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GeneXpert Software 4.0
LIS Interface Protocol Specification

Cepheid®

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Change History

GeneXpert Dx 2.1	Introduce LIS interface with ASTM, Protocol, and HL7 versus Protocol.
GeneXpert Xpertise 4.0 and GeneXpert Dx 4.0	Specimen ID field expanded from 20 characters to 25 characters.

1 Overview

1.1 Purpose

This document is intended to be a guide for implementing the ASTM E 1394-97 protocol or the HL7 v2.5 protocol for a host to communicate with the GeneXpert System. The host interface is supported by various GeneXpert software applications. A host could be a Laboratory Information System (LIS) or a Data Management System (DMS). In this guide, you will find detailed information about all of the data that can be exchanged between the GeneXpert System and the host.

1.2 How this Document is Organized

The implementation of the protocols in the GeneXpert System follows the rules described in the ASTM and HL7 standards as much as possible, but some interpretation of it has been necessary when the standard was not detailed enough to complete the implementation. Changes were only made to the standard in order to ease the development of the interface between the GeneXpert System and the LIS. This document describes any interpretation or deviation of the standard that was made in the development of the GeneXpert System connectivity.

For ASTM protocol implementation, refer to:

- Section 2 Physical Layer
- Section 3 Lower Level Transport Protocol
- Section 4 ASTM Message Structure And Content
- Section 5 ASTM Message Transmission Control
- Section 6 ASTM Transmission Scenario

For HL7 protocol implementation, refer to:

- Section 2 Physical Layer
- Section 3 Lower Level Transport Protocol
- Section 7 HL7 Message Structure And Content
- Section 8 HL7 Message Transmission Control
- Section 9 HL7 Transmission Scenario

1.3 Definitions and Acronyms

Host	A host could be a Laboratory Information System (LIS) or a Data Management System (DMS).
LIS	Laboratory Information System
DMS	Data Management System
GX	GeneXpert
ISID	Instrument Specimen Identification

1.4 References

Ref	Description
R1	ASTM E 1394-97 *Standard specification for transferring information between clinical instruments and computer systems* Approved December 10, 1997 – Published March 1998
R2	HL7 v.2.5 *Health Level 7 Messaging Standard* Approved June 26, 2003
R3	LIS1-A formerly ASTM E-1381-02 Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems
R4	*GeneXpert Dx System Operator Manual* or *GeneXpert Infinity-48 System Operator Manual*.

1.5 Document Convention

This protocol document specifies the communication between a GeneXpert System and host computer. Data transmitted from a host computer to a GeneXpert System is called *download*.

Data transmitted from a GeneXpert System to a host computer is called *upload*.

When describing the syntax of the protocol, the following conventions shall be used:

Convention	Meaning
X	1 Element X is required and can only appear once
{X}	1* Element X is required and can appear more than once
[X]	0,1 Element X is not required and can only appear once
[{X}]={[X]}	0* Element X is not required and can appear more than once

Each record is described in table format, with the following columns:

- Field
- Field Name
- Description.

ASTM definitions for the field are:

- Comp.: If the field has only one component, it is empty. If the field has only one repeat, it indicates the component (1, 2, 3). If it has more than one repeat, it indicates the repeat and component (1.1, 1.2, 1.3, 2.1, 2.2).
- Data Type: The data type of the field. Note, there are differences between ASTM and HL7 data types.
- Max. Len.: A dash indicates that length is implicit in the field or that it has no maximum.
- Req.:
  - R: Required.
  - O: Optional.
- Allow repeat: Y (yes) or N (no)
- Values Formats and Comments:
  - Quoted text shall appear exactly as they are written.

1.6 Configuring the GeneXpert LIS Communication Settings

Refer to the appropriate operator manual for instructions on how to configure the GeneXpert LIS Communication Settings:

- For Xpertise 4.0 software, see Chapter 5 (Operating with Host Connectivity) in the *GeneXpert Infinity-48 System Operator Manual* (P/N 300-7381).
- For GX Dx 4.0 software, see Chapter 7 (Operating with Host Connectivity) in the *GeneXpert DX System Operator Manual* (P/N 300-7607).

1.6.1 Setting Up a Test Code for Ordering Tests And Uploading Results

The operator manual provides instructions on how to setup the Assay Host Test Code and Result Test Code. See Chapter 7 (Operating with Host Connectivity) in the *GeneXpert DX System Operator Manual* or Chapter 5 (Operating with Host Connectivity) in the *GeneXpert Infinity-48 System Operator Manual* for details.

2 Physical layer

The GeneXpert LIS interface is built on top of TCP/IP. It is also assumed that the LIS and GeneXpert PC reside in the same network that is protected by a firewall. The transmission of information between the two systems is in clear text.

The GeneXpert System may be configured to support one of the two modes of connection:

- LIS as client and GeneXpert PC as server
- LIS as server and GeneXpert PC as client

3 Lower Level Transport Protocol

3.1 Background

The data link layer has procedures for link connection and release, delimiting and synchronism, sequential control, error detection and error recovery. The application messages passed from the upper layer are framed and then transmitted. The received frames are packaged and then passed to the upper layer. A primary function of this layer is to prevent loss of data between devices.

The Data Link Layer protocol supported by the GeneXpert System is the ASTM E-1381 protocol.

3.2 The ASTM E-1381 Protocol

3.2.1 Overview

This standard uses a character-oriented protocol to send messages between directly connected systems. The coding is the ANSI X3.4-1986 character set, also known as 7-bit ASCII code, and some restrictions are placed on the characters that can appear in the message content.

The data link mode of operation is a one-way transfer of information with alternate supervision. It is a simple stop-and-wait protocol in which information only flows in one direction at a time. Replies occur after information is sent and never at the same time. The sender and receiver use timeouts to detect the loss of communication between them and to provide a method for recovery of the communication.

Once connected, the TCP connection between the two systems is always on. When the two systems are not actively transferring information, the data link is in a Neutral State. There are three phases involved in the transmission of message frames as described below:

Establishment Phase (or Link Connection): determines the direction of information flow and prepares the receiver to accept information.

Transfer Phase: the sender transmits messages to the receiver using frames.

Termination Phase: the link is released and the sender notifies the receiver that all messages are sent.

3.2.2 Establishment Phase (Link Connection)

3.2.2.1 Operation

The establishment phase determines the direction of the information flow and prepares the receiver to accept the information.

The system with information available (sender) initiates the establishment phase to notify the receiver that information is available.

A system that does not have information to send monitors the data link to detect the *Establishment Phase*. It acts as a receiver, waiting for the other system.

The sequence is as follows:

1. The sender determines that the data link is in a *Neutral State*.
2. The sender sends the **<ENQ>** transmission control character to the receiver. The sender will ignore all responses other than **<ACK>**, **<NAK>** or **<ENQ>**.
3. At this point, there are two cases that can occur:
   a. If the receiver is prepared to receive data, it responds with the <ACK> character to the sender. The link connection is established and the *Transfer Phase* is entered.
   b. If the receiver is not ready to receive data, it responds with the **<NAK>** character. Upon receiving a **<NAK>,** the sender will wait at least **10 seconds** before transmitting another **<ENQ>** transmission control character.

3.2.2.2 Contention

When the two systems simultaneously transmit **<ENQ>,** the data link is in *Contention*. In this case, the device has priority.

When an **<ENQ>** is received in response to an **<ENQ>**, the situation is solved as follows:

- The system with priority waits at least **1 second** before sending another **<ENQ>**.
- The system without priority must stop trying to transmit and prepare to receive. When the next **<ENQ>** is received, it replies with an **<ACK>** or **<NAK>** depending on its readiness to receive.

3.2.3 Transfer Phase

During the *Transfer Phase*, the sender will transmit messages to the receiver until all messages are sent.

3.2.3.1 Frames

Messages are sent in frames. Each frame contains a maximum of N+7 bytes (where N= message text characters plus 7 control characters). N is a configurable number which ranges from 240 to 64,000.

Messages longer than N bytes are divided between two or more frames.

Multiple messages are never merged into a single frame. Every message must begin in a new frame.

A frame is one of two types: the *Intermediate Frame* (IF) or the *End Frame* (EF). The only difference is one transmission control character; however, they are semantically different (see below for details)

Intermediate frame	<STX> FN Text <**ETB**> C1 C2 <CR> <LF>
End frame	<STX> FN Text <**ETX**> C1 C2 <CR> <LF>

The last frame of a message is always an *End Frame*. All previous frames are sent as *Intermediate Frames*.

A message containing 240 characters or less is sent in a single *End Frame*.

Longer messages are sent in *Intermediate Frames* with the last part of the message sent in an *End Frame*.

A brief description for each part of a frame is described in the table below:

Frame Part	Frame Part Description
<STX>	Start of Text transmission control character
FN	Frame Number (single digit comprised in the range 0-7) – See details in section 3.2.3.1.1 Frame Number
Text	Data content of Message
<ETB>	End of Transmission Block transmission control character
<ETX>	End of Text transmission control character
C1	Most significant character of checksum (belonging to {0-9, A-F}) – See details in section 3.2.3.1.2 Checksum
C2	Least significant character of checksum (belonging to {0-9, A-F}) – See details in section 3.2.3.1.2 Checksum
<CR>	Carriage Return ASCII character
<LF>	Line Feed ASCII character

3.2.3.1.1 Frame Number

The frame number (FN) permits the receiver to distinguish between new and retransmitted frames.

The frame number begins at 1 for the first frame of the Transfer phase (see below). The frame number is incremented by one for every new frame that is transmitted. After 7, the frame number stops incrementing and starts over at 0, and continues in this fashion.

3.2.3.1.2 Checksum

The checksum permits the receiver to detect a defective frame. The checksum is encoded as two characters.

The checksum is computed by adding the binary values of the characters and keeping the least significant eight bits of the result. It is an addition modulo 256.

The checksum is initialized to zero with the <STX> character. The checksum computation uses the FN, all characters belonging to Text, and <ETB> or <ETX>. The computation for the checksum does not include <STX>, the checksum characters, or the trailing <CR> and <LF>.

The checksum is an integer of eight bits and can be considered as two groups of four bits. Both groups of four bits are converted to the ASCII characters of the hexadecimal representation and transmitted as the message checksum.

Example: A checksum of 91 can be represented as 01011011 in binary or 5B in hexadecimal. The checksum is transmitted as the ASCII character 5 followed by the ASCII character B.

3.2.3.1.3 Acknowledgements

After a frame is sent, the sender stops transmitting until a reply is received (stop-and-wait protocol). The receiver can reply to each frame in three ways:

- A reply of <ACK> means the last frame was successfully received and the receiver is ready to receive the next one. The sender must send a new frame or terminate.
- A reply of <NAK> means the last frame was not successfully received and the receiver is prepared to receive the frame again.
- A reply of <EOT> means the last frame was successfully received, but the receiver requests the sender to stop transmitting.

This reply must be transmitted within the timeout period specified in section 3.2.5.2 Timeouts.

3.2.3.1.4 Receiver Interrupts

During the transfer phase, if the receiver responds to a frame with an <EOT> in place of the usual <ACK>, the sender must interpret this reply as a receiver interrupt request. The <EOT> is a positive acknowledgement of the end frame, signifying the receiver is prepared to receive next frame and is a request to the sender to stop transmitting.

If the sender chooses to ignore the <EOT>, the receiver must re-request the interrupt for the request to remain valid.

If the sender chooses to honor the <EOT>, it must first enter the *Termination Phase* to return the data link to the *Neutral State*. The original sender must not enter the *Establishment Phase* for at least 15 seconds or until the receiver has sent a message and returned the data link to the *Neutral State*.

GeneXpert usage: the GeneXpert System will ignore the interrupt request. The instrument system ignores the <EOT> until the message transmission is completed. If the instrument system receives an <EOT> as an answer to the last frame, it waits 15 seconds before going to the *Establishment Phase*.

3.2.4 Termination Phase (link release)

The *Termination Phase* returns the data link to the *Neutral State*. The sender initiates the *Termination Phase* by transmitting the **<EOT>** character and then regards the link to be in the *Neutral State*. After receiving the **<EOT>**, the receiver also considers the link to be in the *Neutral State*.

3.2.5 Error Recovery

3.2.5.1 Defective Frames

A receiver checks every frame to guarantee it is valid. A reply of <NAK> is transmitted for invalid frames. Upon receiving the <NAK>, the sender re-transmits the last frame with the same frame number.

A frame should be rejected if any of the following situations occur:

- Any character errors are detected (parity errors, framing error).
- The frame checksum does not match the checksum computed on the received frame.
- The frame number is not the same as the last accepted frame or one number higher (modulo 8).
- There are invalid characters in the message body.

Any characters occurring before <STX> or <EOT>, or after the end of the block characters (<ETB> or <ETX>), are ignored by the receiver when checking for frame validity.

Every time the sender tries to transmit a particular frame and receives a <NAK> or any other character different from <ACK> or <EOT> (a <NAK> condition), a re-transmission counter for the given frame is increased. If this counter shows a single frame was sent and not accepted six times, the sender must abort the message by proceeding to the *Termination Phase*.

3.2.5.2 Timeouts

The sender and the receiver use timers to detect loss of communication between them:

- During the *Establishment Phase*, the sender sets a timer when transmitting the <ENQ>. A timeout occurs if a reply of an <ACK>, <NAK> or <ENQ> is not received within 15 seconds. After a timeout, the sender enters the *Termination Phase*.
- During the *Establishment Phase*, if the system without priority detects contention, it sets a timer. If the subsequent <ENQ> is not received within **20 seconds**, it will consider the link to be in the *Neutral State*.
- During the *Transfer Phase*, the sender sets a timer when transmitting the last character of a frame. If the reply is not received within **15 seconds**, a timeout occurs. After a timeout, the sender aborts the message transfer by proceeding to the *Termination Phase*.
- During the *Transfer Phase*, the receiver sets a timer when first entering the transfer phase or when replying to a frame. If a frame or an <EOT> is not received within 30 seconds, a timeout occurs. After a timeout, the receiver discards the last incomplete message and considers the link to be in the *Neutral State*.
- A receiver must reply to a frame within **15 seconds** or the sender will timeout.

3.2.6 Valid Characters in the Text Part

The data link protocol is designed for sending character based message text. There are restrictions on which characters may appear in the message text. These restrictions make it simpler to recognize frames, replies and avoid interfering with software controls for devices.

The restricted characters are: <SOH>, <STX>, <ETX>, <EOT>, <ENQ>, <ACK>, <DLE>, <NAK>, <SYN>, <ETB>, <LF>, <DC1>, <DC2>, <DC3> and <DC4>.

3.2.6.1 Checking Channel Status

To test the connection, the GeneXpert System transmits the ASCII <ENQ> transmission control character, decimal value 5. If the receiving system responds within 15 seconds with one of the following values, the Instrument system will enter the *Termination Phase* and the result of the connection test will be considered a success:

- The ASCII <ACK> transmission control character, decimal value 6,
- The ASCII <NAK> transmission control character, decimal value 21, or
- <ENQ>.

If the instrument system does not receive one of the above responses within 15 seconds, the instrument system will enter the *Termination Phase* and the result of the connection test will be considered a failure.

This is the Lower Level Protocol used to communicate with the LIS Host. The following sections explain the message structure and content.

4 ASTM Message Structure and Content

Messages consist of a hierarchy of records of various types. A record can be defined as an aggregate of fields describing one aspect of the complete message. A field can be seen as a specific attribute of a record, which may contain aggregates of data elements that further define the basic attribute.

4.1 Message Length

The standard does not impose a maximum record length. Outgoing messages can be any length.

4.2 Records

4.2.1 ASTM Records

4.2.1.1 Organization and Hierarchy of Records

The hierarchy of records is comprised of several levels. The record types allowed in each hierarchy level and the hierarchical dependencies between record types are shown below.

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message Header (H)				
	Comment (C)			
	Request Information (Q)			
		Comment (C)		
	Patient Information (P)			
		Comment (C)		
		Test Order (O)		
			Comment (C)	
			Result (R)	
				Comment (C)
Message Terminator (L)				

Due to the use of this hierarchical structure, the following rules have been established:

- A message will always be preceded by a message header record (H), and finished by a message terminator record (L).
- An order record (O) will never appear without a preceding patient information record (P).
- A result record (R) will never appear without a preceding order record (O).
- Comment records (C) can be inserted at any level in the hierarchy (except after a Message Terminator), and it refers to the prior higher-level record.

According to the records hierarchy described above, the following is an example of a message structure and corresponding content:

(Level 0)	MESSAGE HEADER
(Level 1)	PATIENT_1
(Level 2)	COMMENT_1
(Level 2)	ORDER_1
(Level 3)	COMMENT_1
(Level 3)	RESULT_1
(Level 3)	RESULT_2
(Level 4)	COMMENT_1
(Level 4)	COMMENT_2
	.
(Level 3)	RESULT_N
(Level 2)	ORDER_2
(Level 3)	RESULT_1
(Level 3)	RESULT_2
	.
(Level 3)	RESULT_N
	.
(Level 2)	ORDER_N
(Level 3)	RESULT_1
	.
(Level 1)	PATIENT_2
	.
(Level 1)	PATIENT_N
(Level 0)	MESSAGE TERMINATOR

A sequence of patient information records, order records, or result records at one level will be terminated by the appearance of a record type of the same or higher level.

4.3 Fields

4.3.1 Structure

A field is a specific attribute of a record that may contain aggregates of data elements that further define the basic attribute. There are two kinds of fields within a message – the repeat field and the component field.

Repeat field – a single data element that expresses a duplication of the field definition. Each element of a repeat field is treated as having equal priority to associated repeat fields.

Component field – single data element or data elements that express a finer aggregate or extension of data elements which precede it.

Example: A sender's information is recorded as System ID, System Name, and Software Version in a message header, each of which is separated by a component delimiter.

4.3.2 Length

The standard does not impose a maximum field length and assumes that all fields are variable in length. The instrument system implementation restricts the maximum field length to a specific value depending on the field, but never uses more characters than required by the given field value (according to the standard).

Example: For a ten-character length field, only ten character spaces will be used in the message to allow the field content to be between the delimiters.

4.3.3 Character Codes

All data is represented as eight-bit values and single-byte as defined in ISO 8859-1:1987. The eight-bit values within the range from 0 to 127 of ISO 8859-1:1987 correspond to the ASCII standard character set (ANSI X3.4-1986). Values between 128 and 255 are undefined by this standard and are sent using the codepage specified in the instrument system configuration. The use of different codepages allows characters from different cultures to be exchanged without problems. Other characters not represented using the specified codepage are sent escaped using UTF-16 as described in 4.4.3.

Allowed characters in the message: **9, 13, 32-126, 128-254**

Disallowed characters in the message: **0-8, 10-12, 14-31, 127, 255**

The Latin-1 character 13 is reserved as the record terminator.

4.3.4 Data Types

Data Type is the basic building block used to restrict the contents of a data field. In the messages, the following data types are used by the instrument system.

ASTM Data Types used by the GeneXpert System:

Name	Description	Default Length
String	String. Can have a maximum length	
Numeric	Number coded as string. Can have a maximum and minimum value.	
ASTM Date	Timestamp (Date and Time)	14

4.4 Delimiters

4.4.1 Types

Delimiters are used to establish separate sections within a message. There are five different delimiters as described below:

- Record delimiter: it signals the end of any of the defined record type. It is fixed to carriage return character Latin-1 (13) (ASCII 13).
- Field delimiter: it is used to separate adjacent fields. It is configurable and is specified in the message header record. It must be a single character excluding Latin-1 (13) (ASCII 13).
- Repeat delimiter: it is used to separate variable number of descriptors for fields containing parts of equal members of the same set. It is configurable and is specified in the message header record. It must be a single character, excluding Latin-1 (13) (ASCII 13) and the value used by the field delimiter.
- Component delimiter: it is used to separate data elements of fields of a hierarchical or qualifier nature. It is configurable and is specified in the message header record. It must be a single character, excluding Latin-1 (13) (ASCII 13), the value used by the field delimiter and the value used by the repeat delimiter.
- Escape delimiter: it is used within text fields to signify special case operations. It is configurable and is specified in the message header record. It has a complex structure, but mainly uses a single character. The chosen character must be different from Latin-1 (13) (ASCII 13) and the field, repeat, and component delimiter values.

4.4.2 Considerations

Alphanumeric characters should not be used as delimiters, according to the standard. The instrument system implementation allows the use of the following characters as delimiters (boundary values are also included):

- Any value from ASCII (33) to ASCII (47)
- Any value from ASCII (58) to ASCII (64)
- Any value from ASCII (91) to ASCII (96)
- Any value from ASCII (123) to ASCII (126)

The following is the set of instrument system default delimiters for ASTM:

Field delimiter – vertical bar (ASCII 124)	(|) Latin-1 (124)
Repeat delimiter – at (ASCII 64)	(@) Latin-1 (64)
Component delimiter – caret (ASCII 94)	(^) Latin-1 (94)
Escape delimiter – backslash (ASCII 92)	(\ ) Latin-1 (92)

Fields shall be identified by their position, which is determined by counting field delimiters from the front of the record. This position-sensitive identification procedure requires that when the contents of the field are null, its corresponding field delimiter must be included in the record to ensure that the i'th field can be found by counting (i-1) delimiters. Delimiters are not included for trailing null fields.

Example:

For ASTM: |@^\

The following escape sequences are pre-defined:

\H\ (*)	start highlighting text
\N\ (*)	normal text (end highlighting)
\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 See 4.4.3 for more information
\Zcccc\	Local defined escape sequences, used to send characters not represented in the configured codepage. See 4.4.4 for more information.

No escape sequence contains a nested escape sequence, according to the standard.

(*) The escape sequences marked above with an asterisk are ignored by the instrument system

4.4.3 Hexadecimal Escaping

The escaping of ASTM disallowed characters occurs when the instrument system wants to send a character that is not allowed in ASTM. ASCII characters 10, 13, 127, 255 are characters that can be escaped. In this case, the character will be escaped using the hexadecimal escaping. For example, if the instrument system wants to send the character 127, it will be escaped to \X7F\.

4.4.4 Local Escape Sequence

Local escape sequence is used to exchange characters not represented using the configured codepage. For example, if the instrument system wants to send a Japanese character (e.g.., the Unicode character U+34C8) using the English codepage, the character would be lost in a normal transmission because it cannot be represented in that specific codepage.

To avoid losing any characters, those characters that are not represented in the selected codepage are escaped using the local escape sequence. For example, a Japanese character will be sent in four hexadecimal digits as \Z34C8\. Also note, many non-represented codepage characters can be added in the same escape sequence.

5 ASTM Message transmission control

5.1 ASTM Transmission Control

5.1.1 Error Recovery

In order to ensure proper error logging and error recovery, the following rule has been established and is followed according to the standard.

Storage Rule: Since data content is structured in hierarchical fashion, any decreasing change in the hierarchical level triggers storage of all data transmitted prior to said level change, and not previously saved.

An example of the prior rule application is shown below.

Record #	Record Type	Level	(level variation)	Storage action
1	Message Header	L0	(0)	
2	Patient1	L1	(+1)	
3	Order 1	L2	(+1)	
4	Result1	L3	(+1)	
5	Order2	L2	(-1)	{Save 1 – 4}
6	Order3	L2	(0)	
7	Patient2	L1	(-1)	{Save 5 – 6}
8	Order 1	L2	(+1)	
9	Comment1	L3	(+1)	
10	Result 1	L3	(0)	
11	Comment 1	L4	(+1)	
12	Result2	L3	(-1)	{Save 7 – 11}
13	Order 2	L2	(-1)	{Save 12}
14	Patient3	L1	(-1)	{Save 13}
15	Order 1	L2	(+1)	
16	Result 1	L3	(+1)	
17	Message Terminator	L0	(-3)	{Save 14 – 16}

Note: Record # 17 is assumed to be saved by virtue of the record type function.

If a transmission failure occurs, the transmission starts at the last record that is not presumed saved. In order to fulfill hierarchical record level requirements, all records that are necessary to reach the restart record point are repeated prior to transmitting the record where the line failure originally occurred.

An example of required re-transmissions is shown below.

Line failure at	Record Type	Level	(variation)	Storage action	Retransmission of
1	Message Header	L0	(0)	1	
2	Patient1	L1	(+1)	1, 2	
3	Order 1	L2	(+1)		1, 2, 3
4	Result1	L3	(+1)		1, 2, 3, 4
5	Order2	L2	(-1)	{Save 1 – 4}	1, 2, 3, 4, 5
6	Order3	L2	(0)		1, 2, 5, 6
7	Patient2	L1	(-1)	{Save 5 – 6}	1, 2, 5, 6, 7
8	Order 1	L2	(+1)		1, 7, 8
9	Comment1	L3	(+1)		1, 7, 8, 9
10	Result1	L3	(0)		1, 7, 8, 9, 10
11	Comment1	L4	(+1)		1, 7, 8, 9, 10, 11
12	Result2	L3	(-1)	{Save 7 – 11}	1, 7, 8, 9, 10, 11, 12
13	Order2	L2	(-1)	{Save 12}	1, 7, 8, 12, 13
14	Patient3	L1	(-1)	{Save 13}	1, 7, 13, 14
15	Order 1	L2	(+1)		1, 14, 15
16	Result1	L3	(+1)		1, 14, 15, 16
17	Message Terminator	L0	(-3)	{Save 14 – 16}	1, 14, 15, 16, 17

5.1.2 Error Messages

Any error detected by the system communications module is traced in the Synapse folder in the "Windows Event Viewer" in **Settings\Control Panel\Administrative Tools**. **Contact Cepheid Technical Support for an "GX_LIS_Interface_Trace_Utility.bat" batch file, which enables tracing in the Synapse folder. See sections 5.1.2.1 through 5.1.2.3 for details on LIS message tracing**.

The system distinguishes between syntactic and semantic errors which are treated differently:

Syntactic errors occur when the received message does not follow the general protocol rules or the more specific rules defined by the system. Below is a list of errors notified to the LIS host:

- Invalid message: the incoming message is invalid and the system does not know what information is being delivered. This may occur when there are invalid characters in the message or when an unexpected message is received. For example, when the system receives a response and no request has been made.
- Invalid syntax: the incoming message has an invalid syntax. For example, if the hierarchy of records is not followed appropriately.
- Invalid value: the incoming message has a value that is not supported. Consistency among values in different fields is not checked.
- Missing mandatory value: the incoming message does not provide a value for a mandatory field.
- Incomplete message: the incoming message was incomplete.

Semantic errors are errors that are syntactically correct, but the action cannot be executed by the system. The following is a list of semantic errors returned to the LIS host:

- Duplicated test: a test has been received twice. The test is removed.
- Invalid test: the test ordered by the LIS host is unknown. The order is removed.
- Disabled or inconsistent test: the test ordered by the LIS host is disabled or is inconsistent. The order is removed.
- Invalid instrument specimen ID: the LIS host retrieved an invalid instrument specimen ID. The test is removed.
- LIS request not allowed: the system does not allow the LIS host to perform requests for any data. If a request from the LIS is received, the request is cancelled and no data is retrieved.

When any of the errors, syntatic and semantic, listed above are found, the system skips the incorrect part of the message, and continues interpreting it as if no error exists. For extended error information about the part of the message that was skipped, check the synapse event viewer to view the reason, as well as, the protocol part of the message that was discarded.

The following rules describe the part of the message that is rejected when an error is found:

- An error in a header record invalidates the whole message.
- An error in a patient record invalidates all of the orders associated with that patient in the protocol message hierarchy.
- An error in an Order Record invalidates only that Order Record.
- An error in a Comment Record invalidates only the Comment Record, but the Patient or Order Record is accepted if more orders or results exist for that patient/order.

5.1.2.1 Enabling LIS Message Tracing

Enabling LIS Message tracing involves adding a value to the registry. You will need to have the batch file "GX_LIS_Interface_Trace_Utility.bat" to perform these steps.

1. Add the registry entry to enable tracing:
   - Double click on **GX_LIS_Interface_Trace_Utility.bat** and follow the prompts to enable LIS Message tracing.
2. Log off and log on to the PC

   This ensures the registry is reloaded.

5.1.2.2 Generating, Viewing and Troubleshooting Using Trace

1. Ensure there is only one order to be downloaded from the LIS system.
   - When the QueryAll is performed (in step 5), we want to ensure only one order is downloaded from LIS to the GeneXpert.

   This prevents flooding the synapse folder with multiple trace events.
2. Open Event Viewer, Clear the Synapse Events:
   - **Control Panel -> Administrative Tools -> Event Viewer**.
   - Right-click on the Synapse event log, and choose Clear **All Events**.

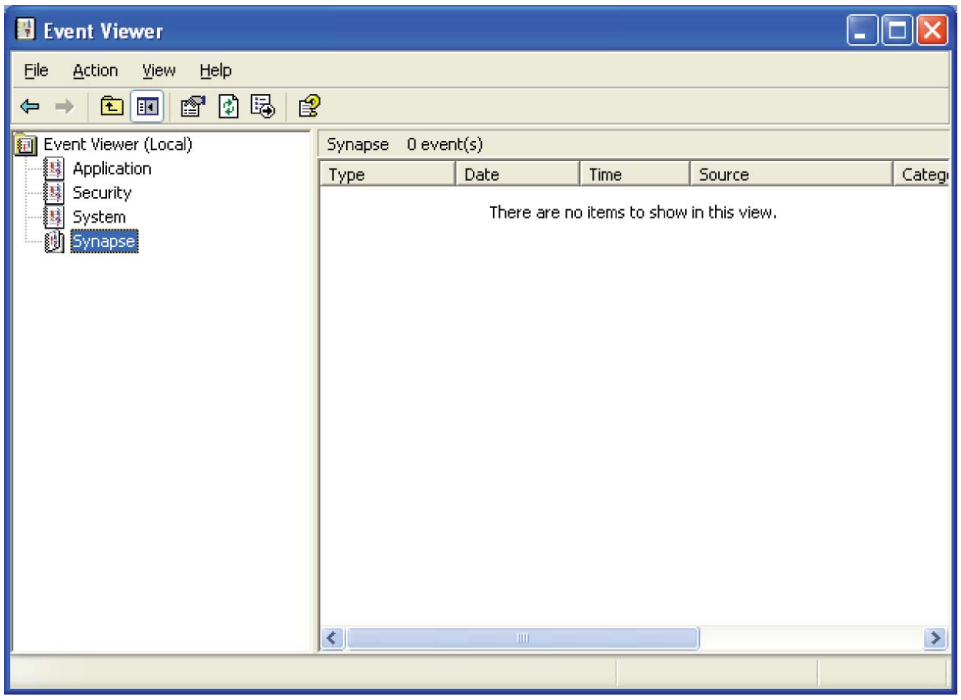


Figure 1— Event Viewer for Synapse

3. Start GeneXpert, (enabling LIS connectivity) perform Host Query.
   - Start GeneXpert, then click **Create Test -> Manual Query.**

   Note: Do not scan a Sample ID or a cartridge barcode. We just want the plain QueryAll followed by the response from the LIS system.

   This will allow the Synapse Events to capture query request from GeneXpert to LIS.

   It will also capture the response from LIS to GX in the Synapse Events.
4. Open, Review and Save the Synapse Events to a log file.
   - Reopen Event Viewer and select the Synapse Event queue (if previously closed).

     - OR -

     Right-click on the Synapse event log, and choose **Refresh** (if not closed).
   - Right-click on the Synapse event log, and choose **Save Log File as…**
   - Enter a log file name (leave the extension as .evt).
   - Email the .evt file to Cepheid Technical Support.

5.1.2.3 Disabling LIS Message Tracing

1. Double-click on **GX_LIS_Interface_Trace_Utility.bat** (the same file used to enable the NTE tracing) and follow the prompts to disable the LIS Message tracing capability.
2. Log off and log on to the PC.

6 ASTM Transmission scenarios

This section details all of the possible scenarios to exchange data between the system and a LIS host using the ASTM protocol.

6.1 Specimen Identification

The system is able to support LIS hosts that reuse Specimen IDs. This means that different patients can have the same Specimen ID in different periods. If this period is short enough (e.g. two consecutive days), some care is required in specimen management.

In order to support these potential situations, the system provides a configurable option Use Instrument Specimen ID to avoid incorrect specimen identification.

If the Use Instrument Specimen ID option is disabled in the GeneXpert System, the Specimen ID is a unique identifier for a specimen. The messages related to uploading the Instrument Specimen ID to the host will not be sent. All fields related to this ISID will be left empty.

If the LIS Host reuses Specimen ID(s), the Use Instrument Specimen ID option must be enabled in the LIS Communications Setting screen in the GeneXpert System . Usually, these laboratories reuse their Specimen ID(s) every week, every day, or even several times in a day. If the laboratory operates in this way, it is possible to find different specimens with the same Specimen ID in normal operation.

The procedure can be described as follows:

1. The LIS host sends to the system information about a specimen with an identifier.
2. The system responds to the LIS host by sending the Specimen ID and an internally generated code (i.e. the Instrument Specimen ID).
3. Both the LIS host and the system agree to use the pair (Instrument Specimen ID and Specimen ID) as the main identifier.
4. Further orders or messages between the LIS host and the system regarding the specimen must use both identifiers as the main identifier.

The Instrument Specimen ID:

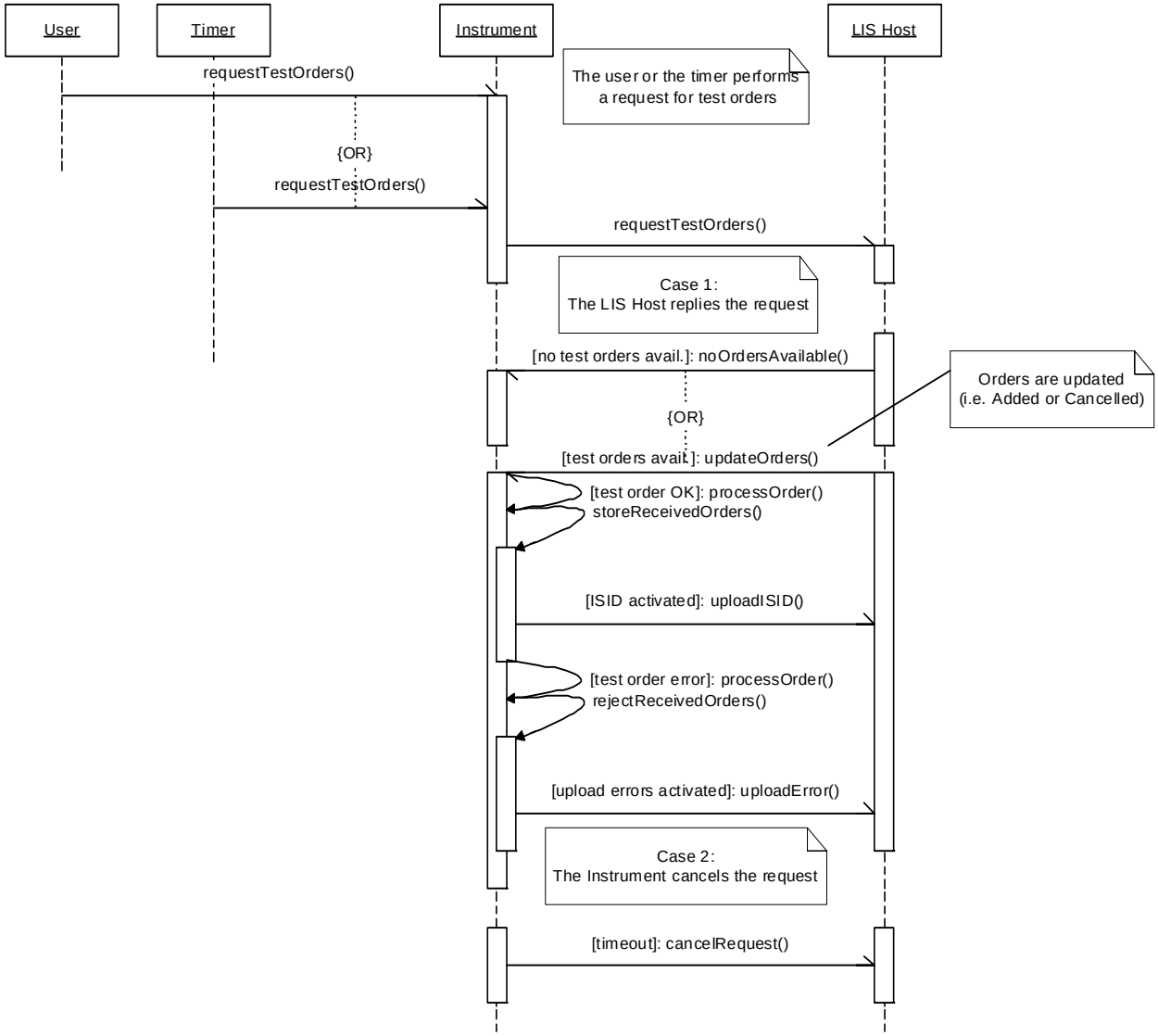
- is generated by the system and reused by the LIS Host.
- is unique within the scope of one system. Different specimens might have the same Instrument Specimen ID in different systems.
- If the Instrument Specimen ID received from the LIS does not match any Instrument Specimen ID stored in the system, the test order is rejected.

6.2 Scenarios

In the following sections, the different types of messages are explained. For each type, there is a sequence diagram that represents the message flow.

6.2.1 Instrument System Queries for All Test Orders and Uploads Instrument Specimen ID to LIS Host

Note: ISID activation and Upload ISID are only applicable if Use ISID is enabled in the GeneXpert instrument software.



6.2.1.1 Instrument System Queries for All Test Orders

This scenario takes place when the system, via a manual or an automatic command, launches a request to the LIS host with the intention to download all available test orders.

- ASTM Messages section 6.3.1

6.2.1.2 Instrument System Returns Instrument Specimen ID for a Downloaded Order

This scenario is applicable only if Use ISID is enabled in the GeneXpert instrument software.

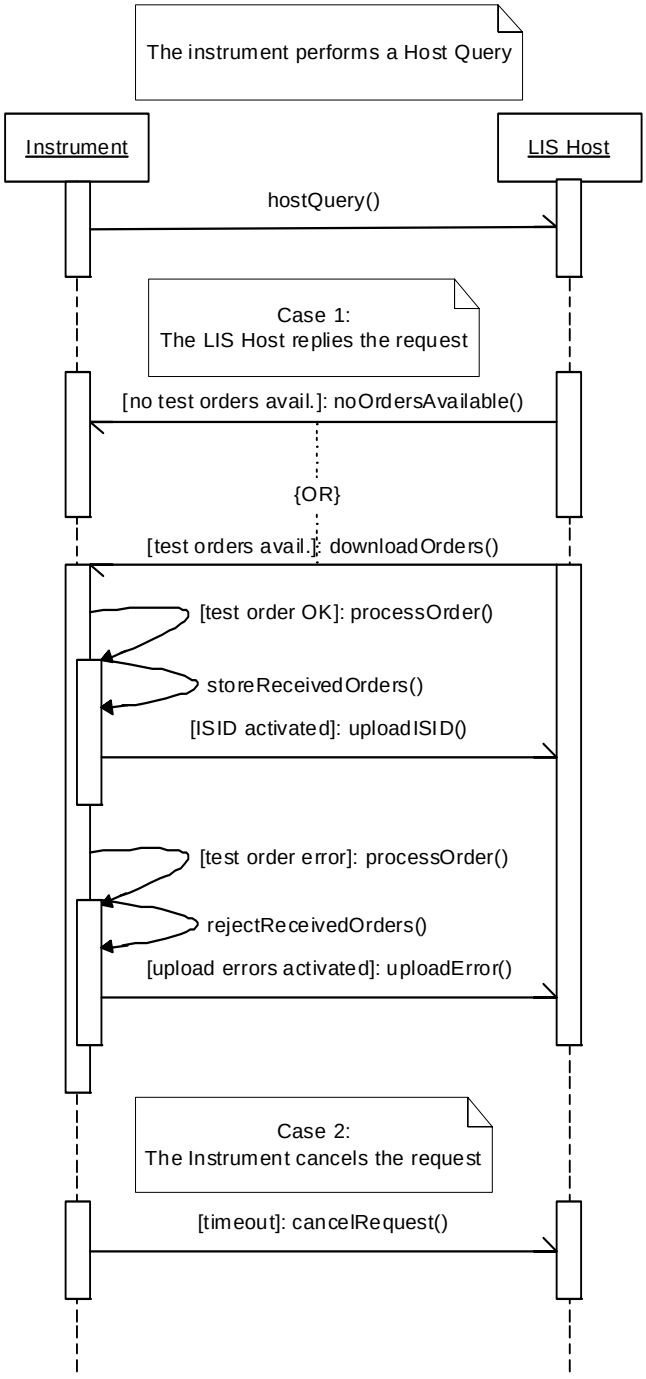
This scenario takes place when the system receives a list of test orders from the LIS host and has the Use Instrument Specimen ID option enabled. For every new specimen that is received, the system generates an internal Specimen ID (known as 'Instrument Specimen ID' in ASTM terminology) and sends it back to the LIS host.

Future LIS host references to these specimens will be performed using both identifiers: 'Specimen ID' and 'Instrument Specimen ID'. In the same way, all information sent back to the LIS host by the instrument will be accompanied by both identifiers.

This scenario takes place after test orders are delivered to the system.

- ASTM Messages section 6.3.3

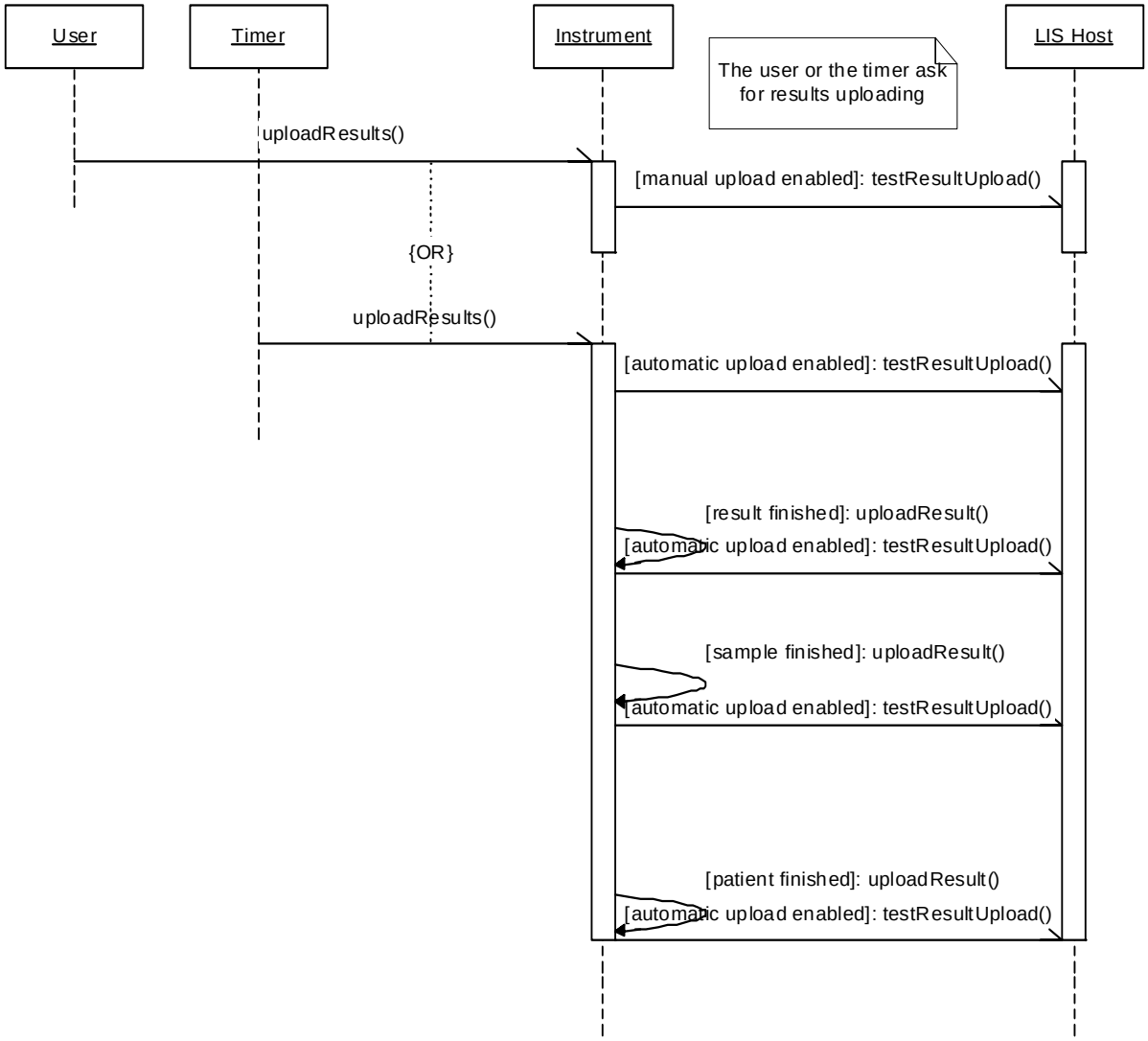
6.2.2 Instrument System Initiates Host Query for One or More Samples



This scenario is triggered when the user performs the host query functionality in the system. The host query allows selective downloading of test orders, taking as input, a single Sample ID or a set of them.

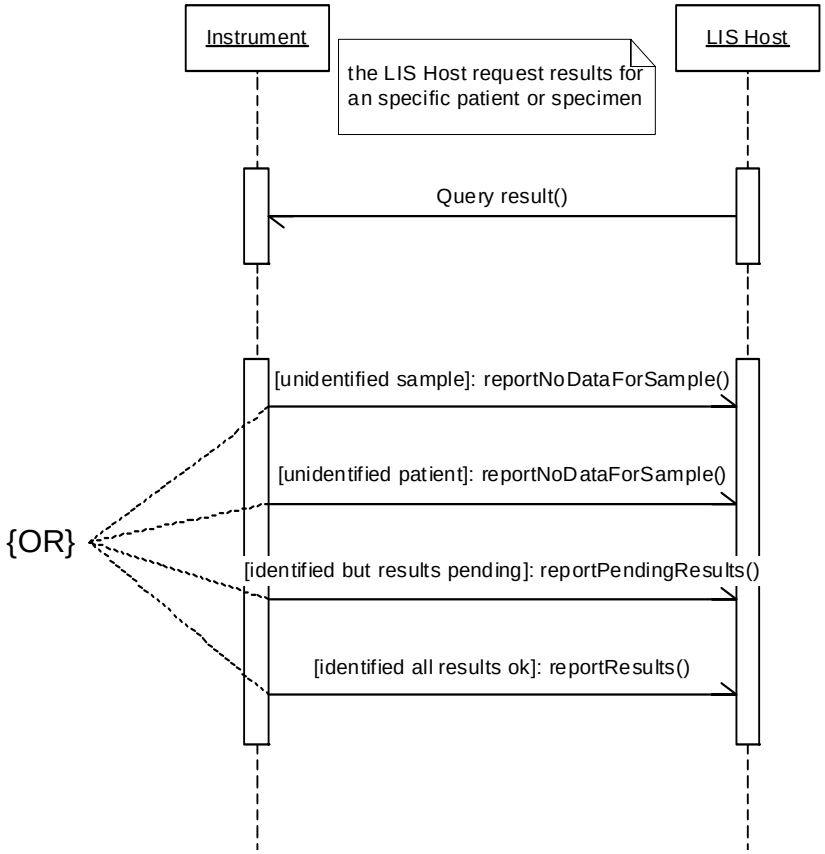
- ASTM Messages section 6.3.2

6.2.3 Instrument System Uploads Test Results



This scenario takes place when the system has been requested to send available test results to the LIS host. This scenario can be executed because the action is triggered manually or automatically. This scenario cannot be triggered by a request from the LIS host.

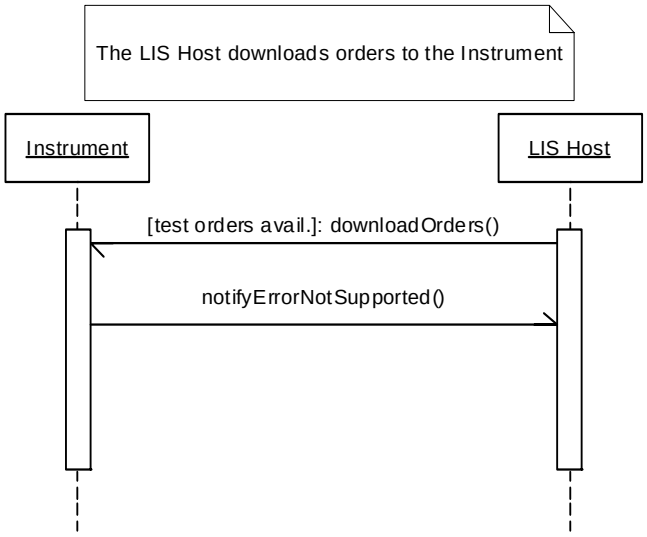
6.2.4 Host Requests Test Results



This scenario takes place when the LIS host launches a request to the system, to upload available test results.

- ASTM Messages section 6.2.5

6.2.5 Host Downloads Unsolicited Test Orders



This scenario takes place when the LIS host decides to download all available test orders to the system. This system does not support operating in this way; consequently, all unsolicited orders downloaded will be rejected.

- See section 6.3.6 “Host Downloads Unsolicited Test Orders” on page 63.

6.3 ASTM Messages

6.3.1 Instrument System Queries for All Test Orders

6.3.1.1 Upload Message – Instrument System Queries for All Test Orders

6.3.1.1.1 Message Structure

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message header (H)				
	Request information (Q)			
Message terminator (L)				

6.3.1.1.2 Message Header Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'H'
2	Delimiter Definition	Define the delimiters to be used throughout the subsequent records of the message	1	String	4	R	N	See section 4.4 for more information
3	Message ID	Uniquely identifies the message	1	String	32	R	N	
5	Sender Name or ID	System ID	1	String	50	R	N	The System Name defined in the system configuration
		System Name	2	String	50	R	N	'GeneXpert'
		Software version	3	String	16	R	N	
10	Receiver ID	Name or ID of the receiver	1	String	20	R	N	The Host ID defined in the system configuration
12	Processing ID	Indicates how this message is to be processed.	1	String	1	R	N	'P' (Production)
13	Version No.	Version level of the current ASTM version specification.	1	String	7	R	N	'1394-97'
14	Date and Time of Message	Date and time the message was generated	1	ASTM Date		R	N	

6.3.1.1.3 Request Information Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'Q'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	String	1	R	N	1
3	Starting Range ID Number		1	String	32	R	N	'ALL'
13	Request Information Status Codes		1	String	1	R	Y	'O' (req. test order) + repetition delimiter + 'N' (request new) (e.g. 'O@N')

6.3.1.1.4 Message Terminator Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'L'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	String	1	R	N	1
3	Termination Code	Provides explanation of end of session	1	String	1	R	N	'N' (normal termination)

6.3.1.1.5 Example of Upload Message – Instrument System Queries for All Test Orders

```
H|@^\|12X||ICU^GeneXpert^1.0|||||LIS||P|1394-97|20070521100245
Q|1|ALL||||||||O@N
L|1|N
```

6.3.1.2 Upload Message – Instrument System Cancels Query for All Test Orders

The system can cancel the last request performed if it hasn't received any message from the LIS host. The cancellation for the last request allows the system to perform another request with higher priority.

Note: Remember that only one request can be performed at a time. The sender cannot transmit another request until the previous one has been answered by the receiver or cancelled by the sender. The system will automatically cancel the request if no answer has been received in 60 seconds.

6.3.1.2.1 Message Structure

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message header (H)				
	Request information (Q)			
		Comment (C)		
Message terminator (L)				

6.3.1.2.2 Message Header Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'H'
2	Delimiter Definition	Define the delimiters to be used throughout the subsequent records of the message	1	String	4	R	N	See section 4.4 for more information
3	Message ID	Uniquely identifies the message	1	String	32	R	N	
5	Sender Name or ID	System ID	1	String	50	R	N	The System Name defined in the system configuration
		System Name	2	String	50	R	N	'GeneXpert'
		Software version	3	String	16	R	N	
10	Receiver ID	Name or ID of the receiver	1	String	20	R	N	The Host ID defined in the system configuration
12	Processing ID	Indicates how this message is to be processed.	1	String	1	R	N	'P' (Production)
13	Version No.	Version level of the current ASTM version specification.	1	String	7	R	N	'1394-97'
14	Date and Time of Message	Date and time the message was generated	1	ASTM Date		R	N	

6.3.1.2.3 Request Information Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'Q'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	String	1	R	N	1
13	Request Information Status Codes		1	String	1	R	N	'A' (abort last request)

6.3.1.2.4 Comment Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'C'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	String		R	N	1,2,3,...n
3	Comment Source	Comment origination point	1	String	1	R	N	'I'
4	Comment Text	Comment id	1	String	50	O	N	'timeout'
		Comment description	2	String	500	O		'last request has been cancelled'
5	Comment Type	Comment type qualifier	1	String	1	R	N	'I'

6.3.1.2.5 Message Terminator Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'L'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	String	1	R	N	1
3	Termination Code	Provides explanation of end of session	1	String	1	R	N	'N' (normal termination)

6.3.1.2.6 Example of Upload Message – Instrument System Cancels Query for all Test Orders

```
H|@^\|ccc6ade20d364214b1a63e287f2314ad||ICU^GeneXpert^1.0|||||LIS||P|1394-97|20070521100245
Q|1||||||||||A
C|1|I|timeout^last request has been cancelled|I
L|1|N
```

6.3.1.3 Download Message – Host Responds with Test Orders for Query

6.3.1.3.1 Message Structure

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message header (H)				
	Patient Information (P)			
		Test Order (O)		
Message terminator (L)				

6.3.1.3.2 Message Header Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'H'
2	Delimiter Definition	Define the delimiters to be used throughout the subsequent records of the message	1	String	4	R	N	See section 4.4 for more information
3	Message ID	Uniquely identifies the message	1	String	32	R	N	
5	Sender Name or ID	Name or ID of the sender	1	String	20	R	N	The Host ID defined in the system configuration
10	Receiver ID	System ID	1	String	50	R	N	The System Name defined in the system configuration
		System Name	2	String	50	R	N	'GeneXpert'
		Software version	3	String	16	R	N	

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
12	Processing ID	Indicates how this message is to be processed.	1	String	1	R	N	'P' (Production)
13	Version No.	Version level of the current ASTM version specification.	1	String	7	R	N	'1394-97'
14	Date and Time of Message	Date and time the message was generated	1	ASTM Date		R	N	

6.3.1.3.3 Patient Information Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record as PIR	1	String	1	R	N	'P'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	Numeric		R	N	1,2,3,...n
5	Patient ID	Patient identification	1	String	32	O	N	

6.3.1.3.4 Test Order Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'O'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	Numeric		R	N	1,2,3,...n
3	Specimen ID	A unique identifier for the specimen assigned by the HOST	1	String	25	R	N	
4	Instrument Specimen ID	A unique identifier for the specimen assigned by the system.	1	String	32	O	N	If Use ISID is enabled, the host must retrieve the ISID if it is available
5	Univ. Test ID	System defined Test ID	4	String	15	R	N	This Assay Test Code field contains the identification of the test

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
6	Priority		1	String	1	R	N	'S' (Stat), 'R' (normal)
7	Ordered Date and Time			ASTM Date	1	O	N	If empty, the current date and time is used
12	Action code	The action that needs to be taken with the order	1	String	1	R	N	'A' (Added in previous specimen or creates a new specimen following the rules of the sample life cycle) 'C' (Cancel order)
16	Specimen Descriptor	Specimen type	1	String	5	R	N	'ORH' ('Other' according to POCT1-A standard)
26	Report Type	Intention of the information contained in the record	1	String	1	R	N	'Q' (Response to query)

6.3.1.3.5 Message Terminator Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record as MTR	1	String	1	R	N	'L'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	String	1	R	N	1
3	Termination Code	Provides explanation of end of session	1	String	1	R	N	'F' (last request processed)

6.3.1.3.6 Example of Download Message – Host with Test Orders for Query

```
H|@^\|ccc6ade20d3623314sffa3e287f2314ad||LIS||||ICU^GeneXpert^1.0||P|1394-97|20070521100245
P|1
O|1|SID-818||^^^TestId-12|S|20070812140500|||||A||||ORH|||||||||Q
O|2|SID-818||^^^TestId-14|R|20070812140600|||||A||||ORH|||||||||Q
O|3|SID-818||^^^TestId-16|R|20070812140700|||||A||||ORH|||||||||Q
P|2
O|1|SID-811||^^^TestId-12|R|20070812140800|||||C||||ORH|||||||||Q
O|2|SID-811||^^^TestId-13|R|20070812140900|||||A||||ORH|||||||||Q
O|3|SID-8|ISID-31|^^^TestId-133|R|20070812150000|||||A||||ORH|||||||||Q
L|1|F
```

6.3.1.4 Download Message – Host Responds with No Available Test Order for Query

This message will appear when there is no test order to download. Also note that if the LIS host doesn't transmit any response and the timeout is reached (60 seconds), the system will assume that the LIS host has no test orders available. In this case, the system will cancel the request as specified in 6.3.1.2.

Note: It is recommended that the LIS host implementers always provide a response to a request. Otherwise, the communication will be stopped until the 60 seconds timeout is reached.

6.3.1.4.1 Message Structure

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message header (H)				
Message terminator (L)				

6.3.1.4.2 Message Header Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'H'
2	Delimiter Definition	Define the delimiters to be used throughout the subsequent records of the message	1	String	4	R	N	See section 4.4 for more information
3	Message ID	Uniquely identifies the message	1	String	32	R	N	
5	Sender Name or ID	Name or ID of the sender	1	String	20	R	N	The Host ID defined in the system configuration
10	Receiver ID	System ID	1	String	50	R	N	The System Name defined in the system configuration
		System Name	2	String	50	R	N	'GeneXpert'
		Software version	3	String	16	R	N	
12	Processing ID	Indicates how this message is to be processed.	1	String	1	R	N	'P' (Production)
13	Version No.	Version level of the current ASTM version specification.	1	String	7	R	N	'1394-97'
14	Date and Time of Message	Date and time the message was generated	1	ASTM Date		R	N	

6.3.1.4.3 Message Terminator Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record as MTR	1	String	1	R	N	'L'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	String	1	R	N	1
3	Termination Code	Provides explanation of end of session	1	String	1	R	N	'I' (no info from last query)

6.3.1.4.4 Example of Download Message – Host Responds with No Available Test Order for Query

```
H|@^\|12XFFFASFASFG11||LIS|||||ICU^GeneXpert^1.0||P|1394-97|20070521100245
L|1|I
```

6.3.1.5 Upload Message – Instrument System Rejects Test Order Initiated From Query

6.3.1.5.1 Message Structure

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message header(H)				
	Patient (P)			
		Order(O)		
			Comment (C)	
Message terminator (L)				

6.3.1.5.2 Message Header Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'H'
2	Delimiter Definition	Define the delimiters to be used throughout the subsequent records of the message	1	String	4	R	N	See section 4.4 for more information
3	Message ID	Uniquely identifies the message	1	String	32	R	N	
5	Sender Name or ID	System ID	1	String	50	R	N	The System Name defined in the system configuration
		System Name	2	String	50	R	N	'GeneXpert'

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
		Software version	3	String	16	R	N	
10	Receiver ID	Name or ID of the receiver	1	String	20	R	N	The Host ID defined in the system configuration
12	Processing ID	Indicates how this message is to be processed.	1	String	1	R	N	'P' (Production)
13	Version No.	Version level of the current ASTM version specification.	1	String	7	R	N	'1394-97'
14	Date and Time of Message	Date and time the message was generated	1	ASTM Date		R	N	

6.3.1.5.3 Patient Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record as PIR	1	String	1	R	N	'P'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	Numeric		R	N	1,2,3,...n
5	Patient ID	Patient identification	1	String	32	O	N	

6.3.1.5.4 Test Order Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'O'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	Numeric		R	N	1
3	Specimen ID	A unique identifier for the specimen assigned by the HOST	1	String	25	R	N	
4	Instrument Specimen ID	A unique identifier for the specimen assigned by the system.	1	String	32	O	N	If Use ISID is enabled, the host must retrieve the ISID if it is available
5	Univ. Test ID	System defined Test ID	4	String	15	R	N	This Assay Host Test Code field contains the identification of the test
6	Priority		1	String	1	R	N	'S' (Stat), 'R' (normal)
7	Ordered Date and Time			ASTM Date	1	O	N	If empty, the current date and time is used
12	Action code	The action that needs to be taken with the order	1	String	1	R	N	'C' (Cancel order)
16	Specimen Descriptor	Specimen type	1	String	5	R	N	'ORH' ('Other' according to POCT1-A standard)
26	Report Type	Intention of the information contained in the record	1	String	1	R	N	'X' (Order cannot be done, cancelled)

6.3.1.5.5 Comment Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'C'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	String		R	N	1
3	Comment Source	Comment origination point	1	String	1	R	N	'I'
4	Comment Text	Comment id	1	String	50	O	N	'InvalidSpecimenData'/ 'DuplicatedTest'/ 'InvalidTestData'/ 'InvalidPatientData'/ 'InvalidTransmissionInformation'
		Comment description	2	String	500	O		'Invalid Instrument Specimen ID or Specimen ID' / 'Duplicated test order'/ 'Test unknown, test disabled or inconsistent test' / 'Invalid Patient identification'/ 'The order has a bad format'
5	Comment Type	Comment type qualifier	1	String	1	R	N	'N' (negative result/error info)

6.3.1.5.6 Message Terminator Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record as MTR	1	String	1	R	N	'L'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	String	1	R	N	1
3	Termination Code	Provides explanation of end of session	1	String	1	R	N	'N' (error in last request)

6.3.1.5.7 Example (this example assumes Use ISID is enabled)

```
H|@^\|c0c1b2a9c40b46e9915d5685af122688||ICU^GeneXpert^1.0|||||LIS||P|1394-97|20070521100245
P|1|||PatientID-1234
O|1|SpecimenID-888|Instr_SpecID-333|^^^MRSA IUO|R|20070521101245|||||C||||ORH|||||||||X
C|1|I|invalidSpecimenData^Invalid Instrument Specimen ID or Specimen ID|N
P|2|||
O|1|SpecimenID-888|Instr_SpecID-333|^^^MRSA IUO|R|20070521101246|||||C||||ORH|||||||||X
C|1|I|invalidSpecimenData^Invalid Instrument Specimen ID or Specimen ID|N
O|2|SpecimenID-888|Instr_SpecID-333|^^^MRSA IUO|R|20070521201245|||||C||||ORH|||||||||X
C|1|I|invalidSpecimenData^Invalid Instrument Specimen ID or Specimen ID |N
L|1|N
```

6.3.2 Instrument System Initiates Host Query for Specific Sample

6.3.2.1 Upload Message – Instrument System Sends Host Query

6.3.2.1.1 Message Structure

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message header (H)				
	Request information (Q)			
Message terminator (L)				

6.3.2.1.2 Message Header Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'H'
2	Delimiter Definition	Define the delimiters to be used throughout the subsequent records of the message	1	String	4	R	N	See section 4.4 for more information
3	Message ID	Uniquely identifies the message	1	String	32	R	N	
5	Sender Name or ID	System ID	1	String	50	R	N	The System Name defined in the system configuration
		System Name	2	String	50	R	N	'GeneXpert'
		Software version	3	String	16	R	N	
10	Receiver ID	Name or ID of the receiver	1	String	20	R	N	The Host ID defined in the system configuration

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
12	Processing ID	Indicates how this message is to be processed.	1	String	1	R	N	'P' (Production)
13	Version No.	Version level of the current ASTM version specification.	1	String	7	R	N	'1394-97'
14	Date and Time of Message	Date and time the message was generated	1	ASTM Date		R	N	

6.3.2.1.3 Request Information Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'Q'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	String	1	R	N	1
3	Starting Range ID Number	Patient ID	1	String	32	O	N	
		Specimen ID	2	String	25	R	N	
13	Request Information Status Codes		1	String	1	R	Y	'O' (req. test order) + repetition delimiter + 'N' (request new orders still not downloaded) (e.g. 'O@N')

6.3.2.1.4 Message Terminator Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'L'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	String	1	R	N	1
3	Termination Code	Provides explanation of end of session	1	String	1	R	N	'N' (normal termination)

6.3.2.1.5 Example of Upload Message – Instrument System Sends Host Query

```
H|@^\|b4a88d9adab947a7b3dca2b534119c25||ICU^GeneXpert^1.0|||||LIS||P|1394-97|20070521100245
Q|1|PatientID-556^SpecimenID-888|||||||||O@N
L|1|N
```

6.3.2.2 Upload Message – Instrument System Cancels Host Query

See section 6.3.1.2 “Upload Message – Instrument System Cancels Query for All Test Orders” on page 23 for more information.

6.3.2.3 Download Message – Host Responds with Test Order(s) for Host Query

The LIS host retrieves test orders for the specified specimen IDs and sends them to the GeneXpert System. The response message has the structure of the message described in section 6.3.1.3.

Example:

System sends Host Query

```
H|@^\|ODM-DjgIkZRA-03||GeneXpert PC^GeneXpert^1.9.32 demo|||||LIS||P|1394-97|200
71121133420
Q|1|^s1|||||||||O@N
L|1|N
```

Host responses with 2 new orders

```
H|@^\|ab067bb88634475187eab185e5651fcb||LIS|||||GeneXpert PC^GeneXpert^1.9.32 de
mo||P|1394-97|20071121133420
P|1|||p1
O|1|s1||^^^FT|R|20071116133208|||||A||||ORH|||||||||Q
O|2|s1||^^^BC|R|20071121104253|||||A||||ORH|||||||||Q
L|1|F
```

6.3.2.4 Download Message – Host Responds with No Available Test Order for Host Query

This message will appear when there is no test order to download for the specified specimen IDs. Also note that if the LIS host does not transmit any response and the timeout is reached (60 seconds), the system will assume that the LIS host has no test orders available. In this case, the system will cancel the request as specified in 6.3.1.4.

6.3.2.5 Upload Message – Instrument System Rejects Test Order Initiated From Host Query

If the orders are malformed, or they request an invalid test, the instrument reports a rejection of the orders with the same rules described in section 6.3.1.5.

6.3.3 Instrument System Returns Instrument Specimen ID for a Downloaded Order

This message will be sent only if Use ISID is enabled in the GeneXpert Instrument Software. The ISID is generated by the system and it is sent when a test order is accepted. Further changes or requests related to that order must contain both the specimen ID and the ISID.

6.3.3.1 Upload Message – Instrument System Responds with Instrument Specimen ID for a Downloaded Order

6.3.3.1.1 Message Structure

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message header (H)				
	Patient Information (P)			
		Test Order (O)		
	...			
Message terminator (L)				

6.3.3.1.2 Message Header Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'H'
2	Delimiter Definition	Define the delimiters to be used throughout the subsequent records of the message	1	String	4	R	N	See section 4.4 for more information
3	Message ID	Uniquely identifies the message	1	String	32	R	N	
5	Sender Name or ID	System ID	1	String	50	R	N	The System Name defined in the system configuration
		System Name	2	String	50	R	N	'GeneXpert'
		Software version	3	String	16	R	N	
10	Receiver ID	Name or ID of the receiver	1	String	20	R	N	The Host ID defined in the system configuration
12	Processing ID	Indicates how this message is to be processed.	1	String	1	R	N	'P' (Production)
13	Version No.	Version level of the current ASTM version specification.	1	String	7	R	N	'1394-97'
14	Date and Time of Message	Date and time the message was generated	1	ASTM Date		R	N	

6.3.3.1.3 Patient Information Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record as PIR	1	String	1	R	N	'P'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	Numeric		R	N	1,2,3,...n
5	Patient ID	Patient identification	1	String	32	O	N	

6.3.3.1.4 Test Order Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'O'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	Numeric		R	N	1
3	Specimen ID	A unique identifier for the specimen assigned by the Host	1	String	25	R	N	
4	Instrument Specimen ID	A unique identifier for the specimen assigned by the instrument	1	String	32	R	N	
12	Action code	The action that needs to be taken with the order	1	String	1	R	N	'P' (pending specimen)
16	Specimen Descriptor	Specimen type	1	String	5	R	N	'ORH' ('Other' following POCT1-A)
26	Report Type	Intention of the information contained in the record	1	String	1	R	N	'I' (Pending in system)

6.3.3.1.5 Message Terminator Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'L'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	String	1	R	N	1
3	Termination Code	Provides explanation of end of session	1	String	1	R	N	'N' (normal termination)

6.3.3.1.6 Example (this example demonstrates Use ISID is enabled)

```
H|@^\|2d315f507a81482eaff8bccdd7c52718||ICU^GeneXpert^1.0|||||LIS||P|1394-97|20070521100245
P|1|||
O|1|SpecimenID-777|Instr_SpecID-555|||||||P||||ORH|||||||||I
P|2|||
O|1|SpecimenID-888|Instr_SpecID-333|||||||P||||ORH|||||||||I
L|1|N
```

6.3.4 Instrument System Uploads Test Results

6.3.4.1 Upload Message – Instrument System Uploads Results

The instrument can upload two types of test results: single-result test results and multi-result test results.

For a single test, each Test Order record is followed by a Result Record.

The system can upload three levels of results:

- Test result (Main result) identified by the test code followed by
- Analyte results (Secondary results for each analyte in the test) followed by
- Complementary results (results related to each analyte) like the Ct, EndPt, etc.

Errors and Notes related to the order are reported on the Comment Records following the Order Record.

If a Test has an error, the Error is reported on the Result Record (Error message) and Comment Record (Error detailed message).

If the system is reporting a panel or battery of tests, each result has the structure described above. In this case, the Order Record contains information about the panel/battery and it is followed by each test result.

For a multi-result test, the system can upload three levels of results:

- Test result (one for each of the multiple results) identified by the assay host test code, result test codes and a result name followed by
- Analyte results (secondary results for each analyte used in this result) followed by XXXX.
- Complementary results (results related to each analyte) like the Ct, EndPt, etc.

Errors and Notes related to the order are reported on the Comment Records following the Order Record.

If a Test has an error, the Error is reported on the Result Record (Error message) and Comment Record (Error detailed message).

6.3.4.1.1 Message Structure

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message header (H)				
	Patient Information (P)			
		Test Order (O)		
			Errors / Notes (C)	
			Main Result (R)	
			Analyte Result (R)	
			Complementary results (R)	
				Error / Notes I(C)
Message terminator (L)				

6.3.4.1.2 Message Header Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'H'
2	Delimiter Definition	Define the delimiters to be used throughout the subsequent records of the message	1	String	4	R	N	See section 4.4 for more information
3	Message ID	Uniquely identifies the message	1	String	32	R	N	
5	Sender Name or ID	System ID	1	String	50	R	N	The System Name defined in the system configuration
		System Name	2	String	50	R	N	'GeneXpert'
		Software version	3	String	16	R	N	
10	Receiver ID	Name or ID of the receiver	1	String	20	R	N	The Host ID defined in the system configuration
12	Processing ID	Indicates how this message is to be processed.	1	String	1	R	N	'P' (Production)
13	Version No.	Version level of the current ASTM version specification.	1	String	7	R	N	'1394-97'
14	Date and Time of Message	Date and time the message was generated	1	ASTM Date		R	N	

6.3.4.1.3 Patient Information Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record as PIR	1	String	1	R	N	'P'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	Numeric		R	N	1,2,3,...n
5	Patient ID	Patient identification	1	String	32	O	N	

6.3.4.1.4 Test Order Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'O'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	Numeric		R	N	1,2,3,...n
3	Specimen ID	A unique identifier for the specimen assigned by the HOST	1	String	25	R	N	
4	Instrument Specimen ID	A unique identifier for the specimen assigned by the system	1	String	32	O	N	If Use ISID is enabled, this is a required field. If Use ISID is disabled, this field is empty.
5	Universal Test ID	System defined Test ID	4	String	15	R	N	This Assay Host Test Code field contains the identification of the test.
6	Priority		1	String	1	R	N	'S' (Stat), 'R' (normal)
7	Ordered Date and Time			ASTM Date	1	O	N	If empty, the current date and time is used
12	Action code	The action that needs to be taken with the order	1	String	1	R	Y	'Q' (if this is a Quality Control specimen) 'C' (order cancelled), 'P' (pending in system), Empty (otherwise)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
16	Specimen Descriptor	Specimen type	1	String	5	R	N	'ORH' ('Other' following POCT1-A)
26	Report Type	Intention of the information contained in the record	1	String	1	R	N	'F' (Final results) 'X' (Order cannot be done, cancelled) 'I' (Test status is pending)

6.3.4.1.5 Comment Record (optional, in case of error)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'C'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	String		R	N	1,2,3,...n
3	Comment Source	Comment origination point	1	String	1	R	N	'I'
		Comment Code	2	String	50	R	N	Error Code
		Comment description	3	String	500	O	N	Error description
5	Comment Type	Comment type qualifier	1	String	1	R	N	'I' (notes) 'N' (error)

6.3.4.1.6 Result Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'R'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	Numeric		R	N	1,2,3,...n
3	Universal Test ID	System defined Panel Test ID	2	String	15	O	N	Empty for a single result test. Assay panel ID for a multi- result test.
		System defined Test ID	4	String	15	R	N	For single-result test, this is the Assay Host Test Code. For multi-result test, this is the Result test code in system configuration.

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
		System defined Test name	5	String	20	O*	N	The assay name shown in system configuration (only at main result for single result or multi-result test); Empty for analyte or complementary results.
		System defined Test version	6	String	4	O*	N	The assay version shown in system configuration (only at main or one of the multi- result)
		Analyte Name / Result name	7	String	20	O	N	Possible values: Result Test Code for a main result in multi-result test. Empty: for a main result in single- result test Analyte Name: for analyte result or complementary result
		Complementary Result Name	8	String	10	O	N	Only used for complementary results (otherwise it is empty). Possible values: 'Ct'/'EndPt'/'Delta Ct'/'Conc' Empty for main result or analyte result.
4	Data or Measurement Value	Observed, calculated or implied result value (Qualitative) Error message if test with error. (i.e. Field 9 = 'X')	1	String	256	O	N	
		Observed, calculated or implied result value (Quantitative)	2	String	20	O	N	Numeric value
5	Units	Abbreviation of units for numerical results	1	String	10	O	N	'%' or empty or to be defined

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
7	Result Abnormal Flags	This field shall indicate the normalcy status of the result.	1	String	2	O	N	L–below low normal H–above high normal LL–below panic normal HH–above panic high <–below absolute low, that is off low scale on an instrument >–above absolute high, that is off high scale on an instrument N–normal A–abnormal U–significant change up D–significant change down B–better, use when direction not relevant or not defined W–worse, use when direction not relevant or not defined
9	Result Status		1	String	1	O*	Y	'F' (final result), 'I' (pending result), 'X' (result cannot be done) And also, eventually, 'C' (Correction of previous result) (e.g. 'F@C')
11	Operator Identification	Operator full name for the test performer	1	String	32	O*	N	Required for overall result
12	Date Time Test Started	Date and time the system started the test	1	ASTM Date		O*	N	Required for overall result
13	Date Time Test Completed	Date and time the system completed the test	1	ASTM Date		O*	N	Required for overall result
14	Instrument Identification	Identifies the PC connected to the instrument	1	String	20	O*	N	Computer System Name
		Identifies the instrument that performed this measurement	2	Numeric		O*	N	Instrument S/N
		Identifies the module that performed this measurement	3	Numeric		O*	N	Module S/N

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
		Identifies the cartridge that performed this measurement	4	Numeric		O*	N	Cartridge S/N
		Reagent Lot ID	5	String	10	O*	N	
		Expiration Date	6	ASTM Date		O*	N	

*These fields are required for the overall result record.

6.3.4.1.6.1 Parsing a result record

To determine if the test has single result or multi-result:

Single or Multi-Result Test	Condition
Single-Result Test	Field 3, component 2 = empty
Multi-Result Test	Field 3, component 2 = not empty (contains Assay Panel ID)

A result record can be in one of the three levels of results:

- Main test result (Main result) followed by one or many Analyte results
- Analyte results (Secondary results for each analyte in the test) followed by one or many Complementary results
- Complementary results (Complementary result belong to each analyte) like the Ct, EndPt, etc.

To determine the result level, these are the rules:

Result Level	Condition	Processing
Main result	Field 3, component 5 = not empty (contains assay name)	For single-result test: Field 3, Component 4 = Host Assay Test Code For multi-result test: Field 3, Component 2 = Host Assay Test Code Field 3, Component 4 = Result Test Code For both types, Field 3, Component 5 = assay name Field 3, Component 6 = the optional assay version number. Field 3, Component 7 = the result name for multi-result test only. Field 4, Component 1 = the qualitative result for this main result. Field 4, Component 2 = the quantitative result for this main result. etc. This main result contains one or more analyte result.
Analyte result	Field 3, component 5 = empty and Field 3, component 7 = not empty (contains analyte name) and Field 3, Component 8 = empty	Field 3, component 7 = analyte name Field 4, Component 1 = the qualitative result for this analyte result. Field 4, Component 2 is not applicable to this analyte result. See Section 6.3.4.1.6 for details about the rest of the fields. This analyte result contains one or more complementary results.

Result Level	Condition	Processing
Complementary result	Field 3, component 5 = empty and Field 3, component 7 = not empty (contains analyte name) and Field 3, component 8 = not empty (contains Complementary result name such as Ct, endPt, Delta Ct)	Field 3, component 7 = analyte name containing this complementary result Field 3, component 8 = complementary result name Field 4, Component 1 is not applicable to this complementary result. Field 4, Component 2 = the quantitative result for this complementary result. See Section 6.3.4.1.6 for details about the rest of the fields.

Example of a single-result test report:

Assay Information

Assay	Assay Version	Assay Type
Xpert EV	2	In Vitro Diagnostic

Test Result: **POSITIVE**

Test and Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result	Curve Fit
EV	33.8	537	POS	PASS	PASS
CIC	36.0	280	NA	PASS	NA

Figure 2— A single-result test report

The Test ID is defined in the Assay Host Test Code field in the "Define Test Code" dialog in the GeneXpert software.

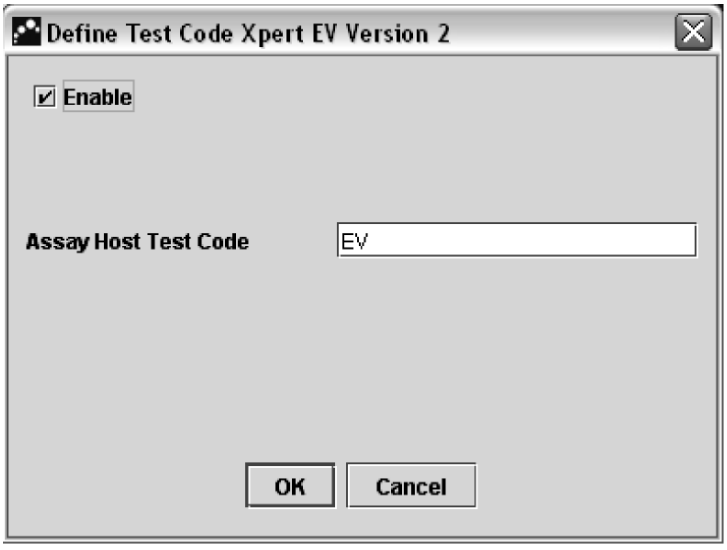


Figure 3— The Define Test Code dialog

Example of a multi-result test report:

Assay Information

Assay	Assay Version	Assay Type
Xpert HemosIL FII & FV	1	In Vitro Diagnostic

Test Result: **FII HOMOZYGOUS;**
FV HOMOZYGOUS

Test and Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
FII 20210G	0	10	NEG	PASS
FII 20210A	24.5	455	POS	PASS
FV 1691G	0	0	NEG	PASS
FV 1691A	25.5	281	POS	PASS

Figure 4— A multi-result test report

The Panel ID is defined in the Assay Host Test Code in the "Define Test Code" dialog in GeneXpert software.

Test ID for each result is defined in the Result Test Code.

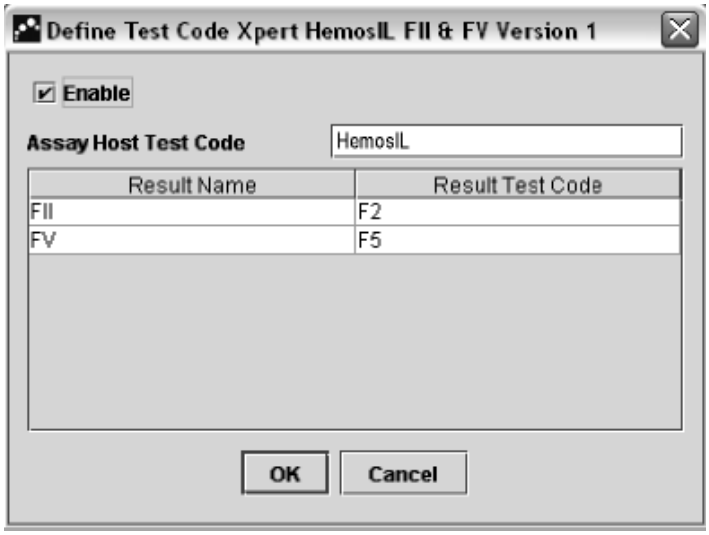


Figure 5— Define Test Code dialog

6.3.4.1.7 Comment Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'C'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	String		R	N	1,2,3,...n
3	Comment Source	Comment origination point	1	String	1	R	N	'I'
4	Comment Text	Comment ID	1	String	10	R	N	'Notes'/'Error'
		Comment Code	2	String	50	O	N	Error Code
		Comment description	3	String	500	R	N	Error description / Note text
		Comment details	4	String	500	O	N	Error details
		Comment Timestamp	5	ASTM Date		O	N	If CommentID is Error, this field is required
5	Comment Type	Comment type qualifier	1	String	1	R	N	'I' (notes) 'N' (error)

6.3.4.1.8 Message Terminator Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'L'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	String	1	R	N	1
3	Termination Code	Provides explanation of end of session	1	String	1	R	N	'N' (normal termination)

6.3.4.1.9 Example of Upload Message – Instrument System Uploads Results Multi-Result Test Result

Note the result name at the main result:

ASTM - Multi-Result Assay

```
H|@^\|URM-Gq3kPdSA-01||CEPHEID^GeneXpert^2.1|||||LIS-1||P|1394-97|20100311153337
P|1|||
O|1|100303FIIFV2001HM+E4||^^^HemosIL|R|20100303114352||||||||ORH|||||||||F
R|1|^HemosIL^^F2^Xpert HemosIL FII & FV^1^FII^|FII HOMOZYGOUS^|||||F||samir alsanady|20100303114352|20100303121429|Sheth-Opt745^704185^602023^26874780^02001^20110912
R|2|^HemosIL^^F2^^^FII 20210G^|NEG^|||
R|3|^HemosIL^^F2^^^FII 20210G^Ct|^0|||
R|4|^HemosIL^^F2^^^FII 20210G^EndPt|^10.0|||
R|5|^HemosIL^^F2^^^FII 20210A^|POS^|||
R|6|^HemosIL^^F2^^^FII 20210A^Ct|^24.5|||
R|7|^HemosIL^^F2^^^FII 20210A^EndPt|^455.0|||
R|8|^HemosIL^^F5^Xpert HemosIL FII & FV^1^FV^|FV HOMOZYGOUS^|||||F||samir alsanady|20100303114352|20100303121429|Sheth-Opt745^704185^602023^26874780^02001^20110912
R|9|^HemosIL^^F5^^^FV 1691G^|NEG^|||
R|10|^HemosIL^^F5^^^FV 1691G^Ct|^0|||
R|11|^HemosIL^^F5^^^FV 1691G^EndPt|^0.0|||
R|12|^HemosIL^^F5^^^FV 1691A^|POS^|||
R|13|^HemosIL^^F5^^^FV 1691A^Ct|^25.5|||
R|14|^HemosIL^^F5^^^FV 1691A^EndPt|^281.0|||
L|1|N
```

6.3.4.1.10 Example of Upload Message – Instrument System Uploads Single-Result Test Result

ASTM – Single Result Assay

```
H|@^\|URM-Q9tSPdSA-01||CEPHEID^GeneXpert^2.1|||||LIS-1||P|1394-97|20100311141419
P|1|||
O|1|100217EVRls2308+M3||^^^EV|R|20100217161021||||||||ORH|||||||||F
R|1|^^^EV^Xpert EV^2^^|POSITIVE^|||||F||Vincent Prakash|20100217161021|20100217184150|Sheth-Opt745^702755^512544^1769789^02308^20110509
R|2|^^^EV^^^EV^|POS^|||
R|3|^^^EV^^^EV^Ct|^33.8|||
R|4|^^^EV^^^EV^EndPt|^537.0|||
R|5|^^^EV^^^CIC^|NA^|||
R|6|^^^EV^^^CIC^Ct|^36.0|||
R|7|^^^EV^^^CIC^EndPt|^280.0|||
L|1|N |
```

6.3.4.1.11 Example of Upload Message – Instrument System Uploads Multi-Result Results with Both Notes and Error:

ASTM - Result - With Error and Notes

```
H|@^\|URM-rEJvTdSA-01||CEPHEID^GeneXpert^2.1|||||LIS-1||P|1394-97|20100312105659

P|1|||

O|1|test-hemo-error||^^^HemosIL|R|20100312084521||||||||ORH|||||||||F

R|1|^HemosIL^^F2^XpertHemosILFII&FV^1^FII^|ERROR^|||||F||support|20100312084521|20100312085758|Sheth-
Opt745^702162^510178^1696533^00901^20110123

C|1|I|Notes^^Iducing Error - Test|I

C|2|I|Error^5006^Post-run analysis error^Error 5006 - [FII 20210G] probe check failed. Probe check value of 491.6 for reading number 1 was
above the maximum of 312.0^20100312085731|N

C|3|I|Error^5006^Post-run analysis error^Error 5006 - [FV 1691G] probe check failed. Probe check value of 258.5 for reading number 1 was above
the maximum of 104.0^20100312085731|N

R|2|^HemosIL^^F2^^^FII 20210G^|NO RESULT^|||

R|3|^HemosIL^^F2^^^FII 20210G^Ct|^0|||

R|4|^HemosIL^^F2^^^FII 20210G^EndPt|^0|||

R|5|^HemosIL^^F2^^^FII 20210A^|NO RESULT^|||

R|6|^HemosIL^^F2^^^FII 20210A^Ct|^0|||

R|7|^HemosIL^^F2^^^FII 20210A^EndPt|^0|||

R|8|^HemosIL^^F5^Xpert HemosIL FII & FV^1^FV^|ERROR^|||||F||support|20100312084521|20100312085758|Sheth-
Opt745^702162^510178^1696533^00901^20110123

C|1|I|Notes^^Iducing Error - Test|I

C|2|I|Error^5006^Post-run analysis error^Error 5006 - [FII 20210G] probe check failed. Probe check value of 491.6 for reading number 1 was
above the maximum of 312.0^20100312085731|N

C|3|I|Error^5006^Post-run analysis error^Error 5006 - [FV 1691G] probe check failed. Probe check value of 258.5 for reading number 1 was above
the maximum of 104.0^20100312085731|N

R|9|^HemosIL^^F5^^^FV 1691G^|NO RESULT^|||

R|10|^HemosIL^^F5^^^FV 1691G^Ct|^0|||

R|11|^HemosIL^^F5^^^FV 1691G^EndPt|^0|||

R|12|^HemosIL^^F5^^^FV 1691A^|NO RESULT^|||

R|13|^HemosIL^^F5^^^FV 1691A^Ct|^0|||

R|14|^HemosIL^^F5^^^FV 1691A^EndPt|^0|||

L|1|N
```

6.3.4.2 Download Message – Host Rejects Uploaded Test Result

If there is an error in the information retrieved by the system from the LIS host, the LIS host cannot retrieve any error information from the system. There are no records transmitted between the system and the LIS host.

6.3.5 Host requests Test Results

6.3.5.1 Download Message – Host Requests Test Result

The instrument allows the LIS host to request results to the instrument system for the available results. The LIS host can ask for results from multiple samples and multiple tests, but only for a single patient.

6.3.5.1.1 Message Structure

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message header (H)				
	Request information (Q)			
Message terminator (L)				

6.3.5.1.2 Message Header Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'H'
2	Delimiter Definition	Define the delimiters to be used throughout the subsequent records of the message	1	String	4	R	N	See section 4.4 for more information
3	Message ID	Uniquely identifies the message	1	String	32	R	N	
5	Sender Name or ID	Name or ID of the sender	1	String	20	R	N	The Host ID defined in the system configuration
10	Receiver ID	System ID	1	String	50	R	N	The System Name defined in the system configuration
		System Name	2	String	50	R	N	'GeneXpert'
		Software version	3	String	16	R	N	
12	Processing ID	Indicates how this message is to be processed.	1	String	1	R	N	'P' (Production)
13	Version No.	Version level of the current ASTM version specification.	1	String	7	R	N	'1394-97'
14	Date and Time of Message	Date and time the message was generated	1	ASTM Date		R	N	

6.3.5.1.3 Request Information Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'Q'
2	Sequence Number	Defines the i-th occurrence of the associated record type	1	String	1	R	N	1
3	Starting Range ID Number	Patient ID	1	String	32	O	N	The Patient ID must be repeated as many times as there are different specimen id or instrument specimen ID. However, it must be the same for all repetitions.
		Specimen ID	2	String	25	R	Y	
		Instrument Specimen ID	3	String	32	O	Y	If Use ISID is enabled, this is a required field. If Use ISID is disabled, this field is ignored.
5	Test ID	System defined Test ID	4	String	15	O	Y	This field contains the identification of the test. The number of repetitions must match the repetitions on component 3.
13	Request Information Status Codes		1	String	1	R	N	'F' (Final Results)

6.3.5.1.4 Message Terminator Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'L'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	String	1	R	N	1
3	Termination Code	Provides explanation of end of session	1	String	1	R	N	'N' (normal termination)

6.3.5.1.5 Example of Download Message – Host requests Test Result

With Patient ID:

```
H|@^\|12XDFASFEE||LIS|||||ICU^GeneXpert^1.0||P|1394-97|20070521100245
Q|1|PatID-12^SpecID-1231^ISID-1121@PatID-12^SpecID-31||^^^TestId@^^^TestId2|||||||F
L|1|N
```

Without Patient ID:

```
H|@^\|12XDFASFEE||LIS|||||ICU^GeneXpert^1.0||P|1394-97|20070521100245
Q|1|^SpecID-1231^ISID-1121@^SpecID-31||^^^TestId@^^^TestId2|||||||F
L|1|N
```

6.3.5.2 Upload Message – Instrument System Returns Results Initiated by Result Request

The system can upload the results for a patient or a specimen. In this scenario, the patient or the specimen is identified.

A maximum of 20 test results can be returned from the instrument.

6.3.5.2.1 Message Structure

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message header (H)				
	Patient Information (P)			
		Test Order (O)		
			Errors (C)	
			Overall Result (R)	
			Secondary	
			Result (R)	
			Complementary results (R)	
				Errors / Notes (C)
Message terminator (L)				

6.3.5.2.2 Message Header Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'H'
2	Delimiter Definition	Define the delimiters to be used throughout the subsequent records of the message	1	String	4	R	N	See section 4.4 for more information
3	Message ID	Uniquely identifies the message	1	String	32	R	N	
5	Sender Name or ID	System ID	1	String	50	R	N	The System Name defined in the system configuration
		System Name	2	String	50	R	N	'GeneXpert'
		Software version	3	String	16	R	N	
10	Receiver ID	Name or ID of the receiver	1	String	20	R	N	The Host ID defined in the system configuration
12	Processing ID	Indicates how this message is to be processed.	1	String	1	R	N	'P' (Production)
13	Version No.	Version level of the current ASTM version specification.	1	String	7	R	N	'1394-97'
14	Date and Time of Message	Date and time the message was generated	1	ASTM Date		R	N	

6.3.5.2.3 Patient Information Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record as PIR	1	String	1	R	N	'P'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	Numeric		R	N	1,2,3,...n
5	Patient ID	Patient identification	1	String	32	O	N	

6.3.5.2.4 Test Order Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'O'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	Numeric		R	N	1,2,3,...n
3	Specimen ID	A unique identifier for the specimen assigned by the Host	1	String	25	R	N	
4	Instrument Specimen ID	A unique identifier for the specimen assigned by the system	1	String	32	O	N	If Use ISID is enabled, this is a required field. If Use ISID is disabled, this field is empty.
5	Universal Test ID	System defined Test ID	4	String	15	R	N	This field contains the identification of the test.
6	Priority		1	String	1	R	N	'S' (Stat), 'R' (normal)
7	Ordered Date and Time			ASTM Date	1	O	N	If empty, the current date and time is used
12	Action code	The action that needs to be taken with the order	1	String	1	R	Y	'Q' (if this is a Quality Control specimen) 'C' (order cancelled) 'P' (pending in system) Empty (otherwise)
16	Specimen Descriptor	Specimen type	1	String	5	R	N	'ORH' ('Other' following POCT1-A)
26	Report Type	Intention of the information contained in the record	1	String	1	R	Y	'Q' (response to query) AND one of these options: 'F' (Final results) 'X' (Order cannot be done, cancelled). 'I' (Test status is pending) e.g.: 'Q@I'

6.3.5.2.5 Comment Record (optional, in case of error)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'C'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	String		R	N	1,2,3,...n
3	Comment Source	Comment origination point	1	String	1	R	N	'I'
		Comment Code	2	String	50	R	N	Error Code
		Comment description	3	String	500	O	N	Error description
5	Comment Type	Comment type qualifier	1	String	1	R	N	'I' (notes) 'N' (error)

6.3.5.2.6 Result Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'R'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	Numeric		R	N	1,2,3,...n
3	Universal Test ID	System defined Panel Test ID	2	String	15	O	N	The host test code defined in system configuration for a multi-result assay
		System defined Test ID	4	String	15	R	N	The host test code defined in system configuration for a single result assay or result within a multi-result assay. If Component 2 and this component are the same, this result is the global result of a multi-result test. Not all multi- result tests have a global result.
		System defined Test name	5	String	20	O*	N	The assay name shown in system configuration (only at main or one of the multi-result)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
		System defined Test version	6	String	4	O*	N	The assay version shown in system configuration (only at main or one of the multi- result)
		Analyte Name / Result name	7	String	20	O	N	Analyte name (empty for main result, required for analyte results) OR Result name (only if this a main result)
		Complementary Result Name	8	String	10	O	N	Only used for complementary results (otherwise it is empty). Possible values: 'Ct'/'EndPt'/'Delta Ct'/'Conc'
4	Data or Measurement Value	Observed, calculated or implied result value (Qualitative) Error message if test with error. (i.e. Field 9 = 'X')	1	String	256	O	N	
		Observed, calculated or implied result value (Quantitative)	2	String	20	O	N	Numeric value
5	Units	Abbreviation of units for numerical results	1	String	10	O	N	'%' or empty or to be defined
7	Result Abnormal Flags	This field shall indicate the normalcy status of the result.	1	String	2	O	N	L–below low normal H–above high normal LL–below panic normal HH–above panic high <–below absolute low, that is off low scale on an instrument >–above absolute high, that is off high scale on an instrument N–normal A–abnormal U–significant change up D–significant change down B–better, use when direction not relevant or not defined W–worse, use when direction not relevant or not defined

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
9	Result Status		1	String	1	O*	Y	'F' (final result), 'I' (pending result), 'X' (result cannot be done) And also, eventually, 'C' (Correction of previous result) (e.g. 'F@C')
11	Operator Identification	Operator full name for the test performer	1	String	32	O*	N	Required for overall result
12	Date Time Test Started	Date and time the system started the test	1	ASTM Date		O*	N	Required for overall result
13	Date Time Test Completed	Date and time the system completed the test	1	ASTM Date		O*	N	Required for overall result
14	Instrument Identification	Identifies the PC connected to the instrument	1	String	20	O*	N	Computer System Name
		Identifies the instrument that performed this measurement	2	Numeric		O*	N	Instrument S/N
		Identifies the module that performed this measurement	3	Numeric		O*	N	Module S/N
		Identifies the cartridge that performed this measurement	4	Numeric		O*	N	Cartridge S/N
		Reagent Lot ID	5	String	10	O*	N	
		Expiration Date	6	ASTM Date		O*	N	

* These fields are required for the overall result record.

6.3.5.2.7 Comment Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'C'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	String		R	N	1,2,3,...n
3	Comment Source	Comment origination point	1	String	1	R	N	'I'
4	Comment Text	Comment ID	1	String	10	R	N	'Notes'/'Error'
		Comment Code	2	String	50	O	N	Error Code
		Comment description	3	String	500	R	N	Error description / Note text
		Comment details	4	String	500	O	N	Error details
		Comment Timestamp	5	ASTM Date		O	N	If CommentID is Error, this field is required
5	Comment Type	Comment type qualifier	1	String	1	R	N	'I' (notes) 'N' (error)

6.3.5.2.8 Message Terminator Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record as MTR	1	String	1	R	N	'L'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	String	1	R	N	1
3	Termination Code	Provides explanation of end of session	1	String	1	R	N	'F' (last request processed)

6.3.5.2.9 Example of Upload Message – Instrument System Returns Results Initiated by Result Request

```
H|@^\|f05227a2aacc49ca942d8b5a08963ced||ICU^GeneXpert^1.0|||||LIS||P|1394-97|20070521100245

P|1|||PatientID-5678

O|1|SpecimenID-888||^^^MRSA IUO|R|20070521101245|||||||ORH|||||||||Q@F

R|1|^^^MRSA IUO^msra test^1.0^^|MRSA POSITIVE^50|||N||F||lab tech
Five|20070521100245|20070521103245|111010100^700668^501562^1147782^201^20070521

R|2|^^^MRSA IUO^^^SCC^|POS^|||N

R|3|^^^MRSA IUO^^^SCC^Ct|^285|||

O|2|SpecimenID-888||^^^MRSA3|R|20070521101245|||||P||||ORH|||||||||Q@I

L|1|F
```

6.3.5.3 Upload Message – Instrument System Returns Results Responding to Request for an Unidentified Patient or Specimen.

The system can upload the results for a patient or a specimen. In this scenario, the patient or the specimen is unidentified in the system. An error message is sent.

6.3.5.3.1 Message Structure

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message header (H)				
	Patient Record (P)			
		Order Record (O)		
Message terminator (L)				

6.3.5.3.2 Message Header Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'H'
2	Delimiter Definition	Define the delimiters to be used throughout the subsequent records of the message	1	String	4	R	N	See section 4.4 for more information
3	Message ID	Uniquely identifies the message	1	String	32	R	N	
5	Sender Name or ID	System ID	1	String	50	R	N	The System Name defined in the system configuration
		System Name	2	String	50	R	N	'GeneXpert'
		Software version	3	String	16	R	N	

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
10	Receiver ID	Name or ID of the receiver	1	String	20	R	N	The Host ID defined in the system configuration
12	Processing ID	Indicates how this message is to be processed.	1	String	1	R	N	'P' (Production)
13	Version No.	Version level of the current ASTM version specification.	1	String	7	R	N	'1394-97'
14	Date and Time of Message	Date and time the message was generated	1	ASTM Date		R	N	

6.3.5.3.3 Patient Information Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record as PIR	1	String	1	R	N	'P'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	Numeric		R	N	1,2,3,...n
5	Patient ID	Patient identification	1	String	32	O	N	

6.3.5.3.4 Test Order Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'O'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	Numeric		R	N	1
3	Specimen ID	A unique identifier for the specimen assigned by the HOST	1	String	25	R	N	
4	Instrument Specimen ID	A unique identifier for the specimen assigned by the GeneXpert System.	1en	String	32	O	N	If Use ISID is enabled, this is a required field. If Use ISID is disabled, this field is empty.
5	Universal Test ID	System defined Test ID	4	String	15	O	N	This field contains the identification of the test.

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
6	Priority		1	String	1	R	N	'S' (Stat), 'R' (normal)
7	Ordered Date and Time			ASTM Date	1	O	N	If empty, the current date and time is used
12	Action code	The action that needs to be taken with the order	1	String	1	O	N	'C' (cancel)
16	Specimen Descriptor	Specimen type	1	String	5	R	N	'ORH' ('Other' following POCT1-A)
26	Report Type	Intention of the information contained in the record	1	String	1	R	Y	'Q' (response to query) AND one of these options: 'Y' (Invalid Test ID) 'Z' (Invalid Patient ID), 'V' (Invalid specimen identification) 'E' (The query has a bad format) e.g.: 'Q@Z'

6.3.5.3.5 Message Terminator Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'L'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	String	1	R	N	1
3	Termination Code	Provides explanation of end of session	1	String	1	R	N	'Q' (error from last query)

6.3.5.3.6 Example of Upload Message – Instrument System Returns Results Responding to Request for an Unidentified Patient or Specimen.

```
H|@^\|4e075416e50c470cba55ed3350c9bec5||ICU^GeneXpert^1.0|||||LIS||P|1394-97|20070521100245
P|1|||
O|1|SID-123456||^^^|R|20070521101245|||||C||||ORH|||||||||Q@Y
O|2|SID-123456||^^^|R|20070521101246|||||C||||ORH|||||||||Q@Y
L|1|Q
```

6.3.6 Host Downloads Unsolicited Test Orders

Host initiated test order download is not supported. If the GeneXpert System receives an order delivery message (section 6.3.6.1) without a pending query, it will send a rejection message detailed in section 6.3.6.2. This scenario may also happen when the host sends an order delivery message after the query was timed out.

6.3.6.1 Download Message – Host Downloads Unsolicited Test Orders

6.3.6.1.1 Message Structure

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message header (H)				
	Patient Information (P)			
		Test Order (O)		
Message terminator (L)				

6.3.6.1.2 Message Header Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'H'
2	Delimiter Definition	Define the delimiters to be used throughout the subsequent records of the message	1	String	4	R	N	See section 4.4 for more information
3	Message ID	Uniquely identifies the message	1	String	32	R	N	
5	Sender Name or ID	Name or ID of the sender	1	String	20	R	N	The Host ID defined in the system configuration
10	Receiver ID	System ID	1	String	50	R	N	The System Name defined in the system configuration
		System Name	2	String	50	R	N	'GeneXpert'
		Software version	3	String	16	R	N	
12	Processing ID	Indicates how this message is to be processed.	1	String	1	R	N	'P' (Production)
13	Version No.	Version level of the current ASTM version specification.	1	String	7	R	N	'1394-97'
14	Date and Time of Message	Date and time the message was generated	1	ASTM Date		R	N	

6.3.6.1.3 Patient Information Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record as PIR	1	String	1	R	N	'P'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	Numeric		R	N	1,2,3,...n
5	Patient ID	Patient identification	1	String	32	O	N	

6.3.6.1.4 Test Order Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'O'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	Numeric		R	N	1,2,3,...n
3	Specimen ID	A unique identifier for the specimen assigned by the HOST	1	String	25	R	N	
4	Instrument Specimen ID	A unique identifier for the specimen assigned by the system	1	String	32	O	N	If Use ISID is enabled, this is a required field. If Use ISID is disabled, this field is empty.
5	Univ. Test ID	System defined Test ID	4	String	15	R	Y	This field contains the identification of the test.
6	Priority		1	String	1	R	N	'S' (Stat), 'R' (normal)
7	Ordered Date and Time			ASTM Date	1	O	N	If empty, the current date and time is used
12	Action code	The action that needs to be taken with the order	1	String	1	R	Y	'A' (Added in previous specimen or creates a new specimen following the rules of the sample life cycle), 'C' (Cancel a previous test request)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
16	Specimen Descriptor	Specimen type	1	String	1	R	N	'ORH' ('Other' according to POCT1-A standard)
26	Report Type	Intention of the information contained in the record	1	String	1	R	Y	'O' (Order record)

6.3.6.1.5 Message Terminator Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'L'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	String	1	R	N	1
3	Termination Code	Provides explanation of end of session	1	String	1	R	N	'N' (normal termination)

6.3.6.1.6 Example of Download Message – Host Downloads Unsolicited Test Orders

```
H|@^\|12X||LIS|||||ICU^GeneXpert^1.0||P|1394-97|20070521100245
P|1|||PatientID-5678
O|1|SID-818|ISID-331|^^^TestId-12|R|20070812140501|||||A||||ORH|||||||||O
O|2|SID-118|ISID-331|^^^TestId-14|R|20070812140601|||||A||||ORH|||||||||O
O|3|SID-811|ISID-431|^^^TestId-16|R|20070812140701|||||A||||ORH|||||||||O
P|2|||
O|1|SID-811|ISID-431|^^^TestId-12|S|20070812140801|||||C||||ORH|||||||||O
O|2|SID-11|ISID-111|^^^TestId-12|R|20070812140901|||||A||||ORH|||||||||O
O|3|SID-8|ISID-31|^^^TestId-133|R|20070812100501|||||A||||ORH|||||||||O
L|1|N
```

6.3.6.2 Upload Message – Instrument System Rejects Unsolicited Test Orders

6.3.6.2.1 Message Structure

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message header (H)				
	Comment (C)			
Message terminator (L)				

6.3.6.2.2 Message Header Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'H'
2	Delimiter Definition	Define the delimiters to be used throughout the subsequent records of the message	1	String	4	R	N	See section 4.4 for more information
3	Message ID	Uniquely identifies the message	1	String	32	R	N	
5	Sender Name or ID	System ID	1	String	50	R	N	The System Name defined in the system configuration
		System Name	2	String	50	R	N	'GeneXpert'
		Software version	3	String	16	R	N	
10	Receiver ID	Name or ID of the receiver	1	String	20	R	N	The Host ID defined in the system configuration
12	Processing ID	Indicates how this message is to be processed.	1	String	1	R	N	'P' (Production)
13	Version No.	Version level of the current ASTM version specification.	1	String	7	R	N	'1394-97'
14	Date and Time of Message	Date and time the message was generated	1	ASTM Date		R	N	

6.3.6.2.3 Comment Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record	1	String	1	R	N	'C'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	String		R	N	1,2,3,...n
3	Comment Source	Comment origination point	1	String	1	R	N	'I'
4	Comment Text	Comment id	1	String	50	O	N	'invalidTransmissionInformation'
		Comment description	2	String	500	O		'Unsolicited downloading orders not supported'
5	Comment Type	Comment type qualifier	1	String	1	R	N	'N' (negative result/ error info)

6.3.6.2.4 Message Terminator Record

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Record Type ID	Identifies the record as MTR	1	String	1	R	N	'L'
2	Sequence Number	Defines the i'th occurrence of the associated record type	1	String	1	R	N	1
3	Termination Code	Provides explanation of end of session	1	String	1	R	N	'N' (error)

6.3.6.2.5 Example of Upload Message – Instrument System Rejects Unsolicited Test Orders

```
H|@^\|45a6a54631c74a1daefb503de5ba7947||ICU^GeneXpert^1.0|||||LIS||P|1394-97|20070521100245
C|1|I|invalidTransmissionInformation^Unsolicited downloading orders not supported|N
L|1|N
```

7 HL7 Message Structure and Content

Messages consist of a hierarchy of records of various types. A record can be defined as an aggregate of fields describing one aspect of the complete message. A field can be seen as a specific attribute of a record, which may contain aggregates of data elements that further define the basic attribute.

7.1 Message Length

The standard does not impose a maximum record length. Outgoing messages can be of any length.

7.2 Records

7.2.1 HL7 Records

7.2.1.1 Message Structure and Content

This section defines the components of messages and provides the methodology for defining abstract messages that are used in later sections. A message is the atomic unit of data transferred between systems. It is comprised of a group of segments in a defined sequence. Each message has a message type that defines its purpose. For example, the ADT Message type is used to transmit portions of a patient's Patient Administration (ADT) data from one system to another. A three-character code contained within each message identifies its type. Messages used by the GeneXpert System are listed below.

HL7 Messages used by the GeneXpert System:

Message	Description
ACK	General Acknowledgement Message
OML	Laboratory Order Message
ORF	Query for Results of Observation
ORU	Observation Result Unsolicited Message
QBP	Query by Parameter
QCN	Cancel Query
QRY	Unsolicited Laboratory Observation Message
RSP	Segment Pattern Response
SSU	Specimen Status Update Message

The real-world event that initiates an exchange of messages is called a trigger event. These events (a three letter code) represent values such as 'A patient is admitted' or 'An order event occurred'. There is a one-to-many relationship between message types and trigger event codes. The same trigger event code may not be associated with more than one message type; however, a message type may be associated with more than one trigger event. Triggers used by the **GeneX**pert System are listed below.

HL7 Triggers used by the GeneXpert System:

Trigger	Description	Initiated by
QBP^Z01	(User defined) Test Order Request	GX
QBP^Z03	(User defined) Host Query	GX
QCN^J01	Cancel Query	GX
SSU^U03	Specimen Update Stats	GX
ORU^R01	Test Results Delivery	GX
QRY^R02	General Query – Request for Results	LIS HOST
OML^O21	Download Orders	LIS HOST

7.2.1.2 Segments

A **segment** is a logical grouping of **data fields**. Segments of a message may be required or optional. They may occur only once in a message or they may be allowed to repeat. Each segment is given a name. For example, the ADT message may contain the following segments: Message Header (MSH), Event Type (EVN), Patient ID (PID), and Patient Visit (PV1).

Each segment is identified by a unique three-character code known as the Segment ID. Segments used by the GeneXpert System are listed below.

HL7 Segments used by the GeneXpert:

Segment	Description
EQU	Equipment Detail
MSA	Message Acknowledgment
MSH	Message Header
NTE	Notes and Comments
OBR	Observation Request
OBX	Observation
ORC	Common Order
PID	Patient Identification
QAK	Query Acknowledgement
QID	Query Identification
QPD	Query Parameter Definition
QRD	Original-Style Query Definition
RCP	Response Control Parameter
SAC	Specimen and Container Detail
SPM	Specimen
TQ1	Timing/Quantity

7.3 Fields

7.3.1 Structure

A field is a specific attribute of a record that may contain aggregates of data elements that further define the basic attribute. There are two kinds of fields within a message – the repeat field and the component field.

Repeat field – a single data element that expresses a duplication of the field definition. Each element of a repeat field is to be treated as having equal priority to associated repeat fields.

Component field – single data element or data elements that express a finer aggregate or extension of data elements which precede it.

Example: A sender's information is recorded as System ID, System Name, and Software Version in a message header, each of which is separated by a component delimiter.

7.3.2 Length

The standard does not impose a maximum field length and assumes that all fields are variable in length. The instrument system implementation restricts the maximum field length to a specific value depending on the field, but never uses more characters than required by the given field value (according to the standard).

Example: For a ten characters length field, only ten characters space will be used in the message to allow the field content to be between the delimiters.

7.3.3 Character Codes

All data is represented as eight bit values and single-byte as defined in ISO 8859-1:1987. The eight-bit values within the range from 0 to 127 of ISO 8859-1:1987 correspond to the ASCII standard character set (ANSI X3.4-1986). Values between 128 and 255 are undefined by this standard and are sent using the codepage specified in the instrument system configuration. The use of different codepages allows characters from different cultures to be exchanged without problems. Other characters not represented using the specified codepage are sent escaped using UTF-16 as described in 4.4.3.

Allowed characters in the message: **9, 13, 32-126, 128-254**

Disallowed characters in the message: **0-8, 10-12, 14-31, 127, 255**

The Latin-1 character 13 is reserved as the record terminator.

7.3.4 Data Types

Data Type is the basic building block used to restrict the contents of a data field. In the messages, the following data types are used by the instrument system.

HL7 Data Types used by the GeneXpert System:

Name	Description	Default Length
ST	String. Can have a maximum length	
HD	System identifier. Coded as string (can have several components)	
ID	Identifier. Coded as string with a limited number of valid values.	
TS	Timestamp (Date and Time)	26
SI	Sequence Integer. Positive integer.	4
MSG	Message Type. Composed by two or three strings that identifies a HL7 message	

7.4 Delimiters

7.4.1 Types

Delimiters are used to establish separate sections within a message. There are five different delimiters as described below:

- Record delimiter: It signals the end of any of the defined record types. It is fixed to carriage return character Latin-1 (13) (ASCII 13).
- Field delimiter: it is used to separate adjacent fields. It is configurable, and is specified in the message header record. It must be a single character excluding Latin-1 (13) (ASCII 13).
- Repeat delimiter: it is used to separate variable number of descriptors for fields containing parts of equal members of the same set. It is configurable, and is specified in the message header record. It must be a single character, excluding Latin-1 (13) (ASCII 13) and the value used by the field delimiter.
- Component delimiter: it is used to separate data elements of fields of a hierarchical or qualifier nature. It is configurable, and is specified in the message header record. It must be a single character, excluding Latin-1 (13) (ASCII 13), the value used by the field delimiter and the value used by the repeat delimiter.
- Subcomponent delimiter: it separates adjacent subcomponents of data fields where allowed. If there are no subcomponents, this character may be omitted.
- Escape delimiter: it is used within text fields to signify special case operations. It is configurable, and is specified in the message header record. It has a complex structure, but mainly uses a single character. The chosen character must be different from Latin-1 (13) (ASCII 13) and the field, repeat, and component delimiter values.

7.4.2 Considerations

Alphanumeric characters should not be used as delimiters, according to the standard. The instrument system implementation allows the use of the following characters as delimiters (Boundary values are also included):

- Any value from ASCII (33) to ASCII (47)
- Any value from ASCII (58) to ASCII (64)
- Any value from ASCII (91) to ASCII (96)
- Any value from ASCII (123) to ASCII (126)

The following is the set of instrument system default delimiters for HL7:

- Field delimiter – vertical bar (|) Latin-1 (124) (ASCII 124)
- Component delimiter – caret (^) Latin-1 (94) (ASCII 94)
- Repeat delimiter – at (~) Latin-1 (126) (ASCII 126)
- Escape delimiter – backslash (\ ) Latin-1 (92) (ASCII 92)
- Subcomponent delimiter (&) Latin-1 (38) (ASCII 38)

Fields must be identified by their position, which is determined by counting field delimiters from the front of the record. This position-sensitive identification procedure requires that when the contents of the field are null, its corresponding field delimiter must be included in the record to ensure that the i'th field can be found by counting (i-1) delimiters. Delimiters are not included for trailing null fields.

Ex:

For HL7: |^~\&

The following escape sequences are pre-defined:

\H\ (*)	start highlighting text
\N\ (*)	normal text (end highlighting)
\F\	embedded field delimiter character
\S\	embedded component field delimiter character
\R\	embedded repeat field delimiter character
\E\	embedded escape delimiter character
\T\	embedded subcomponent delimiter character
\Xhhhh\	hexadecimal data See 4.4.3for more information
\Zcccc\	Local defined escape sequences, used to send characters not represented in the configured codepage. See section 4.4.4 for more information.

No escape sequence contains a nested escape sequence, according to the standard.

(*) The escape sequences marked above with an asterisk are ignored by the instrument system

7.4.3 Hexadecimal Escaping

The escaping of ASTM disallowed characters occurs when the instrument system wants to send a character that is not allowed in ASTM. ASCII characters 10, 13, 127, 255 are characters that can be escaped. In this case, the character will be escaped using the hexadecimal escaping. For example, if the instrument system wants to send the character 127, it will be escaped to \X7F\.

7.4.4 Local Escape Sequence

Local escape sequence is used to exchange characters not represented using the configured codepage. For example, if the instrument system wants to send a Japanese character (e.g., the Unicode character U+34C8) using the English codepage, the character would be lost in a normal transmission because it cannot be represented in that specific codepage.

To avoid losing a character, those characters that are not represented in the selected codepage are escaped using the local escape sequence. For example, a Japanese character will be sent in four hexadecimal digits as \Z34C8\. Also note, that many non-represented codepage characters can be added in the same escape sequence.

8 HL7 Message transmission control

8.1 HL7 Transmission control

The HL7 protocol prescribes two types of acknowledgement – original and enhanced. The GeneXpert System must support the original and the enhanced acknowledgement mode.

The following sections describe the exchange for both types of acknowledgement.

8.1.1 Initiation

The initiation application creates a message with data values according to the rules described in 1.1.

The Message Header Segment (MSH) contains several fields that control the later message flow:

- MSH-10 contains a unique identifier for the message. Acknowledgements must refer to this ID.
- MSH-15 is set to AL, which means that the message requires an accept acknowledgement.
- MSH-16, depending on the nature of the message, can be set to:
  - AL: The message requires an application acknowledgement
  - NE: The message does not require an application acknowledgement.

8.1.2 Response

The responding system returns a general acknowledgment message (ACK) with:

1. A commit accept (CA) in *MSA-1-acknowledgment code* if the message can be accepted for processing.
2. A commit reject (CR) in *MSA-1-acknowledgment code* if the one of the values of *MSH-9-message type*, *MSH-12-version ID* or *MSH-11-processing ID* is not acceptable to the receiving application.
3. A commit error (CE) in *MSA-1-acknowledgment code* if the message cannot be accepted for any other reason (e.g., sequence number error or a required field is not present).

The ACK message contains a NE in fields MSH-15 and MSH-16.

Upon successful validation by the responding system, the message is passed to the receiving application which performs one of these functions:

a. Message processed successfully, which generates the functional response message with a value of AA in MSA-1-acknowledgment code.

b. Error response sent, which provides error information for functional segments that will be included in the response message with a value of AE in MSA-1-acknowledgment code.

c. Failed to process (reject) the message for reasons unrelated to its content or format (system down, internal error, etc.). In most of these cases, it is likely that the responding system will be able to accept the same message at a later time. The implementers must decide on an application-specific basis whether the message should be automatically sent again. The response message contains a value of AR in MSA-1-acknowledgment code.

8.1.3 Error Recovery

8.1.3.1 Resend Timeout

When the GeneXpert System acts as the initiator, the accept acknowledgement must be received in 60 seconds. If it is not, the GeneXpert System must resend the message and wait for the accept acknowledgement. The same message can only be sent a maximum of 3 times.

8.1.3.2 Non–Expected Message Received

If the message does not require an accept acknowledge, the software must take no action.

If the message requires accept acknowledge, the software must reply with a message that contains the defined structure below.

HL7. Upload ACK of a Non Expected Message:

Message	Comments
MSH	Message Header Record
MSA	Message Acknowledgement

The following is an example of a high-level acknowledgement message:

8.1.3.2.1 Message Header Record (MSH)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Field Separator		1	ST	1	R	N	'|'
2	Encoding Characters		1	ST	4	R	N	See 4.4 for more information
4	Sending Application	Name or ID of the sender	1	ST	50	R	N	
6	Receiver ID	System ID	1	ST	50	R	N	The System Name defined in the system configuration
		System Name	2	ST	50	R	N	'GeneXpert'
		Software Version	3	ST	16	R	N	
7	Date and time of Message	Date and time the message was generated	1	TS		R	N	
9	Message Type		1	MSG	15	R	N	'ACK'
10	Message ID	Unique message identifier	1	ST	32	R	N	
11	Processing ID		1	ID	3	R	N	'P' (Production)
12	Version Number	Version of protocol	1	ID	60	R	N	'2.5'
15	Accept Ackn.		1	ID	2	O	N	'NE' (Never)
16	Application Ack.		1	ID	2	O	N	'NE' (Never)

8.1.3.2.2 Message Acknowledgment (MSA)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Acknowl-edgement Code	Acknowledge-ment 'ode		ID	2	R	N	'CR'
2	Message Control ID	From MSH-10 of associated message		ST	20	R	N	
3	Text Message Note			ST	250	N	N	'Non-expected message received'

8.1.4 Error Messages

Any error detected by the system communications module is traced in the Synapse folder in the 'Windows Event Viewer' in **Settings\Control Panel\Administrative Tools. Contact Cepheid Technical Support for an "GX_LIS_Interface_Trace_Utility.bat" batch file, which enables tracing in the Synapse folder. See sections 5.1.2.1 through 5.1.2.3 for details on LIS message tracing**.

9 HL7 Transmission Scenarios

This section details all of the possible scenarios to exchange data between the system and a LIS host. The messages are described for the HL7 protocol.

9.1 Specimen Identification

The system is able to support LIS hosts that reuse Specimen IDs. This means that different patients can have the same Specimen ID in different periods. If this period is short enough, (e.g. two consecutive days) some care is required in specimen management.

In order to support these potential situations, the system provides a configurable option 'Use Instrument Specimen ID' to avoid incorrect specimen identification.

If the Use Instrument Specimen ID option is disabled in the GX Diagnostics Software, the Specimen ID is the unique identifier for a specimen. The messages related to uploading the Instrument Specimen ID to the host will not be sent. All fields related to this ISID will be left empty.

If the LIS Host reuse Specimen ID(s), the Use Instrument Specimen ID option must be enabled in the LIS Communications Setting screen in the GeneXpert Software. Usually, these laboratories reuse their Specimen ID(s) every week, every day, or even several times in a day. If the laboratory operates in this way, it is possible to find different specimens with the same Specimen ID in normal operation.

The procedure can be described as follows:

1. The LIS host sends to the system information about a specimen with an identifier.
2. The system responds to the LIS host sending the Specimen ID and an internally generated code (i.e. the Instrument Specimen ID).
3. Both the LIS host and the system agree to use the pair (Instrument Specimen ID and Specimen ID) as the main identifier.
4. Further orders or messages between the LIS host and the system regarding the specimen must use both identifiers as the main identifier.

The Instrument Specimen ID:

- is generated by the system and reused by the LIS Host.

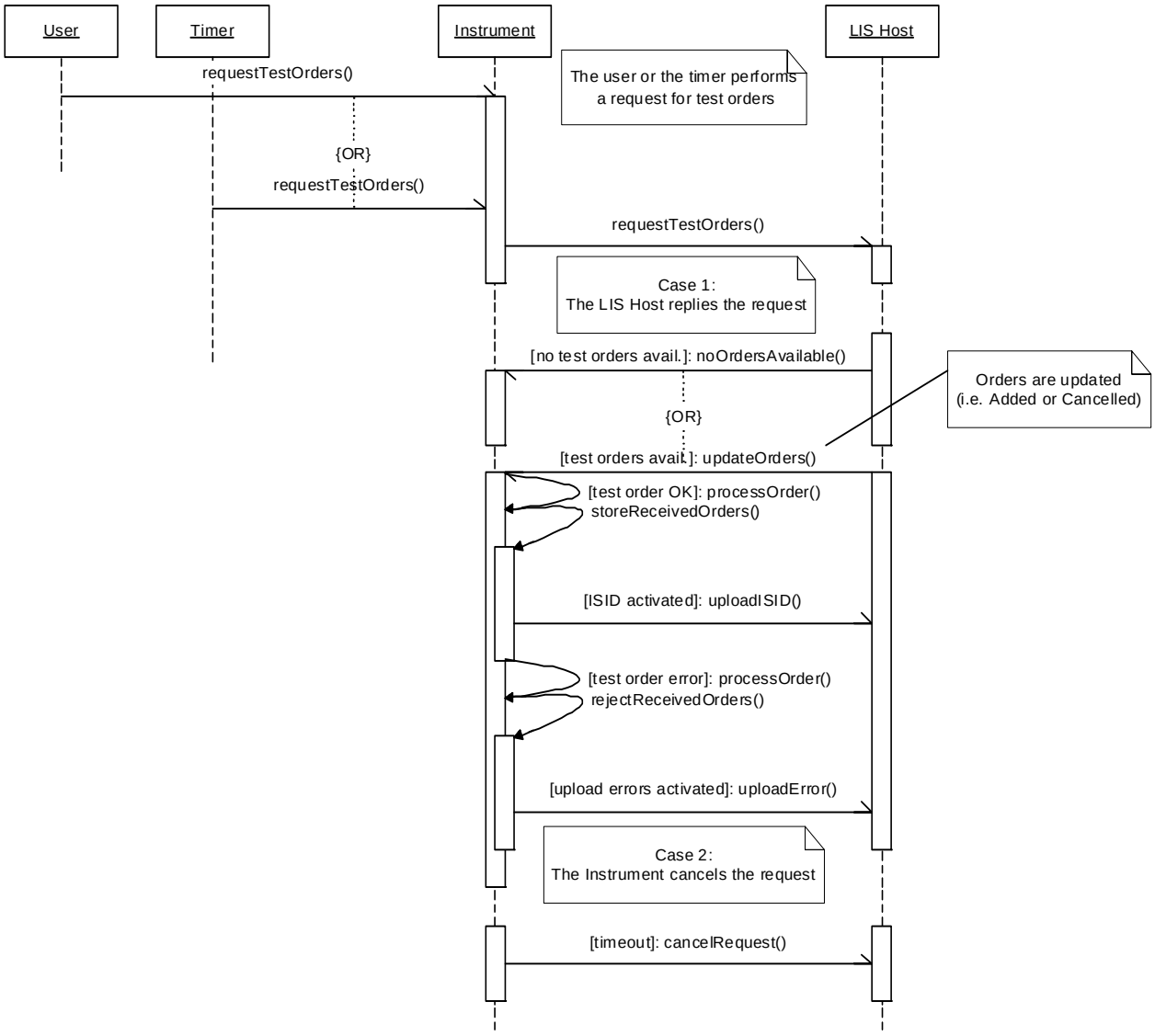
- is unique within the scope of one system. Different specimens might have the same Instrument Specimen ID in different systems.
- If the Instrument Specimen ID received from the LIS does not match any Instrument Specimen ID stored in the system, the test order is rejected.

9.2 Scenarios

In the following sections, the different types of messages are explained. For each type, there is a sequence diagram that represents the message flow.

9.2.1 Instrument System Queries for All Test Orders and Uploads Instrument Specimen IDs to the LIS Host

Note: ISID activation and Upload ISID are only applicable if Use ISID is enabled in the GeneXpert instrument software.



9.2.1.1 Instrument System Queries for All Test Orders

This scenario takes place when the system, via a manual or an automatic command, launches a request to the LIS host with the intention to download all available test orders.

- HL7 Implementation 9.3.1

9.2.1.2 Instrument System Returns Instrument Specimen ID for a Downloaded Order

This scenario is applicable only if Use ISID is enabled in the GeneXpert instrument software.

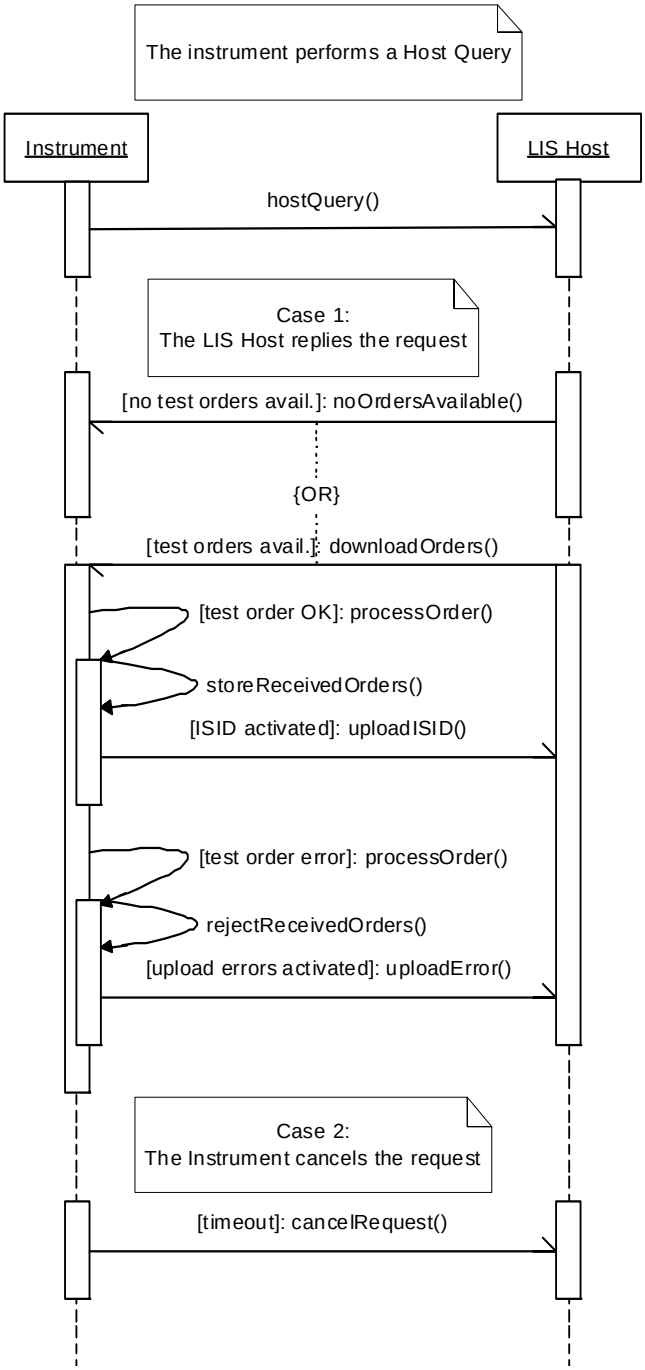
This scenario takes place when the system receives a list of test orders from the LIS host and has the Use Instrument specimen ID option is enabled. For each new specimen that is received, the system generates an internal specimen ID (known as the Instrument Specimen ID in ASTM terminology) and sends it back to the LIS host.

Future LIS host references to these specimens will be performed using both identifiers: Specimen ID and Instrument Specimen ID. In the same way, all information sent back to the LIS host by the instrument will be accompanied by both identifiers.

This scenario takes place after test orders are delivered to the system.

- HL7 Implementation 9.3.3

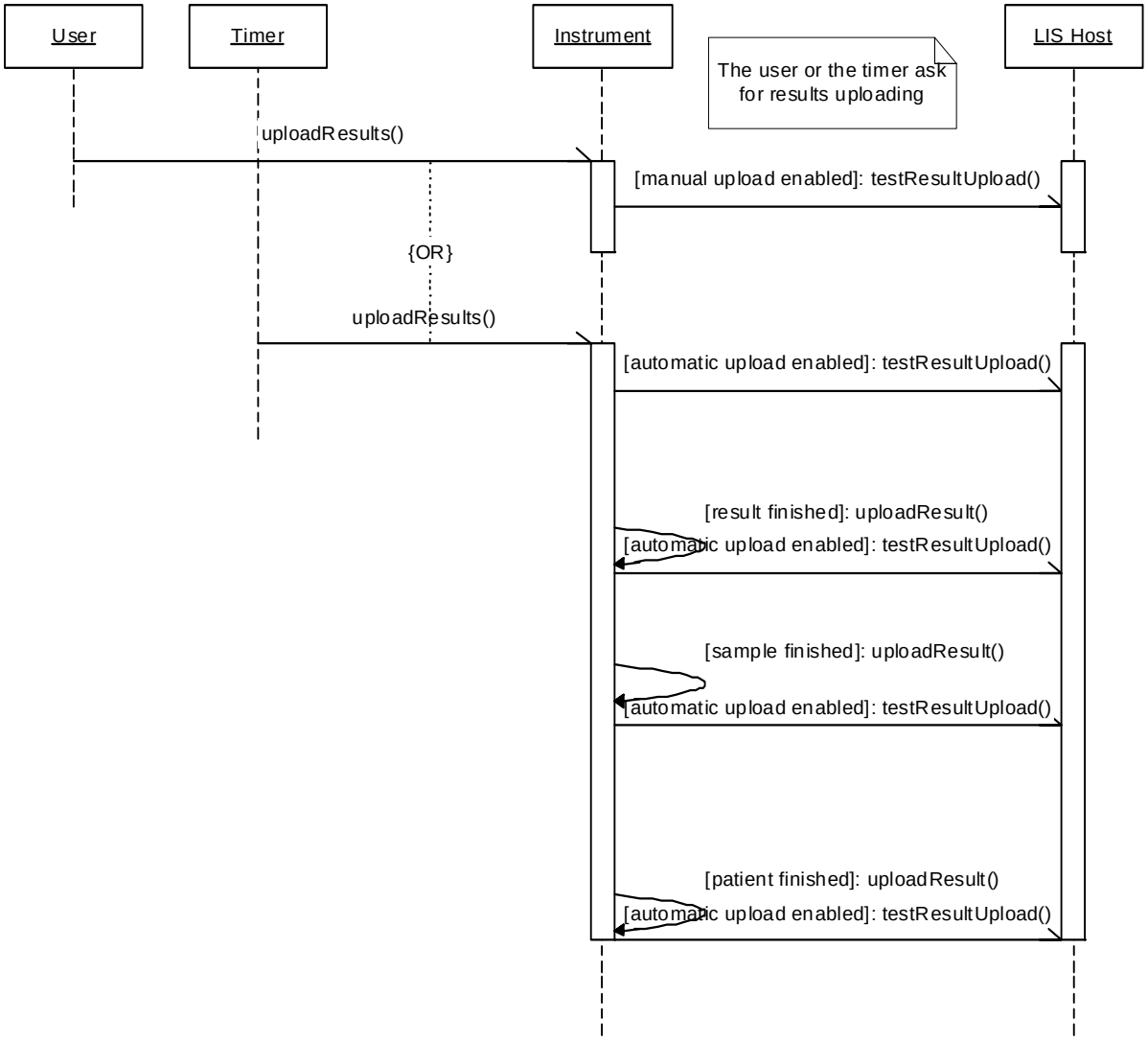
9.2.2 Instrument System Initiates Host Query for One or More Samples



This scenario is triggered when the user performs the host query functionality in the system. The host query allows selective downloading of test orders, taking as input, a single Specimen ID (Sample ID) or a set of them.

- HL7 Implementation 9.3.2

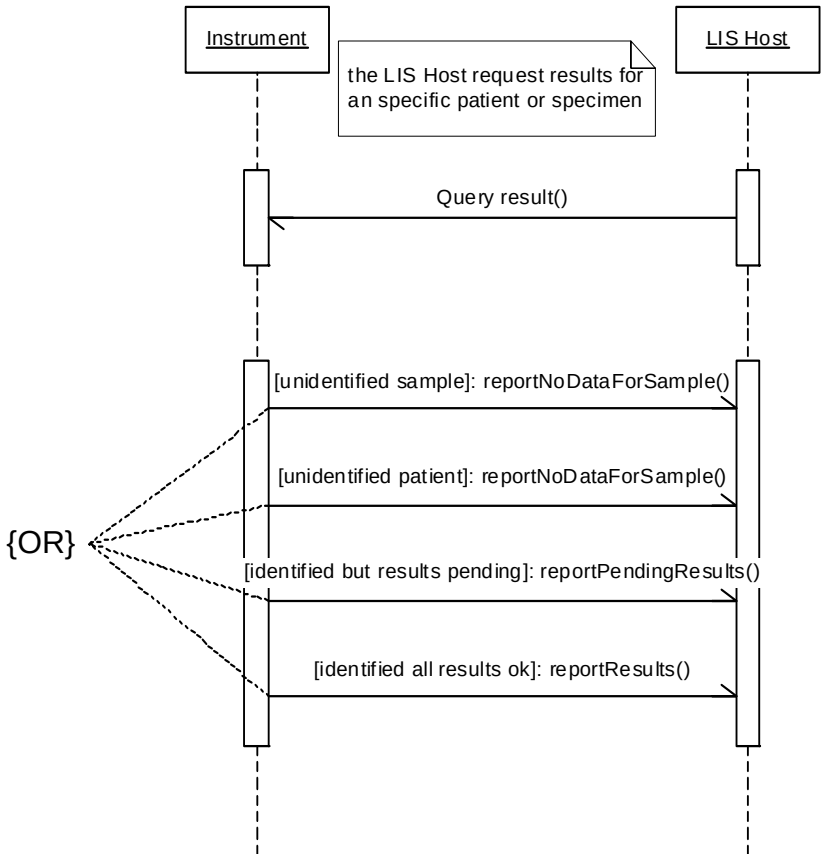
9.2.3 Instrument System Uploads Test Results



This scenario takes place when the system has been requested to send available test results to the LIS host. This scenario can be executed because the action is triggered manually or automatically. This scenario cannot be triggered by a request from the LIS host. Remember, this system does not support a request message for test results that are in the process of uploading.

- HL7 Implementation 9.3.4

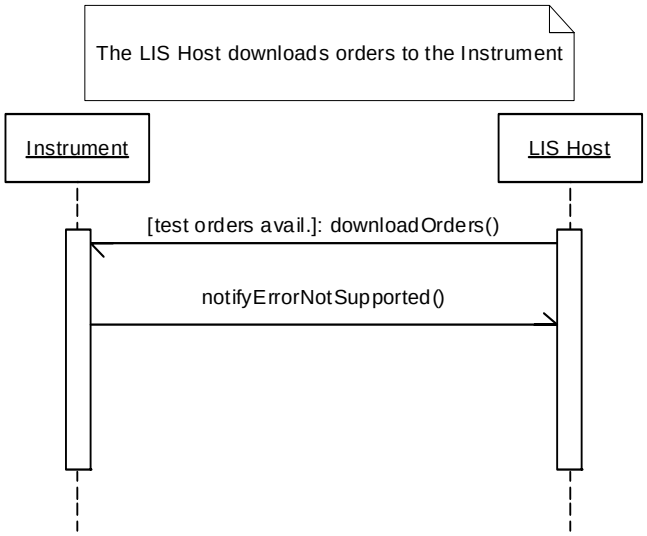
9.2.4 Host requests Test Results



This scenario takes place when the LIS host launches a request to the system, to upload available test results.

- HL7 Implementation 9.3.5

9.2.5 Host Downloads Unsolicited Test Orders



This scenario takes place when the LIS host decides to download all available test orders to the system. This system does not support operating in this way; consequently, all unsolicited orders that are downloaded will be rejected.

- HL7 Implementation 9.3.6

9.3 HL7 Messages

9.3.1 Instrument System Queries for All Test Orders

HL7 recommends one primary way with 3 basic variants for specifying a query (Refer to R2 HL7 specification).

- Query By Simple Parameter
- Query By Example
- Query using the QSC

This service implements the first variant, called the Simple Parameter query. In the simple parameter query, the input parameters are passed in order as successive fields of an HL7 segment. This is the most basic form of the query.

9.3.1.1 Upload Message – Instrument System Queries for All Test Orders (QBP^Z01)

9.3.1.1.1 Message Structure

Message	Comments
MSH	Message Header
QPD	Query Parameter Definition
RCP	Response Control Parameter

9.3.1.1.2 Message Header Segment (MSH)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Field Separator			ST	1	R	N	'|'
2	Encoding Characters			ST	4	R	N	See 7.4.2 for more information
3	Sending Application	System ID	1	ST	50	R	N	The System Name defined in the system configuration
		System Name	2	ST	50	R	N	'GeneXpert'
		Software Version	3	ST	16	R	N	
5	Receiver ID	Name or ID of the receiver	1	ST	50	R	N	The host ID defined in the system configuration
7	Date and time of Message	Date and time the message was generated	1	TS		R	N	
9	Message Type		1	ID	3	R	N	'QBP'
			2	ID	3	R	N	'Z01'
			3	ID	7	O	N	'QBP_Z01'
10	Message ID	Unique message identifier	1	ST	32	R	N	
11	Processing ID		1	ID	3	R	N	'P' (Production)
12	Version Number	Version of protocol	1	ID	60	R	N	'2.5'

9.3.1.1.3 Query Parameter Definition (QPD)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Message Query Name	This field contains the name of the query. These names are assigned by the function-specific chapters of this specification. It is one to one with the conformance statement for this query name, and it is in fact an identifier for that conformance statement. Site-specific query names begin with the letter 'Z.'	1	ST	3	R	N	'Z01'- User defined trigger
			2	ST	100	R	N	'REQUEST TEST ORDERS'
2	Query Tag	Valued by the initiating system to identify the query, and used to match response messages to the originating query. The responding system is required to echo it back as the first field in the query acknowledgement segment (QAK). This field differs from MSA-2-Message control ID in that its value remains constant for each message (i.e. all continuation messages) associated with the query, whereas MSA-2 Message control ID may vary with each continuation message, since it is associated with each individual message, not the query as a whole.	1	ST	32	R	N	Unique identifier
3	User Parameter 1	Indicates that all the order records must be retrieved	1	ST	32	R	N	'ALL'

9.3.1.1.4 Response Control Parameter (RCP)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Query Priority	Deferred (D) or Immediate (I)	1	ID	1	R	N	'I' – Immediate

9.3.1.1.5 Example of Upload Message – Instrument System Queries for All Test Orders (QBP^Z01)

```
MSH|^~\&|ICU^GeneXpert^1.0||LIS||20070521100245||QBP^Z01^QBP_Z01|94799a8b48bb4b7fb2fce229c3a371c8|P|2.5
QPD|Z01^REQUEST TEST ORDERS|94799a8b48bb4b7fb2fce229c3a371c8|ALL
RCP|I
```

9.3.1.2 Upload Message– Instrument System Cancels Query for All Test Orders (QCN^J01 / ACK^J01)

The system can cancel the last request performed if it hasn't received any message from the LIS host. The cancellation for the last request allows the system to perform another request with higher priority.

Note: Remember that only one request can be performed at a time. The sender cannot transmit another request until the previous one has been answered by the receiver or cancelled by the sender. The system will automatically cancel the request if no answer has been received in 60 seconds.

This message must be acknowledged by the LIS host using an ACK^J01 message. More information below.

9.3.1.2.1 QCN^J01 – Message Structure

Message	Comments
MSH	Message Header
QID	Query Identification

9.3.1.2.2 QCN^J01 – Message Header Record (MSH)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Field Separator		1	ST	1	R	N	'|'
2	Encoding Characters		1	ST	4	R	N	See 7.4.2 for more information
3	Sending Application	System ID	1	ST	50	R	N	The System Name defined in the system configuration
		System Name	2	ST	50	R	N	'GeneXpert'
		Software Version	3	ST	16	R	N	
5	Receiver ID	Name or ID of the receiver	1	ST	50	R	N	The host ID defined in the system configuration
7	Date and time of Message	Date and time the message was generated	1	TS		R	N	
9	Message Type		1	ID	3	R	N	'QCN'
			2	ID	3	R	N	'J01'
			3	ID	7	O	N	'QCN_J01'

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
10	Message ID	Unique message identifier	1	ST	32	R	N	
11	Processing ID		1	ID	3	R	N	'P' (Production)
12	Version Number	Version of protocol	1	ID	60	R	N	'2.5'
15	Accept Ackn.		1	ID	2	N	N	'AL' (Always)
16	Application Ack.		1	ID	2	N	N	'NE' (Never)

9.3.1.2.3 QCN^J01 – Query Identification Segment (QID)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Query Tag	Unique identifier for the query	1	ST	32	R	N	Must match QPD-2
2	Query Name		1	ST	250	R	N	Not used

9.3.1.2.4 LIS Acknowledgement (ACK^J01)

9.3.1.2.4.1 ACK^J01 – Message Structure

Message	Comments
MSH	Message Header
MSA	Message Acknowledgment

9.3.1.2.4.2 ACK^J01 – Message Header Record (MSH)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Field Separator		1	ST	1	R	N	'|'
2	Encoding Characters		1	ST	4	R	N	See 7.4.2 for more information
3	Sending Application	Name or ID of the sender	1	HD	50	R	N	The host ID defined in the instrument system configuration
5	Receiver ID	System ID	1	HD	50	R	N	The System Name defined in the system configuration
		System Name	2		50	R	N	'GeneXpert'
		Software Version	3		16	R	N	
7	Date and time of Message	Date and time the message was generated	1	TS		R	N	If empty, the current date and time is assumed
9	Message Type		1	MSG	15	R	N	'ACK'
10	Message ID	Unique message identifier	1	ST	32	R	N	
11	Processing ID		1	PT	3	R	N	'P' (Production)
12	Version Number	Version of protocol	1	ID	60	R	N	'2.5'
15	Accept Ackn.		1	ID	2	O	N	'NE' (Never)
16	Application Ack.		1	ID	2	O	N	'NE' (Never)

9.3.1.2.4.3 ACK^J01 – Message Acknowledgement (MSA)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Acknowledgement Code	Acknowledgement Code	1	ID	2	R	N	'CA'
2	Message Control ID	From MSH-10 of associated message	1	ST	32	R	N	

9.3.1.2.5 Example of Upload Message– Instrument System Cancels Query for all Test Orders (QCN^J01 / ACK^J01)

GeneXpert message:

```
MSH|^~\&|ICU^GeneXpert^1.0||LIS||20070713114254||QCN^J01^QCN_J01|UDC000|P|2.5|||AL|NE
QID|9e5ca0c1f05b4aa2aec1e2868beb6982|N/D
```

LIS Acknowledgement:

```
MSH|^~\&|LIS||ICU^GeneXpert^1.0||20070521101245||ACK|12Y|P|2.5|||NE|NE
MSA|CA|UDC000
```

9.3.1.3 Download Message – Host Responds with Test Orders for Query (RSP^Z02)

9.3.1.3.1 Message Structure

Message	Comments
MSH	Message Header Segment
MSA	Message Acknowledgement
QAK	
QPD	Query Parameter Definition Segment
{	
PID	Patient Identification Segment
{	
ORC	Common Order Segment
OBR	Observation Request Segment
TQ1	Timing/Quantity Segment
SPM	Specimen Segment
}	
}	

9.3.1.3.2 Message Header Record (MSH)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Field Separator		1	ST	1	R	N	'|'
2	Encoding Characters		1	ST	4	R	N	See 7.4.2 for more information
3	Sending Application	Name or ID of the sender	1	ST	50	R	N	The host ID defined in the system configuration
5	Receiver ID	System ID	1	ST	50	R	N	The System Name defined in the system configuration
		System Name	2	ST	50	R	N	'GeneXpert'
		Software Version	3	ST	16	R	N	
7	Date and time of Message	Date and time the message was generated	1	TS		R	N	If empty, the current date and time is assumed
9	Message Type		1	ID	3	R	N	RSP
			2	ID	3	R	N	Z02
10	Message ID	Unique message identifier	1	ST	32	R	N	
11	Processing ID		1	ID	3	R	N	'P' (Production)
12	Version Number	Version of protocol	1	ID	60	R	N	'2.5'
15	Accept Ackn.		1	ID	2	O	N	'NE' (Never)
16	Application Ack.		1	ID	2	O	N	'NE' (Never)

9.3.1.3.3 Message Acknowledgment (MSA)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Acknowledgement Code	Acknowledgement Code	1	ID	2	R	N	'AA'
2	Message Control ID	From MSH-10 of associated message	1	ST	20	R	N	

9.3.1.3.4 Query Acknowledgement (QAK)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Query Tag	Valued by the initiating system to identify the query, and used to match response messages to the originating query. The responding system is required to echo it back as the first field in the query acknowledgement segment (QAK). This field differs from MSA-2-Message control ID in that its value remains constant for each message (i.e. all continuation messages) associated with the query, whereas MSA-2 Message control ID may vary with each continuation message, since it is associated with each individual message, not the query as a whole.	1	ST	32	R	N	Query Tag sent by the system in QPD-2.
2	Query Response Status	OK: Data found, no errors (this is the default) NF: No data found, no errors AE: Application error AR: Application reject	1	ID	2	R	N	'OK': The query was successful. (NF/AE/AR are not possible since they are sent in the MSA)
3	Message Query Name	This field contains the name of the query. These names are assigned by the function-specific chapters of this specification. It is one to one with the conformance statement for this query name, and it is in fact an identifier for that conformance statement. Site-specific query names begin with the letter 'Z.'	1	ST	3	R	N	'Z01'- User defined trigger
			2	ST	100	R	N	'REQUEST TEST ORDERS'

9.3.1.3.5 Query Parameter Definition (QPD)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Message Query Name	This field contains the name of the query. These names are assigned by the function-specific chapters of this specification. It is one to one with the conformance statement for this query name, and it is in fact an identifier for that conformance statement. Site-specific query names begin with the letter 'Z.'	1	ST	3	R	N	'Z01'- User defined trigger
			2	ST	100	R	N	'REQUEST TEST ORDERS'
2	Query Tag	Valued by the initiating system to identify the query, and used to match response messages to the originating query. The responding system is required to echo it back as the first field in the query acknowledgement segment (QAK). This field differs from MSA-2-Message control ID in that its value remains constant for each message (i.e. all continuation messages) associated with the query, whereas MSA-2 Message control ID may vary with each continuation message, since it is associated with each individual message, not the query as a whole.	1	ST	32	R	N	Query Tag sent by the System in QPD-2.
3	User Parameter 1	Indicates that all the order records must be retrieved	1	ST	32	R	N	'ALL'

9.3.1.3.6 Patient Identification Record (PID)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Sequence Number	Defines the i'th occurrence of the associated record type		SI		R	N	1,2,3,...n
3	Patient ID	Patient identification		ST	32	O	N	

9.3.1.3.7 Common Order Segment (ORC)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Order Control			ID	2	R	N	'NW' : New order 'OC': order cancelled
2	Order Number			SI		R	N	1,2,3,...n
9	Date / Time of the order			TS		O	N	If empty, current date and time is used

9.3.1.3.8 Observation Request Segment (OBR)

Field No.	Field Name	Description	Component/ subcomponent	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Sequence Number	Defines the i'th occurrence of the associated record type		SI		R	N	1,2,3,...n
4	Universal Test ID	System defined Test ID	1	ID	15	R	N	This field contains the identification of the test.
11	Specimen Action Code			ID	1	R	N	'A' (Added in previous specimen or creates a new specimen following the rules of the sample life cycle)

9.3.1.3.9 Timing/Quantity (TQ1)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
9	Priority			ID	1	R	N	'S' (Stat) / 'R' (Routine)

9.3.1.3.10 Specimen Segment (SPM)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Sequence Number			SI	64	R	N	1,2,3,...n
2	Specimen ID	A unique identifier for the specimen assigned by the HOST	1	ST	25	R	N	
	Instrument Specimen ID	A unique identifier for the specimen assigned by the system. This must be retrieved from the LIS if it is known.	2	ST	32	O	N	This field will be ignored if the Use Instrument Specimen ID option is disabled
4	Specimen Type			ID	5	R	N	'ORH' (Other) ('Other' according to POCT1-A standard)
11	Specimen Role			ID	1	R	N	'Q' (For Quality control) 'P' (For Sample Patient)

9.3.1.3.11 Example of Download Message – Host responds with Test Orders for Query (RSP^Z02)

```
MSH|^~\&|LIS||ICU^GeneXpert^1.0||20070521100245||RSP^Z02|12Y|P|2.5|||NE|NE
MSA|AA|94799a8b48bb4b7fb2fce229c3a371c8
QAK|94799a8b48bb4b7fb2fce229c3a371c8|OK|Z01^REQUEST TEST ORDERS
QPD|Z01^REQUEST TEST ORDERS|94799a8b48bb4b7fb2fce229c3a371c8|ALL
PID|1||PatientID-1234
ORC|NW|1||||||20070421100245
OBR|1|||Test_ID-212||||||A
TQ1|||||||R
SPM|1|SID-888^ISID-333||ORH||||||P
ORC|NW|2||||||20070421100235
OBR|2|||Test_ID-214||||||A
TQ1|||||||R
SPM|2|SID-188^ISID-313||ORH||||||P
PID|2||PatientID-5678
ORC|NW|1||||||20070421100255
OBR|1|||Test_ID-213||||||A
TQ1|||||||S
SPM|1|SID-818^ISID-331||ORH||||||P
```

9.3.1.4 Download Message – Host Responds with No Available Test Order for Query (RSP^Z02)

This message can appear when there are no available orders to download. Also note that if the LIS host doesn't transmit any information and the timeout is reached (60 seconds), the system will assume that the LIS host has no test orders to download . In this case, the system will cancel the request as specified in 9.3.1.2.

Note: It is recommended that the LIS host developers always provide a response to a request; otherwise, the communication will be stopped until the 60 seconds timeout is reached.

9.3.1.4.1 Message Structure

Message	Comments
MSH	Message Header Segment
MSA	Message Acknowledgement
QAK	Query Acknowledgment
QPD	Query Parameter Definition Segment

9.3.1.4.2 Message Header Record (MSH)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Field Separator		1	ST	1	R	N	'|'
2	Encoding Characters		1	ST	4	R	N	See 7.4.2 for more information
3	Sending Application	Name or ID of the sender	1	ST	50	R	N	The host ID defined in the system configuration
5	Receiver ID	System ID	1	ST	50	R	N	The System Name defined in the system configuration
		System Name	2	ST	50	R	N	'GeneXpert'
		Software Version	3	ST	16	R	N	
7	Date and time of Message	Date and time the message was generated	1	TS		R	N	If empty, the current date and time is assumed
9	Message Type		1	ID	3	R	N	'RSP'
			2	ID	3	R	N	'Z02'
10	Message ID	Unique message identifier	1	ST	32	R	N	
11	Processing ID		1	ID	3	R	N	'P' (Production)
12	Version Number	Version of protocol	1	ID	60	R	N	'2.5'
15	Accept Ackn.		1	ID	2	O	N	'NE' (Never)
16	Application Ack.		1	ID	2	O	N	'NE' (Never)

9.3.1.4.3 Message Acknowledgment (MSA)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Acknowledge-ment Code	'Acknowledge-ment Code	1	ID	2	R	N	'AA'
2	Message Control ID	From MSH-10 of associated message	1	ST	20	R	N	

9.3.1.4.4 Query Acknowledgement (QAK)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Query Tag	Valued by the initiating system to identify the query, and used to match response messages to the originating query. The responding system is required to echo it back as the first field in the query acknowledgement segment (QAK). This field differs from MSA-2-Message control ID in that its value remains constant for each message (i.e. all continuation messages) associated with the query, whereas MSA-2 Message control ID may vary with each continuation message, since it is associated with each individual message, not the query as a whole.	1	ST	32	R	N	Query Tag sent by the system in QPD-2.
2	Query Response Status	OK: Data found, no errors (this is the default) NF: No data found, no errors AE: Application error AR: Application reject	1	ID	2	R	N	'OK': The query was successful. (NF/AE/AR are not possible since they are sent in the MSA)
3	Message Query Name	This field contains the name of the query. These names are assigned by the function-specific chapters of this specification. It is one to one with the conformance statement for this query name, and it is in fact an identifier for that conformance statement. Site-specific query names begin with the letter 'Z.'	1	ST	3	R	N	'Z01'- User defined trigger
			2	ST	100	R	N	'REQUEST TEST ORDERS'

9.3.1.4.5 Query Parameter Definition (QPD)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Message Query Name	This field contains the name of the query. These names are assigned by the function-specific chapters of this specification. It is one to one with the conformance statement for this query name, and it is in fact an identifier for that conformance statement. Site-specific query names begin with the letter 'Z.'	1	ST	3	R	N	'Z01'- User defined trigger
			2	ST	100	R	N	'REQUEST TEST ORDERS'
2	Query Tag	Valued by the initiating system to identify the query, and used to match response messages to the originating query. The responding system is required to echo it back as the first field in the query acknowledgement segment (QAK). This field differs from MSA-2-Message control ID in that its value remains constant for each message (i.e. all continuation messages) associated with the query, whereas MSA-2 Message control ID may vary with each continuation message, since it is associated with each individual message, not the query as a whole.	1	ST	32	R	N	Query Tag sent by the System in QPD-2.
3	User Parameter 1	Indicates that all the order records must be retrieved	1	ST	32	R	N	'ALL'

9.3.1.4.6 Example

```
MSH|^~\&|LIS||ICU^GeneXpert^1.0||20070521100245||RSP^Z02|12YYDSSDF|P|2.5|||NE|NE
MSA|AA|94799a8b48bb4b7fb2fce229c3a371c
QAK|94799a8b48bb4b7fb2fce229c3a371c|OK|Z01^REQUEST TEST ORDERS
QPD|Z01^REQUEST TEST ORDERS|234|ALL
```

9.3.1.5 Upload Message – Instrument System Rejects Test Order Initiated From Query (ORU^R01 – ACK^R01)

This message must be acknowledged by the LIS host using an ACK^R01 message. More information is included in the sections below.

9.3.1.5.1 ORU^R01 – Message Structure

Message	Comments
MSH	Message Header Segment
{	
PID	Patient Identification Segment
{	
ORC	Order Common Segment
OBR	Observation Request Segment
NTE	Error description (related to order)
TQ1	Timing / Quantity Segment
SPM	Specimen Segment
}	
}	

9.3.1.5.2 ORU^R01 – Message Header Record (MSH)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Field Separator		1	ST	1	R	N	'|'
2	Encoding Characters		1	ST	4	R	N	See 7.4.2 for more information
3	Sending Application	System ID	1	ST	50	R	N	The System Name defined in the system configuration
		System Name	2	ST	50	R	N	'GeneXpert'
		Software Version	3	ST	16	R	N	
5	Receiver ID	Name or ID of the receiver	1	ST	50	R	N	The host ID defined in the system configuration
7	Date and time of Message	Date and time the message was generated	1	TS		R	N	
9	Message Type		1	ID	3	R	N	'ORU'
			2	ID	3	R	N	'R32'
			3	ID	7	O	N	'ORU_R30'
10	Message ID	Unique message identifier	1	ST	32	R	N	
11	Processing ID		1	ID	3	R	N	'P' (Production)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
12	Version Number	Version of protocol	1	ID	60	R	N	'2.5'
15	Accept Ackn.		1	ID	2	O	N	'AL' (Always)
16	Application Ack.		1	ID	2	O	N	'NE' (Never)

9.3.1.5.3 ORU^R01 – Patient Identification Record (PID)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Sequence Number	Defines the i'th occurrence of the associated record type		SI		R	N	1,2,3,...n
3	Patient ID	Patient identification		ST	32	O	N	

9.3.1.5.4 ORU^R01 – Order Common Segment (ORC)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Order Control			ID	2	R	N	'OC': order cancelled
2	Order Number			SI		R	N	1,2,3,...n
9	Date / Time of the order			TS		R	N	Date time of the order

9.3.1.5.5 ORU^R01 – Observation Request Segment (OBR)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Sequence Number	Defines the i'th occurrence of the associated record type		SI		R	N	1
4	Universal Test ID	System defined Test ID	1	ID	15	R	N	This field contains the identification of the test.
25	Order Status			ID	1	R	N	'X' (Order cannot be done, cancelled)

9.3.1.5.6 ORU^R01 – Notes and Comment Segment (NTE)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Sequence Number	Defines the i'th occurrence of the associated record type	1	SI		R	N	1
2	Source of Comment		1	ID	1	R	N	'L'
3	Comment Text	Comment ID	1	ID	50	R	N	'Error'
		Comment Code	2	ST	50	R	N	'InvalidSpecimen-Data'/ 'DuplicatedTest'/ 'InvalidTestData'/ 'InvalidPatient-Data'/ 'InvalidTransmis-sionInformation'
		Comment description	3	ST	500	O	N	'Invalid Instrument Specimen ID or Specimen ID' / 'Duplicated test order'/ 'Test unknown, test disabled or inconsis-tent test' / 'Invalid Patient identification'/ 'The order has a bad format'

9.3.1.5.7 ORU^R01 – Timing / Quantity Segment (TQ1)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
9	Priority	Describes the urgency of the request		ID	1	R	N	'S' (Stat) or 'R' (Normal)

9.3.1.5.8 ORU^R01 – Specimen Segment (SPM)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Sequence Number			SI	64	R	N	1,2,3,...n
2	Specimen ID	A unique identifier for the specimen assigned by the HOST	1	ST	25	R	N	
	Instrument Specimen ID	A unique identifier for the specimen assigned by the system. This must be retrieved from the LIS if it is known.	2	ST	32	O	N	This field will be ignored if the Use Instrument Specimen ID option is disabled
4	Specimen Type			ID	5	R	N	'ORH' (Other) ('Other' according to POCT1-A standard)
11	Specimen Role			ID	1	R	N	'Q' (For Quality control) 'P' (For Sample Patient)

9.3.1.5.9 LIS Host Acknowledgement (ACK^R01)

9.3.1.5.9.1 ACK^R01 – Message Structure

Message	Comments
MSH	Message Header
MSA	Message Acknowledgment

9.3.1.5.9.2 ACK^R01 – Message Header Record (MSH)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Field Separator		1	ST	1	R	N	'|'
2	Encoding Characters		1	ST	4	R	N	See 7.4.2 for more information
3	Sending Application	Name or ID of the sender	1	ST	50	R	N	The host ID defined in the instrument configuration
5	Receiver ID	System ID	1	ST	50	R	N	The System Name defined in the system configuration
		System Name	2	ST	50	R	N	'GeneXpert'
		Software Version	3	ST	16	R	N	

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
7	Date and time of Message	Date and time the message was generated	1	TS		R	N	
9	Message Type		1	MSG	3	R	N	'ACK'
10	Message ID	Unique message identifier	1	ST	32	R	N	
11	Processing ID		1	ID	3	R	N	'P' (Production)
12	Version Number	Version of protocol	1	ID	60	R	N	'2.5'
15	Accept Ackn.		1	ID	2	O	N	'NE' (Never)
16	Application Ack.		1	ID	2	O	N	'NE' (Never)

9.3.1.5.9.3 ACK^R01 – Message Acknowledgment (MSA)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Acknowledge-ment Code 'Acknowledge-ment Code	1	ID	2	R	N	N	'CA'
2	Message Control ID	From MSH-10 of associated message	1	ST	20	R	N	

9.3.1.5.10 Example of ACK^R01 – Message Acknowledgment (MSA)

GeneXpert message:

```
MSH|^~\&|ICU^GeneXpert^1.0||LIS||20070521100245||ORU^R32^ORU_R30|48c0947bfa244b46977f81ce598879a3|P|2.5|||AL|NE
PID|1||PatientID-1234
ORC|OC|1||||||20070521101245
OBR|1|||MRSA IUO||||||||||||||||||X
NTE|1|L|Error^invalidSpecimenData^Invalid Instrument Specimen ID or Specimen ID
TQ1|||||||||R
SPM|1|SpecimenID-888^Instr_SpecID-333||ORH||||||P
PID|2||
ORC|OC|1||||||20070521101246
OBR|1|||MRSA IUO||||||||||||||||||X
NTE|1|L|Error^invalidSpecimenData^Invalid Instrument Specimen ID or Specimen ID
TQ1|||||||||R
SPM|1|SpecimenID-888^Instr_SpecID-333||ORH||||||P
ORC|OC|2||||||20070521201245
OBR|2|||MRSA IUO||||||||||||||||||X
NTE|1|L|Error^invalidSpecimenData^Invalid Instrument Specimen ID or Specimen ID
TQ1|||||||||R
SPM|2|SpecimenID-888^Instr_SpecID-333||ORH||||||P
```

LIS host acknowledgement:

```
MSH|^~\&|LIS||ICU^GeneXpert^1.0||20070521101245||ACK|12YASSAQQWE|P|2.5|||NE|NE
MSA|CA|48c0947bfa244b46977f81ce598879a3
```

9.3.2 Instrument System Initiated Host Query for Specific Sample

9.3.2.1 Upload Message – Instrument System Sends Host Query (QBP^Z03)

9.3.2.1.1 Message Structure

Message	Comments
MSH	Message Header
QPD	Query Parameter Definition
RCP	Response Control Parameter

9.3.2.1.2 Message Header Segment (MSH)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Field Separator		1	ST	1	R	N	'|'
2	Encoding Characters		1	ST	4	R	N	See 7.4.2 for more information
3	Sending Application	System ID	1	ST	50	R	N	The System Name defined in the system configuration
		System Name	2	ST	50	R	N	'GeneXpert'
		Software Version	3	ST	16	R	N	
5	Receiver ID	Name or ID of the receiver	1	ST	50	R	N	The host ID defined in the system configuration
7	Date and time of Message	Date and time the message was generated	1	TS		R	N	
9	Message Type		1	ID	3	R	N	'QBP'
			2	ID	3	R	N	'Z03'
			3	ID	7	O	N	'QBP_Z03'
10	Message ID	Unique message identifier	1	ST	32	R	N	
11	Processing ID		1	ID	3	R	N	'P' (Production)
12	Version Number	Version of protocol	1	ID	60	R	N	'2.5'

9.3.2.1.3 Query Parameter Definition (QPD)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Message Query Name	This field contains the name of the query. These names are assigned by the function-specific chapters of this specification. It is one to one with the conformance statement for this query name, and it is in fact an identifier for that conformance statement. Site-specific query names begin with the letter 'Z.'	1	ST	3	R	N	'Z03'- User defined trigger
			2	ST	100	R	N	'HOST QUERY'
2	Query Tag	Valued by the initiating system to identify the query, and used to match response messages to the originating query. The responding system is required to echo it back as the first field in the query acknowledgement segment (QAK). This field differs from MSA-2-Message control ID in that its value remains constant for each message (i.e. all continuation messages) associated with the query, whereas MSA-2 Message control ID may vary with each continuation message, since it is associated with each individual message, not the query as a whole.	1	ST	32	R	N	Unique identifier
3	User Parameter 1	Patient ID	1	ST	32	O	N	
4	User Parameter 2	Specimen ID	1	ST	25	R	N	

9.3.2.1.4 Response Control Parameter (RCP)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Query Priority	Deferred (D) or Immediate (I)	1	ID	1	R	N	'I' – Immediate

9.3.2.1.5 Example of a Response Control Parameter

```
MSH|^~\&|ICU^GeneXpert^1.0||LIS||20070521100245||QBP^Z03^QBP_Z03|662f165ebb1b4354b100cba090f1e7e5|P|2.5
QPD|Z03^HOST QUERY|662f165ebb1b4354b100cba090f1e7e5|PatientID-556|SpecimenID-888
RCP|I
```

9.3.2.2 Upload Message – Instrument System Cancels Host Query (QCN^J01 / ACK^J01)

This message is detailed in section 9.3.1.2. This message must also be acknowledged by the LIS Host.

9.3.2.2.1 Example of an Upload Message – Instrument System Cancels Host Query (QCN^J01 / ACK^J01)

GeneXpert message:

```
MSH|^~\&|ICU^GeneXpert^1.0||LIS||20070713114254||QCN^J01^QCN_J01|UDC000|P|2.5|||AL|NE
QID|662f165ebb1b4354b100cba090f1e7e5|N/D
```

LIS Acknowledgement:

```
MSH|^~\&|LIS||ICU^GeneXpert^1.0||20070521101245||ACK|12Y|P|2.5|||NE|NE
MSA|CA|UDC000
```

9.3.2.3 Download Message – Host Responds to Host Query with Test Order(s) (RSP^Z02)

The LIS host retrieves data for the specified specimen IDs and sends the orders to the system. The response message has the structure of the message described in section 9.3.1.3. Note, if there is a multiple host query and there are specimens that have pending orders and other specimens that do not, the host query response only needs to retrieve the pending specimens. The system will assume that there are no orders for the specimens that are not listed in the host query response.

9.3.2.3.1 Example of Download Message – Host Responds to Host Query with Test Order(s) (RSP^Z02)

System sends Host Query:

```
MSH|^~\&|GeneXpert PC^GeneXpert^1.9.32 demo||LIS||20071121133825||QBP^Z03^QBP_Z0
3|ODM-+ecJkZRA-07|P|2.5
QPD|Z03^HOST QUERY|ODM-+ecJkZRA-07||s1
RCP|I
```

Host Responses with 2 new orders:

```
MSH|^~\&|LIS||GeneXpert PC^GeneXpert^1.9.32 demo||20071121133826||RSP^Z02|4c49f0
5b68bf4929a8df728f4a6d49af|P|2.5||||
MSA|AA|ODM-+ecJkZRA-07|
QAK|ODM-+ecJkZRA-07|OK|Z03^HOST QUERY
QPD|Z03^HOST QUERY|ODM-+ecJkZRA-07||s1
PID|1||p1
ORC|NW|1|||||||20071116133208
OBR|1|||FT|||||||A
TQ1|||||||||R
SPM|1|s1^||ORH|||||||P
ORC|NW|2|||||||20071121104253
OBR|2|||BC|||||||A
TQ1|||||||||R
SPM|2|s1^||ORH|||||||P
```

9.3.2.4 Download Message – Host Responds with No Available Test Order for Host Query (RSP^Z02)

This message can appear when there is no test order to download for a specific specimen. Also note that if the LIS host does not transmit any response and the timeout is reached (60 seconds), the system will assume that the LIS host has no test orders to program. In this case, the system will cancel the request as specified in 9.3.1.2.

Note: It is recommended that the LIS host developers always provide a response to a request; otherwise, the communication will be stopped until the 60 seconds timeout is reached.

9.3.2.4.1 Message Structure

Message	Comments
MSH	Message Header Segment
MSA	Message Acknowledgement
QAK	Query Acknowledgment
QPD	Query Parameter Definition Segment
	Message Header Segment

9.3.2.4.2 Message Header Record (MSH)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Field Separator		1	ST	1	R	N	'|'
2	Encoding Characters		1	ST	4	R	N	See `7.4.2 for more infor mation
3	Sending Application	Name or ID of the sender	1	ST	50	R	N	The host ID defined in the system configuration

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
5	Receiver ID	System ID	1	ST	50	R	N	The System Name defined in the system configuration
		System Name	2	ST	50	R	N	'GeneXpert'
		Software Version	3	ST	16	R	N	
7	Date and time of Message	Date and time the message was generated	1	TS		R	N	If empty, the current date and time is assumed
9	Message Type		1	ID	3	R	N	'RSP'
			2	ID	3	R	N	'Z02'
10	Message ID	Unique message identifier	1	ST	32	R	N	
11	Processing ID		1	ID	3	R	N	'P' (Production)
12	Version Num ber	Version of pro tocol	1	ID	60	R	N	'2.5'
15	Accept Ackn.		1	ID	2	O	N	'NE' (Never)
16	Application Ack.		1	ID	2	O	N	'NE' (Never)

9.3.2.4.3 Message Acknowledgment (MSA)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Acknowledge ment Code	'Acknowledge ment Code	1	ID	2	R	N	1
2	Message Con trol ID	From MSH-10 of associated message	1	ST	20	R	N	2

9.3.2.4.4 Query Acknowledgement (QAK)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Query Tag	Valued by the initiating system to identify the query, and used to match response messages to the originating query. The responding system is required to echo it back as the first field in the query acknowledgement segment (QAK). This field differs from MSA-2-Message control ID in that its value remains constant for each message (i.e. all continuation messages) associated with the query, whereas MSA-2 Message control ID may vary with each continuation message, since it is associated with each individual message, not the query as a whole.	1	ST	32	R	N	Query Tag sent by the system in QPD-2.
2	Query Response Status	OK: Data found, no errors (this is the default) NF: No data found, no errors AE: Application error AR: Application reject	1	ID	2	R	N	'OK': The query was successful. (NF/AE/AR are not possible since they are sent in the MSA)
	Message Query Name	This field contains the name of the query. These names are assigned by the function-spe cific chapters of this specification. It is one to one with the conform ance statement for this query name, and it is in fact an identifier for that conformance statement. Site-specific query names begin with the letter 'Z.'	1	ST	3	R	N	'Z03'- User defined trigger
			2	ST	100	R	N	'HOST QUERY'

9.3.2.4.5 Query Parameter Definition (QPD)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1		This field contains the name of the query. These names are assigned by the function-spe cific chapters of this specifi cation. It is one to one with the conformance statement for this query name, and it is in fact an identifier for that conformance statement. Site-specific query names begin with the letter 'Z.'	1	ST	3	R	N	'Z03'- User defined trigger
			2	ST	100	R	N	'HOST QUERY'
2	Query Tag	Valued by the initiating sys tem to identify the query, and used to match response mes sages to the originating query. The responding system is required to echo it back as the first field in the query acknowledgement segment (QAK). This field differs from MSA-2-Message control ID in that its value remains constant for each message (i.e. all continu ation messages) associated with the query, whereas MSA-2 Message control ID may vary with each continua tion message, since it is asso ciated with each indi-vidual message, not the query as a whole.	1	ST	32	R	N	Query Tag sent by the System in QPD-2.
3	User Parameter 1	Indicates that all the order records must be retrieved	1	ST	32	R	N	'ALL'

9.3.2.4.6 An Example with No Available Test Orders

```
MSH|^~\&|LIS||ICU^GeneXpert^1.0||20070521100245||RSP^Z02|12X|P|2.5|||NE|NE
MSA|AA|662f165ebb1b4354b100cba090f1e7e5
QAK|662f165ebb1b4354b100cba090f1e7e5|OK|Z03^HOST QUERY
QPD|Z03^HOST QUERY|662f165ebb1b4354b100cba090f1e7e5|PatientID-1234|SpecimenID-888
```

9.3.2.5 Upload Message – Instrument System Rejects Test Order Initiated From Host Query (ORU^R01 – ACK^R01)

If the orders are malformed, or they request an invalid test the instrument reports a rejection of the orders with the same rules described in section 9.3.1.5. Upload message - Instrument system rejects test order initiated from query (ORU^R01 - ACK^R01) .

9.3.3 Instrument System Returns Instrument Specimen ID for a Downloaded Order

9.3.3.1 Upload Message – Instrument System Responds with Instrument Specimen ID for a Downloaded Order (SSU^U03/ACK^U03)

This message will be sent only if the Use Instrument Specimen ID option is enabled in the GeneXpert software.

This message must be acknowledged by the LIS host using an ACK^J01 message. More information is included in the sections below.

9.3.3.1.1 SSU^U03 – Message Structure

Message	Comments
MSH	Message Header
EQU	Equipment Detail
{	
SAC	Specimen and Container Detail
SPM	Specimen
}	

9.3.3.1.2 SSU^U03 – Message Header Segment (MSH)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Field Separator		1	ST	1	R	N	'|'
2	Encoding Characters		1	ST	4	R	N	See 7.4.2 for more information
3	Sending Application	System ID	1	ST	50	R	N	The System Name defined in the system configuration
		System Name	2	ST	50	R	N	'GeneXpert'
		Software Version	3	ST	16	R	N	
5	Receiver ID	Name or ID of the receiver	1	ST	50	R	N	The host ID defined in the system configuration
7	Date and time of Message	Date and time the message was generated	1	TS		R	N	
9	Message Type		1	ID	3	R	N	'SSU'
			2	ID	3	R	N	'U03'
			3	ID	7	O	N	'SSU_U03'
10	Message ID	Unique message identifier	1	ST	32	R	N	

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
11	Processing ID		1	ID	3	R	N	'P' (Production)
12	Version Number	Version of protocol	1	ID	60	R	N	'2.5'
15	Accept Ackn.		1	ID	2	O	N	'AL' (Always)
16	Application Ack.		1	ID	2	O	N	'NE' (Never)

9.3.3.1.3 SSU^U03 – Equipment Detail Segment (EQU)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Equipment Instance Identifier		1	ST	50	R	N	Not used
2	Event Date/ Time		1	TS		R	N	Current datetime.

9.3.3.1.4 SSU^U03 – Specimen Container Detail Segment (SAC) [Dummy field, for HL7 compliance]

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	External accession	This field identifies the laboratory accession	1	String	50	O	N	Not used

9.3.3.1.5 SSU^U03 – Specimen Segment (SPM)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Sequence Number			SI	64	R	N	1,2,3,...n
2	Specimen ID	A unique identifier for the specimen assigned by the HOST	1	ST	25	R	N	
	Instrument Specimen ID	A unique identifier for the specimen assigned by the system. This must be retrieved from the LIS if it is known.	2	ST	32	R	N	
4	Specimen Type			ID	5	R	N	'ORH' (Other) ('Other' according to POCT1-A standard)
11	Specimen Role			ID	1	R	N	'Q' (For Quality control) 'P' (For Sample Patient)

9.3.3.1.6 LIS Acknowledgement (ACK^U03)

9.3.3.1.6.1 ACK^U03 – Message Structure

Message	Comments
MSH	
MSA	

9.3.3.1.6.2 ACK^U03 – Message Header Record (MSH)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Field Separator		1	ST	1	R	N	'|'
2	Encoding Characters		1	ST	4	R	N	See 7.4.2 for more information
3	Sending Application	Name or ID of the sender	1	ST	50	R	N	The host ID defined in the instrument configuration
5	Receiver ID	System ID	1	ST	50	R	N	The System Name defined in the system configuration
		System Name	2	ST	50	R	N	'GeneXpert'
		Software Version	3	ST	16	R	N	
7	Date and time of Message	Date and time the message was generated	1	TS		R	N	If empty, the current date and time is used.
9	Message Type		1	MSG	3	R	N	'ACK'
10	Message ID	Unique message identifier	1	ST	32	R	N	
11	Processing ID		1	ID	3	R	N	'P' (Production)
12	Version Number	Version of protocol	1	ID	60	R	N	'2.5'
15	Accept Ackn.		1	ID	2	O	N	'NE' (Never)
16	Application Ack.		1	ID	2	O	N	'NE' (Never)

9.3.3.1.7 ACK^U03 – Message Acknowledgement (MSA)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Acknowledgement Code	Acknowledgement Code	1	ID	2	R	N	'CA'
2	Message Control ID	From MSH-10 of associated message	1	ST	32	R	N	

9.3.3.1.8 Example of Upload Message – Instrument System Responds with Instrument Specimen ID for a Downloaded Order (SSU^U03/ACK^U03)

GeneXpert message:

```
MSH|^~\&|ICU^GeneXpert^1.0||LIS||20070521100245||SSU^U03^SSU_U03|a8c20c78490741c881d77b66207a66c8|P|2.5|||AL|NE
EQU|N/D|20070713120450
SAC|N/D
SPM|1|SpecimenID-777^Instr_SpecID-555||ORH||||||P
SAC|N/D
SPM|2|SpecimenID-888^Instr_SpecID-333||ORH||||||P
```

LIS Host acknowledgement

```
MSH|^~\&|LIS||ICU^GeneXpert^1.0||20070521101245||ACK|12Y|P||||NE|NE
MSA|CA| a8c20c78490741c881d77b66207a66c8
```

9.3.4 Instrument System Uploads Test Results

9.3.4.1 Upload Message – Instrument System Uploads Results (ORU^R01 – ACK^R01)

The instrument can upload two types of test results: single-result test results and multi-result test results.

For a single test, each Test Order record is followed by a Result Record.

The system can upload three levels of results:

- Test result (Main result) identified by the test code followed by
- Analyte results (Secondary results for each analyte in the test) followed by
- Complementary results (results related to each analyte) like the Ct, EndPt, etc

Errors and Notes related to the order are reported on the Comment Records following the Order Record.

If a Test has an error, the Error is reported on the Result Record (Error message) and Comment Record (Error detailed message).

If the system is reporting a panel or battery of tests, each result has the structure described above. In this case, the Order Record contains information about the panel/battery and it is followed by each test result.

For a multi-result test, the system can upload three levels of results:

- Test result (one for each of the multiple resultsone organism) identified by the assay host test code, result test codes and a result name followed by
- Analyte results (secondary results for each analyte used in this result) followed by
- Complementary results (results related to each analyte) like the Ct, EndPt, etc

Errors and Notes related to the order are reported on the Comment Records following the Order Record.

If a Test has an error, the Error is reported on the Result Record (Error message) and Comment Record (Error detailed message).

The following table highlights information about the two types of result uploads.

This message must be acknowledged by the LIS host using an ACK^J01 message. More information is included in the section below.

9.3.4.1.1 ORU^R01 – Message Structure

Message	Comments
MSH	Message Header Segment
{	
PID	Patient Identification Segment
{	
ORC	Order Common Segment
OBR	Observation Request Segment
[NTE]	Notes and comments (related to order)
TQ1	Timing/Quantity
{	
OBX	Observation Result Segment
[NTE]	Notes and comments (related to result)
}	
SPM	Specimen Segment
}	
}	

9.3.4.1.2 ORU^R01 – Message Header Record (MSH)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Field Separator		1	ST	1	R	N	'|'
2	Encoding Characters		1	ST	4	R	N	See 7.4.2 for more information
3	Sending Application	System ID	1	ST	50	R	N	The System Name defined in the system configuration
		System Name	2	ST	50	R	N	'GeneXpert'
		Software Version	3	ST	16	R	N	
5	Receiver ID	Name or ID of the receiver	1	ST	50	R	N	The host ID defined in the system configuration
7	Date and time of Message	Date and time the message was generated	1	TS		R	N	If empty, the current date and time is used.
9	Message Type		1	ID	3	R	N	'ORU'
			2	ID	3	R	N	'R32'
			3	ID	7	O	N	'ORU_R30'

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
10	Message ID	Unique message identifier	1	ST	32	R	N	
11	Processing ID		1	ID	3	R	N	'P' (Production)
12	Version Number	Version of protocol	1	ID	60	R	N	'2.5'
15	Accept Ackn.		1	ID	2	O	N	'AL' (Always)
16	Application Ack.		1	ID	2	O	N	'NE' (Never)

9.3.4.1.3 ORU^R01 – Patient Identification Record (PID)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Sequence Number	Defines the i'th occurrence of the associated record type		SI		R	N	1,2,3,...n
3	Patient ID	Patient identification		ST	32	O	N	

9.3.4.1.4 ORU^R01 –Common Order Segment (ORC)

Field No.	Field Name	Description	Component	Data Type	Max.m Length	Req	Allow Repeat	Allowed values
1	Order Control			ID	2	R	N	'RE' : Observations 'OC': Order cancelled
2	Order Number			SI		R	N	1,2,3,...n
9	Date / Time of the order			TS		O	N	If empty, current date and time is used

9.3.4.1.5 ORU^R01 – Observation Request Segment (OBR)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Sequence Number	Defines the i'th occurrence of the associated record type		SI		R	N	1,2,3,...n
4	Universal Test ID	System defined Test ID	1	ID	15	R	N	This field contains the identification of the test.
25	Order Status			ID	1	R	N	'F' (Final results) 'X' (Order cannot be done, cancelled) 'I' (Test status is pending)

9.3.4.1.6 ORU^R01 – Notes and Comment Segment (NTE) [optional, in case of error]

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Sequence Number	Defines the i'th occurrence of the associated record type	1	SI		R	N	1,2,3,...n
2	Source of Comment		1	ID	1	R	N	'L'
3	Comment text	Comment ID	1	ID	50	R	N	'Error'
3		Comment Code	2	ST	50	O	N	Error Code
		Comment description	3	ST	500	R	N	Error description

9.3.4.1.7 ORU^R01 – Timing/Quantity (TQ1)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
7	Start Date/ Time	Date and time the system started the test		TS		O	N	
8	End Date/ Time	Date and time the system completed the test		TS		O	N	
9	Priority	Describes the urgency of the request		ID	1	R	N	'S' (Stat) or 'R' (Normal)

9.3.4.1.8 ORU^R01 – Observation Result Segment (OBX)

Field No.	Field Name	Description	Component		Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Sequence Number	Defines the i'th occurrence of the associated record type	1		SI		R	N	1,2,3,...n
2	Value Type	'ST' for String 'NM' for Numeric	1		ID	2	R	N	'ST'
3	Observation Identifier	System defined Test Panel ID	1	1	ST	15	O	N	Empty for a single result test. Assay panel ID for a multi-result test
		System defined Test ID		2	ST	15	R	N	For single-result test, this is the Assay Host Test Code. For multi-result test, this is the Result test code in system configuration.
		System defined Test name		3	ST	20	O*	N	The assay name defined in instrument system
		System defined Test version		4	ST	4	O*	N	The assay version defined in instrument system
4	Observation Sub-ID	Analyte Name / Result Name	1	1	ST	20	O	N	Test Code for a main result in multi-result test. Empty: for a main result in single- result test Analyte Name: for analyte result or complementary result
		Complementary Result Name		2	ST	10	O	N	Only used for complementary results (otherwise it is empty). Possible values: 'Ct'/'EndPt'/'Delta Ct'/'Conc' Empty for main result or analte result

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
5	Observation Value	Observed, calculated or implied result value (Qualitative) If the test has an error (Field 11 = 'X'), here is the error message.	1	ST	150	O	N	To be defined
		Observed, calculated or implied result value (Quantitative)	2	ST	7	O	N	Numeric value
6	Units		1	ST	1	O	N	'%' or empty
8	Abnormal Flags	This field shall indicate the normalcy status of the result.	1	IS	2	O**	N	L-Below low normal H-Above high normal LL-Below lower panic limits HH-Above upper panic limits < Below absolute low-off instrument scale > Above absolute high-off instrument scale N-Normal (applies to non-numeric results) A-Abnormal (applies to non-numeric results) U-Significant change u–D Significant change down B-Better--use–hen direction not relevant W-Worse--use when direction not relevant
11	Result Status		1	ID	1	O*	N	'X' (result cannot be done) 'C' (Result is a correction of a previously transmitted result) 'F' (final results)
16	Responsible Observer	Family Name	2	ST	15	O*	N	The only field used by GX is this one. The other ones are ignored
18	Equipment Instance	Identifies the instrument that performed this measurement.	1	ST	10	O*	Y	See comments below.

*: These fields are only required for the main result (i.e. the segment where field 4 is empty)

**: Complementary results 'Ct' and 'EndPt' do not have interpretation

Field OBX-18 must represent the hierarchy of the subcomponents that made the measurement. This is represented as follows:

- Each component is a repetition of the field.
- The hierarchy will be represented from the lowest to the highest level.
- Therefore, the hierarchy of the components that will be represented are (most particular to most general): Expiration Date, Reagent Lot ID, Cartridge Serial Number, Module Serial Number, System Serial Number and Computer System Name.

Example of the field:

YYYYMMDD~[ReagentLotId]~[CartridgeSerialNumber]~[ModuleSerialNumber]~[SystemSerialNumber]~ [ComputerSystemName]

9.3.4.1.8.1 Parsing An Observation Results Segment (OBX)

To determine if the test has single result or multi-result:

Single or Multi-result Test	Condition
Single-Result Test	Field 3, component 1, subcomponent 1 = empty
Multi-Result Test	Field 3, Component 1, subcomponent 1= not empty (contains assay panel ID

A result record can be in one of the three levels of results:

- Main test result (Main result) followed by one or many Analyte results
- Analyte results (Secondary results for each analyte in the test) followed by one or many Complementary results
- Complementary results (Complementary result belong to each analyte) like the Ct, EndPt, etc.

To determine the result level, these are the rules:

Result Level	Condition	Processing
Main Result	Field 3, Component 1, subcomponent 3 = not empty (contains assay name)	For single-result test: Field 3, Component 1, Subcomponent 2 = Host Assay Test Code For multi-result test: Field 3, Component 1, Subcomponent 1 = Host Assay Test Code Field 3, Component 1, Subcomponent 2 = Result Test Code For both types, Field 3, Component 1, Subcomponent 3 = the assay name. Field 3, Component 1, Subcomponent 4 = the optional assay number. Field 4, Component 1, Subcomponent 1 = the result name for multi-result test only. Field 5, Component 1 is the qualitative result for this main result. Field 5, Component 2 is the quantitative result for this main result etc This main result contains one or more analyte result.

Result Level	Condition	Processing
Analyte Result	Field 3, Component 1 , subcomponent 3 = empty and Field 4, Component 1, subcomponent 1= not empty (contains analyte name) and Field 4, Component 1, subcomponent 2 = empty	Field 4, Component 1, Subcomponent 1 = analyte name. Field 5, Component 1 is the qualitative result for this analyte result. Field 5, Component 2 is not applicable to this analyte result. See Section 9.3.4.1.8 for details about the rest of the fields. This analyte result contains one or more complementary results.
Complementary Result	Field 3, Component 1 , subcomponent 3 = empty and Field 4, Component 1, subcomponent 1= not empty (contains analyte name) and Field 4, Component 1, subcomponent 2 = Not empty (contains complementary result name)	Field 4, Component 1, Subcomponent 1 = analyte name containing this complementary result. Field 4, Component 1, Subcomponent 2 = complementary result name. Field 5, Component 1 is not applicable to this complementary result. Field 5, Component 2 is the quantiative result for this complementary result. See Section 9.3.4.1.8 for details about the rest of the fields.

Example for a single-result test report:

Assay Information

Assay	Assay Version	Assay Type
Xpert EV	2	In Vitro Diagnostic

Test Result: **POSITIVE**

Test and Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result	Curve Fit
EV	33.8	537	POS	PASS	PASS
CIC	36.0	280	NA	PASS	NA

Figure 6— Single-result test report

The Test ID is defined in the Assay Host Test Code field in the "Define Test Code" dialog in the GeneXpert Software.

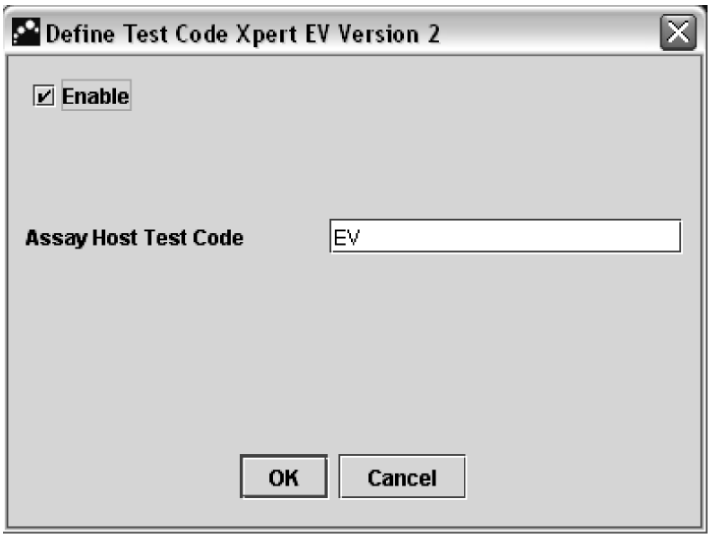


Figure 7— The Define Test Code dialog

Example for a multi-result test report:

Assay Information

Assay	Assay Version	Assay Type
Xpert HemosIL FII & FV	1	In Vitro Diagnostic

Test Result: **FII HOMOZYGOUS;**
FV HOMOZYGOUS

Test and Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
FII 20210G	0	10	NEG	PASS
FII 20210A	24.5	455	POS	PASS
FV 1691G	0	0	NEG	PASS
FV 1691A	25.5	281	POS	PASS

Figure 8— Multiple-result test report

The Panel ID is defined in Assay Host Test Code in "Define Test Code" dialog in GeneXpert software. The Test ID for each result is defined in the Result Test Code.

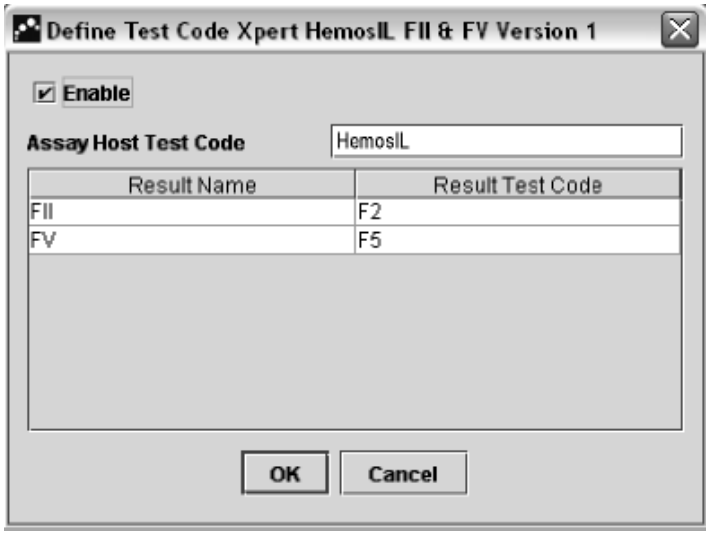


Figure 9— Define Test Code dialog

9.3.4.1.9 ORU^R01 – Notes and Comment Segment (NTE)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Sequence Number	Defines the i'th occurrence of the associated record type	1	SI		R	N	1,2,3,...n
2	Source of Comment		1	ID	1	R	N	'L'
3	Comment Text	Comment ID	1	ID	50	R	N	'Notes'/'Error'
		Comment Code	2	ST	50	R	N	Error Code
		Comment description	3	ST	500	O	Y	Note text / Error description
		Comment details	4	ST	500	O	N	Error details
		Comment Times-tamp	5	TS		O	N	If CommentID is Error, this field is required

9.3.4.1.10 ORU^R01 – Specimen Segment (SPM)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Sequence Number			SI	64	R	N	1,2,3,...n
2	Specimen ID	A unique identifier for the specimen assigned by the HOST	1	ST	25	R	N	
	Instrument Specimen ID	A unique identifier for the specimen assigned by the system. This must be retrieved from the LIS if it is known.	2	ST	32	O	N	This field will be ignored if the Use Instrument Specimen ID option is disabled
4	Specimen Type			ID	5	R	N	'ORH' (Other) ('Other' according to POCT1-A standard)
11	Specimen Role			ID	1	R	N	'Q' (For Quality control) 'P' (For Sample Patient)

9.3.4.1.11 LIS Host Acknowledgement

9.3.4.1.11.1 ACK^R01 – Message Structure

Message	Comments
MSH	Message Header
MSA	Message Acknowledgment

9.3.4.1.11.2 ACK^R01 – Message Header Record (MSH)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Field Separator		1	ST	1	R	N	'|'
2	Encoding Characters		1	ST	4	R	N	See **7.4.2** for more information
3	Sending Application	Name or ID of the sender	1	ST	50	R	N	The Host ID defined in the instrument configuration
5	Receiver ID	System ID	1	ST	50	R	N	The System Name defined in the system configuration
		System Name	2	ST	50	R	N	'GeneXpert'
		Software Version	3	ST	16	R	N	
7	Date and time of Message	Date and time the message was generated	1	TS		R	N	
9	Message Type		1	MSG	3	R	N	'ACK'
10	Message ID	Unique message identifier	1	ST	32	R	N	
11	Processing ID		1	ID	3	R	N	'P' (Production)
12	Version Number	Version of protocol	1	ID	60	R	N	'2.5'
15	Accept Ackn.		1	ID	2	O	N	'NE' (Never)
16	Application Ack.		1	ID	2	O	N	'NE' (Never)

9.3.4.1.11.3 ACK^R01 – Message Acknowledgment (MSA)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Acknowledgement Code	Acknowledgement Code	1	ID	2	R	N	'CA'
2	Message Control ID	From MSH-10 of associated message	1	ST	20	R	N	

9.3.4.1.12 Example of Upload Message – Instrument System Uploads Results (ORU^R01 – ACK^R01)

Example of a multi-result test result. GeneXpert message:

HL7 - Multi-Result Assay

```
MSH|^~\&|CEPHEID^GeneXpert^2.1||LIS-1||20100311152740||ORU^R32^ORU_R30|URM-cYgjPdSA-02|P|2.5|||AL|NE
PID|1||
ORC|RE|1||||||20100303114352
OBR|1|||HemosIL||||||||||||||||||||F
TQ1||||||20100303114352|20100303121429|R
OBX|1|ST|HemosIL&F2&Xpert HemosIL FII \T\ FV&1|FII|FII HOMOZYGOUS^|||||F|||||^samir alsa-
nady||20110912~02001~26874780~602023~704185~Sheth-Opt745
OBX|2|ST|HemosIL&F2|FII 20210G|NEG^|||
OBX|3|ST|HemosIL&F2|FII 20210G&Ct|^0|
OBX|4|ST|HemosIL&F2|FII 20210G&EndPt|^10.0|
OBX|5|ST|HemosIL&F2|FII 20210A|POS^|||
OBX|6|ST|HemosIL&F2|FII 20210A&Ct|^24.5|
OBX|7|ST|HemosIL&F2|FII 20210A&EndPt|^455.0|
OBX|8|ST|HemosIL&F5&Xpert HemosIL FII \T\ FV&1|FV|FV HOMOZYGOUS^|||||F|||||^samir alsa-
nady||20110912~02001~26874780~602023~704185~Sheth-Opt745
OBX|9|ST|HemosIL&F5|FV 1691G|NEG^|||
OBX|10|ST|HemosIL&F5|FV 1691G&Ct|^0|
OBX|11|ST|HemosIL&F5|FV 1691G&EndPt|^0.0|
OBX|12|ST|HemosIL&F5|FV 1691A|POS^|||
OBX|13|ST|HemosIL&F5|FV 1691A&Ct|^25.5|
OBX|14|ST|HemosIL&F5|FV 1691A&EndPt|^281.0|
SPM|1|100303FIIFV2001HM+E4^||ORH||||||P
```

9.3.4.1.13 Example of a Single-Result Test Result

HL7 – Single Result Assay

```
MSH|^~\&|CEPHEID^GeneXpert^2.1||LIS-1||20100311144225||ORU^R32^ORU_R30|URM-xtJZPdSA-01|P|2.5|||AL|NE
PID|1||
ORC|RE|1||||||20100217161021
OBR|1|||EV||||||||||||||||||F
TQ1||||||20100217161021|20100217184150|R
OBX|1|ST|&EV&Xpert EV&2||POSITIVE^|||||F|||||^Vincent Prakash||20110509~02308~1769789~512544~702755~Sheth-Opt745
OBX|2|ST|&EV|EV|POS^|||
OBX|3|ST|&EV|EV&Ct|^33.8|
OBX|4|ST|&EV|EV&EndPt|^537.0|
OBX|5|ST|&EV|CIC|NA^|||
OBX|6|ST|&EV|CIC&Ct|^36.0|
OBX|7|ST|&EV|CIC&EndPt|^280.0|
SPM|1|100217EVRls2308+M3^||ORH||||||P
```

LIS Host acknowledgement:

```
MSH|^~\&|LIS|| GeneXpert Micro ^ GeneXpert ^2.1||20071217110823||ACK|12YSADASSDDA|P|2.5|||NE|NE
MSA|CA|URM-6DcgpbRA-01
```

9.3.4.2 Download Message – Host Rejects Uploaded Test Result

If there is an error in the information retrieved by the system from the LIS host, the LIS host cannot retrieve any error information from the system. There are no records transmitted between the system and the LIS host.

9.3.5 Host requests Test Results

9.3.5.1 Download Message – Host requests Test Result (QRY^R02)

The instrument allows the LIS host to request test results for the available results. The LIS host can ask for results from multiple samples and multiple tests, but only one patient.

A maximum of 20 test results can be returned from the instrument.

9.3.5.1.1 Message Structure

Message	Comments
MSH	Message Header
QRD	Original-Style Query Definition

9.3.5.1.2 Message Header Segment (MSH)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Field Separator		1	ST	1	R	N	'|'
2	Encoding Characters		1	ST	4	R	N	See 7.4.2 for more information
3	Sending Application	Name or ID of the sender	1	HD	50	R	N	The host ID defined in the instrument configuration
5	Receiver ID	System ID	1	HD	50	R	N	The System Name defined in the system configuration
		System Name	2		50	R	N	'GeneXpert'
		Software Version	3		16	R	N	
7	Date and time of Message	Date and time the message was generated	1	TS		R	N	If empty, the current date and time is used.
9	Message Type		1	ID	3	R	N	'QRY'
			2	ID	3	R	N	'R02'
			3	ID	7	O	N	'QRY_R02'
10	Message ID	Unique message identifier	1	ST	32	R	N	
11	Processing ID		1	PT	3	R	N	'P' (Production)
12	Version Number	Version of protocol	1	VID	60	R	N	'2.5'

9.3.5.1.3 Query Definition Segment (QRD)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Query Date/ Time	Contains the date the query was generated by the application program.	1	TS		R	N	
2	Query Format Code	D/R/T	1	ID	1	R	N	'R'- Response is in record-oriented format
3	Query Priority	Contains the time frame in which the response is expected	1	ID	1	R	N	'I'- Immediate
4	Query ID	Contains a unique identifier for the query. Assigned by the querying application. Returned intact by the responding application	1	ST	32	R	N	Unique Identifier
7	Quantity Limited Request	Contains the maximum length of the response that can be accepted by the requesting system. Valid responses are numerical values (in the first component) given in the units specified in the second component	1	ST	4	R	N	20
			2	ST	2	R	N	RD
8	Who Subject Filter	This field should not have been a required field. However, for backwards compatibility it remains a required field. There are some queries in the standard that have not required this field.	1	ST	250	R	N	Not used
9	What Subject Filter	Describes the kind of information that is required to satisfy the request. Valid values define the type of transaction inquiry and may be extended locally during implementation.	1	ID	250	R	N	'RES'

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
10	What Department Data Code	This field should not have been a required field. However, for backwards compatibility it remains a required field. There are some queries in the standard that have not required this field.	1	ST	250	R	N	Not used
11	What Data Code Value Qual.	Patient Identification	1	ST	32	O	Y	Patient ID. (required if component 2 is empty). The Patient ID must be repeated as many times as there are different specimen id or instrument specimen id. However, it must be the same for all repetitions.
		Specimen identification	2	ST	25	R	Y	Specimen ID (required if component 1, Patient ID, is empty). If Use ISID is enabled and Patient ID is not present, both field 2 Specimen ID and field 3 Instrument Specimen ID must be present.
		Instrument Specimen ID	3	ST	32	O	Y	Instrument Specimen ID If Use ISID is enabled and Patient ID is not present, ISID must present together with field 2, Specimen ID If Use ISID is disabled, ISID is ignored.
		Test Id	4	ST	15	O	Y	

9.3.5.1.4 Example of Download Message – Host Requests Test Result (QRY^R02)

With Patient ID:

```
MSH|^~\&|LIS||ICU^GeneXpert^1.0||20070521100245||QRY^R02^QRY_R02|12XGGFFD|P|2.5
QRD|20070521100245|R|I|1123|||1000^RD|N/D|RES|N/D|PatId-122^SpecimenID-123456^^QC EV IO~ PatId-122^SpecimenID-7890^ISID-111^QC EV 2
```

Without Patient ID:

```
MSH|^~\&|LIS||ICU^GeneXpert^1.0||20070521100245||QRY^R02^QRY_R02|12XGGFFD|P|2.5
QRD|20070521100245|R|I|1123|||1000^RD|N/D|RES|N/D|^SpecimenID-123456^^QC EV IO~^SpecimenID-123456^ISID-555^QC EV 2
```

9.3.5.2 Upload Message – Instrument System Returns Results Initiated by Result Request (ORF^R04)

A maximum of 20 test results can be returned from the instrument.

9.3.5.2.1 ORF^R04 – Message Structure

Message	Comments
MSH	Message Header
MSA	Message Acknowledgment
QRD	Original-Style Query Definition
PID	Patient Identification Segment
{	
ORC	Order Common Segment
OBR	Observation Request Segment
[NTE]	Notes and comments (related to order)
TQ1	Timing/Quantity
{	
OBX	Observation Result Segment
[NTE]	Notes and comments (related to result)
}	
SPM	Specimen Segment
}	

9.3.5.2.2 ORF^R04 – Message Header Segment (MSH)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Field Separator		1	ST	1	R	N	'|'
2	Encoding Characters		1	ST	4	R	N	See 7.4.2 for more information
3	Sending Application	System ID	1	ST	50	R	N	The System Name defined in the system configuration
		System Name	2	ST	50	R	N	'GeneXpert'
		Software Version	3	ST	16	R	N	
5	Receiver ID	Name or ID of the receiver	1	ST	50	R	N	The Host ID defined in the system configuration

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
7	Date and time of Message	Date and time the message was generated	1	TS		R	N	
9	Message Type		1	ID	3	R	N	'ORF'
			2	ID	3	R	N	'R04'
			3	ID	7	O	N	'ORF_R04'
10	Message ID	Unique message identifier	1	ST	32	R	N	
11	Processing ID		1	ID	3	R	N	'P' (Production)
12	Version Number	Version of protocol	1	ID	60	R	N	'2.5'
15	Accept Ackn.		1	ID	2	O	N	'NE' (Never)
16	Application Ack.		1	ID	2	O	N	'NE' (Never)

9.3.5.2.3 ORF^R04 – Message Acknowledgement (MSA)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Acknowledge-ment Code	Acknowledge-ment Code		ID	2	R	N	'AA'
2	Message Control ID	From MSH-10 of associated message		ST	32	R	N	

9.3.5.2.4 ORF^R04 – Query Definition Segment (QRD)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Query Date/ Time	Contains the date the query was generated by the application program.	1	TS		R	N	
2	Query Format Code	D/R/T	1	ID	1	R	N	'R'- Response is in record-oriented format
3	Query Priority	Contains the time frame in which the response is expected	1	ID	1	R	N	'I'- Immediate
4	Query ID	Contains a unique identifier for the query. Assigned by the querying application. Returned intact by the responding application	1	ST	32	R	N	Unique identifier
7	Quantity Limited Request	Contains the maximum length of the response that can be accepted by the requesting system. Valid responses are numerical values (in the first component) given in the units specified in the second component	1	ST	4	R	N	'20
			2	ST	2	R	N	'RD'
8	Who Subject Filter	This field should not have been a required field. However, for backwards compatibility it remains a required field. There are some queries in the standard that have not required this field.	1	ST	250	R	N	Not used
9	What Subject Filter	Describes the kind of information that is required to satisfy the request. Valid values define the type of transaction inquiry and may be extended locally during implementation.	1	ID	250	R	N	'RES'

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
10	What Department Data Code	This field should not have been a required field. However, for backwards compatibility it remains a required field. There are some queries in the standard that have not required this field.	1	ST	250	R	N	Not used
11	What Data Code Value Qual.	Patient Identification	1	ST	32	O	N	
		Specimen identification	2	ST	25	R	N	
		Instrument Specimen ID	3	ST	32	O	N	If Use ISID is enabled, this is a required field. If Use ISID is disabled, this field is empty.
		Test ID	4	ST	15	O	N	

9.3.5.2.5 ORF^R04 – Patient Identification Record (PID)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Sequence Number	Defines the i'th occurrence of the associated record type		SI		R	N	1,2,3,...n
3	Patient ID	Patient identification		ST	32	O	N	

9.3.5.2.6 ORF^R04 – Order Common Segment (ORC)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Order Control			ID	2	R	N	'RE' : Observations 'OC': Order cancelled
2	Order Number			SI		R	N	1,2,3,...n
9	Date / Time of the order			TS		O	N	If empty, current date and time is used

9.3.5.2.7 ORF^R04 – Observation Request Segment (OBR)

Field No.	Field Name	Description	Component / subcomponent	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Sequence Number	Defines the i'th occurrence of the associated record type		SI		R	N	1,2,3,...n
4	Universal Test ID	System defined Test ID	1	ID	15	R	N	This field contains the identification of the test.
25	Order Status			ID	1	R	N	'A' (Some but not all results available) 'I' (No results available) 'X' (Result cannot be done, cancelled), or 'F' (Final Results)

9.3.5.2.8 ORF^R04 – Notes and Comments Segment (NTE) [optional, in case of error]

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Sequence Number	Defines the i'th occurrence of the associated record type	1	SI		R	N	1,2,3,...n
2	Source of Comment		1	ID	1	R	N	'L'
3	Comment text	Comment ID	1	ID	50	R	N	'Error'
3		Comment Code	2	ST	50	O	N	Error Code
		Comment description	3	ST	500	R	N	Error description

9.3.5.2.9 ORF^R04 – Timing/Quantity (TQ1)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
7	Start Date/ Time	Date and time the system started the test		TS		R	N	
8	End Date/ Time	Date and time the system completed the test		TS		R	N	
9	Priority	Describes the urgency of the request		ID	1	R	N	'S' (Stat) or 'R' (Normal)

9.3.5.2.10 ORF^R04 – Observation Result Segment (OBX)

Field No.	Field Name	Description	Component		Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Sequence Number	Defines the i'th occurrence of the associated record type	1		SI		R	N	1,2,3,...n
2	Value Type	'ST' for String 'NM' for Numeric	1		ID	2	R	N	'ST'
3	Observation Identifier	System defined Test Panel ID	1	1	ST	32	O	N	The host test code defined in system configuration for a multi-result assay
		System defined Test ID		2	ST	32	R	N	The host test code defined in system configuration for a single result assay or result within a multi-result assay. If subcomponent 1 and this component are the same, this result is the global result of a multi-result test. Not all multi-result tests have a global result.
		System defined Test name		3	ST	20	O*	N	The assay name shown in system configuration
		System defined Test version		4	ST	4	O*	N	The assay version shown in system configuration
4	Observation Sub-ID	Analyte Name / Organism name	1	1	ST	20	O	N	Analyte name (empty form main result, required for analyte results) OR Result name (only if this a main result)
		Complementary Result Name		2	ST	10	O	N	Only used for complementary results (otherwise it is empty). Possible values: 'Ct'/'EndPt'/'Delta Ct'/'Conc'
5	Observation Value	Observed, calculated or implied result value (Qualitative) If the test has an error (Field 11 = X), here is the error message.	1		ST	150	O	N	To be defined
		Observed, calculated or implied result value (Quantitative)	2		ST	7	O	N	Numeric value
6	Units		1		ST	1	O	N	'%' or empty

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
8	Abnormal Flags	This field shall indicate the normalcy status of the result.	1	IS	2	O	N	L Below low normal H Above high normal LL Below lower panic limits HH Above upper panic limits < Below absolute low-off instrument scale > Above absolute high-off instrument scale N Normal (applies to non-numeric results) A Abnormal (applies to non-numeric results) U Significant change up D Significant change down B Better--use when direction not relevant W Worse--use when direction not relevant
11	Result Status		1	ID	1	O*	N	'X' (result cannot be done) 'C' (Result is a correction of a previously transmitted result) 'F' (final results)
16	Responsible Observer	Family Name	2	ST	32	O*	N	Full Name. The rest of the components are ignored.
18	Equipment Instance	This field identifies the Equipment Instance (e.g., Analyzer, Analyzer module, group of Analyzers,...) responsible for the production of the observation. It should be possible to retrieve from this master list the equipment type, serial number, etc., however it is not planned to transfer this information with every OBX. The repeating of this field allows for the hierarchical representation of the equipment (lowest level first), e.g., module of an instrument, instrument consisting of modules, cluster of multiple instruments, etc.	1	ST	10	O*	Y	See comments below.

Field OBX-18 must represent the hierarchy of the subcomponents that made the measurement. This is represented as follows:

- Each component is a repetition of the field
- The hierarchy will be represented from the lowest to the highest level.
- Therefore, the hierarchy of components represented are (most particular to most general): Expiration Date, Reagent Lot ID, Cartridge Serial Number, Module Serial Number, System Serial Number and Computer System Name.
- All of the fields are required, except Expiration Date and Reagent Lot ID which are optional.
- The field is required only on the first record if the remainder of the result record has the same information.

Example of the field (including cases where the optional fields are not present)

```
YYYYMMDD~[ReagentLotId]~[CartridgeSerialNumber]~
[ModuleSerialNumber]~[InstrumentSerialNumber]~
[ ComputerSystemName]

~[ReagentLotId]~[CartridgeSerialNumber]~[ModuleSerialNumber]~[InstrumentSeri-
alNumber]~[ ComputerSystemName]

YYYYMMDD~~[CartridgeSerialNumber]~[ModuleSerialNumber]~[InstrumentSerialNum-
ber]~[ ComputerSystemName]

~~[CartridgeSerialNumber]~[ModuleSerialNumber]~[InstrumentSerialNumber]~[ Com-
puterSystemName]
```

9.3.5.2.11 ORF^R04 – Notes and Comment Segment (NTE)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Sequence Number	Defines the i'th occurrence of the associated record type	1	SI		R	N	1,2,3,...n
2	Source of Comment		1	ID	1	R	N	'L'
3	Comment Text	Comment ID	1	ID	50	R	N	'Notes'/'Error'
		Comment Code	2	ST	50	R	N	Error Code
		Comment description	3	ST	500	O	Y	Note text / Error description
		Comment details	4	ST	500	O	N	Error details
		Comment Timestamp	5	TS		O	N	If CommentID is Error, this field is required

9.3.5.2.12 ORF^R04 – Specimen Segment (SPM)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Sequence Number			SI	64	R	N	1,2,3,...n
2	Specimen ID	A unique identifier for the specimen assigned by the HOST	1	ST	25	R	N	
	Instrument Specimen ID	A unique identifier for the specimen assigned by the system. This must be retrieved from the LIS if it is known.	2	ST	32	R	N	
4	Specimen Type			ID	5	R	N	'ORH' (Other) ('Other' according to POCT1-A standard)
11	Specimen Role			ID	1	R	N	'Q' (For Quality control) 'P' (For Sample Patient)

9.3.5.2.13 Example with a Multi-Result Test with Both Notes and Error

MSH|^~\&|CEPHEID^GeneXpert^2.1||LIS-1||20100312113508||ORU^R32^ORU_R30|URM-zD43TdSA-01|P|2.5|||AL|NE

PID|1||

ORC|RE|1||||||20100312084521

OBR|1|||HemosIL|||||||||||||||||||F

TQ1||||||20100312084521|20100312085758|R

OBX|1|ST|HemosIL&F2&Xpert HemosIL FII \T\ FV&1|FII|ERROR^|||||F|||||^support||20110123~00901~1696533~510178~702162~Sheth-Opt745

NTE|1|L|Notes^^Iducing Error - Test

NTE|2|L|Error^5006^Post-run analysis error^Error 5006 - [FII 20210G] probe check failed. Probe check value of 491.6 for reading number 1 was above the maximum of 312.0^20100312085731

OBX|2|ST|HemosIL&F2|FII 20210G|NO RESULT^|||

OBX|3|ST|HemosIL&F2|FII 20210G&Ct|^0|

OBX|4|ST|HemosIL&F2|FII 20210G&EndPt|^0|

OBX|5|ST|HemosIL&F2|FII 20210A|NO RESULT^|||

OBX|6|ST|HemosIL&F2|FII 20210A&Ct|^0|

OBX|7|ST|HemosIL&F2|FII 20210A&EndPt|^0|

OBX|8|ST|HemosIL&F5&Xpert HemosIL FII \T\ FV&1|FV|ERROR^|||||F|||||^support||20110123~00901~1696533~510178~702162~Sheth-Opt745

NTE|1|L|Notes^^Iducing Error - Test

NTE|2|L|Error^5006^Post-run analysis error^Error 5006 - [FII 20210G] probe check failed. Probe check value of 491.6 for reading number 1 was above the maximum of 312.0^20100312085731

OBX|9|ST|HemosIL&F5|FV 1691G|NO RESULT^|||

OBX|10|ST|HemosIL&F5|FV 1691G&Ct|^0|

OBX|11|ST|HemosIL&F5|FV 1691G&EndPt|^0|

OBX|12|ST|HemosIL&F5|FV 1691A|NO RESULT^|||

OBX|13|ST|HemosIL&F5|FV 1691A&Ct|^0|

OBX|14|ST|HemosIL&F5|FV 1691A&EndPt|^0|

SPM|1|test-hemo-error^||ORH||||||P

9.3.5.3 Upload Message – Instrument System Returns Results Responding to Request for an Unidentified Patient or Specimen (ORF^R04)

9.3.5.3.1 ORF^R04 – Message Structure

Message	Comments
MSH	Message Header
MSA	Message Acknowledgment
QRD	Original-Style Query Definition
PID	Patient Identification Segment
{	
ORC	Order Common Segment
OBR	Observation Request Segment
}	

9.3.5.3.2 ORF^R04 – Message Header Segment (MSH)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Field Separator		1	ST	1	R	N	'|'
2	Encoding Characters		1	ST	4	R	N	See 7.4.2 for more information
3	Sending Application	System ID	1	ST	50	R	N	The System Name defined in the system configuration
		System Name	2	ST	50	R	N	'GeneXpert'
		Software Version	3	ST	16	R	N	
5	Receiver ID	Name or ID of the receiver	1	ST	50	R	N	The host ID defined in the system configuration
7	Date and time of Message	Date and time the message was generated	1	TS		R	N	
9	Message Type		1	ID	3	R	N	'ORF'
			2	ID	3	R	N	'R04'
			3	ID	7	O	N	'ORF_R04'
10	Message ID	Unique message identifier	1	ST	32	R	N	
11	Processing ID		1	ID	3	R	N	'P' (Production)
12	Version Number	Version of protocol	1	ID	60	R	N	'2.5'
15	Accept Ackn.		1	ID	2	O	N	'NE' (Never)
16	Application Ack.		1	ID	2	O	N	'NE' (Never)

9.3.5.3.3 ORF^R04 – Message Acknowledgement (MSA)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Acknowledgement Code	Acknowledgement Code		ID	2	R	N	'AA'
2	Message Control ID	From MSH-10 of associated message		ST	32	R	N	

9.3.5.3.4 ORF^R04 – Query Definition Segment (QRD)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Query Date/Time	Contains the date the query was generated by the application program.	1	TS		R	N	
2	Query Format Code	D/R/T	1	ID	1	R	N	'R'- Response is in record-oriented format
3	Query Priority	Contains the time frame in which the response is expected	1	ID	1	R	N	'I'- Immediate
4	Query ID	Contains a unique identifier for the query. Assigned by the querying application. Returned intact by the responding application	1	ST	32	R	N	Unique identifier
7	Quantity Limited Request	Contains the maximum length of the response that can be accepted by the requesting system. Valid responses are numerical values (in the first component) given in the units specified in the second component	1	ST	4	R	N	'20'
			2	ST	2	R	N	'RD'
8	Who Subject Filter	This field should not have been a required field. However, for backwards compatibility it remains a required field. There are some queries in the standard that have not required this field.	1	ST	250	R	N	Not used
9	What Subject Filter	Describes the kind of information that is required to satisfy the request. Valid values define the type of transaction inquiry and may be extended locally during implementation.	1	ID	250	R	N	'RES'

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
10	What Department Data Code	This field should not have been a required field. However, for backwards compatibility it remains a required field. There are some queries in the standard that have not required this field.	1	ST	250	R	N	Not used
11	What Data Code Value Qual.	Patient Identification	1	ST	32	O	N	
		Specimen identification	2	ST	25	R	N	
		Instrument Specimen ID	3	ST	32	O	N	If Use ISID is enabled, this is a required field. If Use ISID is disabled, this field is empty.
		Test ID	4	ST	15	O	N	

9.3.5.3.5 ORF^R04 – Patient Identification Record (PID)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Sequence Number	Defines the i'th occurrence of the associated record type		SI		R	N	1,2,3,...n
3	Patient ID	Patient identification		ST	32	O	N	

9.3.5.3.6 ORF^R04 – Common Order Segment (ORC)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Order Control			ID	2	R	N	'OC' : Cancelled
2	Order Number			SI		R	N	1,2,3,...n
9	Date / Time of the order			TS		O	N	If empty, current date and time is used

9.3.5.3.7 ORF^R04 – Observation Request Segment (OBR)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Sequence Number	Defines the i'th occurrence of the associated record type		SI		R	N	1,2,3,...n
4	Universal Test ID	System defined Test ID	2	ID	15	O	N	This field contains the identification of the test.
25	Order Status			ID	1	R	N	'Y' (Invalid Test ID) 'Z' (Invalid Patient ID), 'V' (Invalid Specimen ID or Instrument Specimen ID) 'E' (The query has a bad format)

9.3.5.3.8 Example of Upload Message – Instrument System Returns Results Responding to Request for an Unidentified Patient or Specimen (ORF^R04)

Unidentified Specimen

```
MSH|^~\&|ICU^GeneXpert^1.0||LIS||20070521100245||ORF^R04^ORF_R04|04126fc6-ab05-4394-affc-e2907e819080|P|2.5
MSA|AA|12XGGFFD
QRD|20070521100245|R|I|1123|||1000^RD|N/D|RES|N/D|^SID-123456^ISID-555^MRSA IUO
PID|1||
ORC|OC|1||||||20070521101245
OBR|1||| ||||||||||||||||||V
ORC|OC|2||||||20070521101246
OBR|1||||||||||||||||||||V
```

Unidentified Patient

```
MSH|^~\&|ICU^GeneXpert^1.0||LIS||20070521100245||ORF^R04^ORF_R04|312f1db6-d516-4b89-b678-191d58db825b|P|2.5
MSA|AA|12XGGFFD
QRD|20070521100245|R|I|1123|||1000^RD|N/D|RES|N/D|^SID-123456^ISID-555^MRSA IUO
PID|1||
ORC|OC|1||||||20070521101245
OBR|1||||||||||||||||||||Z
ORC|OC|2||||||20070521101246
OBR|2||||||||||||||||||||Y
```

9.3.6 Host Downloads Unsolicited Test Orders

Host initiated test order download is not supported. If the GeneXpert System receives an order delivery message without pending query (see section 9.3.6.1), it will send a rejection message as detailed in section 9.3.6.2 and 9.3.6.3. This scenario may also happen when the host sends an order delivery message after the query was timed out.

9.3.6.1 Download Message – Host Downloads Unsolicited Test Orders (OML^O21-ORL^O22)

This message can be configured with two different responses. The configuration will depend on how the LIS host wants to be answered.

Option I:

If an LIS does not require the application acknowledgement from the instrument and only requests a high-level acknowledgement, an ACK message is returned. However, this ACK message does not indicate the rejection of the action. The LIS must be notified by another means that the orders are not accepted.

Option II:

If the LIS host specifies that it requires an application acknowledgement, it will receive the message ORL^O22. This message contains the rejection code and the explanation.

9.3.6.1.1 OML^O21 – Message Structure

Message	Comments
MSH	Message Header
PID	Patient identification
{	
ORC	Common Order
OBR	Observation Request
TQ1	Quantity / Timing
SPM	Specimen
}	

9.3.6.1.2 OML^O21 –Message Header Segment (MSH)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Field Separator		1	ST	1	R	N	'|'
2	Encoding Characters		1	ST	4	R	N	See 7.4.2 for more information
3	Sending Application	Name or ID of the receiver	1	ST	50	R	N	The host ID defined in the system configuration
5	Receiver ID	System ID	1	ST	50	R	N	The System Name defined in the system configuration
		System Name	2	ST	50	R	N	'GeneXpert'
		Software Version	3	ST	16	R	N	
7	Date and time of Message	Date and time the message was generated	1	TS		R	N	If empty, the current date and time is used.
9	Message Type		1	ID	3	R	N	'OML'
			2	ID	3	R	N	'O21'
			3	ID	7	O	N	'OML_O21'
10	Message ID	Unique message identifier	1	ST	32	R	N	
11	Processing ID		1	ID	3	R	N	'P' (Production)
12	Version Number	Version of protocol	1	ID	60	R	N	'2.5'
15	Accept Ackn.		1	ID	2	O	N	Option I: 'AL' (Always) Option II:'NE' (Never)
16	Application Ack.		1	ID	2	O	N	Option I: 'NE' (Never) Option II: :'AL' (Always)

9.3.6.1.3 OML^O21 – Patient Identification Record (PID)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Sequence Number	Defines the i'th occurrence of the associated record type		SI		R	N	1,2,3,...n
3	Patient ID	Patient identification		ST	32	O	N	

9.3.6.1.4 OML^O21 – Common Order Segment (ORC)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Order Control			ID	2	R	N	'NW' : New order 'OC': order cancelled
2	Order Number			SI		R	N	1,2,3,...n
9	Date / Time of the order			TS		O	N	If empty, current date and time is used

9.3.6.1.5 OML^O21 – Observation Request Segment (OBR)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Sequence Number	Defines the i'th occurrence of the associated record type		SI		R	N	1,2,3,...n
4	Universal Test ID	System defined Test ID	1	ID	15	R	N	This field contains the identification of the test.
11	Specimen Action Code			ID	1	R	N	'A' (Added in previous specimen or creates a new specimen following the rules of the sample life cycle)

9.3.6.1.6 OML^O21 – Timing/Quantity (TQ1)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
9	Priority			ID	1	R	N	'S' (Stat) / 'R' (Routine)

9.3.6.1.7 OML^O21 – Specimen Segment (SPM)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Sequence Number			SI	64	R	N	1,2,3,...n
2	Specimen ID	A unique identifier for the specimen assigned by the HOST	1	ST	25	R	N	
	Instrument Specimen ID	A unique identifier for the specimen assigned by the system. This must be retrieved from the LIS if it is known.	2	ST	32	O	N	This field will be ignored if the Use Instrument Specimen ID option is disabled
4	Specimen Type			ID	5	R	N	'ORH' (Other) ('Other' according to POCT1-A standard)
11	Specimen Role			ID	1	R	N	'Q' (For Quality control) 'P' (For Sample Patient)

9.3.6.2 Option I Upload Message – Instrument System Rejects Unsolicited Test Orders with a High-Level Acknowledgement

9.3.6.2.1 (Option I) ACK – Message Structure

Message	Comments
MSH	Message Header
MSA	Message Acknowledgment

9.3.6.2.2 (Option I) ACK – Message Header Record (MSH)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Field Separator		1	ST	1	R	N	'|'
2	Encoding Characters		1	ST	4	R	N	See 7.4.2 for more information
3	Sending Application	System ID	1	ST	50	R	N	The System Name defined in the system configuration
		System Name	2	ST	50	R	N	'GeneXpert'
		Software Version	3	ST	16	R	N	
5	Receiver ID	Name or ID of the receiver	1	ST	50	R	N	The host ID defined in the system configuration
7	Date and time of Message	Date and time the message was generated	1	TS		R	N	
9	Message Type		1	ID	3	R	N	'ACK'
			2	ID	3	R	N	'O22'
10	Message ID	Unique message identifier	1	ST	32	R	N	
11	Processing ID		1	ID	3	R	N	'P' (Production)
12	Version Number	Version of protocol	1	ID	60	R	N	'2.5'
15	Accept Ackn.		1	ID	2	O	N	'NE' (Never)
16	Application Ack.		1	ID	2	O	N	'NE' (Never)

9.3.6.2.3 (Option I) ACK – Message Acknowledgement (MSA)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Acknowledgement Code	Acknowledgement Code	1	ST	2	R	N	'CA'
2	Message Control ID	From MSH-10 of associated message	1	ST	32	R	N	

9.3.6.2.4 Option I Example

Message sent by the LIS Host:

```
MSH|^~\&|LIS||ICU^GeneXpert^1.0||20070521100245||OML^O21^OML_O21|12XASDASF|P|2.5|||AL|NE
PID|1||PatientID-1234
ORC|NW|1||||||20070421100245
OBR|1|||Test_ID-212||||||A
TQ1|||||||||R
SPM|1|SID-888||ORH||||||P
ORC|NW|2||||||20070421100235
OBR|2|||Test_ID-214||||||A
TQ1|||||||||R
SPM|2|SID-188||ORH||||||P
PID|2||PatientID-5678
ORC|NW|1||||||20070421100255
OBR|1|||Test_ID-213||||||A
TQ1|||||||||S
SPM|1|SID-818||ORH||||||P
```

High level ACK:

```
MSH|^~\&|ICU^GeneXpert^1.0||LIS||20070521100245||ACK|ddc3f515130f41819318343d04751fa1|P|2.5
MSA|CA|12XASDASF
```

9.3.6.3 Option II Upload Message – Instrument System Rejects Unsolicited Test Orders (ORL^O22) with an Application Acknowledgement

9.3.6.3.1 (Option II) ORL^O22 – Message Structure

Message	Comments
MSH	Message Header
MSA	Message Acknowledgment
ERR	Error message

9.3.6.3.2 (Option II) ORL^O22 – Message Header Record (MSH)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Field Separator		1	ST	1	R	N	'|'
2	Encoding Characters		1	ST	4	R	N	See 7.4.2 for more information
3	Sending Application	System ID	1	ST	50	R	N	The System Name defined in the system configuration
		System Name	2	ST	50	R	N	'GeneXpert'
		Software Version	3	ST	16	R	N	
5	Receiver ID	Name or ID of the receiver	1	ST	50	R	N	The host ID defined in the system configuration
7	Date and time of Message	Date and time the message was generated	1	TS		R	N	
9	Message Type		1	ID	3	R	N	'ORL'
			2	ID	3	R	N	'O22'
			3	ID	7	O	N	'ORL_O22'
10	Message ID	Unique message identifier	1	ST	32	R	N	
11	Processing ID		1	ID	3	R	N	'P' (Production)
12	Version Number	Version of protocol	1	ID	60	R	N	'2.5'
15	Accept Ackn.		1	ID	2	O	N	'NE' (Never)
16	Application Ack.		1	ID	2	O	N	'NE' (Never)

9.3.6.3.3 (Option II) ORL^O22 – Message Acknowledgement (MSA)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
1	Acknowledge-ment Code	Acknowledgement Code	1	ST	2	R	N	'AR'
2	Message Control ID	From MSH-10 of associated message	1	ST	32	R	N	

9.3.6.3.4 (Option II) ORL^O22 – Message Acknowledgement (ERR)

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
3	HL7 Error Code		1	ST	3	R	N	'200' (HL7 error code: unsupported message type)
		Error description	2	ST	255	R	N	'Unsolicited download of orders is not supported'
4	Severity			ST	1	R	N	'E' (Error)

9.3.6.3.5 Option II Example

Message sent by the LIS Host:

```
MSH|^~\&|LIS||ICU^GeneXpert^1.0||20070521100245||OML^O21^OML_O21|12XASDASF|P|2.5|||NE|AL
PID|1||PatientID-1234
ORC|NW|1||||||20070421100245
OBR|1|||Test_ID-212||||||A
TQ1|||||||||R
SPM|1|SID-888||ORH||||||P
ORC|NW|2||||||20070421100235
OBR|2|||Test_ID-214||||||A
TQ1|||||||||R
SPM|2|SID-188||ORH||||||P
PID|2||PatientID-5678
ORC|NW|1||||||20070421100255
OBR|1|||Test_ID-213||||||A
TQ1|||||||||S
SPM|1|SID-818||ORH||||||P
```

Application Acknowledgement (ORL^O22):

```
MSH|^~\&|ICU^GeneXpert^1.0||LIS||20070521100245||ORL^O22^ORL_O22|ddc3f515130f41819318343d04751fa1|P|2.5
MSA|AR|12XASDASF
ERR|||200^Unsolicited download of orders is not supported|E
```

10 Relation of ASTM and HL7 records

10.1 ASTM Messages

Table 1: ASTM records by type

UPLOAD MESSAGES	
Record type	Pages
H	22, 24, 30, 34, 37, 40, 54, 60, 66
P	31, 38, 41, 55, 61
O	32, 38, 41, 55, 61
Q	23, 25, 35
C	25, 33, 42, 48, 56, 59, 67
R	42, 56
L	23, 25, 33, 35, 38, 48, 59, 62, 66
DOWNLOAD MESSAGES	
H	26, 29, 51, 63
P	27, 64
O	27, 64
Q	52
C	
R	
L	28, 30, 52, 65

10.2 HL7 Messages

Table 2: HL7 segments by type

UPLOAD MESSAGES	
Segment Type	Pages
MSH	81, 83, 95, 101, 108, 113, 128, 138, 146, 148
QPD	82, 102
RCP	82, 102
QID	84
EQU	109
SAC	109
SPM	98, 110, 121, 136
PID	96, 114, 131, 140
ORC	96, 114, 131, 140
OBR	96, 115, 132, 141
TQ1	97, 115, 132
OBX	116, 133
NTE	97, 115, 121, 132, 135
MSA	129, 138, 146, 148
QRD	130, 139
ERR	149
DOWNLOAD MESSAGES	
MSH	85 ,87, 92, 98 ,104, 111, 122, 125
PID	89, 144
ORC	90, 144
OBR	90, 144
TQ1	90, 144
SPM	91, 145
QRD	126
MSA	85, 87, 93, 99, 105 , 111, 122
QAK	88, 93, 106
QPD	89, 94, 107

11 Troubleshooting the LIS Interface

11.1 System configuration problems

Table 3 lists the possible system configuration problems you might encounter. To contact Cepheid Technical Support, see the Assistance section in the Preface of the *GeneXpert DX System Operator Manual* or *GeneXpert Infinity-48 System Operator Manual* for the contact information.

Table 3: System configuration problems

Problem	Cause	Solution
Cannot Edit Test Code for old versions of an assay, if LIS Admin updates test code it will only apply to new version of the assay.	Upgrade of assay to new version.	Change the test code prior to upgrade of assay.
Upload of test results with duplicate System Name cannot tell which instrument results came from.	Duplicate System Name.	1. System Name must be Unique. 2. LIS Interface to check for duplicate instrument system names. 3. LIS Admin to control process for defining System name.
User Error in Selecting the Assay when defining Test Codes	User Error in Selecting the Assay.	LIS Admin to configure correct test code; for example, CPT code for test or Abbreviate Assay Name.

11.2 Order management problems

Table 4 lists the possible order management problems you might encounter. To contact Cepheid Technical Support, see the Assistance section in the Preface of the *GeneXpert DX System Operator Manual* or *GeneXpert Infinity-48 System Operator Manual* for the contact information.

Table 4: Order management problems

Problem	Cause	Solution
Multiple system receive same test order - both assign **ISID**.	Test order sent to multiple GX systems in parallel.	1. Operator to cancel test order. 2. LIS Admin to switch to Host Query configuration instead of Query All. 3. Prevent the LIS from downloading to multiple systems.
Test Orders Downloaded to Incorrect GX System.	Duplicate System Name.	1. System name must be Unique. 2. LIS Interface to check for duplicate instrument system name. 3. LIS Admin to control process for defining System name.
Incorrect Assay is run	User Error in entereing the Host Test Code.	1. Verify that the test code in test order table is active in GX configuration. 2. LIS Admin to configure correct test code.
Moderate complexity user runs a high complexity assay.	Query all gives GX and SC test orders.	If your facility has both GeneXpert and Smart Cyclers Interface to LIS, then use unique test code (do not repeat test codes across different systems).

11.3 Result management problems

Table 5 lists the possible result management problems you might encounter. To contact Cepheid Technical Support, see the Assistance section in the Preface of the *GeneXpert DX System Operator Manual* or *GeneXpert Infinity-48 System Operator Manual* for the contact information.

Table 5: Result management problems

Problem	Cause	Solution
LIS asks for all results on specific specimen ID.	Request for upload only includes specimen ID.	LIS Interface to setup proper handling of duplicate result upload; for example, take the latest result.
Upload duplicate test results.	User uplaods test results that have previously been uploaded.	LIS Admin to administer proper handling of duplicate result upload.
Re-upload confirmation pass or fail.	Re-upload fails.	Interface to address failed attempt to re-upload result.