dL	mg/L	µmol/L
PROT	mg/dL	g/L	mg/L
SALI	mg/dL	mg/L	mmol/L
ALC	mg/dL	g/L	mmol/L
AMON	µmol/L	µg/dL	µmol/L
CHE	U/mL	kU/L	U/L
AcP	U/L	hkat/L	U/L
Li	mmol/L	mEq/L	mmol/L
DGXN	ng/mL	µg/L	nmol/L
PHBR	µg/mL	mg/L	µmol/L
PHYT	µg/mL	mg/L	µmol/L
CRP	mg/L	µg/dL	mg/dL
CRBM	µg/mL	mg/L	µmol/L
ACET	µg/mL	mg/dL	µmol/L
UPRO	mg/dL	mg/L	g/L
CRPJ	mg/L	µg/dL	mg/dL
ALTJ	U/L	µkat/L	U/L
ALT2	U/L	µkat/L	U/L
ASTJ	U/L	µkat/L	U/L
dHDL	mg/dL	g/L	mmol/L
TRFRN	mg/dL	-	g/L
IgG	mg/dL	-	g/L
IgM	mg/dL	-	mg/L
IgA	mg/dL	-	mg/L
PALB	mg/dL	-	mg/L
mALB	mg/L	-	

ApoA1	mg/dL	-	g/L
ApoB	mg/dL	-	g/L
hsCRP	mg/L	-	mg/L
C3	mg/dL	-	mg/L
C4	mg/dL	-	mg/L
VALP	µg/mL	mg/L	µmol/L
GENT	µg/mL	mg/L	µmol/L
TOBRA	µg/mL	mg/L	µmol/L
VANC	µg/mL	mg/L	µmol/L
CAFFN	µg/mL	mg/L	µmol/L
HDLmt	mg/dL	g/L	mmol/L
dLDL	mg/dL	-	mmol/L
RF	IU/mL	-	kU/L
U/CR		-	
AGPK	mmol/L	-	mmol/L
AGP	mmol/L	-	mmol/L
A/G	-	-	-
NBIL	mg/dL	mg/L	µmol/L
DBIL	mg/dL	mg/L	µmol/L
DELB	mg/dL	mg/L	µmol/L
%MB	%	%	%
OSMO	mosm/kg	-	mosm/kg
GLOB	g/dL	-	g/L
LDLmt	mg/dL	g/L	mmol/L
VLDL	mg/dL	g/L	mmol/L
AMPH	ng/mL	-	ug/L
BARB	ng/mL	-	ug/L

BENZ	ng/mL	-	ug/L
THC	ng/mL	-	ug/L
COCM	ng/mL	-	ug/L
METD	ng/mL	-	ug/L
OP-LO	ng/mL	-	ug/L
OP-HI	ng/mL	-	ug/L
PCP	ng/mL	-	ug/L
HCY2	umol/L	-	-
dTIBC	ug/dL	mg/L	umol/L
ASO	lU/mL	KIU/L	IU/mL
HPT	mg/dL	-	g/L
AAT	mg/dL	-	g/L
dHA1c	g/dL	-	g/L
dHb	g/dL	-	g/L
C/Hmt	-	-	-
d%A1c	%NGSP	-	-
%SAT	%	-	-
C/H	-	-	-
HEM	-	-	-
ICT	-	-	-
TUR	-	-	-
LDL	mg/dL	g/L	mmol/L
mmA1c	mmol/mol	-	-
A1c	g/dL	-	-
Hb	g/dL	-	-
%A1c	%NGSP	-	-
HbA1c	mmol/mol	-	-

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Download Messages

Code Number	Message	Condition	Action
0	No download condition.		
1	Missing sample ID.	The sample program has a blank sample ID.	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 field(s) could be too long or could contain invalid characters.	Refer to the permitted field size for patient records. Refer to the ASCII Character Chart for a listing of valid characters Correct any size or character errors, 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.	Add the sample position and download program again.
		The sample program has a sample position but no tray name specified.	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 database, but the patient names do not match (last, first, and 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.	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.
14	Invalid assay requested.	An assay was requested which is currently not supported by the VITROS 5,1 FS Chemistry System. The program is accepted but the unsupported assay is deleted from the program.	Refer to 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. The program is accepted and the requested derived test is calculated.	Delete requests for replicating of derived tests and download sample program again. (Derived tests are not allowed to be replicated.)
16	Too many assays.	The sample program includes more than the maximum number of assays allowed (including volume checks).	Edit assay requests so that the sample program does not exceed 40 assays 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 sample on 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 sample from the tray specified in the downloaded program.
19	No assay: 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 between 1 and 100. The product of test dilution factor and standard dilution factor is equal to 1.1 or 1.2.	Change the dilution factor and download the sample program again.
22	Body fluid unknown.	The sample program included a body fluid that the analyzer does not currently support.	Refer to 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 another program including non-pretreated assays. Run each program separately.

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Host Query

The Host Query feature is user configurable to be turned ON or OFF.

A query occurs when a barcoded sample is scanned at primary or STAT metering. No queries occur at the reflex station.

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

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

The analyzer processes all downloaded sample programs (either requested or unsolicited) while the query feature is configured ON.

Host Query Timeout

The user sets a host query timeout (through Options & Configuration - Configure Communications - Configure LIS) to determine how long the analyzer waits for a response to a query.

A timer change goes into effect with the next query.

The host query timer starts when the query record has been 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.
- The analyzer receives indication that no sample program is available for the query (I in the termination code field of the Message Termination Record).
- The analyzer receives indication that an error has occurred (Q in the termination code field of the Message Termination Record).
- The timer expires.

If a query is requested and the timer expires prior to a response to the query, an attention error posts with text substitution displaying the timer value.

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

If a query request is sent and the timer expires, the analyzer sends a query cancel message.

Sending and Receiving Messages

Each query sent is separate message.

Priority of requests from highest to lowest is:

- 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).

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.

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 shall be posted.

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 completes.

Note: If host query is turned OFF, while there are pending queries, those queries waiting to be sent are purged.

Host Query Priority

If a host query request is needed to be sent to the LIS while messages are being downloaded, the download of the current message completes.

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

If results are being uploaded, and a query is requested, the upload stops on a frame boundary, unless the next frame to send is the last.

When a results upload is interrupted due to a query request, the analyzer sends a T (sender cancel) in the Termination Code field of the Message Termination record.

The messages shall upload when no additional queries are pending.

If the upload of results for a patient record was interrupted due to a host query request, all previously transmitted results for that patient are resent along with those results not sent, once upload resumes.

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

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Inventory Query

The system shall accept incoming inventory queries when all the following are met:

- the system is at least at ready state and configured to send and receive
- the hardware required is connected

The system shall send an inventory response when:

- the system is at least at ready state and configured to send and receive
- the hardware required is connected
- no downloads are occurring at the time
- no host queries are in process
- an inventory query was received from the lab computer

An inventory response message shall contain 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 shall contain 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 an inventory query can not be processed the system shall respond with a message containing only a Header and Trailer record. The Termination Code of the Trailer record will be Q (Error in Last Request).

If no inventory could be found for the requested type, the system shall respond with a message containing only a Header and Trailer record. The Termination Code of the Trailer record will be I (No Information Available).

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Asynchronous Notifications

The system shall send a message containing an Automation Configuration Record when all the following are met:

- the system is at least at ready state and configured to send and receive
- the system is configured to send asynchronous messages
- the hardware required is connected
- no downloads are in process
- no host queries are in process
- no inventory queries are in process
- a user has changed automation configuration settings

The system shall send a message containing Error Records when all the following are met:

- the system is at least at ready state and configured to send and receive
- the system is configured to send asynchronous messages
- the hardware required is connected
- no downloads are in process
- no host queries are in process
- an inventory queries are in process
- one or more condition codes have been posted

The system shall exclude the following types of condition codes from transmission:

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

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Character Encoding

By default the system treats all strings as UTF-8 encoded strings (of which ASCII is a subset) enabling the system to handle multi-lingual strings. The UTF-8 standard is ISO/IEC 10646-1. All ASCII characters used in ASTM comply with ANSI Standard X3.4-1986. The Analyzer can be configured to accept extended ASCII strings as specified in ISO-8859-1, instead of UTF-8.

ASCII	Decimal	Hexadecimal	ASCII	Decimal	Hexadecimal	ASCII	Decimal	Hexadecimal
NUL	0	00	+	43	2B	V	86	56
SOH	1	01	, (comma)	44	2C	W	87	57
STX	2	02	-	45	2D	X	88	58
ETX	3	03	.	46	2E	Y	89	59
EOT	4	04	/>	47	2F	Z	90	5A
ENQ	5	05	0	48	30	[	91	5B
ACK	6	06	1	49	31	\	92	5C
BEL	7	07	2	50	32	]	93	5D
BS	8	08	3	51	33	Λ	94	5E
HT	9	09	4	52	34	_ (underscore)	95	5F
LF	10	0A	5	53	35	` (left apostrophe)	96	60
VT	11	0B	6	54	36	a	97	61
FF	12	0C	7	55	37	b	98	62
CR	13	0D	8	56	38	c	99	63
SO	14	0E	9	57	39	d	100	64
SI	15	0F	:	58	3A	e	101	65
DLE	16	10	;	59	3B	f	102	66

DC1	17	11	<	60	3C	g	103	67
DC2	18	12	=	61	3D	h	104	68
DC3	19	13>	>	62	3E	i	105	69
DC4	20	14	?	63	3F	j	106	6A
NAK	21	15	@	64	40	k	107	6B
SYN	22	16	A	65	41	l	108	6C
ETB	23	17	B	66	42	m	109	6D
CAN	24	18	C	67	43	n	110	6E
EM	25	19	D	68	44	o	111	6F
SUB	26	1A	E	69	45	p	112	70
ESC	27	1B	F	70	46	q	113	71
FS	28	1C	G	71	47	r	114	72
GS	29	1D	H	72	48	s	115	73
RS	30	1E	I	73	49	t	116	74
US	31	1F	J	74	4A	u	117	75
SP (space)	32	20	K	75	4B	v	118	76
!	33	21	L	76	4C	w	119	77
"	34	22	M	77	4D	x	120	78
#	35	23	N	78	4E	y	121	79
$	36	24	O	79	4F	z	122	7A
%	37	25	P	80	50	{	123	7B
&	38	26	Q	81	51	|	124	7C
' (apostrophe)	39	27	R	82	52	}	125	7D
(	40	28	S	83	53	~	126	7E
)	41	29	T	84	54	DEL	127	7F
*	42	2A	U	85	55			

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