GeneXpert
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GeneXpert® LIS Interface Protocol Specification

For Cepheid Software versions:
GeneXpert® DX v4.7b and above
GeneXpert® Omni Mobile Application 1.2 and above
GeneXpert® Xpress 5.1 and above
Infinity Xpertise v6.4b and above

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Change History

Version	Changes
301-2002	
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.
GeneXpert Dx 4.5	1.Quantitative Results Features and Appropriate Fields 2.Removed Organism Name from Result Field.
Xpertise v6.2 and above and GeneXpert Dx v4.6 and above	Revised incorrect references to Infinity-48.
Xpertise v4.6, Xpertise v6.2 and above, and GeneXpert Dx v4.6 and above	Add support for Infinity-48 Xpertise 4.6 and above software to title.
Infinity-48 Xpertise v4.6a and above, Infinity Xpertise v6.4a and above, and GeneXpert® DX v4.7b and above.	Revised Sections 6.3.4.1, 6.3.4.1.9, 6.3.4.1.10, 9.3.4.1, 9.3.4.1.12, 9.3.4.1.13, and 9.3.5.2.13, to revise error code handling and to restore deleted text from a previous document version. Corrected minor paragraph mis-numbering. Split manual to Show Infinity-48 in sections 12 through 23.
302-2261	
Infinity Xpertise v6.4b and above, and GeneXpert® DX v4.7b and above.	Removed: • Section 10: Relation of ASTM/HL7 records • Section 12-22: Infinity-48, Xpertise v4.6a, legacy software Updated: • Section 1.7: Removed reference to legacy documents • Section 3.2.3.1: Added ASTM LLP message example describing frame numbers • Section 5.3: Added information on LIS tracing for various versions of software • Section 6.1 & Section 9.3: Moved repetitive segment mapping tables to Section 6.3, added hyper-links on records on message structure tables, and updated all message examples • Section 7.2.1.2: Added ERR and INV segments to table Added: • Section 1.4: Supported GeneXpert Instrument Models • Section 1.8: Supported Workflows • Section 1.9: Non-Standard Implementation Guide • Section 3.2.7: ASTM LLP message example • Section 6.3: ASTM Message Mapping Format • Section 8.1.5: HL7 message example • Section 9.4: HL7 Message Mapping Format

Version	Changes
GeneXpert Omni Mobile Application 1.2 and above	Removed: Section 1.5: Removed reference to legacy documents; removed 2019 Version # row Section 1.9.1: Removed GeneXpert Xpress version 5.1 reference Section 5.2: Deleted “traces” from first bulleted paragraph Section 7.2.1.2: Removed “ERR” row from table Added: Cover: Added GeneXpert Omni Mobile Application 1.2 and above Section 1: GeneXpert Omni Mobile Application 1.2 and above Section 1.4: GeneXpert Omni column added to table Section 1.5: GeneXpert Omni System Operator Manual row added to table Section 1.7: Bulleted item referencing Omni Mobile Application added Section 1.7.1: GeneXpert Omni Operator Manual reference added Section 1.8: GeneXpert Omni version 1.2added; Column added to table for GeneXpert Omni Mobile Application v2.1 and above; Note added below table concerning Workflow 4 supporting Omni Mobile Application. Section 1.8.3: GeneXpert Omni 1.2 added Section 2: Note concerning Omni phone with SIM card added Section 4.2.1.1: GeneXpert Omni Mobile Application version 1.2 and above column added to table; Added “and above” to GeneXpert Xpress 6.1 column Section 5.2: Third bulleted item added regarding GeneXpert Omni Mobile Application Section 5.3: Paragraph added concerning LIS Message Tracing for GeneXpert Omni Mobile Application Section 7.2.1.2: Column added to table regarding GeneXpert Omni Mobile Application Section 10.1: GeneXpert Omni System Operator Manual added to first paragraph Section 10.3: GeneXpert Omni System Operator Manual added to first paragraph

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1 Overview

This section describes how GeneXpert Instruments interface with LIS using ASTM and HL7 protocols. It includes a summary of the supported workflows and any non-standard protocol implementation.

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This specification supports the following GeneXpert Instruments: GeneXpert DX v4.7b and above, Infinity Xpertise v6.4b and above, GeneXpert Xpress v5.1 and above, GeneXpert Omni Mobile Application 1.2 and above.

1.1 Purpose

This document is intended to be a guide for implementing the ASTM E1394-97 protocol or the HL7 v2.5 protocol for a host to communicate with the GeneXpert System, both using ASTM E1381-02 low level protocol. 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:

- Chapter 2, Physical Layer
- Chapter 3, Lower Level Transport Protocol
- Chapter 4, ASTM Message Structure and Content
- Chapter 5, ASTM Message Transmission Control
- Chapter 6, ASTM Transmission Scenarios

For HL7 protocol implementation, refer to:

- Chapter 2, Physical Layer
- Chapter 3, Lower Level Transport Protocol
- Chapter 7, HL7 Message Structure and Content
- Chapter 8, HL7 Message Transmission Control
- Chapter 9, HL7 Transmission Scenarios

1.3 Definitions and Acronyms

- ASTM: American Society for Testing and Materials
- DMS: Data Management System
- GX: GeneXpert
- HL7: Health Level 7 protocol
- Host: A host could be a Laboratory Information System (LIS) or a Data Management System (DMS)
- ISID: Instrument Specimen Identification
- LIS: Laboratory Information System

1.4 Supported GeneXpert Instrument Models

Instrument Name	GeneXpert® Xpress	GeneXpert® DX	GeneXpert® Infinity	GeneXpert® Omni
Model Name	GeneXpert Xpress	GeneXpert	GeneXpert Infinity	GeneXpert Omni
Software Name	GeneXpert Xpress	GeneXpert Dx	Xpertise	Omni Mobile Application
ASTM	X	X	X	X
HL7	X	X	X	X

1.5 References

Ref	Description
R1	ASTM E1394-97 *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 E1381-02 Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems
R4	*GeneXpert Dx System Operator Manual*, *GeneXpert Infinity System Operator Manual*, *GeneXpert Omni System Operator Manual* and *GeneXpert Xpress System User's Guide*
R5	*Cepheid C360 Admin Manual*

1.6 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
- 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.

1.7 Configuring the GeneXpert LIS Communication Settings

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

- For GX Dx 6.1 software, see Chapter 2 (Host Communication Settings Tab) and Chapter 5 (Operating with Host Connectivity) in the *GeneXpert DX System Operator Manual.*
- For Xpertise software, see Chapter 2 (Host Communication Settings Workspace) and Chapter 5 (Operating with Host Connectivity) in the *GeneXpert Infinity System Operator Manual*.
- For the Xpress software, see Chapter 3 (Operating with Host Connectivity) and Chapter 4 (Host Management and Settings) in the *GeneXpert Xpress System User's Guide*.
- For the Omni Mobile Application, see Chapter 7.7 (Configuring a Laboratory Information System) in the *GeneXpert Omni System Operator manual*.

1.7.1 Setting Up a Test Code for Ordering Tests and Uploading Results

The operator manual provides instructions on how to set up the Assay Host Test Code and Result Test Code. See Chapter 5 (Operating with Host Connectivity) in the *GeneXpert DX System Operator Manual*, the *GeneXpert Infinity System Operator Manual* or the *GeneXpert Xpress System User's Guide* for details. See Chapter 7.7.6 (Configuring the Test Code Settings) in the *GeneXpert Omni System Operator manual*.

1.8 Supported Workflows

The GeneXpert systems support four workflows to communicate with the LIS, that are supported by both ASTM and HL7 communication protocols. The only exception is GeneXpert Xpress version 5.1 and GeneXpert Omni version 1.2 that is a Unidirectional (Result only) interface.

Workflows	GeneXpert® Xpress 5.1	GeneXpert® Xpress 6.1	GeneXpert® DX 4.7b above	GeneXpert® Infinity 6.4b above	GeneXpert® Omni Mobile Application v2.1 and above
1- Solicited ALL Test Order Submission		X	X	X	
2- Solicited Test Order Submission		X	X	X	
3- Test Result Upload	X	X	X	X	X
4- LIS Host Requests Test Results	X	X	X	X	X
5- Unsolicited Test Order	Not Supported				

Note Workflow 4 is supported in Omni Mobile Application when LIS Host is in client mode.

1.8.1 Solicited ALL Test Orders Submission

The GeneXpert (GX) systems request a test order from the LIS for all available samples.

- If order(s) are available, the LIS sends all available order(s). If GeneXpert system is configured to use Instrument Specimen ID (ISID), the GeneXpert system sends the LIS the assigned ISID(s) for each sample.
- If order(s) are not available, the LIS responds with a negative query.

Note If the LIS host does not 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.

Direction	HL7 Message
Instrument System Queries for All Test Orders (Section 6.3.1.1)	
Gx → LIS	QBP^Z01
IF LIS order is available: Host Responds with Test Orders for Query for All Test Orders (Section 6.3.1.3)	
Gx ← LIS	RSP^Z02
IF use ISID is on:	
Gx → LIS	SSU^U03

Direction	HL7 Message
LIS Host Acknowledgment	
Gx ← LIS	ACK^U03
Instrument System Rejects Test Order Initiated from Query for All (Section 6.3.1.5)	
Gx → LIS	ORU^R01
LIS Host Acknowledgment	
Gx ← LIS	ACK^R01
OR	
IF LIS order is not available: Host Responds with No Available Test Order for Query for All (Section 6.3.1.4)	
Gx ← LIS	RSP^Z02
OR	
Instrument System Cancels Query for All Test Orders (Section 6.3.1.2)	
Gx → LIS	QCN^J01
LIS Host Acknowledgment	
Gx ← LIS	ACK^J01

1.8.2 Solicited Test Orders Submission

The GeneXpert systems request a test order from the LIS for each sample after sample recognition.

- If an order is available, the LIS sends the requested order. If GX system is configured to use Instrument Specimen ID (ISID), the GX system sends the LIS the assigned ISID(s).
- If order(s) are not available, the LIS responds with a negative query.

Note

If the LIS host does not 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.

Direction	HL7 Message
Instrument System Sends Host Query for Specific Specimen(s) (Section 6.3.2.1)	
Gx → LIS	QBP^Z03
IF LIS order is available: Host Responds with Test Order(s) for Host Query for Specific Specimen(s) (Section 6.3.2.3)	
Gx ← LIS	RSP^Z02
IF use ISID is on: Instrument System Responds with Instrument Specimen ID for a Downloaded Order (Section 6.3.3)	
Gx → LIS	SSU^U03
LIS Host Acknowledgment	
Gx ← LIS	ACK^U03
Instrument System Rejects Test Order Initiated from Host Query for Specific Specimen (Section 6.3.2.5)	
Gx → LIS	ORU^R01
LIS Host Acknowledgment	
Gx ← LIS	ACK^R01
OR	
IF LIS order is not available: Host Responds with No Available Test Order for Host Query for Specific Specimen (Section 6.3.2.4)	
Gx ← LIS	RSP^Z02
OR	
Instrument System Cancels Host Query for Specific Specimen(s) (Section 6.3.2.2)	
Gx → LIS	QCN^J01
LIS Host Acknowledgment	
Gx ← LIS	ACK^J01

1.8.3 Test Result Upload

The GeneXpert systems send test results to the LIS.

The GeneXpert Xpress version 5.1 and GeneXpert Omni 1.2 is a Unidirectional (Result only) interface.

Direction	HL7 Message
Instrument System Uploads Results (Section 6.3.4.1)	
Gx → LIS	ORU^R01
LIS Host Acknowledgment	
Gx ← LIS	ACK^R01

1.8.4 LIS Host Requests Test Results

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.

Direction	HL7 Message
Host Requests Test Result (Section 6.3.5.1)	
Gx ← LIS	QRY^R02
Instrument System Returns Results Initiated by Result Request (Section 6.3.5.2)	
Gx → LIS	ORF^R04
OR	
Instrument System Returns Results Responding to Request for an Unidentified Patient or Specimen (Section 6.3.5.3)	
Gx → LIS	ORF^R04

1.8.5 Unsolicited Test Order (Not supported)

The LIS sends an unsolicited test order to the GX system(s).

Direction	HL7 Message
Host Downloads Unsolicited Test Orders (Section 6.3.6.1)	
Gx ← LIS	OML^O21
Instrument System Rejects Unsolicited Test Orders (option I) (Section 6.3.6.2)	
Gx → LIS	ORL^O21
OR	
Instrument System Rejects Unsolicited Test Orders (option II) (Section 6.3.6.2)	
Gx → LIS	ORL^O22

1.9 Non-Standard Implementation Guide

1.9.1 Communication Protocol

- The HL7 protocol uses the ASTM E1381-02 protocol for low-level communication.
- The GeneXpert system does not automatically identifies the protocol from incoming messages. Make sure the correct protocol is configured on both sides of the LIS interface. Misconfiguration can occur, transmissions can be lost and will be logged as errors.
- When using HL7, results will be marked as “uploaded” by GX upon sending the low-level ASTM end of transmission (EOT) instead of processing the LIS MSH/MSA acknowledge response.

1.9.2 Sample Type Value

- Customer sites have to work around the fact that GX only supports a fixed sample type value (“ORH”) and set up unique host assays for each sample type/test code combination.

1.9.3 LIS Request Test Results

- When a LIS Requests “F” Final Test Results, the GX instrument system includes Final results and Pending orders in the response.

1.9.4 Instrument Sends Host Query for Test Orders

- Although the GeneXpert application user interface may allow querying for Patient ID only, the instrument will transmit a Query for ALL instead. There are 3 ways to Query the Host LIS for Test Orders:
  - Query ALL
  - Query for Specimen ID
  - Query Patient ID and Specimen ID
  - Query for Patient ID only (not supported)
- The GeneXpert instrument system will accept and process all test orders, including multiple specimens, if the queried specimen identification is found and transmitted by the LIS Host. GeneXpert will not send a rejection for an unsolicited order.

1.9.5 Unsolicited Test Orders

- In HL7, if the LIS sends an Unsolicited Test Order to the GX system(s), the GX instrument should reject and transmit the following HL7 messages ORL^O21 (option I) or ORL^O22 (option II).

Note This feature is not available.

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

Note

Omni phone with SIM card is not available in all markets. If Omni phone is using the SIM card, then the Omni as a Server mode is not supported.

3 Lower Level Transport Protocol

This chapter describes the ASTM E1381-02 low-level protocol, representing the establishment, transfer, and termination phases. It includes an example of a successful host query, followed by an order download and a patient result transfer with all low-level character's present. Please note both ASTM and HL7 protocols use the ASTM E1381-02.

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 E1381-02 protocol.

3.2 The ASTM E1381-02 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 the 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.

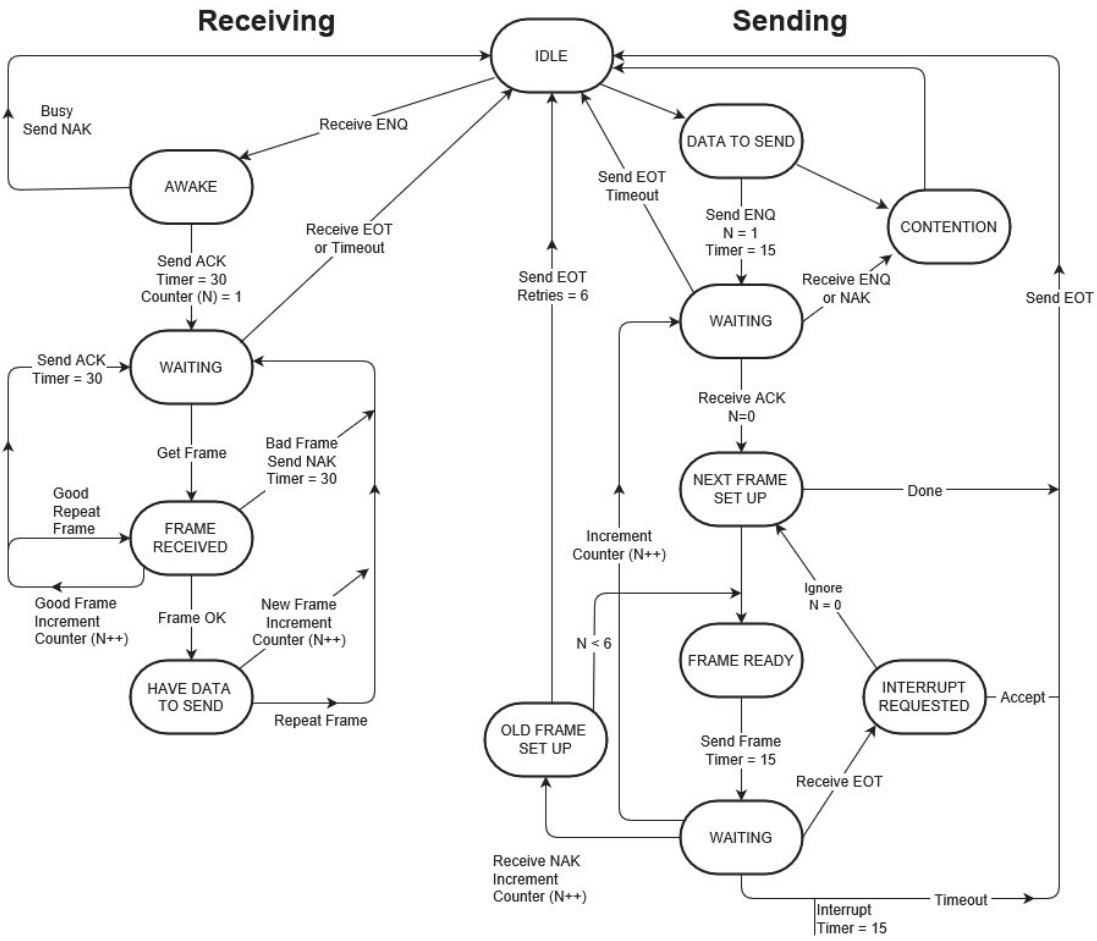

Figure 3-1. ASTM E1381-02 Protocol

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:
    - 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.
    - 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 240+7 bytes (240 message text plus 7 control characters).

Messages longer than 240 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:

Table 3-1. Frame Part Description

Frame Part	Description
<STX>	Start of Text transmission control character
FN	Frame Number (single digit comprised in the range 0-7). See details in Frame Number, on page 3-6.
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 Checksum, on page 3-7.
C2	Least significant character of checksum (belonging to {0-9, A-F}). See details in Checksum, on page 3-7.
<CR>	Carriage Return ASCII character
<LF>	Line Feed ASCII character

Transmissions

Typical transmission between GeneXpert Instrument (s) and Host:

Table 3-2. Typical Transmission between GeneXpert Instrument(s) and Host

GeneXpert Instrument	< >	Host
<ENQ>	>	
	<	<ACK>
<STX>1 …. Data … <CR><ETB>XX<CR><LF>	>	
	<	<ACK>
<STX>2 …. Data … <CR><ETB>XX<CR><LF>	>	
	<	<ACK>
<STX>3 …. Data … <CR><ETX>XX<CR><LF>	>	
	<	<ACK>
<EOT>	>	

Typical transmission between Host and GeneXpert Instrument (s):

Table 3-3. Typical Transmission between Host and GeneXpert Instrument(s)

Host	< >	GeneXpert Instrument
<ENQ>	>	
	<	<ACK>
<STX>1 …. Data … <CR><ETB>XX<CR><LF>	>	
	<	<ACK>
<STX>2 …. Data … <CR><ETB>XX<CR><LF>	>	
	<	<ACK>
<STX>3 …. Data … <CR><ETX>XX<CR><LF>	>	
	<	<ACK>
<EOT>	>	

Line Contention between Host and GeneXpert Instrument, or vice versa: In this case, the Host is the Master of the communication so the instrument gives up the line.

Table 3-4. Line Contention between Host and GeneXpert Instrument

Host	< >	GeneXpert Instrument
<ENQ>	>	
	<	<ENQ>
Wait 2 seconds…		
<ENQ>	>	
	<	<ACK>

Negative Acknowledgment of defective frame:

Table 3-5. Negative Acknowledgment of Defective Frame

GeneXpert Instrument	< >	Host
<ENQ>	>	
	<	<ACK>
<STX>1 …. Data … <CR><ETB>XX<CR><LF>	>	
	<	<NAK>
<STX>1 …. Data … <CR><ETB>XX<CR><LF>	>	
	<	<ACK>
<STX>2 …. Data … <CR><ETX>XX<CR><LF>	>	
	<	<ACK>
<EOT>	>	

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.

GX -> Host <ENQ>

Host -> GX <ACK>

GX -> Host <STX>1H|@^\|GXM-35607015733||GeneXpert PC^GeneXpert^6.1|||||LIS Simulator||P|1394-97|20190404092948<CR>P|1||||^^^^|||||||||||||||||||||||||||<CR>O|1|123||^^^CTNG|R|20160331184630||||||||ORH|||||||||F<CR>R|1|^CTNG^^CT^Xpert CT_NG^3^CT^|DETECTED^|||||F<ETB>A2<0D><0A>

Host -> GX <ACK>

GX -> Host <STX>2|Ashly Bastee|20160331184630|20160331201429|DESKTOP-ML3S693^703639^604320^457775983^07916^20180107|<CR>R|2|^CTNG^^CT^^^CT1^|POS^|||<CR>R|3|^CTNG^^CT^^^CT1^Ct|^20.1|||<CR>R|4|^CTNG^^CT^^^CT1^EndPt|^304.0|||<CR>R|5|^CTNG^^CT^^^SAC^|NA^|||<CR>R|6|^CTNG^^CT^^<ETB>50<0D><0A>

Host -> GX <ACK>

GX -> Host <STX>3^SAC^Ct|^20.2|||<CR>R|7|^CTNG^^CT^^^SAC^EndPt|^260.0|||<CR>R|8|^CTNG^^CT^^^SPC^|NA^|||<CR>R|9|^CTNG^^CT^^^SPC^Ct|^31.7|||<CR>R|10|^CTNG^^CT^^^SPC^EndPt|^282.0|||<CR>R|11|^CTNG^^NG^Xpert CT_NG^3^NG^|NOT DETECTED^|||||F||Ashly Bastee|20160331184630|20160331<ETB>FF<0D><0A>

Host -> GX <ACK>

GX -> Host <STX>4201429|DESKTOP-ML3S693^703639^65e04320^457775983^07916^20180107|<CR>R|12|^CTNG^^NG^^^NG2^|NEG^|||<CR>R|13|^CTNG^^NG^^^NG2^Ct|^0.0|||<CR>R|14|^CTNG^^NG^^^NG2^EndPt|^-1.0|||<CR>R|15|^CTNG^^NG^^^NG4^|NEG^|||<CR>R|16|^CTNG^^NG^^^NG4^Ct|^0.0|||<CR>R|17|^CTNG^^NG^^^<ETB>80<0D><0A>

Host -> GX <ACK>

GX -> Host <STX>5NG4^EndPt|^-1.0|||<CR>R|18|^CTNG^^NG^^^SAC^|NA^|||<CR>R|19|^CTNG^^NG^^^SAC^Ct|^20.2|||<CR>R|20|^CTNG^^NG^^^SAC^EndPt|^260.0|||<CR>R|21|^CTNG^^NG^^^SPC^|NA^|||<CR>R|22|^CTNG^^NG^^^SPC^Ct|^31.7|||<CR>R|23|^CTNG^^NG^^^SPC^EndPt|^282.0|||<CR>L|1|N<ETX>39<0D><0A>

Host -> GX <ACK>

GX -> Host <EOT>

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.

Acknowledgments

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.

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 acknowledgment 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.

3.2.7 ASTM Message Transaction Example with Low-Level Characters

The example below describes normal behavior of the ASTM interface between the GeneXpert Instrument System and the Host. The Instrument Sends Host Query for Specific Specimen (“123”), the Host Responds with Test Order(s) for Host Query and finally the Instrument Uploads Test Results.

GX -> Host <ENQ>

Host -> GX <ACK>

GX -> Host <STX>1H|@^\|GXM-2887872136287||GeneXpert PC^GeneXpert^6.1|||||LIS Simulator||P|1394-97|20190404092545<CR>Q|1|^123^^||^^^|||||||O@N<CR>L|1|N<ETX>78<0D><0A>

Host -> GX <ACK>

GX -> Host <EOT>

Host -> GX <ENQ>

GX -> Host <ACK>

Host -> GX <STX>1H|\^&|ccc6ade20d||LIS Simulator|||||GeneXpert PC^GeneXpert^1.0||P|1394-97|20070521100245<CR>P|1|PID2||PID1|smith^anna<CR>O|1|123||^^^CTNG|S|20070812140500|||||A||||ORH|||||||||Q<CR>L|1|F<CR><ETX>35<0D><0A>

GX -> Host <ACK>

Host -> GX <EOT>

GX -> Host <ENQ>

Host -> GX <ACK>

GX -> Host <STX>1H|@^\|GXM-35607015733||GeneXpert PC^GeneXpert^6.1|||||LIS Simulator||P|1394-97|20190404092948<CR>P|1||||^^^^||||||||||||||||||||||||||||<CR>O|1|123||^^^CTNG|R|20160331184630|||||||||ORH|||||||||F<CR>R|1|^CTNG^^CT^Xpert CT_NG^3^CT^|DETECTED^|||||F<ETB>A2<0D><0A>

Host -> GX <ACK>

GX -> Host <STX>2|Ashly Bastee|20160331184630|20160331201429|DESKTOP-ML3S693^703639^604320^457775983^07916^20180107|<CR>R|2|^CTNG^^CT^^^CT1^|POS^|||<CR>R|3|^CTNG^^CT^^^CT1^Ct|^20.1|||<CR>R|4|^CTNG^^CT^^^CT1^EndPt|^304.0|||<CR>R|5|^CTNG^^CT^^^SAC^|NA^|||<CR>R|6|^CTNG^^CT^^<ETB>50<0D><0A>

Host -> GX <ACK>

GX -> Host <STX>3^SAC^Ct|^20.2|||<CR>R|7|^CTNG^^CT^^^SAC^EndPt|^260.0|||<CR>R|8|^CTNG^^CT^^^SPC^|NA^|||<CR>R|9|^CTNG^^CT^^^SPC^Ct|^31.7|||<CR>R|10|^CTNG^^CT^^^SPC^EndPt|^282.0|||<CR>R|11|^CTNG^^NG^Xpert CT_NG^3^NG^|NOT DETECTED^|||||F||Ashly Bastee|20160331184630|20160331<ETB>FF<0D><0A>

Host -> GX <ACK>

GX -> Host <STX>4201429|DESKTOP-ML3S693^703639^65e04320^457775983^07916^20180107|<CR>R|12|^CTNG^^NG^^^NG2^|NEG^|||<CR>R|13|^CTNG^^NG^^^NG2^Ct|^0.0|||<CR>R|14|^CTNG^^NG^^^NG2^EndPt|^-1.0|||<CR>R|15|^CTNG^^NG^^^NG4^|NEG^|||<CR>R|16|^CTNG^^NG^^^NG4^Ct|^0.0|||<CR>R|17|^CTNG^^NG^^^<ETB>80<0D><0A>

Host -> GX <ACK>

GX -> Host <STX>5NG4^EndPt|^-1.0|||<CR>R|18|^CTNG^^NG^^^SAC^|NA^|||<CR>R|19|^CTNG^^NG^^^SAC^Ct|^20.2|||<CR>R|20|^CTNG^^NG^^^SAC^EndPt|^260.0|||<CR>R|21|^CTNG^^NG^^^SPC^|NA^|||<CR>R|22|^CTNG^^NG^^^SPC^Ct|^31.7|||<CR>R|23|^CTNG^^NG^^^SPC^EndPt|^282.0|||<CR>L|1|N<ETX>39<0D><0A>

Host -> GX <ACK>

GX -> Host <EOT>

4 ASTM Message Structure and Content

This chapter describes the ASTM message structure and its content; how records are organized within the message, how the ASTM message is parsed into fields, and the default list of delimiters used to parse the message.

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 ASTM Records Supported by Each Instrument Model

ASTM Record ID	Record Definition	GeneXpert® Xpress 5.1	GeneXpert® Xpress 6.1 and above	GeneXpert® Dx 4.7b and above	GeneXpert® Infinity 6.4b and above	GeneXpert® Omni v1.2 and above
H	Header	X	X	X	X	X
P	Patient	X	X	X	X	X
O	Order	X	X	X	X	X
R	Result	X	X	X	X	X
C	Comment	X	X	X	X	X
Q	Query (Request Information Order)		X	X	X	
S	Scientific					
M	Manufacturer					
L	Terminator	X	X	X	X	X

4.2.1.2 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.

Table 4-1. Record Types Allowed and Hierarchical Dependencies

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 Section 4.4.3, Hexadecimal Escaping.

- 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.

Table 4-2. ASTM Data Types used by the GeneXpert System

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

4.4 Delimiters

4.4.1 Types

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

\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 Section 4.4.3 for 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.
(*) 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

The 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

This chapter describes various error messages scenarios and data recovery after an error has occurred. It also includes detailed information on how to enable and disable LIS communication message tracing.

5.1 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 a 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

5.2 Error Messages

Any error detected by the system communications module is stored and is available for debugging.

- GeneXpert Xpress and DX versions 4.7b and below, and Infinity Xpertise software stores the errors 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.
- DX version 6.1 and above store the error messages in a text log file located at C:\GeneXpert\log\genexpert-YYYY.MM.DD_HH.MM.SS.MS-X.

- Error messages are available for GeneXpert Omni Mobile Application version 1.2 and above - contact Cepheid Technical support for assistance in accessing the Error Messages

For more information on how to capture and store the Error Messages, see Section 5.3, Enabling 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 canceled, and no data is retrieved.

When any of the errors, syntactic 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.

5.3 Enabling LIS Message Tracing

LIS Message tracing are available for GeneXpert Omni Mobile Application version 1.2 and above - contact Cepheid Technical support for assistance in Enabling LIS Message Tracing.

5.3.1 Xpress/DX version 4.7b and above, and Infinity Xpertise (all versions)

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.

5.3.2 Generating, Viewing and Troubleshooting Using Trace

1. Ensure there is only one order to be downloaded from the LIS system.

   When the Query All 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**.

3. Right-click on the Synapse event log and choose **Clear All Events**.

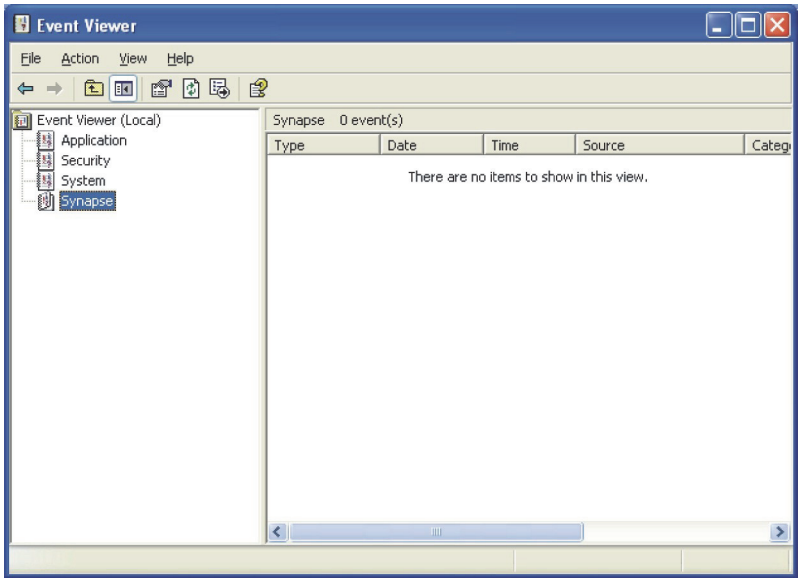

Figure 5-1. Event Viewer for Synapse

4. 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 Query All 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 n the Synapse Events.

5. Open, Review and Save the Synapse Events to a log file.

   A. Reopen Event Viewer and select the Synapse Event queue (if previously closed).

   - OR -

   A. Right-click on the Synapse event log and choose **Refresh** (if not closed).

   B. Right-click on the Synapse event log, and choose **Save Log File as...**

   C. Enter a log file name (leave the extension as ".evt").

   D. Email the ".evt" file to Cepheid Technical Support.

DX version 6.1 and Above

DX version 6.1 and above store the error messages in a log XML file located at C:/Program Files/Cepheid/GeneXpert Dx/Dx/config/log4j.xml.

To enable LIS Tracing, open the log4j.xml file and add the following lines.

```
<logger name="com.cepheid.nexus.lis">
   <level value="debug"/>
</logger>
```

5.3.3 Disabling LIS Message Tracing

DX version 4.7b and above, and Infinity Xpertise (all versions)

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.

DX version 6.1 and Above

Due to the nature of the error log file, it is very important to disable the LIS Message Tracing after debugging is complete. The log4j.xml file will keep Protected Health Information (PHI) for up to 6 months, when it gets purged after expiration.

Error Log File path: C:\GeneXpert\log

Configuration Log File path: C:/Program Files/Cepheid/GeneXpert Dx/Dx/config/log4j.xml.

6 ASTM Transmission Scenarios

This chapter details each of the workflow scenarios supported by the LIS interface, including sequence diagrams, message examples, and the ASTM record mapping format. It also 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.

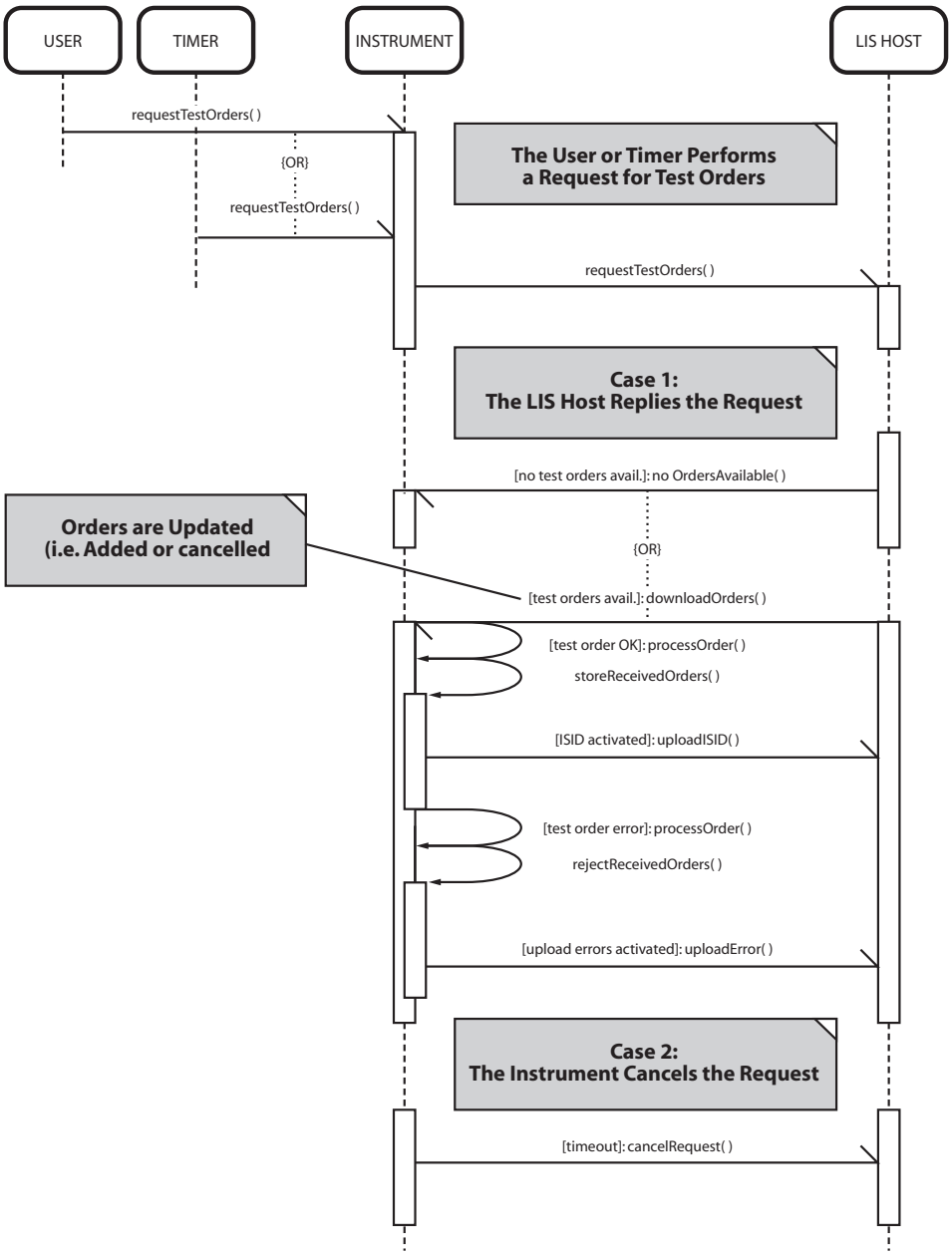

Figure 6-1. Instrument System Queries for All Test Orders

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 Implementation, 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. The same internal Instrument Specimen ID is assigned to all the host test orders that have the same specimen ID.

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 Implementation, Section 6.3.3

6.2.2 Instrument System Initiates Host Query for One or More Samples 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.

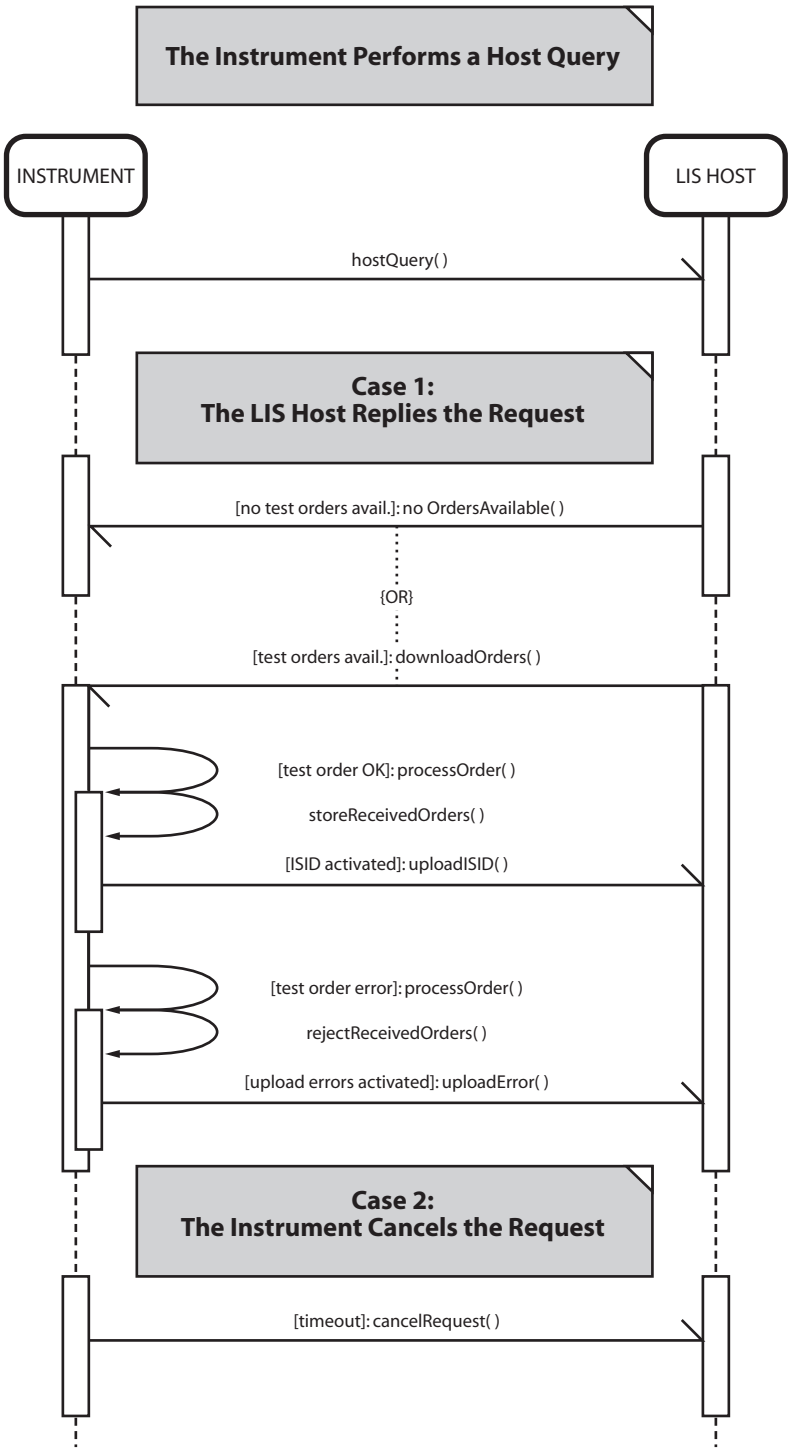

Figure 6-2. Instrument System Initiates Host Query for One or More Samples

Instrument System Queries for Test Orders for an Specific Specimen(s)

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 Implementation, Section 6.3.2

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. The same internal Instrument Specimen ID is assigned to all the host test orders that have the same specimen ID.

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 Implementation, Section 6.3.3

6.2.3 Instrument System Uploads Test Results

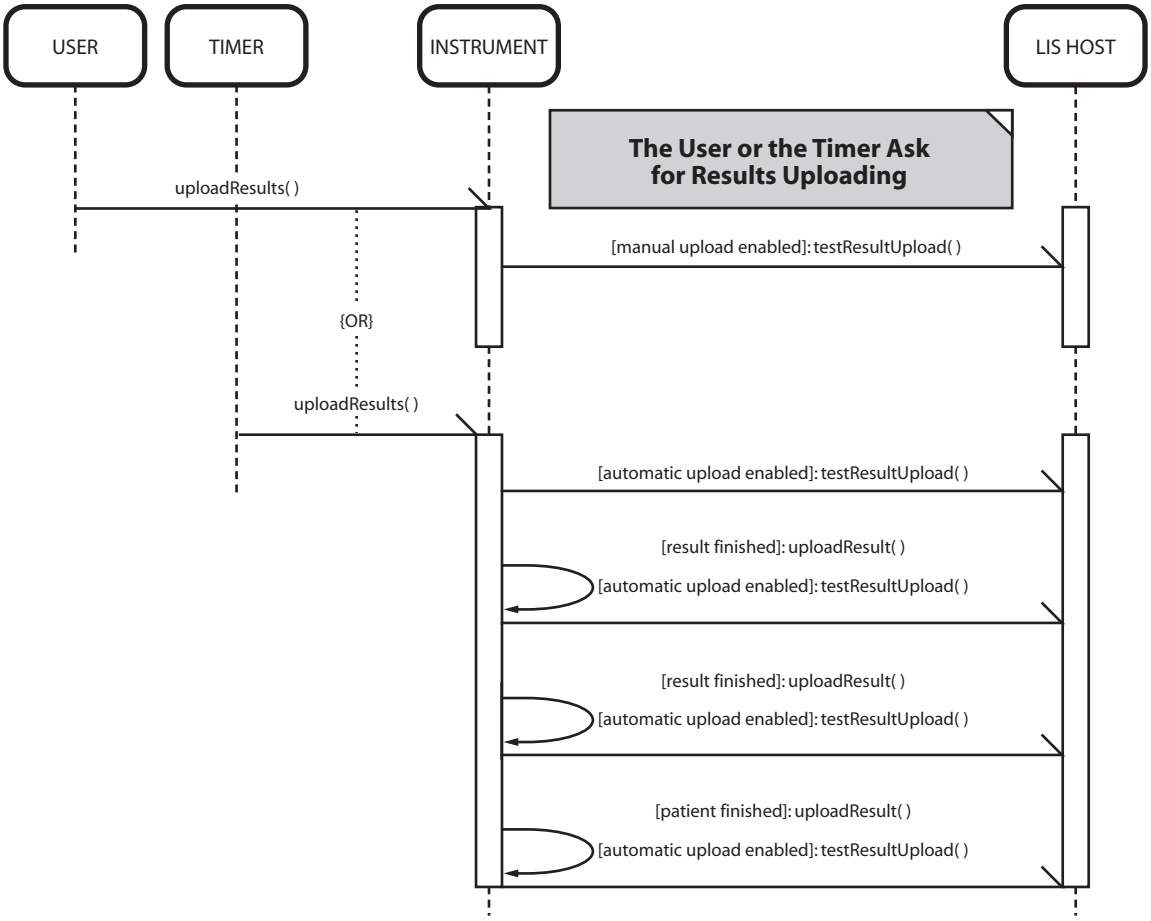

Figure 6-3. Instrument System Uploads Test Results

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.

- ASTM Implementation, Section 6.3.4

6.2.4 Host Requests Test Results

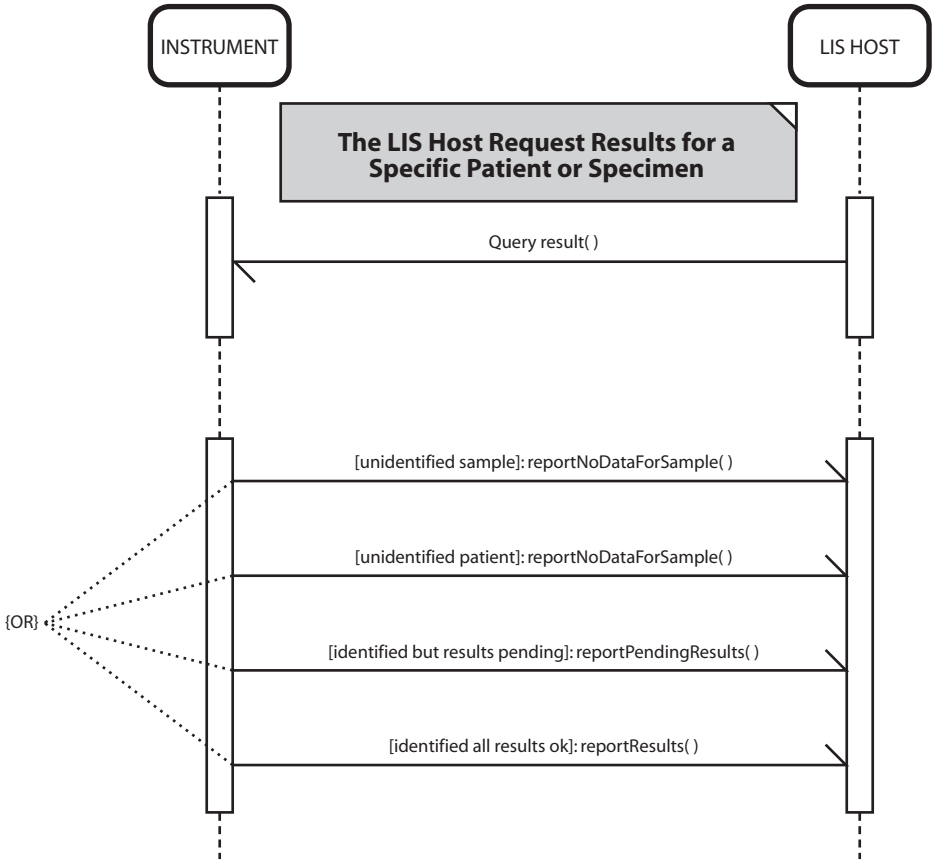

Figure 6-4. Host Requests Test Results

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

- ASTM Implementation, Section 6.3.5

6.2.5 Host Downloads Unsolicited Test Orders

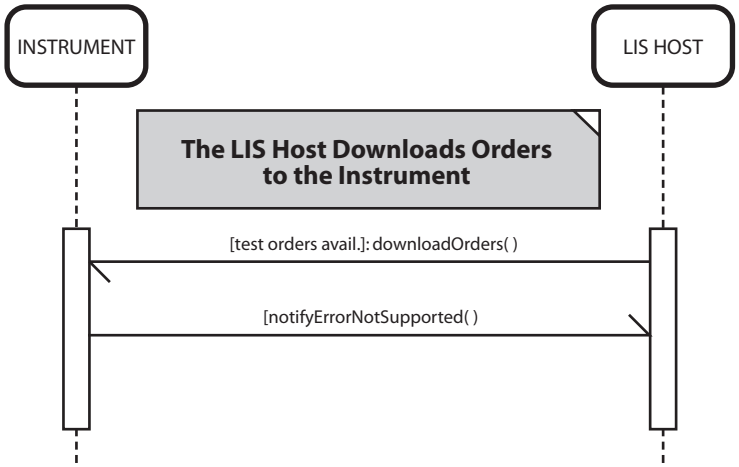

Figure 6-5. Host Downloads Unsolicited Test Orders

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 acknowledged and suppressed by the instrument system.

- ASTM Implementation, Section 6.3.6

6.3 ASTM Messages

For a detailed message field mapping for each of the records please refer to Section 6.4.

6.3.1 Instrument System Queries for All Test Orders

6.3.1.1 Upload Message – Instrument System Queries for All Test Orders

Message Structure

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message Header (H) (Section 6.4.1.1)				
	Request Information (Q) (Section 6.4.1.2)			
Message Terminator (L) (Section 6.4.1.8)				

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

```
H|@^\|12X||GeneXpert PC^GeneXpert^6.1|||||LIS||P|1394-
97|20190521100245
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.

Message Structure

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message Header (H) (Section 6.4.1.1)				
	Request Information (Q) (Section 6.4.1.2)			
		Comment (C) (Section 6.4.1.5)		
Message Terminator (L) (Section 6.4.1.8)				

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

```
H|@^\|ccc6ade20d364214b1||GeneXpert PC^GeneXpert^6.1|||||LIS||P|1394-
97|20190521100245
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 for All Test Orders

Message Structure

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message Header (H) (Section 6.4.2.1)				
	Patient Information (P) (Section 6.4.2.2)			
		Test Order (O) (Section 6.4.2.3)		
Message Terminator (L) (Section 6.4.2.5)				

Example of Download Message – Host Responds with Test Orders for Query for All

```
H|@^\|ccc6ade20d36233||LIS|||||GeneXpert PC^GeneXpert^6.1||P|1394-
97|20190521100245
P|1|PID2||PID1|Armstrong^Neil^Scott^JR^DR
O|1|SID-818||^^^MRSA|S|20190812140500|||||A||||ORH||||||||||Q
O|2|SID-818||^^^CTNG|R|20190812140600|||||A||||ORH||||||||||Q
O|3|SID-818||^^^EV|R|20190812140700|||||A||||ORH||||||||||Q
P|2|PID123||PID345|Smith^Amanda^G.
O|1|SID-811||^^^CARBA|R|20190812140800|||||C||||ORH||||||||||Q
O|2|SID-811||^^^ABC|R|20190812140900|||||A||||ORH||||||||||Q
O|3|SID-8||^^^GBSLB|R|20190812150000|||||A||||ORH||||||||||Q
L|1|F
```

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

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.

Message Structure

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message Header (H) (Section 6.4.2.1)				
Message Terminator (L) (Section 6.4.2.5)				

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

```
H|@^\|12XFFFASFASFG11||LIS|||||GeneXpert PC^GeneXpert^6.1||P|1394-
97|20190521100245
L|1|I
```

6.3.1.5 Upload Message – Instrument System Rejects Test Order Initiated from Host Query for All

Message Structure

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message Header (H) (Section 6.4.1.1)				
	Patient (P) (Section 6.4.1.3)			
		Order (O) (Section 6.4.1.4)		
			Notes (C) (Section 6.4.1.5)	
Message Terminator (L) (Section 6.4.1.8)				

Example

This example assumes Use ISID is enabled.

```
H|@^\|c0c1b2a9c40b||GeneXpert PC^GeneXpert6.1|||||LIS||P|1394-
97|20190521100245

P|1|PID2||PID1|Armstrong^Neil^Scott^JR^DR

O|1|SpecimenID-888|Instr_SpecID-333|^^^MRSA
IUO|R|20190521101245|||||C||||ORH|||||||||X

C|1|I|invalidSpecimenData^Invalid Instrument Specimen ID or Specimen
ID|N

P|2|PID123||PID345|Smith^Amanda^G

O|1|SpecimenID-888|Instr_SpecID-333|^^^MRSA
IUO|R|20190521101246|||||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|20190521201245|||||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 Specimen(s)

6.3.2.1 Upload Message – Instrument System Sends Host Query for Specific Specimen(s)

Message Structure

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message Header (H) (Section 6.4.1.1)				
	Request Information (Q) (Section 6.4.1.2)			
Message Terminator (L) (Section 6.4.1.8)				

Examples

Query for Specific Patient ID and Specimen ID combination:

```
H|@^\|b4a88d9adab947a7||GeneXpert PC^GeneXpert^6.1|||||LIS||P|1394-
97|20190521100245
Q|1|PatientID-556^SpecimenID-888||||||||||O@N
L|1|N
```

Query for Specific Specimen ID:

```
H|@^\|b4a88d9adab947a7||GeneXpert PC^GeneXpert^6.1|||||LIS||P|1394-
97|20190521100245
Q|1|^SpecimenID-888||||||||||O@N
L|1|N
```

Note The GeneXpert instrument system does not allow Query for Patient ID only. A Query for ALL will be transmitted instead.

6.3.2.2 Upload Message – Instrument System Cancels Host Query for Specific Specimen(s)

See Section 6.3.1.2, Upload Message – Instrument System Cancels Query for All Test Orders for more information.

Example

```
H|@^\|ccc6ade20d364214b1||GeneXpert PC^GeneXpert^6.1|||||LIS||P|1394-
97|20190521100245
Q|1||||||||||A
C|1|I|timeout^last request has been cancelled|I
L|1|N
```

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

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 6.4.2, Download Message Mapping Format.

Examples

System sends Host Query for Specific Specimen:

```
H|@^\|ODM-DjgIkZRA-03||GeneXpert PC^GeneXpert^6.1|||||LIS||P|1394-
97|20190521100245
Q|1|^SID1||||||||||O@N
L|1|N
```

Host responds with new order:

```
H|@^\|ab067bb88634475187eab185e5651fcb||LIS|||||GeneXpert
PC^GeneXpert^6.1||P|1394-97|20190521100245
P|1|PID2||PID1|Armstrong^Neil^Scott^JR^DR
O|1|SID1||^^^FT|R|20191116133208|||||A||||ORH|||||||||Q
O|2|SID1||^^^BC|R|20191121104253|||||A||||ORH|||||||||Q
L|1|F
```

6.3.2.4 Download Message - Host Responds with No Available Test Order for Host Query for Specific Specimen

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 Section 6.3.1.4, Download Message – Host Responds with No Available Test Order for Query for All.

6.3.2.5 Upload Message – Instrument System Rejects Test Order Initiated from Host Query for Specific Specimen

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 Section 6.3.1.5, Upload Message – Instrument System Rejects Test Order Initiated from Host Query for All.

6.3.3 Instrument System Returns Instrument Specimen ID for a Downloaded Order

Note A test order with a blank Patient ID will not be downloaded during host query test order download if all of the following apply.

1. ISID is enabled
2. There are multiple matching test orders using the same Sample ID
3. One of these matching test orders has a blank Patient ID

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.

Message Structure

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message Header (H) (Section 6.4.1.1)				
	Patient (P) (Section 6.4.1.3)			
		Order (O) (Section 6.4.1.4)		
	...			
Message Terminator (L) (Section 6.4.1.8)				

Example (Use ISID is Enabled)

```
H|@^\|2d315f507a8148||GeneXpert PC^GeneXpert^6.1|||||LIS||P|1394-
97|20190521100245
P|1|PID2||PID1|Armstrong^Neil^Scott^JR^DR
O|1|SpecimenID-777|Instr_SpecID-555|||||||P||||ORH||||||||||I
P|2|PID123||PID345|Smith^Amanda^G.
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
- 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).

For Quantitative Assay, two test results (Main Result) will be uploaded, the first result is identified by the assay host test code; the second result is identified by the assay host test code and “LOG” in the Complementary Result Name.

Secondary and complementary results including analyte result, Ct, EndPt, deltaCt will be uploaded to LIS. Complementary result with Conc/LOG names will be uploaded if applicable. LDA total values for LDA assay will be uploaded with main result to LIS.

Message Structure (Patient and QC Results)

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message Header (H) (Section 6.4.1.1)				
	Patient (P) (Section 6.4.1.3)			
		Order (O) (Section 6.4.1.4)		
			Errors / Notes (C) (Section 6.4.1.5)	
			Main Result (R) (Section 6.4.1.7)	
			Analyte Result (R) (Section 6.4.1.7)	
			Complementary Results (R) (Section 6.4.1.7)	
				Error / Notes I (C) (Section 6.4.1.6)
Message Terminator (L) (Section 6.4.1.8)				

Parsing a result record

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

- 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 Filed 3, Component 8 = Empty or "LOG" 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 Parsing a result record, on page 6-18 for details about the rest of the fields. This analyte result contains one or more complementary results.
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 Parsing a result record, on page 6-18 for details about the rest of the fields.

Single-Result Example

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 6-6. Single-Result Test Report Example

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

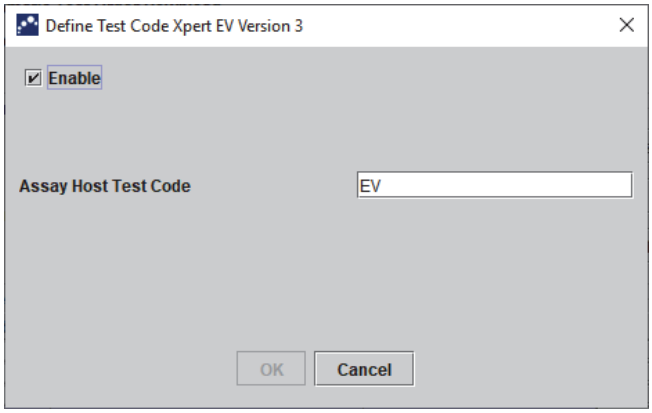

Figure 6-7. Single-Result Define Test Code Dialog

Multi-Result Example

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 6-8. Multi-Result Test Report Example

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.

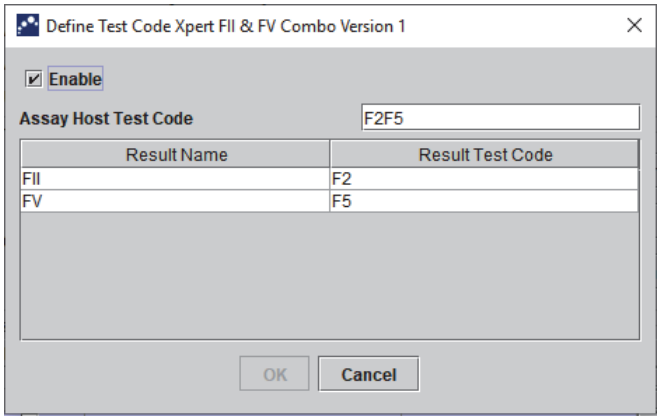

Figure 6-9. Multi-Result Define Test Code Dialog

ASTM – Multi-Result Assay Upload Quantitative Result Example (Two main results uploaded)

```
H|@^\|GXM-42462563664||GeneXpert PC^GeneXpert^6.1|||||LIS||P|1394-
97|20190415093320
P|1|PID2||PID1|Armstrong^Neil^Scott^JR^DR
O|1|CAP TPM-3||^^^F2F5|R|20140402162116|||||||||ORH|||||||||Q@F
R|1|^F2F5^^F2^Xpert FII FV Combo^1^FII|HETEROZYGOUS|||||F||Annie
Au|20140402162116|20140402165155|DESKTOP-
ML3S693^800479^604576^122163180^05201^20150705
R|2|^F2F5^^F2^^^FII 20210G|POS
R|3|^F2F5^^F2^^^FII 20210G^Ct|^26.0
R|4|^F2F5^^F2^^^FII 20210G^EndPt|^336.0
R|5|^F2F5^^F2^^^FII 20210A|POS
R|6|^F2F5^^F2^^^FII 20210A^Ct|^26.4
R|7|^F2F5^^F2^^^FII 20210A^EndPt|^236.0
R|8|^F2F5^^F5^Xpert FII FV Combo^1^FV|NORMAL|||||F||Annie
Au|20140402162116|20140402165155|DESKTOP-
ML3S693^800479^604576^122163180^05201^20150705
R|9|^F2F5^^F5^^^FV 1691G|POS
R|10|^F2F5^^F5^^^FV 1691G^Ct|^26.1
R|11|^F2F5^^F5^^^FV 1691G^EndPt|^402.0
R|12|^F2F5^^F5^^^FV 1691A|NEG
R|13|^F2F5^^F5^^^FV 1691A^Ct|^37.1
R|14|^F2F5^^F5^^^FV 1691A^EndPt|^33.0
L|1|N
```

ASTM – Single-Result Test Result Upload Message Example

```
H|@^\|GXM-70461485121||GeneXpert PC^GeneXpert^6.1|||||LIS||P|1394-
97|20190417072441
P|1|PID2||PID1|Armstrong^Neil^Scott^JR^DR
O|1|2F5DBAB27C04A8D48030B8C78||^^^EV|R|20170518010847|||||||||ORH|||||
|||||Q@F
R|1|^^^EV^Xpert
EV^3|POSITIVE|||||F||<None>|20170518010847|20170518033715|DESKTOP-
ML3S693^706416^623940^80180955^06802^20181104
R|2|^^^EV^^^EV|POS
R|3|^^^EV^^^EV^Ct|^38.0
R|4|^^^EV^^^EV^EndPt|^60.0
R|5|^^^EV^^^CIC|NA
R|6|^^^EV^^^CIC^Ct|^33.2
R|7|^^^EV^^^CIC^EndPt|^392.0
L|1|N
```

ASTM – Multi-Result Assay Upload Message Example (with both notes and error)

```
H|@^\|URM-jUBdXBVA-02||GeneXpert PC^GeneXpert^6.1|||||LIS||P|1394-
97|20191011081036
P|1|PID2||PID1|Armstrong^Neil^Scott^JR^DR
O|1|M+957||^^^MRSA|R|20190724153733|||||||||ORH|||^^|||||||F
R|1|^^^MRSA^Xpert MRSA G3^20^^|ERROR^|||||F||Sally
C|1|I|Notes^^notes for GBS|I
C|2|I|Error^5006^Post-run analysis error^Error 5006: [SCC] probe check
failed. Probe check value of 113 for reading number 1 was above the
maximum of 110^20120724160120|N
C|3|I|Error^5006^Post-run analysis error^Error 5006: [SCC] probe check
failed. Probe check value of 112 for reading number 3 was above the
maximum of 110^20120724160120|N
R|2|^^^MRSA^^^SCC^|NO RESULT^|||
R|3|^^^MRSA^^^SCC^Ct|^0.0|||
R|4|^^^MRSA^^^SCC^EndPt|^0.0|||
R|5|^^^MRSA^^^SPC^|NO RESULT^|||
R|6|^^^MRSA^^^SPC^Ct|^0.0|||
R|7|^^^MRSA^^^SPC^EndPt|^0.0|||
L|1|N
```

ASTM – Instrument System Uploads QC Results Assay Example

```
H|@^\|GXM-34871760663||GeneXpert PC^GeneXpert^6.1|||||LIS||P|1394-
97|20190417071132
P|1|PID2||PID1|Armstrong^Neil^Scott^JR^DR
O|1|id3-05||^^^FLURSV|R|20170323135645|||||Q||||ORH||||||||||Q@F
R|1|^FLURSV^^NULLA^Xpert Flu-RSV XC US-IVD^3^Flu
A|NEGATIVE|||||F||rachel
blackman|20170323135645|20170323145752|DESKTOP-
ML3S693^800479^604572^378920129^04203^20180212
R|2|^FLURSV^^NULLA^^^Flu A 1|NEG
R|3|^FLURSV^^NULLA^^^Flu A 1^Ct|^0.0
R|4|^FLURSV^^NULLA^^^Flu A 1^EndPt|^5.0
R|5|^FLURSV^^NULLA^^^Flu A 2|NEG
R|6|^FLURSV^^NULLA^^^Flu A 2^Ct|^0.0
R|7|^FLURSV^^NULLA^^^Flu A 2^EndPt|^1.0
R|8|^FLURSV^^NULLA^^^SPC|NA
R|9|^FLURSV^^NULLA^^^SPC^Ct|^0.0
R|10|^FLURSV^^NULLA^^^SPC^EndPt|^0.0
R|11|^FLURSV^^NULLB^Xpert Flu-RSV XC US-IVD^3^Flu
B|POSITIVE|||||F||rachel
blackman|20170323135645|20170323145752|DESKTOP-
ML3S693^800479^604572^378920129^04203^20180212
R|12|^FLURSV^^NULLB^^^Flu B|POS
R|13|^FLURSV^^NULLB^^^Flu B^Ct|^24.6
R|14|^FLURSV^^NULLB^^^Flu B^EndPt|^948.0
R|15|^FLURSV^^NULLB^^^SPC|NA
R|16|^FLURSV^^NULLB^^^SPC^Ct|^0.0
R|17|^FLURSV^^NULLB^^^SPC^EndPt|^0.0
R|18|^FLURSV^^RSV^Xpert Flu-RSV XC US-
IVD^3^RSV|NEGATIVE|||||F||rachel
blackman|20170323135645|20170323145752|DESKTOP-
ML3S693^800479^604572^378920129^04203^20180212
R|19|^FLURSV^^RSV^^^RSV|NEG
R|20|^FLURSV^^RSV^^^RSV^Ct|^0.0
R|21|^FLURSV^^RSV^^^RSV^EndPt|^1.0
R|22|^FLURSV^^RSV^^^SPC|NA
R|23|^FLURSV^^RSV^^^SPC^Ct|^0.0
R|24|^FLURSV^^RSV^^^SPC^EndPt|^0.0
```

R|25|^FLURSV^^QC^Xpert Flu-RSV XC US-IVD^3^QC Check||||||F||rachel blackman|20170323135645|20170323145752|DESKTOP-ML3S693^800479^604572^378920129^04203^20180212

R|26|^FLURSV^^QC^^^QC1|NEG

R|27|^FLURSV^^QC^^^QC1^Ct|^0.0

R|28|^FLURSV^^QC^^^QC1^EndPt|^0.0

R|29|^FLURSV^^QC^^^QC2|NEG

R|30|^FLURSV^^QC^^^QC2^Ct|^0.0

R|31|^FLURSV^^QC^^^QC2^EndPt|^0.0

L|1|N

ASTM – Upload Message – Instrument System Uploads Invalid Results

H|@^\|GXM-76014526802||GeneXpert PC^GeneXpert^6.1|||||LIS||P|1394-97|20190417071036

P|1|PID2||PID1|Armstrong^Neil^Scott^JR^DR

O|1|150711060408||^^^MRSASASSTI|R|20150312070933|||||||||ORH||||||||||Q@F

R|1|^MRSASASSTI^^MRSA^Xpert MRSA-SA SSTI G3^5^MRSA|INVALID|||||F||<None>|20150312070933|20150312081057|DESKTOP-ML3S693^706416^609363^58896205^12405^20160124

R|2|^MRSASASSTI^^MRSA^^^SPC|FAIL

R|3|^MRSASASSTI^^MRSA^^^SPC^Ct|^0.0

R|4|^MRSASASSTI^^MRSA^^^SPC^EndPt|^15.0

R|5|^MRSASASSTI^^MRSA^^^SPA|INVALID

R|6|^MRSASASSTI^^MRSA^^^SPA^Ct|^0.0

R|7|^MRSASASSTI^^MRSA^^^SPA^EndPt|^1.0

R|8|^MRSASASSTI^^MRSA^^^mec|INVALID

R|9|^MRSASASSTI^^MRSA^^^mec^Ct|^0.0

R|10|^MRSASASSTI^^MRSA^^^mec^EndPt|^3.0

R|11|^MRSASASSTI^^MRSA^^^SCC|INVALID

R|12|^MRSASASSTI^^MRSA^^^SCC^Ct|^0.0

R|13|^MRSASASSTI^^MRSA^^^SCC^EndPt|^1.0

R|14|^MRSASASSTI^^SA^Xpert MRSA-SA SSTI G3^5^SA|INVALID|||||F||<None>|20150312070933|20150312081057|DESKTOP-ML3S693^706416^609363^58896205^12405^20160124

R|15|^MRSASASSTI^^SA^^^SPC|FAIL

R|16|^MRSASASSTI^^SA^^^SPC^Ct|^0.0

R|17|^MRSASASSTI^^SA^^^SPC^EndPt|^15.0

R|18|^MRSASASSTI^^SA^^^SPA|INVALID

```
R|19|^MRSASASSTI^^SA^^^SPA^Ct|^0.0
R|20|^MRSASASSTI^^SA^^^SPA^EndPt|^1.0
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.

Message Structure

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message Header (H) (Section 6.4.2.1)				
	Request Information (Q) (Section 6.4.2.4)			
Message Terminator (L) (Section 6.4.2.5)				

Examples

With Patient ID:

```
H|@^\|12XDFASFEE||LIS|||||GeneXpert PC^GeneXpert^6.1||P|1394-
97|20190521100245
Q|1|PatID-12^SpecID-1231^ISID-1121@PatID-12^SpecID-31||^^^MRSA
TC@^^^CTNG|||||||F
L|1|N
```

Without Patient ID:

```
H|@^\|12XDFASFEE||LIS|||||GeneXpert PC^GeneXpert^6.1||P|1394-
97|20190521100245
Q|1|^SpecID-1231^ISID-1121@^SpecID-31||^^^MRSA TC@^^^CTNG|||||||F
L|1|N
```

With Specimen ID(s) only:

```
H|@^\|12XDFASFEE||LIS|||||GeneXpert PC^GeneXpert^6.1||P|1394-
97|20190521100245
Q|1|^SpecID-1||^^^MRSA TC|||||||F
L|1|N
```

```
H|@^\|12XDFASFEE||LIS|||||GeneXpert PC^GeneXpert^6.1||P|1394-
97|20190521100245
Q|1|^SpecID-1@^SpecID-2||^^^MRSA TC@^^^CTNG|||||||F
L|1|N
```

With Specimen ID(s) and ISID enabled:

```
H|@^\|12XDFASFEE||LIS|||||GeneXpert PC^GeneXpert^6.1||P|1394-
97|20190521100245
Q|1|^SpecID-1^ISID-1@^SpecID-2^ISID-2||^^^MRSA TC@^^^CTNG|||||||F
L|1|N
```

With Patient ID, Specimen ID(s), and ISID enabled:

```
H|@^\|12XDFASFEE||LIS|||||GeneXpert PC^GeneXpert^6.1||P|1394-
97|20190521100245
Q|1|PatID-1^SpecID-1^ISID-1@PatID-1^SpecID-2^ISID-2||^^^MRSA
TC@^^^CTNG|||||||F
L|1|N
```

With Patient ID, Specimen ID(s), and ISID disabled:

```
H|@^\|12XDFASFEE||LIS|||||GeneXpert PC^GeneXpert^6.1||P|1394-
97|20190521100245
Q|1|PatID1^SpecID-1@PatID1^SpecID-2||^^^MRSA TC@^^^CTNG|||||||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.

Message Structure

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message Header (H) (Section 6.4.1.1)				
	Patient (P) (Section 6.4.1.3)			
		Order (O) (Section 6.4.1.4)		
			Errors (C) (Section 6.4.1.6)	
			Overall Result (R) (Section 6.4.1.7)	
			Secondary Result (R) (Section 6.4.1.7)	
			Result (R) (Section 6.4.1.7)	
			Complementary Results (R) (Section 6.4.1.7)	
				Errors / Notes (C) (Section 6.4.1.6)
Message Terminator (L) (Section 6.4.1.8)				

Examples

Version DX 4.6a – Main Results only:

```
H|@^\|be88978401de4ac78||GeneXpert PC^GeneXpert^Dx4.6a.
|||||LIS||P|1394- 97|20191029171958
P|1|PID2||PID1|Armstrong^Neil^Scott^JR^DR
O|1|SpecID-1231||^^^MRSA
TC|R|20191204093704|||||||||ORH|||^^|||||||Q@F
R|1|^^^MRSA TC^MRSA IUO^1^^|NEGATIVE^|||||F||Rebecca
Buckner|20191204093704|20191204104841|^701737^^^^
L|1|F
```

Version DX 4.7b and above – Main, Analyte and Complementary Results:

```
H|@^\|GXM-34871760663||GeneXpert PC^GeneXpert^6.1|||||LIS||P|1394-
97|20190417071132
```

```
P|1|PID2||PID1|Armstrong^Neil^Scott^JR^DR
O|1|id3-05||^^^FLURSV|R|20170323135645|||||Q||||ORH|||||||||||Q@F
R|1|^FLURSV^^NULLA^Xpert Flu-RSV XC US-IVD^3^Flu
A|NEGATIVE|||||F||rachel
blackman|20170323135645|20170323145752|DESKTOP-
ML3S693^800479^604572^378920129^04203^20180212
R|2|^FLURSV^^NULLA^^^Flu A 1|NEG
R|3|^FLURSV^^NULLA^^^Flu A 1^Ct|^0.0
R|4|^FLURSV^^NULLA^^^Flu A 1^EndPt|^5.0
R|5|^FLURSV^^NULLA^^^Flu A 2|NEG
R|6|^FLURSV^^NULLA^^^Flu A 2^Ct|^0.0
R|7|^FLURSV^^NULLA^^^Flu A 2^EndPt|^1.0
R|8|^FLURSV^^NULLA^^^SPC|NA
R|9|^FLURSV^^NULLA^^^SPC^Ct|^0.0
R|10|^FLURSV^^NULLA^^^SPC^EndPt|^0.0
R|11|^FLURSV^^NULLB^Xpert Flu-RSV XC US-IVD^3^Flu
B|POSITIVE|||||F||rachel
blackman|20170323135645|20170323145752|DESKTOP-
ML3S693^800479^604572^378920129^04203^20180212
R|12|^FLURSV^^NULLB^^^Flu B|POS
R|13|^FLURSV^^NULLB^^^Flu B^Ct|^24.6
R|14|^FLURSV^^NULLB^^^Flu B^EndPt|^948.0
R|15|^FLURSV^^NULLB^^^SPC|NA
R|16|^FLURSV^^NULLB^^^SPC^Ct|^0.0
R|17|^FLURSV^^NULLB^^^SPC^EndPt|^0.0
R|18|^FLURSV^^RSV^Xpert Flu-RSV XC US-
IVD^3^RSV|NEGATIVE|||||F||rachel
blackman|20170323135645|20170323145752|DESKTOP-
ML3S693^800479^604572^378920129^04203^20180212
R|19|^FLURSV^^RSV^^^RSV|NEG
R|20|^FLURSV^^RSV^^^RSV^Ct|^0.0
R|21|^FLURSV^^RSV^^^RSV^EndPt|^1.0
R|22|^FLURSV^^RSV^^^SPC|NA
R|23|^FLURSV^^RSV^^^SPC^Ct|^0.0
R|24|^FLURSV^^RSV^^^SPC^EndPt|^0.0
R|25|^FLURSV^^QC^Xpert Flu-RSV XC US-IVD^3^QC Check||||||F||rachel
blackman|20170323135645|20170323145752|DESKTOP-
ML3S693^800479^604572^378920129^04203^20180212
R|26|^FLURSV^^QC^^^QC1|NEG
```

```
R|27|^FLURSV^^QC^^^QC1^Ct|^0.0
R|28|^FLURSV^^QC^^^QC1^EndPt|^0.0
R|29|^FLURSV^^QC^^^QC2|NEG
R|30|^FLURSV^^QC^^^QC2^Ct|^0.0
R|31|^FLURSV^^QC^^^QC2^EndPt|^0.0
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.

Message Structure

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message Header (H) (Section 6.4.1.1)				
	Patient (P) (Section 6.4.1.3)			
		Order (O) (Section 6.4.1.4)		
Message Terminator (L) (Section 6.4.1.7)				

Example

```
H|@^\|4e075416e50c470cba||GeneXpert PC^GeneXpert^6.1|||||LIS||P|1394-
97|20190521100245
P|1|PID2||PID1|Armstrong^Neil^Scott^JR^DR
O|1|SpecID-1231||^^^|R|20190521101245|||||C||||ORH|||||||||Q@Y
O|2| SpecID-31||^^^|R|20190521101246|||||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

Message Structure

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message Header (H) (Section 6.4.2.1)				
	Patient Information (P) (Section 6.4.2.2)			
		Test Order (O) (Section 6.4.2.3)		
Message Terminator (L) (Section 6.4.2.5)				

Example

```
H|@^\|12X||LIS|||||GeneXpert PC^GeneXpert^6.1||P|1394-
97|20190521100245
P|1|PID2||PID1|Armstrong^Neil^Scott^JR^DR
O|1|SID-818|ISID-331|^^^MRSA|R|20190812140501|||||A||||ORH||||||||||O
O|2|SID-118|ISID-331|^^^CTNG|20190812140601|||||A||||ORH||||||||||O
O|3|SID-811|ISID-
431|^^^STREPA|R|20190812140701|||||A||||ORH||||||||||O
P|2|PID123||PID345|Smith^Amanda^G.
O|1|SID-811|ISID-431|^^^F5|S|20190812140801|||||C||||ORH||||||||||O
O|2|SID-11|ISID-111|^^^F2F5|R|20190812140901|||||A||||ORH||||||||||O
O|3|SID-8|ISID-31|^^^CT|R|20190812100501|||||A||||ORH||||||||||O
L|1|N
```

6.3.6.2 Upload Message – Instrument System Rejects Unsolicited Test Orders

Message Structure

Level 0 records	Level 1 records	Level 2 records	Level 3 records	Level 4 records
Message Header (H) (Section 6.4.2.1)				
	Comment (C) (Section 6.4.2.3)			
Message Terminator (L) (Section 6.4.2.5)				

Example

```
H|@^\|45a6a54631c74a||GeneXpert PC^GeneXpert^6.1|||||LIS||P|1394-
97|20190521100245
C|1|I|invalidTransmissionInformation^Unsolicited downloading orders
not supported|N
L|1|N
```

6.4 ASTM Message Mapping Format

The workflow scenarios described in Section 6.2 have similar message mapping depending on the direction of the message. This section describes how each ASTM record is mapped, listing allowed values and record examples.

Messages originated by the GeneXpert system are called upload message. Download messages are the transmissions originated by the LIS host.

6.4.1 Upload Message Mapping Format

The following upload messages share the message mapping for each record supported.

- Instrument Queries for All Test Orders (Section 6.3.1.1)
- Instrument Cancels Query for All Test Orders (Section 6.3.1.2)
- Instrument Rejects Test Order Initiated from Query for All (Section 6.3.1.5)
- Instrument Sends Host Query for Specific Specimen (Section 6.3.2.1)
- Instrument Cancels Host Query for Specific Specimen (Section 6.3.2.2)
- Instrument Rejects Test Order Initiated from Query for Specific Specimen (Section 6.3.2.5)
- Instrument Returns Specimen ID for a Downloaded Order (Section 6.3.3)
- Instrument Uploads Test Results (Section 6.3.4.1)
- Instrument Returns Results Initiated by Result Request (Section 6.3.5.2)
- Instrument Returns Results Responding to Request for an Unidentified Patient or Specimen (Section 6.3.5.3)
- Instrument Rejects Unsolicited Test Orders (Section 6.3.6.2)

6.4.1.1 Header Record (Upload Message)

Message*

```
H|Delimiter Definition|Message ID||System ID^System Name^Software
Version|||||Receiver ID||Processing ID|Version No.|Date/Time of
Message
```

* **Bold Red** fields are required for the overall record.

Definition

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)

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
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	14	R	N	

6.4.1.2 Request Order Information Record (Upload Message)

Message*

Query for Specific Specimen:

```
Q|1|Patient ID 1^Specimen ID^Patient ID 2||||||||||Request Information Status Codes
```

OR

Query for All Test Orders

```
Q|1|ALL||||||||||Request Information Status Codes
```

* **Bold Red** fields are required for the overall record.

Definition

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
Query for Specific Specimen (Section 6.3.2.1)								
3	Starting Range ID Number	Patient ID 1	1	String	32	O	N	
		Specimen ID	2	String	25	R	N	
		Patient ID 2 (Practice Assigned Patient ID)	3	String	32	O	N	

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
Query for All Test Orders (Section 6.3.1.1)								
3	Starting Range ID Number		1	String	32	R	N	'ALL'
13	Request Information Status Codes		1	String	3	R	Y	Refer to table mapping below for a list of allowed values per type of message.

Request Information Status Codes

Status Codes Q.13.1	Description	Message Types
'O' +repetition delimiter (@) + 'N' (e.g. 'O@N')	Request Test Order	Instrument System Queries for All Test Orders
	New Request	Instrument System Sends Host Query for All Test Orders
A	Abort Last Request	Instrument System Cancels Query for All Test Orders

6.4.1.3 Patient Information Record (Upload Message)

Message*

```
P|1|Patient ID 2||Patient ID 1|Patient Family Name^Patient Given
Name^Patient Middle name or initial^ Prefix^Suffix|
```

* **Bold Red** fields are required for the overall record.

Definition

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
3	Patient ID 2	Practice- Assigned Patient ID	1	String	32	O	N	
5	Patient ID 1	Patient identification	1	String	32	O	N	
6	Patient Name	Patient family name	1	String	194	O	N	
		Patient given name	2	String	30	O	N	
		Patient middle name or initial	3	String	30	O	N	
		Prefix (e.g. JR or III)	4	String	20	O	N	
		Suffix (e.g. DR)	5	String	20	O	N	

6.4.1.4 Test Order Record (Upload Message)

Message*

O|1|Specimen ID|Instrument Specimen ID|**Univ. Test ID**|**Priority**|Ordered Date and Time|||||**Action Code**||||**Specimen Descriptor**|||||||||**Record Type**

Note Instrument System Returns Instrument Specimen ID for a Downloaded Order message has different requirements for Optional/Required fields.

O|1|Specimen ID|Instrument Specimen ID|||||||Action Code||||Specimen Descriptor|||||||||Record Type

* **Bold** fields are required for the overall record.

Definition

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 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		1	ASTM Date	14	O	N	If empty, the current date and time is used

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
12	Action code	The action that needs to be taken with the order	1	String	1	R	N	Refer to table mapping below for a list of allowed values per type of message.
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	Refer to table mapping below for a list of allowed values per type of message.

Report Type

Report Type O.26.1	Description	Message Types
Q	Request to query	Instrument System Returns Results Initiated by Result Request
		Instrument System Returns Results Responding to Request for an Unidentified Patient or Specimen.
X	Order cannot be done, canceled	Instrument System Rejects Test Order Initiated From Query (All or Specific Specimen)
		Instrument System Returns Results Initiated by Result Request
		Instrument System Uploads Results
I	Pending in system	Instrument System Cancels Host Query (All or Specific Specimen)
		Instrument System Uploads Results
		Instrument System Returns Results Initiated by Result Request
F	Final results	Instrument System Uploads Results
		Instrument System Returns Results Initiated by Result Request

Report Type O.26.1	Description	Message Types
Y	Invalid Test ID	Instrument System Returns Results Responding to Request for an Unidentified Patient or Specimen
Z	Invalid Patient ID	
V	Invalid Specimen Identification	
E	The query has a bad format	

Action Code

Action Code O.12.1	Description	Message Types
A	Some but not all results available	Host Requests Test Result
	Added in previous specimen or creates a new specimen following the rules of the sample life cycle	Host Downloads Unsolicited Test Orders
I	No results available	Host Requests Test Result
X	Result cannot be done, canceled	
F	Final results	

6.4.1.5 Comments (Notes) Record - (Upload Message)

Message*

C|1|Comment origination point^Comment code^Comment description**||Comment type**

* **Bold Red** fields are required for the overall record.

Definition

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 Refer to table mapping below for a list of allowed values per type of message
		Comment description	3	String	500	O	N	Error description Refer to table mapping below for a list of allowed values per type of message
5	Comment Type	Comment type qualifier	1	String	1	R	N	I: notes N: error

Comment Record

Comment Record	Expected Values	Message Types
Error Code C.4.1	'timeout'	Instrument Cancels Query (All or Specific Specimen)
	'InvalidSpecimenData'/ 'DuplicatedTest'/ 'InvalidTestData'/ 'InvalidPatientData'/ 'InvalidTransmissionInformation'	Instrument Rejects Test Order Initiated from Host Query
	'invalid Transmission Information'	Instrument Rejects Unsolicited Test Order
Error Description C.5.1	'last request has been canceled'	Instrument Cancels Query (All or Specific Specimen)
	'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'	Instrument Rejects Test Order Initiated from Host Query (All or Specific Specimen)
	Unsolicited down- loading orders not supported'	Instrument Rejects Unsolicited Test Orders
Comment Type C.6.1	N (error)	Instrument System Rejects Test Order Initiated from Query (All or Specific Specimen)
		Instrument System Uploads Results
		Instrument System Rejects Unsolicited Test Orders
	I (notes)	Instrument System Uploads Results

6.4.1.6 Comments (Error) Record - (Upload Message)

Message*

C|1|Comment origination point|Comment ID^Comment code^**Comment description**^Comment details^Comment time-stamp|**Comment type**

* **Bold Red** fields are required for the overall record.

Definition

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'/ Note text
		Comment details	4	String	500	O	N	Error details
		Comment time-stamp	5	ASTM Date		O	N	If Comment ID is Error, this field is required
5	Comment Type	Comment type qualifier	1	String	1	R	N	I: notes N: error

6.4.1.7 Result Record (Upload Message)

Message*

R|**1**|System-defined Panel Test ID^^^**Test ID**^Test Name^Test Version^Analyte Name^Complementary Result Name|**Data Value**|**Units**|**Reference Ranges**|**Result Abnormal Flags**||**Result Status**||**Operator Identification**|**Date Time Test Started**|**Date Time Completed**|**Instrument Identification**

* **Bold Red** fields are required for the overall record.

Note Optional fields (System-defined Test name and System-defined Test version) are required for overall result record.

Definition

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

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
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.
		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-results)

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
3 (cont.)		Analyte Name / Result name	7	String	20	R	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	R	N	Only used for complementary results (otherwise it is empty). Possible values: 'Ct'/'EndPt'/ 'Delta Ct'/ 'Conc/LOG' 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	R	N	
		Observed, calculated or implied result value (Quantitative)	2	String	20	R	N	Numeric value

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
5	Units	Abbreviation of units for numerical results	1	String	20	R	N	Refer to table mapping in Section 9.4.1.15, Observation Result Segment (OBX) - (Upload Message) for a list of allowed values per type of message.
6	Reference Ranges	When available reports the reference ranges	1	String	60	R	N	Lower limit to upper limit; example: “3.5 to 4.5” If no lower limit: “to 4.5” If no upper limit: “3.5 to” Only present if the result is the main one and there is a quantitative result.
7	Result Abnormal Flags	This field shall indicate the normalcy status of the result.	1	String	2	R	N	Refer to table mapping below for a list of allowed values per type of message.
9	Result Status		1	String	1	R	Y	Refer to table mapping below for a list of allowed values per type of message.
11	Operator Identification	Operator full name for the test performer	1	String	32	R	N	
12	Date Time Test Started	Date and time the system started the test	1	ASTM Date	14	R	N	
13	Date Time Test Completed	Date and time the system completed the test	1	ASTM Date	14	R	N	

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
14	Instrument Identification	Identifies the PC connected to the instrument	1	String	20	R	N	Computer System Name
		Identifies the instrument that performed this measurement	2	Numeric		R	N	Instrument S/N
		Identifies the module that performed this measurement	3	Numeric		R	N	Module S/N
		Identifies the cartridge that performed this measurement	4	Numeric		R	N	Cartridge S/N
		Reagent Lot ID	5	String	10	R	N	
		Expiration Date	6	ASTM Date	14	R	N	

Result Flag

Result Flag	Description
<	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

Result Status

Result Status R.9.1	Description	Message Types
F	Final Result	Instrument System Uploads Results
		Instrument System Returns Results Initiated by Result Request
I	Pending Result	Instrument System Uploads Results
		Instrument System Returns Results Initiated by Result Request
X	Result cannot be done	Instrument System Uploads Results
		Instrument System Returns Results Initiated by Result Request
C	Correction of previous result	Instrument System Uploads Results
		Instrument System Returns Results Initiated by Result Request

6.4.1.8 Message Terminator Record (Upload Message)

Message*

L|1|Termination Code

* **Bold Red** fields are required for the overall record.

Definition

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	Refer to table mapping below for a list of allowed values per type of message.

ASTM Terminator Code

ASTM Terminator Code L.3.1	Description	Message Types
N	Normal termination	Instrument System Queries (All or Specific Specimen)
		Instrument System Cancels Query (All or Specific Specimen)
		Instrument System Rejects Test Order Initiated From Query (All or Specific Specimen)
		Instrument System Sends Host Query (All or Specific Specimen)
		Instrument System Uploads Results
		Instrument System Rejects Unsolicited Test Orders
Q	Error in last request for information	Instrument Returns Results Responding to Request for an Unidentified Patient or Specimen.

ASTM Terminator Code L.3.1	Description	Message Types
F	Last request for information processed	Instrument Rejects Test Order Initiated from Host Query (All or Specific Specimen)
		Instrument Returns Results Initiated by Result Request
		Instrument System Returns Results Initiated by Result Request

6.4.2 Download Message Mapping Format

The following download messages share the message mapping for each record supported.

- Host Responds with No Available Test Order for Query for All (Section 6.3.1.4)
- Host Responds with Test Orders for Query for All (Section 6.3.1.3)
- Host Responds with Test Order(s) for Host Query for Specific Specimen (Section 6.3.2.3)
- Host Responds with No Available Test Order for Host Query for Specific Specimen (Section 6.3.2.4)
- Host Requests Test Result (Section 6.3.5.1)
- Host Downloads Unsolicited Test Orders (Section 6.3.6.1)
- Host Rejects Uploaded Test Result (no message is sent from LIS) (Section 6.3.6.2)

6.4.2.1 Message Header Record (Download Message)

Message*

```
H|Delimiter Definition|Message ID||Sender Name|||||System ID^System
Name^Software Version||Processing ID|Version No.|Date/Time of Message
```

* `Bold Red` fields are required for the overall record.

Definition

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

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
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	14	R	N	

6.4.2.2 Patient Information Record (Download Message)

Message*

```
P|1|Patient ID 2||Patient ID 1|Patient Family Name^Patient Given
Name^Patient Middle name or initial^Prefix^Suffix
```

* **Bold Red** fields are required for the overall record.

Definition

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
3	Patient ID 2	Practice-Assigned Patient ID	1	String	32	O	N	
5	Patient ID 1	Patient identification	1	String	32	O	N	
6	Patient Name	Patient family name	1	String	194	O	N	
		Patient given name	2	String	30	O	N	
		Patient middle name or initial	3	String	30	O	N	
		Prefix (e.g. JR or III)	4	String	20	O	N	
		Suffix (e.g. DR)	5	String	20	O	N	

6.4.2.3 Test Order Record (Download Message)

Message*

O|1|Specimen ID|Instrument Specimen ID|Univ. Test ID|Priority|Ordered Date and Time|||||**Action Code**||||**Specimen Descriptor**|||||||||**Record Type**

* **Bold Red** fields are required for the overall record.

Definition

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		1	ASTM Date	14	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	* Refer to table mapping below for a list of allowed values per type of message.

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
16	Specimen Descriptor	Specimen type	1	String	3	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 Q: Response to query

Action Code

Action Code O.12.1	Description	Message Types
C	Cancel order	Instrument System Rejects Test Order Initiated From Query
		Instrument System Uploads Results
		Instrument System Returns Results Initiated by Result Request
		Instrument System Returns Results Responding to Request for an Unidentified Patient or Specimen.
P	Pending specimen	Instrument System Cancels Host Query
		Instrument System Uploads Results
		Instrument System Returns Results Initiated by Result Request
		Instrument System Returns Instrument Specimen ID for a Downloaded Order
Empty		Instrument System Uploads Results
		Instrument System Returns Results Initiated by Result Request
Q	Quality Control	Instrument System Uploads Results
		Instrument System Returns Results Initiated by Result Request

6.4.2.4 Request Result Information Record (Download Message)

Message*

Q|1|Patient ID 1^Specimen ID^**Instrument Specimen ID**^Patient ID 2||^^^Test ID|||||||**Request Information Status Codes**

* **Bold Red** fields are required for the overall record.

Definition

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

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
3	Starting Range ID Number	Patient ID 1	1	String	32	O	N	The Patient ID 1 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	This field is required if the "Use Instrument Specimen ID" option is Enabled. This field will be ignored if the "Use Instrument Specimen ID" option is disabled.
		Patient ID 2 (Practice Patient ID)	4	String	32	O	N	The Patient ID 2 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.
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)

6.4.2.5 Message Terminator Record (Download Message)

Message*

L|1|Termination Code

* **Bold Red** fields are required for the overall record.

Definition

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	Refer to table mapping below for a list of allowed values per type of message.

ASTM Terminator Code

ASTM Terminator Code L.3.1	Description	Message Types
N	Normal termination	Host Requests Test Result
		Host Downloads Unsolicited Test Orders
I	No information available from last query	Host Responds with No Available Test Order for Query
F	Last request for information processed	Host Responds with Test Order(s) for Host Query

7 HL7 Message Structure and Content

This chapter describes the HL7 message structure and its content; how segments are organized within the message, how the HL7 message is parsed into fields, and the default list of delimiters used to parse the message.

Messages consist of a hierarchy of segments of various types. A segment 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 segment, which may contain aggregates of data elements that further define the basic attribute.

7.1 Message Length

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

7.2 Segments

7.2.1 HL7 Segments

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 Acknowledgment 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

Message	Description
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 GeneXpert 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 Status	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 QBP Query for All Test Orders message may contain the following segments: Message Segment Header (MSH), Query Parameter Definition (QPD), and Response Control Parameter (RCP).

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 Instruments:

HL7 Segment ID	Record Definition	GeneXpert® Xpress 5.1	GeneXpert® Xpress 6.1	GeneXpert® DX II, IV, XVI 4.7b and above	GeneXpert® Infinity 6.4b and above	GeneXpert® Omni Mobile Application v1.2 and above
EQU	Equipment Detail	X	X	X	X	
INV	Inventory Detail	X			X	
MSA	Message Acknowledgment	X	X	X	X	
MSH	Message Segment Header	X	X	X	X	X

HL7 Segment ID	Record Definition	GeneXpert® Xpress 5.1	GeneXpert® Xpress 6.1	GeneXpert® DX II, IV, XVI 4.7b and above	GeneXpert® Infinity 6.4b and above	GeneXpert® Omni Mobile Application v1.2 and above
NTE	Notes and Comments	X	X	X	X	X
OBR	Observation Request	X	X	X	X	X
OBX	Observation	X	X	X	X	X
ORC	Common Order	X	X	X	X	X
PID	Patient Identification	X	X	X	X	X
QAK	Query Acknowledgment		X	X	X	
QID	Query Identification		X	X	X	
QPD	Query Parameter Definition		X	X	X	
QRD	Original-Style Query Definition		X	X	X	X
RCP	Response Control Parameter		X	X	X	
SAC	Specimen and Container Detail	X	X	X	X	
SPM	Specimen	X	X	X	X	X
TQ1	Timing/Quantity	X	X	X	X	X

Note The INV segment is only transmitted as a dummy record for QC Results in GeneXpert Xpress/DX versions 4.7b and below, and Infinity Xpertise software. The INV segment is not supported otherwise.

7.3 Fields

7.3.1 Structure

A field is a specific attribute of a segment 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 Section 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 segment 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)	14
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 segment 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 segment header . 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 segment header . 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 segment header . 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 segment header . 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 segment. This position-sensitive identification procedure requires that when the contents of the field are null, its corresponding field delimiter must be included in the segment 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 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 Section 4.4.3 for 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

This chapter describes the two types of HL7 acknowledgments (original and enhanced) supported. It includes an example of a successful host query, followed by an order download and a patient result transfer with all low-level character's present.

8.1 HL7 Transmission Control

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

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

8.1.1 Initiation

The initiation application creates a message with data values according to the rules described in Section 1.1. The Message Segment Header (MSH) contains several fields that control the later message flow:

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

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 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:

1. Message processed successfully, which generates the functional response message with a value of AA in MSA-1-acknowledgment code.
2. 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.
3. 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 acknowledgment must be received in 60 seconds. If it is not, the GeneXpert System must resend the message and wait for the accept acknowledgment 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 Segment Header
MSA	Message Acknowledgment

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

```
MSH|^~\&|LIS||GeneXpert
PC^GeneXpert^6.1||20190521101245||ACK|12Y|P|2.5|||NE|NE
MSA|CR|UDC000|Non-expected message received
```

8.1.4 Error Messages

See Section 5.3 for details on Error Handling and LIS message tracing.

8.1.5 HL7 Message Transaction Examples with (*ASTM E1381-02) Low-Level Characters

The example below describes normal behavior of the HL7 interface between the GeneXpert Instrument System and the Host. The Instrument Sends Host Query for Specific Specimen ("2F5DBAB27C04A8D48030B8C78"), the Host Responds with Test Order(s) for Host Query and finally the Instrument Uploads Test Results.

Query ID ("GXM-30218342867"): 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 acknowledgment 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.

GX -> Host <ENQ>

Host -> GX <ACK>

GX -> Host <STX>1MSH|^~\&|GeneXpert PC^GeneXpert^6.1||LIS Simulator||20190430054224||QBP^Z03^QBP_Z03|GXM-30218342867|P|2.5|||||||||<CR>QPD|Z03^HOST QUERY|GXM-30218342867||2F5DBAB27C04A8D48030B8C78||<CR>RCP|I<ETX>16<0D><0A>

Host -> GX <ACK>

GX -> Host <EOT>

Host -> GX <ENQ>

GX -> Host <ACK>

Host -> GX <STX>1MSH|^~\&|LIS Simulator||GeneXpert PC^GeneXpert^6.1||20190521100245||RSP^Z02|12Y|P|2.5|||NE|NE<CR>MSA|AA|GXM-30218342867<CR>QAK|GXM-30218342867|OK|Z01^REQUEST TEST ORDERS<CR>QPD|Z01^REQUEST TEST ORDERS|GXM-3021834286 7|ALL<CR>PID|1<CR>ORC|NW|1|||||||2007042<CR><ETB>31<0D><0A>

GX -> Host <ACK>

Host -> GX

<STX>21100245<CR>OBR|1|||EV|||||||A<CR>TQ1|||||||||R<CR>SPM|1|2F5DBAB2 7C04A8D48030B8C78||ORH|||||||P<ETX>EA<0D><0A>

GX -> Host <ACK>

Host -> GX <EOT>

GX -> Host <ENQ>

Host -> GX <ACK>

GX -> Host

<STX>1MSH|^~\&|GeneXpert PC^GeneXpert^6.1||LIS Simulator||20190430054301||ORU^R32^ORU_R30|GXM-06774108767|P|2.5|||||||||<CR>PID|1||46E78BFEB03DB1F18029990D4459B783<CR>ORC|RE|1|||||||20170518010847<CR>OBR|1|||EV|||||||||||||||||||<ETB>CD<0D><0A>

Host -> GX <ACK>

GX -> Host

<STX>2||F<CR>TQ1|||||||20170518010847|20170518033715|R<CR>OBX|1|ST|&EV&Xpert
EV&3|&|POSITIVE^||||||F|||||^<None>||20181104~06802~80180955~623940~706416~DESKTOP-ML3S693<CR>OBX|2|ST|&EV&&|EV&|
POS^||<CR>OBX|3|ST|&EV&&|EV&Ct|^38.0||<CR>OBX|4|ST|&EV&&|EV&EndPt|^60.0.44<ETB>44 <0D><0A>

Host -> GX <ACK>

GX -> Host

<STX>3||<CR>OBX|5|ST|&EV&&|CIC&|NA^||<CR>OBX|6|ST|&EV&&|CIC&Ct|^33.2||<CR>OBX|7|ST|&EV&&|CIC&EndPt|^392.0||<CR>SPM|1|2F5DBAB27C04A8D48030B8C78^||ORH|||||||P<ETX>9D<0D>

<0A>

Host -> GX <ACK>

GX -> Host <EOT>

9 HL7 Transmission Scenarios

This chapter details each of the workflow scenarios supported by the LIS interface, including sequence diagrams, message examples, and the HL7 segment mapping format. It also 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.

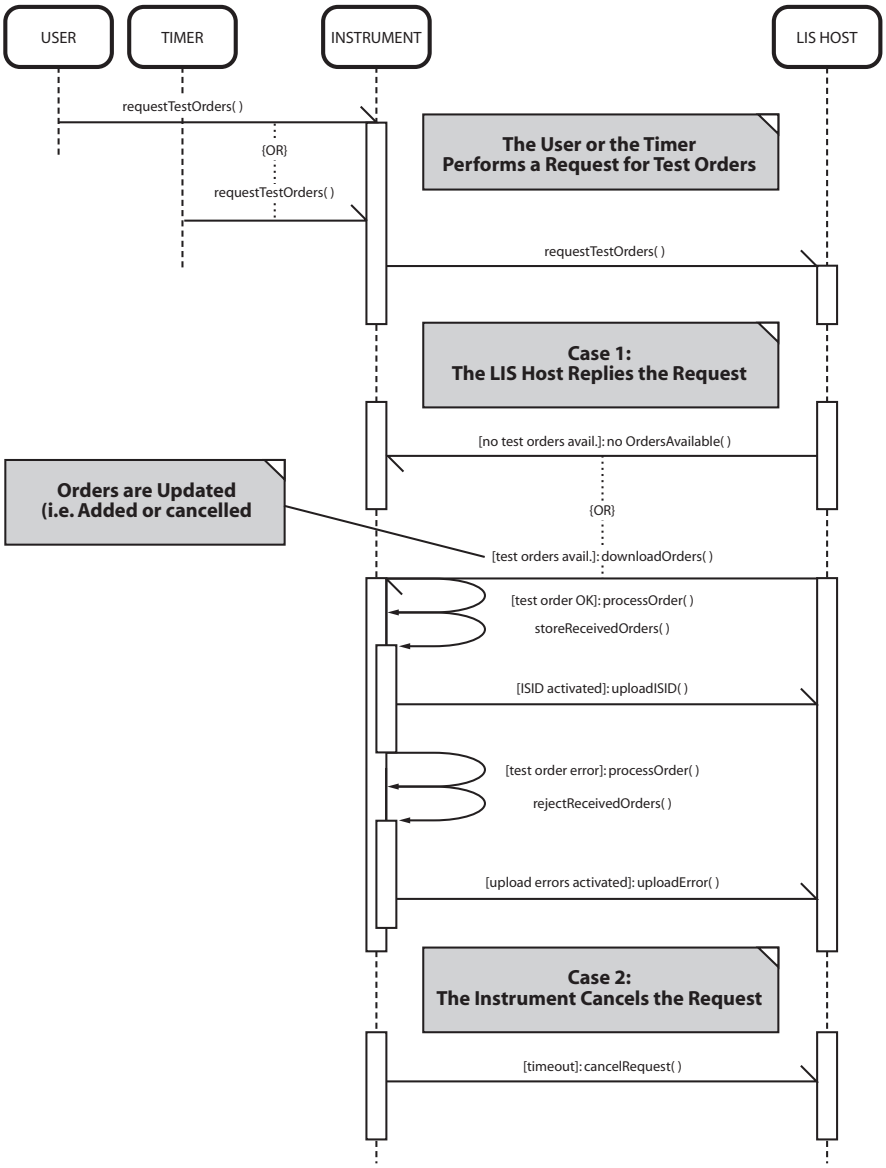

Figure 9-1. Instrument System Queries for All Test Orders

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, Section 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. The same internal Instrument Specimen ID is assigned to all the host test orders that have the same specimen ID.

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, Section 9.3.3

9.2.2 Instrument System Initiates Host Query for One or More Samples 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.

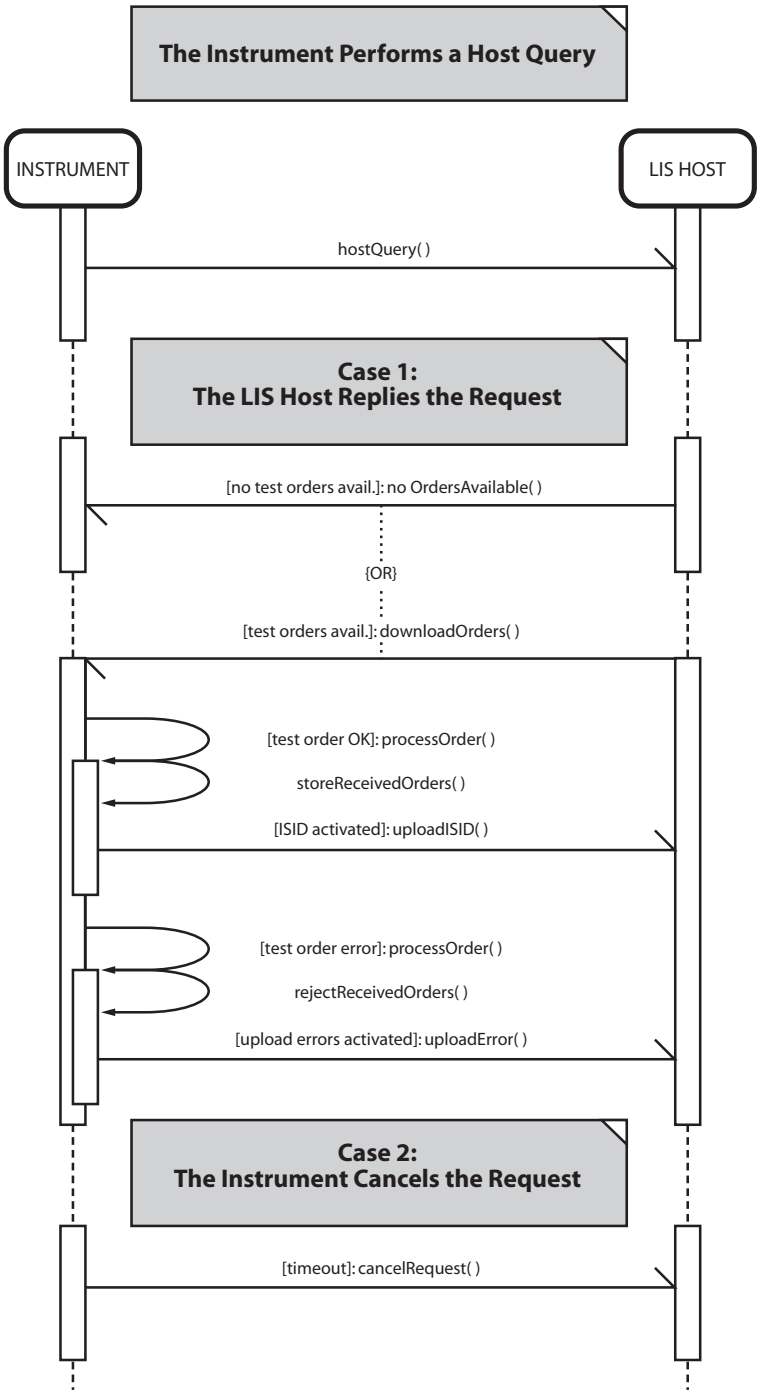

Figure 9-2. Instrument System Initiates Host Query for One or More Samples

9.2.2.1 Instrument System Queries for Test Orders for a Specific Specimen(s)

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, Section 9.3.2

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. The same internal Instrument Specimen ID is assigned to all the host test orders that have the same specimen ID.

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, Section 9.3.3

9.2.3 Instrument System Uploads Test Results

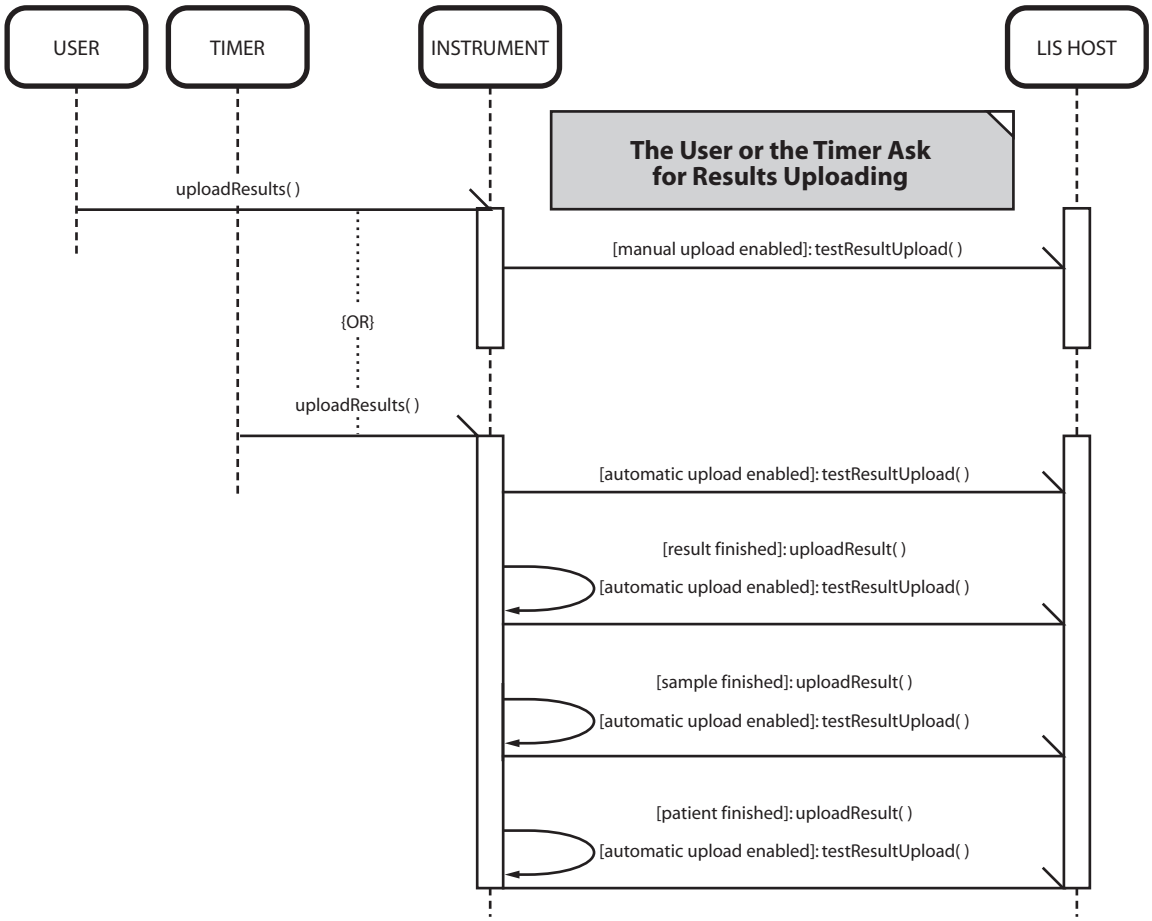

Figure 9-3. Instrument System Uploads Test Results

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, Section 9.3.4

9.2.4 Host Requests Test Results

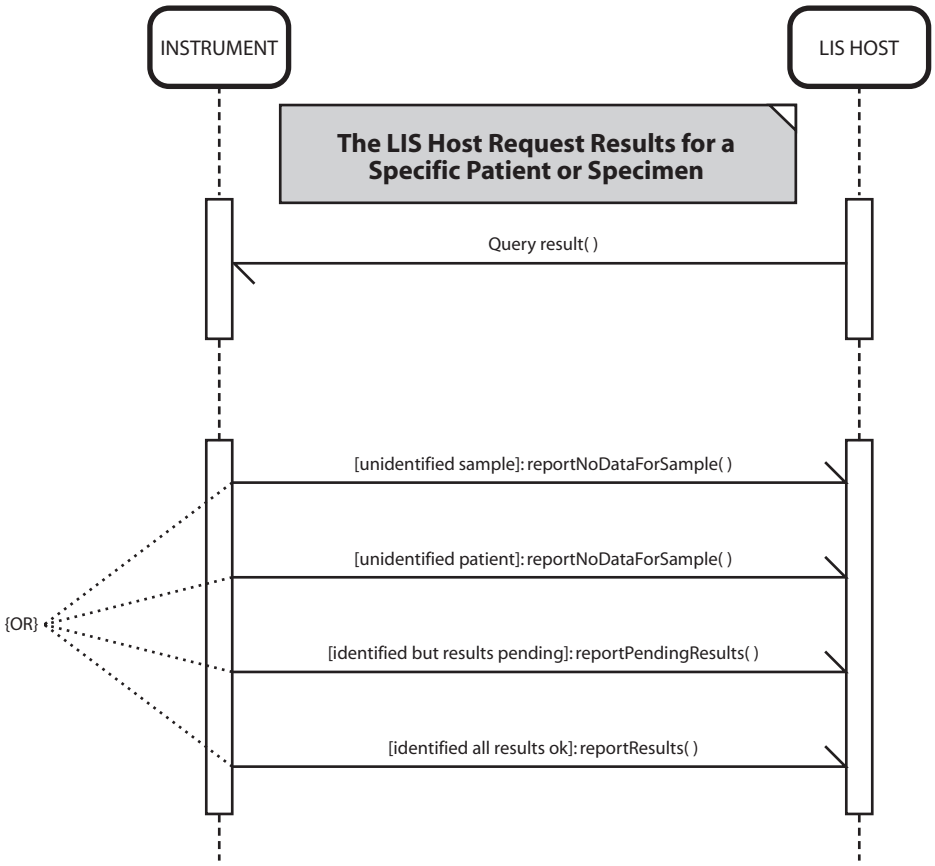

Figure 9-4. Host Requests Test Results

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

- HL7 Implementation, Section 9.3.5

9.2.5 Host Downloads Unsolicited Test Orders

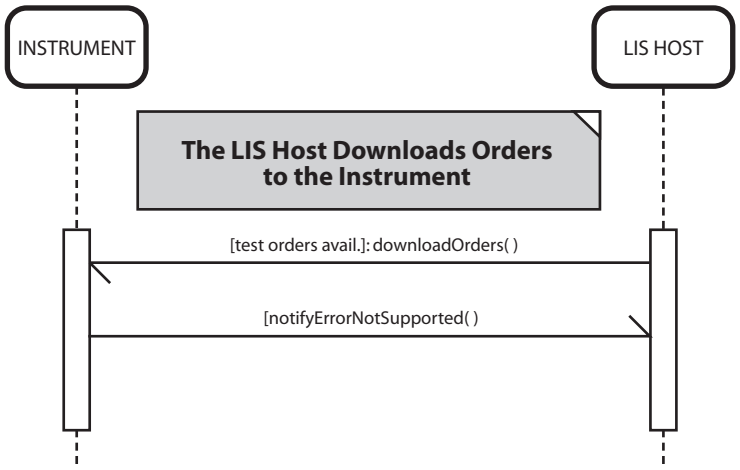

Figure 9-5. Host Downloads Unsolicited Test Orders

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 acknowledged and suppressed by the instrument system.

- HL7 Implementation, Section 9.3.6

9.3 HL7 Messages

For a detailed message field mapping for each of the segments please refer to Section 9.4.

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)

Message Structure

Message	Segment Name
MSH	Message Segment Header (Section 9.4.1.1)
QPD	Query Parameter Definition (Section 9.4.1.4)
RCP	Response Control Parameter (Section 9.4.1.5)

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

```
MSH|^~\&|GeneXpert
PC^GeneXpert^6.1||LIS||20190521100245||QBP^Z01^QBP_Z01|94799a8b48bb4b7
f|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.

QCN^J01 – Message Structure

Message	Segment Name
MSH	Message Segment Header (Section 9.4.1.1)
QID	Query Identification (Section 9.4.1.6)

LIS Host Acknowledgment (ACK^J01)

Message	Segment Name
MSH	Message Segment Header (Section 9.4.2.1)
MSA	Message Acknowledgment (Section 9.4.2.2)

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

GeneXpert message:

```
MSH|^~\&|GeneXpert
PC^GeneXpert^6.1|LIS||20190713114254||QCN^J01^QCN_J01|UDC000|P|2.5|||A
L|NE
QID|9e5- ca0c1f05b4aa2aec1e2868beb6982|N/D
```

LIS Host Acknowledgment (ACK^J01)

```
MSH|^~\&|LIS||GeneXpert
PC^GeneXpert^6.1||20190521101245||ACK|12Y|P|2.5|||NE|NE
MSA|CA|UDC000
```

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

Message Structure

Message	Segment Name
MSH	Message Segment Header (Section 9.4.2.1)
MSA	Message Acknowledgment (Section 9.4.2.2)
QAK	Query Acknowledgment (Section 9.4.2.3)
QPD	Query Parameter Definition Segment (Section 9.4.2.4)
{	
PID	Patient Identification Segment (Section 9.4.2.6)
{	
ORC	Common Order Segment (Section 9.4.2.7)
OBR	Observation Request Segment (Section 9.4.2.8)
TQ1	Timing/Quantity Segment (Section 9.4.2.9)
SPM	Specimen Segment (Section 9.4.2.10)
}	
}	

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

```
MSH|^~\&|LIS||GeneXpert
PC^GeneXpert^6.1||20190521100245||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|||MRSA|||||||A
TQ1|||||||||R
SPM|1|SID-888^ISID-333||ORH|||||||P
ORC|NW|2|||||||20070421100235
OBR|2|||CTNG|||||||A
TQ1|||||||||R
SPM|2|SID-188^ISID-313||ORH|||||||P PID|2||PatientID-5678
ORC|NW|1|||||||20070421100255 OBR|1|||EV |||||||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 for All (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 Section 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.

Message Structure

Message	Comments
MSH	Message Segment Header (Section 9.4.2.1)
MSA	Message Acknowledgment (Section 9.4.2.2)
QAK	Query Acknowledgment (Section 9.4.2.3)
QPD	Query Parameter Definition Segment (Section 9.4.2.4)

Example Host Responds with No Available Test Order for Query for All

```
MSH|^~\&|LIS||GeneXpert
PC^GeneXpert^6.1||20190521100245||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 for All (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.

ORU^R01 – Message Structure

Message	Comments
MSH	Message Segment Header (Section 9.4.1.1)
{	
PID	Patient Identification Segment (Section 9.4.1.7)
{	
ORC	Order Common Segment (Section 9.4.1.8)
OBR	Observation Request Segment (Section 9.4.1.9)
NTE	Error description (related to order) (Section 9.4.1.11)
TQ1	Timing / Quantity Segment (Section 9.4.1.12)
SPM	Specimen Segment (Section 9.4.1.13)
}	
}	

LIS Host Acknowledgment (ACK^R01)

Message	Segment Name
MSH	Message Segment Header (Section 9.4.2.1)
MSA	Message Acknowledgment (Section 9.4.2.2)

Example of ACK^R01 – Message Acknowledgment (MSA)

GeneXpert Result Message:

```
MSH|^~\&|GeneXpertPC^GeneXpert^6.1||LIS||20070521100245||ORU^R32^ORU_R
30|48c0947bfa244|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 Acknowledgment:

```
MSH|^~\&|
LIS||GeneXpertPC^GeneXpert^6.1||20070521101245||ACK|12YASSAQQWE|P|2.5|
||NE|NE
MSA|CA|48c0947bfa244
```

9.3.2 Instrument System Initiated Host Query for Specific Specimen

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

Message Structure

Message	Comments
MSH	Message Segment Header (Section 9.4.1.1)
QPD	Query Parameter Definition (Section 9.4.1.4)
RCP	Response Control Parameter (Section 9.4.1.5)

Query for Specific Patient ID and Specimen ID combination

```
MSH|^~\&|GeneXpertPC^GeneXpert^6.1||LIS||20070521100245||QBP^Z03^QBP_Z
03|662f165|P|2.5
QPD|Z03^HOST QUERY|662f165|PatientID-556|SpecimenID-888
RCP|I
```

Query for Specific Specimen ID

```
MSH|^~\&|GeneXpertPC^GeneXpert^6.1||LIS||20070521100245||QBP^Z03^QBP_Z
03|662f165ebb|P|2.5
QPD|Z03^HOST QUERY|662f165ebb||SpecimenID-888
RCP|I
```

Note The GeneXpert instrument system does not allow Query for Patient ID only. A Query for ALL will be transmitted instead.

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

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

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

GeneXpert message:

```
MSH|^~\&|GeneXpertPC^GeneXpert^6.1||
LIS||20070713114254||QCN^J01^QCN_J01|UDC000|P|2.5|||AL|NE
QID|662f165ebb1b4354b100cba090f1e7e5|N/D
```

LIS Host Acknowledgment (ACK^J01)

```
MSH|^~\&|
LIS||GeneXpertPC^GeneXpert^6.1||20070521101245||ACK|12Y|P|2.5|||NE|NE
MSA|CA|UDC000
```

9.3.2.3 Download Message – Host Responds to Query with Test Order(s) Query for Specific Specimen (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.

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

System sends Host Query:

```
MSH|^~\&|GeneXpert
PC^GeneXpert^6.1||LIS||20191121133825||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^6.1||20191121133826||RSP^Z02|4c49f05b68bf4929|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|||||||20191116133208
OBR|1|||CTNG|||||||A
TQ1|||||||||R
SPM|1|s1^||ORH|||||||P
ORC|NW|2|||||||20191121104253
OBR|2|||MRSA|||||||A
TQ1|||||||||R
SPM|2|s1^||ORH|||||||P
```

9.3.2.4 Download Message - Host Responds with No Available Test Order for Query for Specific Specimen (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 Section 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.

Message Structure

Message	Segment Name
MSH	Message Segment Header (Section 9.4.2.1)
MSA	Message Acknowledgment (Section 9.4.2.2)
QAK	Query Acknowledgment (Section 9.4.2.3)
QPD	Query Parameter Definition Segment (Section 9.4.2.4)

Example with No Available Test Orders:

```
MSH|^~\&|LIS||GeneXpert
PC^GeneXpert^6.1||20190521100245||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.

9.3.3 Instrument System Returns Instrument Specimen ID for a Downloaded Order

Note

A test order with a blank Patient ID will not be downloaded during host query test order download if all of the following apply:
- ISID is enabled
- There are multiple matching test orders using the same Sample ID
- One of these matching test orders has a blank Patient ID.

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.

SSU^U03 – Message Structure

Message	Segment Name
MSH	Message Segment Header (Section 9.4.1.1)
EQU	Equipment Detail (Section 9.4.1.14)
{	
SAC	Specimen and Container Detail (Section 9.4.1.17)
SPM	Specimen (Section 9.4.1.13)
}	

LIS Host Acknowledgment (ACK^U03)

Message	Segment Name
MSH	Message Segment Header (Section 9.4.2.1)
MSA	Message Acknowledgment (Section 9.4.2.2)

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

```
MSH|^~\&|GeneXpert
PC^GeneXpert^6.1||LIS||20190521100245||SSU^U03^SSU_U03|a8c20c78490741|
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 Acknowledgment (ACK^U03)

```
MSH|^~\&|LIS||GeneXpert
PC^GeneXpert^6.1||20190521101245||ACK|12Y|P||||NE|NE
MSA|CA|a8c20c78490741
```

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 segment is followed by a Result segment.

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 Segment following the Order Segment.

If a Test has an error, the Error is reported on the Result Segment (Error message) and Comment Segment (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 Segment 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 X.
- Complementary results (results related to each analyte) like the Ct, EndPt, etc.

Errors and Notes related to the order are reported on the Comment Segments following the Order Segment.

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

For Quantitative Assay, two test results (Main Result) will be uploaded, the first result is identified by the assay host test code; the second result is identified by the assay host test code and “LOG” in the Complementary Result Name.

- Secondary and complementary results including analyte result, Ct, EndPt, deltaCt will be uploaded to LIS.

Complementary result with Conc/LOG names will be uploaded if applicable. LDA total values for LDA assay will be uploaded with main result to LIS. – N/A for version Dx4.6a and Xpertise 6.2a.and below.

ORU^R01 – Message Structure for Patient Results

Message	Segment Name
MSH	Message Segment Header (Section 9.4.1.1)
{	
PID	Patient Identification Segment (Section 9.4.1.7)
{	
ORC	Order Common Segment (Section 9.4.1.8)
OBR	Observation Request Segment (Section 9.4.1.9)
[NTE]	Notes and comments (related to order) (Section 9.4.1.11)
TQ1	Timing/Quantity (Section 9.4.1.12)
{	
OBX	Observation Result Segment (Section 9.4.1.15)
[NTE]	Notes and comments (related to result) (Section 9.4.1.11)
}	
SPM	Specimen Segment (Section 9.4.1.13)
}	
}	

ORU^R01 – Message Structure for QC Results (Xpress/DX version 6.1 and above)

Message	Segment Name
MSH	Message Segment Header (Section 9.4.1.1)
{	
PID	Patient Identification Segment (Section 9.4.1.7)
{	
ORC	Order Common Segment (Section 9.4.1.8)
OBR	Observation Request Segment (Section 9.4.1.9)
[NTE]	Notes and comments (related to order) (Section 9.4.1.11)
TQ1	Timing/Quantity (Section 9.4.1.12)
{	
OBX	Observation Result Segment (Section 9.4.1.15)
[NTE]	Notes and comments (related to result) (Section 9.4.1.11)
}	
SPM	Specimen Segment (Section 9.4.1.13)
}	
}	

ORU^R01 – Message Structure for QC Results (Xpress/DX version 4.7b+, Infinity Xpertise)

Message	Segment Name
MSH	Message Segment Header (Section 9.4.1.1)
{	
PID	Patient Identification Segment (Section 9.4.1.7)
SPM	Specimen Segment (Section 9.4.1.13)
SAC	Specimen and Container Detail (Section 9.4.1.17)
INV	Inventory Detail Segment (Section 9.4.1.18)
{	
OBR	Observation Request Segment (Section 9.4.1.9)
ORC	Order Common Segment (Section 9.4.1.8)
[NTE]	Notes and comments (related to order) (Section 9.4.1.11)
TQ1	Timing/Quantity (Section 9.4.1.12)
{	
OBX	Observation Result Segment (Section 9.4.1.15)
[NTE]	Notes and comments (related to result) (Section 9.4.1.11)
}	
}	
}	

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]
```

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 segment 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 • Field 4, Component 1, Subcomponent 2 = Empty or “LOG” 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 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 quantitative result for this complementary result. See Section 9.3.4.1 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 9-6. Single-Result Test Report

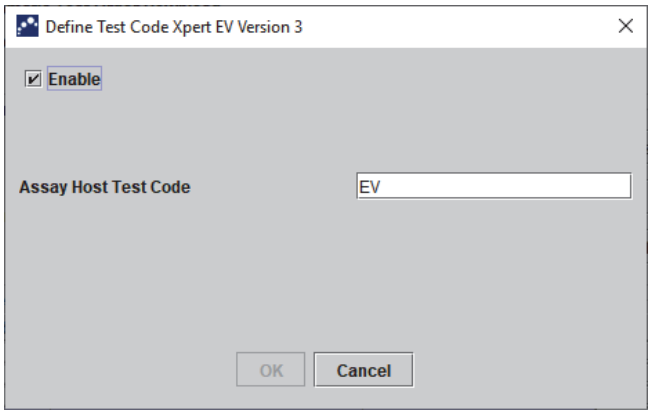

Figure 9-7. Define Test Code Dialog

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

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 9-8. 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.

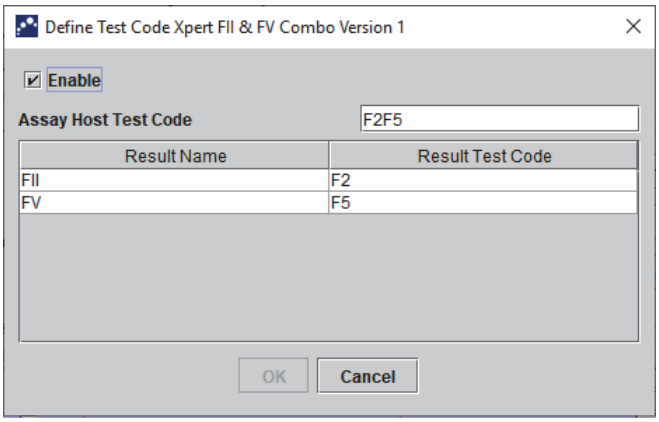

Figure 9-9. Define Test Code Dialog

LIS Host Acknowledgment (ACK^R01)

Message	Segment Name
MSH	Message Segment Header (Section 9.4.2.1)
MSA	Message Acknowledgment (Section 9.4.2.2)

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

Example of a multi-result test result:

```
MSH|^~\&|GeneXpert
PC^GeneXpert^6.1||LIS||20190425052956||ORU^R32^ORU_R30|GXM-
55155304626|P|2.5|||||||||
PID|1|PID2|PID1||Armstrong^Neil^Scott^JR^DR
ORC|RE|1|||||||20180423131917
OBR|1|||F2F5||||||||||||||||||||F
TQ1|||||||20180423131917|20180423134932|R
OBX|1|ST|F2F5&F2&Xpert FII \T\ FV
Combo1|FII&|NORMAL||||||F|||||^<None>||20200706~06905~134563542~688884
~711212~DESKTOP-ML3S693
OBX|2|ST|F2F5&F2&&|FII 20210G&|POS
OBX|3|ST|F2F5&F2&&|FII 20210G&Ct|^26.0
OBX|4|ST|F2F5&F2&&|FII 20210G&EndPt|^478.0
OBX|5|ST|F2F5&F2&&|FII 20210A&|NEG
OBX|6|ST|F2F5&F2&&|FII 20210A&Ct|^0.0
OBX|7|ST|F2F5&F2&&|FII 20210A&EndPt|^15.0
```

```
OBX|8|ST|F2F5&F5&Xpert FII \T\ FV
Combo1|FV&|NORMAL||||||F|||||^<None>||20200706~06905~134563542~688884~
711212~DESKTOP-ML3S693
OBX|9|ST|F2F5&F5&&|FV 1691G&|POS
OBX|10|ST|F2F5&F5&&|FV 1691G&Ct|^26.4
OBX|11|ST|F2F5&F5&&|FV 1691G&EndPt|^373.0
OBX|12|ST|F2F5&F5&&|FV 1691A&|NEG
OBX|13|ST|F2F5&F5&&|FV 1691A&Ct|^0.0
OBX|14|ST|F2F5&F5&&|FV 1691A&EndPt|^21.0
SPM|1|5188264BF78022485EE6DAAB9||ORH|||||||P
```

Example of a Single-Result Test Result: HL7 – Single Result Assay

```
MSH|^~\&|GeneXpert
PC^GeneXpert^6.1||LIS||20190425052952||ORU^R32^ORU_R30|GXM-
33424828723|P|2.5|||||||||
PID|1|PID2|PID1||Armstrong^Neil^Scott^JR^DR
ORC|RE|1|||||||20170518072647
OBR|1|||EV|||||||||||||||||||||F
TQ1|||||||20170518072647|20170518095506|R
OBX|1|ST|&EV&Xpert
EV3|&|NEGATIVE||||||F|||||^<None>||20181104~06802~80180954~623940~7064
16~DESKTOP-ML3S693
OBX|2|ST|&EV&&|EV&|NEG
OBX|3|ST|&EV&&|EV&Ct|^0.0
OBX|4|ST|&EV&&|EV&EndPt|^1.0
OBX|5|ST|&EV&&|CIC&|PASS
OBX|6|ST|&EV&&|CIC&Ct|^35.4
OBX|7|ST|&EV&&|CIC&EndPt|^138.0
SPM|1|73C212E49E6BF509AE8DC6064||ORH|||||||P
```

HL7 (Upload Quantitative Result with result analysis value indicated numerically– two main results are uploaded)

```
MSH|^~\&|GeneXpert
PC^GeneXpert^6.1||LIS||20191010104243||ORU^R32^ORU_R30|URM-8vP2SBVA-
09|P|2.5
PID|1|pid2Q|pidQ||galilei^galileo^
ORC|RE|1|||||||20190109151218
OBR|1|||QUANT|||||||||||||||||||||F
TQ1|||||||20190109151218|20130109151218|R
```

```
OBX|1|ST|&QUANT&LQL-UQL&1||^10192607995.71|IU/mL|1000.00-
100000000000.00|N|||F|||||^Kathy
Kroll||~12399~34563456~867212~455677~REBOLI-HP840
OBX|2|ST|&QUANT&LQL-UQL&1|&LOG|^10.01|IU/mL|3.00-1S0|N|||F|||||^Kathy
Kroll||~12399~34563456~867212~455677~REBOLI- HP840
OBX|3|ST|&QUANT|HBV|POS^|||
OBX|4|ST|&QUANT|HBV&Ct|^24.3||
OBX|5|ST|&QUANT|HBV&EndPt|^366.0||
OBX|6|ST|&QUANT|HBV&DeltaCt|^3.1|||
OBX|7|ST|&QUANT|IQS|PASS^|||
OBX|8|ST|&QUANT|IQS&Ct|^23.2||
OBX|9|ST|&QUANT|IQS&EndPt|^256.0||
OBX|10|ST|&QUANT|IQS&Delta Ct|^|||
OBX|11|ST|&QUANT|CIC|PASS^|||
OBX|12|ST|&QUANT|CIC&Ct|^32.3||
OBX|13|ST|&QUANT|CIC&EndPt|^241.0||
OBX|14|ST|&QUANT|CIC&Delta Ct|^|||
SPM|1|sidQ^||ORH|||||||P
```

Example of a QC Result Test Result

HL7 – QC Result Assay (DX v6.1+)

```
MSH|^~\&|GeneXpert
PC^GeneXpert^6.1||LIS||20190425052958||ORU^R32^ORU_R30|GXM-
74772321302|P|2.5|||||||||
PID|1|PID2|PID1||Armstrong^Neil^Scott^JR^DR
ORC|RE|1|||||||20170323135645
OBR|1|||FLURSV|||||||||||||||||||||F
TQ1|||||||20170323135645|20170323145752|R
OBX|1|ST|FLURSV&NULLA&Xpert Flu-RSV XC US-IVD3|Flu
A&|NEGATIVE||||||F|||||^rachel
blackman||20180212~04203~378920129~604572~800479~DESKTOP-ML3S693
OBX|2|ST|FLURSV&NULLA&&|Flu A 1&|NEG
OBX|3|ST|FLURSV&NULLA&&|Flu A 1&Ct|^0.0
OBX|4|ST|FLURSV&NULLA&&|Flu A 1&EndPt|^5.0
OBX|5|ST|FLURSV&NULLA&&|Flu A 2&|NEG
OBX|6|ST|FLURSV&NULLA&&|Flu A 2&Ct|^0.0
OBX|7|ST|FLURSV&NULLA&&|Flu A 2&EndPt|^1.0
OBX|8|ST|FLURSV&NULLA&&|SPC&|NA
OBX|9|ST|FLURSV&NULLA&&|SPC&Ct|^0.0
```

```
OBX|10|ST|FLURSV&NULLA&&|SPC&EndPt|^0.0
OBX|11|ST|FLURSV&NULLB&Xpert Flu-RSV XC US-IVD3|Flu
B&|POSITIVE||||||F|||||^rachel
blackman||20180212~04203~378920129~604572~800479~DESKTOP-ML3S693
OBX|12|ST|FLURSV&NULLB&&|Flu B&|POS
OBX|13|ST|FLURSV&NULLB&&|Flu B&Ct|^24.6
OBX|14|ST|FLURSV&NULLB&&|Flu B&EndPt|^948.0
OBX|15|ST|FLURSV&NULLB&&|SPC&|NA
OBX|16|ST|FLURSV&NULLB&&|SPC&Ct|^0.0
OBX|17|ST|FLURSV&NULLB&&|SPC&EndPt|^0.0
OBX|18|ST|FLURSV&RSV&Xpert Flu-RSV XC US-
IVD3|RSV&|NEGATIVE||||||F|||||^rachel
blackman||20180212~04203~378920129~604572~800479~DESKTOP-ML3S693
OBX|19|ST|FLURSV&RSV&&|RSV&|NEG
OBX|20|ST|FLURSV&RSV&&|RSV&Ct|^0.0
OBX|21|ST|FLURSV&RSV&&|RSV&EndPt|^1.0
OBX|22|ST|FLURSV&RSV&&|SPC&|NA
OBX|23|ST|FLURSV&RSV&&|SPC&Ct|^0.0
OBX|24|ST|FLURSV&RSV&&|SPC&EndPt|^0.0
OBX|25|ST|FLURSV&QC&Xpert Flu-RSV XC US-IVD3|QC
Check&|||||||F|||||^rachel
blackman||20180212~04203~378920129~604572~800479~DESKTOP-ML3S693
OBX|26|ST|FLURSV&QC&&|QC1&|NEG
OBX|27|ST|FLURSV&QC&&|QC1&Ct|^0.0
OBX|28|ST|FLURSV&QC&&|QC1&EndPt|^0.0
OBX|29|ST|FLURSV&QC&&|QC2&|NEG
OBX|30|ST|FLURSV&QC&&|QC2&Ct|^0.0
OBX|31|ST|FLURSV&QC&&|QC2&EndPt|^0.0
SPM|1|id3-05||ORH|||||||Q
```

HL7 – QC Result Assay (Xpress/DX version 4.7b+, Infinity Xpertise)

```
MSH|^~\&|Community
Hospital^GeneXpert^4.7b||CERNER||20190513100013||OUL^R22^OUL_R22|4WzIy
qWA-03|P|2.5
PID|1||QC GBS LB Positive||^^^^
SPM|1|QC GBS LB Positive^||ORH|||||||Q
SAC|||QC GBS LB Positive^
INV|||||||||||||||
OBR|1|||GBSLB|||||||||||||||||||F
ORC|RE|1|||||||20161215125331
```

```
TQ1|||||||20161215125331|20161215133850|R
OBX|1|ST|&GBSLB&Xpert GBS
LB&1||POSITIVE^||||||F|||||^super1||20180902~08502~78594728~613849~704
296~Cepheid
OBX|2|ST|&GBSLB|SPC|NA^|||
OBX|3|ST|&GBSLB|SPC&Ct|^0.0||
OBX|4|ST|&GBSLB|SPC&EndPt|^2.0||
OBX|5|ST|&GBSLB|GBS|POS^|||
OBX|6|ST|&GBSLB|GBS&Ct|^28.8||
OBX|7|ST|&GBSLB|GBS&EndPt|^219.0||
OBX|8|ST|&GBSLB|IC|NA^|||
OBX|9|ST|&GBSLB|IC&Ct|^30.6||
OBX|10|ST|&GBSLB|IC&EndPt|^43.0||
```

Example of an Invalid Result Test Result

HL7 – Invalid Result Value

```
MSH|^~\&|GeneXpert
PC^GeneXpert^6.1||LIS||20190425053028||ORU^R32^ORU_R30|GXM-
78375164762|P|2.5|||||||||
PID|1|PID2|PID1||Armstrong^Neil^Scott^JR^DR
ORC|RE|1|||||||20170824112637
OBR|1|||STREPA|||||||||||||||||||F
TQ1|||||||20170824112637|20170824114720|R
OBX|1|ST|&STREPA&Xpert Xpress Strep A1|&|INVALID||||||F|||||^sang
nguyen||20180715~06201~312890724~604512~706640~DESKTOP-ML3S693
OBX|2|ST|&STREPA&&|SPC&|FAIL
OBX|3|ST|&STREPA&&|SPC&Ct|^0.0
OBX|4|ST|&STREPA&&|SPC&EndPt|^16.0
OBX|5|ST|&STREPA&&|Strep A&|INVALID
OBX|6|ST|&STREPA&&|Strep A&Ct|^26.9
OBX|7|ST|&STREPA&&|Strep A&EndPt|^18.0
SPM|1|123||ORH|||||||P
```

Example of an Error/No Result Test Result

HL7 – Error/No Result Assay

```
MSH|^~\&|GeneXpert
PC^GeneXpert^6.1||LIS||20190425052948||ORU^R32^ORU_R30|GXM-
58726366431|P|2.5|||||||||
PID|1|PID2|PID1||Armstrong^Neil^Scott^JR^DR
ORC|RE|1|||||||20170529060239
```

```
OBR|1|||EV|||||||||||||||||||||F
TQ1|||||||20170529060239|20170529060249|R
OBX|1|ST|&EV&Xpert EV3|&|NO
RESULT||||||F|||||^<None>||20181104~06802~80181071~623940~706416~DESKT
OP-ML3S693
NTE|1|L|Error^4012^Error occurred^Error 4012: Heater B operation was
not verified.\X0A\Measured temperature changed from 58.4 °C to 74.0
°C^20170529060247
OBX|2|ST|&EV&&|EV&|NO RESULT
OBX|3|ST|&EV&&|EV&Ct|^0.0
OBX|4|ST|&EV&&|EV&EndPt|^0.0
OBX|5|ST|&EV&&|CIC&|NO RESULT
OBX|6|ST|&EV&&|CIC&Ct|^0.0
OBX|7|ST|&EV&&|CIC&EndPt|^0.0
SPM|1|73C212E49E6BF509AE8DC6064||ORH|||||||P
```

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 can- not retrieve any error information from the system. There are no segments 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.

Message Structure

Message	Segment Name
MSH	Message Segment Header (Section 9.4.2.1)
QRD	Original-Style Query Definition (Section 9.4.2.5)

Example of Download Message – Host Requests Test Result (QRY^R02) With Patient ID, SID and ISID:

```
MSH|^~\&|LIS||GeneXpert
PC^GeneXpert^6.1||20190521100245||QRY^R02^QRY_R02|12XGGFFD|P|2.5
QRD|20190521100245|R|I|1123|||1000^RD|N/D|RES|N/D|PatId-
122^SpecimenID-123456^ISID-222_^QC EV IO
```

With SID and ISID:

```
MSH|^~\&|LIS||GeneXpert
PC^GeneXpert^6.1||20190521100245||QRY^R02^QRY_R02|12XGGFFD|P|2.5
QRD|20070521100245|R|I|1123|||1000^RD|N/D|RES|N/D|^SpecimenID-
123456^ISID-222^QC EV IO
```

With SID only:

```
MSH|^~\&|LIS||GeneXpert
PC^GeneXpert^6.1||20190521100245||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
```

With Patient ID, SID(s) and ISID(s):

```
MSH|^~\&|LIS||GeneXpert
PC^GeneXpert^6.1||20190521100245||QRY^R02^QRY_R02|12XGGFFD|P|2.5
QRD|20190521100245|R|I|1123|||1000^RD|N/D|RES|N/D|PatId-
122^SpecimenID-123456^ISID-222^Q
```

With Specimen ID(s) only:

```
MSH|^~\&|LIS||GeneXpert
PC^GeneXpert^6.1||20190521100245||QRY^R02^QRY_R02|12XGGFFD|P|2.5
QRD|20190521100245|R|I|1123|||1000^RD|N/D|RES|N/D|^SpecID-1^^MRSA TC
```

```
MSH|^~\&|LIS||GeneXpert
PC^GeneXpert^6.1||20190521100245||QRY^R02^QRY_R02|12XGGFFD|P|2.5
QRD|20190521100245|R|I|1123|||1000^RD|N/D|RES|N/D|^SpecID-1^^MRSA
TC~^SpecID-2^^CTNG
```

With Specimen ID(s) and ISID enabled:

```
MSH|^~\&|LIS||GeneXpert
PC^GeneXpert^6.1||20190521100245||QRY^R02^QRY_R02|12XGGFFD|P|2.5
QRD|20190521100245|R|I|1123|||1000^RD|N/D|RES|N/D|^SpecID-1^ISID-
1^MRSA TC~^SpecID-2^ISID-2^CTNG
```

With Patient ID, Specimen ID(s), and ISID enabled:

```
MSH|^~\&|LIS||GeneXpertPC^GeneXpert^6.1||20190521100245||QRY^R02^QRY_R
02|12XGGFFD|P|2.5
QRD|20190521100245|R|I|1123|||1000^RD|N/D|RES|N/D|PatID-1^SpecID-
1^ISID-1^MRSA TC~PatID-1^SpecID-2^ISID-2^CTNG
```

With Patient ID, Specimen ID(s), and ISID disabled:

```
MSH|^~\&|LIS||GeneXpertPC^GeneXpert^6.1||20190521100245||QRY^R02^QRY_R
02|12XGGFFD|P|2.5
QRD|20190521100245|R|I|1123|||1000^RD|N/D|RES|N/D|PatID-1^SpecID-
1^^MRSA TC~PatID-1^SpecID-2^^CTNG
```

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.

ORF^R04 – Message Structure

Message	Segment Name
MSH	Message Segment Header (Section 9.4.1.1)
MSA	Message Acknowledgment (Section 9.4.1.2)
QRD	Original-Style Query Definition (Section 9.4.1.16)
PID	Patient Identification Segment (Section 9.4.1.7)
{	
ORC	Order Common Segment (Section 9.4.1.8)
OBR	Observation Request Segment (Section 9.4.1.9)
[NTE]	Notes and comments (related to order) (Section 9.4.1.11)
TQ1	Timing/Quantity (Section 9.4.1.12)
{	
OBX	Observation Result Segment (Section 9.4.1.15)
[NTE]	Notes and comments (related to result) (Section 9.4.1.11)
}	
SPM	Specimen Segment (Section 9.4.1.13)
}	

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

```
MSH|^~\&|GeneXpert
PC^GeneXpert^6.1||LIS||20191011080536||ORU^R32^ORU_R30|URM-SD4bXBVA-
01|P|2.5
PID|1||M+957||^^^^
ORC|RE|1|||||||20190724153733
OBR|1|||MRSA|||||||||||||||||||||F
TQ1|||||||20190724153733|20190724160142|R
OBX|1|ST|&MRSA&Xpert MRSA G3&20||ERROR^||||||F|||||^Sally
Yousif||20190616~06768~38592337~625166~802269~REBOLI-HP840
NTE|1|L|Notes^^notes for Q
NTE|2|L|Error^5006^Post-run analysis error^Error 5006: [SCC] probe
check failed. Probe check value of 113 for reading number 1 was above
the maximum of 110^20190724160120
NTE|3|L|Error^5006^Post-run analysis error^Error 5006: [SCC] probe
check failed. Probe check value of 112 for reading number 3 was above
the maximum of 110^20190724160120
OBX|2|ST|&MRSA|SCC|NO RESULT^|||
OBX|3|ST|&MRSA|SCC&Ct|^0.0||
OBX|4|ST|&MRSA|SCC&EndPt|^0.0||
OBX|5|ST|&MRSA|SPC|NO RESULT^|||
OBX|6|ST|&MRSA|SPC&Ct|^0.0||
OBX|7|ST|&MRSA|SPC&EndPt|^0.0||
SPM|1|M+957^||ORH|||||||P
```

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

ORF^R04 – Message Structure

Message	Segment Name
MSH	Message Segment Header (Section 9.4.1.1)
MSA	Message Acknowledgment (Section 9.4.1.2)
QRD	Original-Style Query Definition (Section 9.4.1.16)
PID	Patient Identification Segment (Section 9.4.1.7)
{	
ORC	Order Common Segment (Section 9.4.1.8)
OBR	Observation Request Segment (Section 9.4.1.9)
}	

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

Unidentified Specimen(s)

```
MSH|^~\&|GeneXpert
PC^GeneXpert^6.1||LIS||20190521100245||ORF^R04^ORF_R04|04126fc6|P|2.5
MSA|AA|12XGGFFD
QRD|20190521100245|R|I|1123|||1000^RD|N/D|RES|N/D|^SID-123456
PID|1||||^^^^|||||^^^^||||||||||
ORC|OC|1|||||||
OBR|1|||QC EV IO|||||||||||||||||||||V
```

Unidentified Patient(s)

```
MSH|^~\&|GeneXpert
PC^GeneXpert^6.1||LIS||20190521100245||ORF^R04^ORF_R04|312f1db6|P|2.5
MSA|AA|12XGGFFD
QRD|20190507091757|R|I|12XGGFFD|||20^RD|N/D|RES|N/D|PatId-
122^SpecimenID-123456^^QC EV IO^
PID|1||PatId-1222||^^^^|||||^^^^||||||||||
ORC|OC|1|||||||
OBR|1|||QC EV IO|||||||||||||||||||||Z
```

Unidentified Ordered Test Assay

```
MSH|^~\&|GeneXpert
PC^GeneXpert^6.1||LIS||20190521100245||ORF^R04^ORF_R04|312f1db6|P|2.5
MSA|AA|12XGGFFD
QRD|20190507091757|R|I|12XGGFFD|||20^RD|N/D|RES|N/D|PatId-
122^SpecimenID-123456^^QC EV IO^
PID|1||PatId-1222||^^^^|||||^^^^||||||||||
ORC|OC|1|||||||
OBR|1|||QC EV IO|||||||||||||||||||||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 Section 9.3.6.2. 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^O21)

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 a LIS does not require the application acknowledgment from the instrument and only requests a high-level acknowledgment, 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 acknowledgment, it will receive the message ORL^O22. This message contains the rejection code and the explanation.

OML^O21 – Message Structure

Message	Segment Name
MSH	Message Segment Header (Section 9.4.2.1)
PID	Patient identification (Section 9.4.2.6)
{	
ORC	Common Order (Section 9.4.2.7)
OBR	Observation Request (Section 9.4.2.8)
TQ1	Quantity / Timing (Section 9.4.2.9)
SPM	Specimen (Section 9.4.2.10)
}	

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

(Option I) ACK – Message Structure

Message	Segment Name
MSH	Message Segment Header (Section 9.4.1.1)
MSA	Message Acknowledgment (Section 9.4.1.2)

Option I Example

Message sent by the LIS Host:

```
MSH|^~\&|LIS||GeneXpert
PC^GeneXpert^6.1||20070521100245||OML^O21^OML_O21|12XASDASF|P|2.5|||AL
|NE
PID|1||PatientID-1234
ORC|NW|1|||||||20190421100245
OBR|1|||Test_ID-212|||||||A
TQ1|||||||||R
SPM|1|SID-888||ORH|||||||P
ORC|NW|2|||||||20190421100235
OBR|2|||Test_ID-214|||||||A
TQ1|||||||||R
SPM|2|SID-188||ORH|||||||P
PID|2||PatientID-5678
ORC|NW|1|||||||20190421100255
OBR|1|||Test_ID-213|||||||A
TQ1|||||||||S
SPM|1|SID-818||ORH|||||||P
```

High level ACK:

```
MSH|^~\&|GeneXpert
PC^GeneXpert^6.1||LIS||20190521100245||ACK|ddc3f515130f41|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 Acknowledgment

(Option II) ORL^O22 – Message Structure

Message	Segment Name
MSH	Message Segment Header (Section 9.4.1.1)
MSA	Message Acknowledgment (Section 9.4.1.2)
ERR	Error Segment (Section 9.4.1.3)

Option II Example

Message sent by the LIS Host:

```
MSH|^~\&|LIS||GeneXpert
PC^GeneXpert^6.1||20190521100245||OML^O21^OML_O21|12XASDASF|P|2.5|||NE|AL
PID|1||PatientID-1234
ORC|NW|1|||||||20190421100245
OBR|1|||Test_ID-212|||||||A
TQ1|||||||||R
SPM|1|SID-888||ORH|||||||P
ORC|NW|2|||||||20190421100235
OBR|2|||Test_ID-214|||||||A
TQ1|||||||||R
SPM|2|SID-188||ORH|||||||P
PID|2||PatientID-5678
ORC|NW|1|||||||20190421100255
OBR|1|||Test_ID-213|||||||A
TQ1|||||||||S
SPM|1|SID-818||ORH|||||||P
```

Application Acknowledgment (ORL^O22):

```
MSH|^~\&|GeneXpert PC
^GeneXpert^6.1||LIS||20190521100245||ORL^O22^ORL_O22|ddc3f515130f4181|
P|2.5
MSA|AR|12XASDASF
ERR|||200^Unsolicited download of orders is not supported|E
```

9.4 HL7 Message Mapping Format

The workflow scenarios described in Section 9.2 have similar message mapping depending on the direction of the message. This section describes how each HL7 segment is mapped, listing allowed values and segment examples.

Messages originated by the GeneXpert system are called upload message. Download messages are the transmissions originated by the LIS host.

9.4.1 Upload Message Mapping Format

The following upload messages share the message mapping for each segment supported.

- Instrument Queries for All Test Orders (QBP^Z01), Section 9.3.1.1
- Instrument Cancels Query for All Test Orders (QCN^J01/ACK^J01), Section 9.3.1.2
- Instrument Rejects Test Order Initiated from Query for All Test Orders (ORU^R01-ACK^R01), Section 9.3.1.4
- Instrument Sends Host Query for Specific Specimen(s) (QBP^Z03), Section 9.3.2.1
- Instrument Cancels Host Query for Specific Specimen(s) (QCN^J01/ACK^J01), Section 9.3.2.2
- Instrument Rejects Test Order Initiated from Query for Specific Specimen(s) (ORU^R01-ACK^R01), Section 9.3.2.5
- Instrument Returns Specimen ID for a Downloaded Order (SSU^U03/ACK^U03), Section 9.3.3.1
- Instrument Uploads Test Results (ORU^R01-ACK^R01), Section 9.3.4.1
- Instrument Returns Results Initiated by Result Request (ORF^R04), Section 9.3.5.2
- Instrument Returns Results Responding to Request for an Unidentified Patient or Specimen (ORF^R04), Section 9.3.5.3
- Instrument Rejects Unsolicited Test Orders with a High-Level Acknowledgment, Section 9.3.6.2
- Instrument Rejects Unsolicited Test Orders (ORL-O22) with Application Acknowledgment, Section 9.3.6.3
- Upload ACK of a Non-Expected Message, Section 8.1.3.2

9.4.1.1 Message Segment Header (MSH) - (Upload Message)

The MSH segment defines the intent, source, destination, and some specifics of the syntax of the message.

Message*

MSH|Field Separator|Encoding Characters|System ID^System Name^Software Version||Receiver ID||Date and time of Message||Message Code^Trigger Event^Message Structure|Message ID|Processing ID|Version Number|||Accept Acknowledgment|Application Acknowledgment

* **Bold Red** fields are required for the overall record.

Definition

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
0	Segment Name		1	MSG	3	R	N	MSH
1	Field Separator		1	ST	1	R	N	'|'
2	Encoding Characters		1	ST	4	R	N	See Section 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	14	R	N	
9	Message Type	Message Code	1	ID	3	R	N	Refer to table mapping below for a list of allowed values per type of message
		Trigger Event	2	ID	3	R	N	
		Message Structure	1	ID	3	R	N	

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 Acknowledgment		1	ID	2	O	N	Refer to table mapping below for a list of allowed values per type of message
16	Application Acknowledgment		1	ID	2	O	N	Refer to table mapping below for a list of allowed values per type of message

Message Type

Message Type MSH.9	HL7 Message Description
QCN^J01^QCN_J01	Instrument System Cancels Query for All Test Orders
	Instrument System Cancels Host Query for Specific Specimen(s)
QBP^Z01^QBP_Z01	Instrument System Queries for All Test Orders
ORU^R32^ORU_R30	Instrument System Rejects Test Order Initiated from Query for All
	Instrument System Rejects Test Order Initiated from Host Query
ORU_R30	Instrument System Uploads Results
QBP^Z03^QBP_Z03	Instrument System Sends Host Query for Specific Specimen(s)
SSU^U03^SSU_U03	Instrument Returns Specimen ID for a Downloaded Order
ORF^R04^ORF_R04	Instrument System Returns Results Initiated by Result Request
	Instrument System Returns Results Responding to Request for an Unidentified Patient or Specimen
ACK^022	Instrument System Rejects Unsolicited Test Orders with a High-Level Acknowledgment – Option I
ORL^022^ORL_022	Instrument System Rejects Unsolicited Test Orders with Application Acknowledgment – Option II
ACK	Upload ACK of a Non-Expected Message

Accept Acknowledgment

Accept Acknowledgment MSH.15	Description	HL7 Message Description
NE	Never	Instrument System Returns Results Initiated by Result Request (ORF^R04)
		Instrument System Returns Results Responding to Request for an Unidentified Patient or Specimen (ORF^R04)
		Instrument System Rejects Unsolicited Test Orders with a High-Level Acknowledgment – Option I
		Instrument System Rejects Unsolicited Test Orders with an Application Acknowledgment – Option II
		Upload ACK of a Non-Expected Message
AL	Always	Instrument System Cancels Query for All Test Orders (QCN^J01 / ACK^J01)
		Instrument System Rejects Test Order Initiated from Query for All (ORU^R01 – ACK^R01)
		Instrument System Responds with Instrument Specimen ID for a Downloaded Order (SSU^U03/ ACK^U03)
		Instrument System Uploads Results (ORU^R01 – ACK^R01)

Application Acknowledgment

Application Acknowledgment MSH.16	Description	HL7 Message Description
NE	Never	Instrument System Returns Results Initiated by Result Request (ORF^R04)
		Instrument System Returns Results Responding to Request for an Unidentified Patient or Specimen (ORF^R04)
		Instrument System Rejects Unsolicited Test Orders with a High-Level Acknowledgment – Option I
		Instrument System Cancels Query for All Test Orders (QCN^J01 / ACK^J01)
		Instrument System Rejects Test Order Initiated from Query for All (ORU^R01 – ACK^R01)
		Instrument System Responds with Instrument Specimen ID for a Downloaded Order (SSU^U03/ ACK^U03)
		Instrument System Uploads Results (ORU^R01 – ACK^R01)
		Upload ACK of a Non-Expected Message
AL	Always	Instrument System Rejects Unsolicited Test Orders with an Application Acknowledgment – Option II

9.4.1.2 ACK – Message Acknowledgment (MSA) - (Upload Message)

The MSA segment contains information sent while acknowledging another message.

Message*

MSA|Acknowledgment Code|Message Control ID

* **Bold Red** fields are required for the overall record.

Definition

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
0	Segment Name		1	MSG	3	R	N	MSA
1	Acknowledgment Code	Acknowledgment Code	1	ST	2	R	N	Refer to table mapping below for a list of allowed values per type of message
2	Message Control ID	From MSH-10 of associated message	1	ST	32	R	N	

Acknowledgment Code

Acknowledgment Code MSA.1.1	HL7 Message Description
CA	Instrument System Rejects Unsolicited Test Orders with a High-Level Acknowledgment – Option I
AA	Instrument System Returns Results Initiated by Result Request (ORF^R04)
AR	Instrument System Rejects Unsolicited Test Orders (ORL^O22) with an Application Acknowledgment – Option II
CR	Upload ACK of a Non-Expected Message

9.4.1.3 Error Segment (ERR) - (Upload Message)

The ERR segment is used to add error information to the acknowledgment messages. This segment is sent only when the accompanying MSA segment, MSA-1 acknowledgment code is ‘AR or ‘AE’.

Message*

```
ERR|||Error Code^Error description|Severity
```

* **Bold Red** fields are required for the overall record.

Definition

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
0	Segment Name		1	MSG	3	R	N	ERR
3	HL7 Error Code	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		1	ST	1	R	N	‘E’ (Error)

9.4.1.4 Query Parameter Definition (QPD) - (Upload Message)

This segment provides the specimen information for the query.

Message*

Instrument System Queries for All Test Orders (QBP^Z01)

```
QPD|User defined trigger^Message Query Name|Query Tag|User Parameter
1
```

OR

Instrument System Sends Host Query For Specific Specimen (QBP^Z03)

```
QPD|User defined trigger^Message Query Name|Query Tag|User Parameter
1|User Parameter 2|User Parameter 3|
```

* **Bold Red** fields are required for the overall record.

Definition

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
0	Segment Name		1	MSG	3	R	N	QPD
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	Refer to table mapping below for a list of allowed values per type of message
			2	ST	100	R	N	
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 acknowledgment 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 segments must be retrieved	1	ST	32	R	N	'ALL'

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
4	User Parameter 2	Specimen ID	1	ST	25	R*	N	
5	User Parameter 3	Practice Assigned Patient ID-Patient ID 2	1	ST	32	O*	N	

Message Query Name

Message Query Name QPD.1	HL7 Message Description
Z03^HOST QUERY	Instrument System Sends Host Query for Specific Specimen (QBP^Z03)
Z01^REQUEST TEST ORDERS	Instrument System Queries for All Test Orders (QBP^Z01)

9.4.1.5 Response Control Parameter (RCP) - (Upload Message)

This segment provides additional information about the expected query response.

Message*

```
RCP|Query Priority
```

* **Bold Red** fields are required for the overall record.

Definition

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
0	Segment Name		1	MSG	3	R	N	
1	Query Priority		1	ID	1	R	N	D: Deferred I: Immediate

9.4.1.6 Query Identification Segment (QID) - (Upload Message)

The QID segment contains the information necessary to uniquely identify a query. Its primary use is in query cancellation or subscription cancellation.

Message*

```
QID|Query Tag|Query Name
```

* **Bold Red** fields are required for the overall record.

Definition

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
0	Segment Name		1	MSG	3	R	N	QID
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	“N/D”

9.4.1.7 Patient Identification Segment (PID) - (Upload Message)

The PID segment is used by all applications as primary means of communicating patient identification information. This segment contains permanent patient identifying and demographic information that, for the most part, is not likely to change frequently.

Message*

```
PID|Sequence Number|Patient ID 2|Patient ID 1||Family Name^ Given
Name^ Second Given Name^Suffix^Prefix
```

* **Bold Red** fields are required for the overall record.

Definition

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
0	Segment Name		1	MSG	3	R	N	PID
1	Sequence Number	Defines the i’th occurrence of the associated segment type	1	SI	4	R	N	1,2,3 … n
2	Patient ID 2	Patient identification	1	ST	32	O	N	

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
3	Patient ID 1	Patient identification	1	ST	32	O	N	
5	Family Name	Patient last name	1	ST	194	O	N	
	Given Name	Patient first name	2	ST	30	O	N	
	Second Given Name	Middle name or initial	3	ST	30	O	N	
	Suffix	e.g. JR or III	4	ST	20	O	N	
	Prefix	e.g. DR	5	ST	20	O	N	

9.4.1.8 Order Common Segment (ORC) - (Upload Message)

The Common Order segment (ORC) is used to transmit elements that are common to all of the tests ordered.

Message*

```
ORC|Order Control|Order Number|||||||Date/Time of the order
```

* **Bold Red** fields are required for the overall record.

Definition

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
0	Segment Name		1	MSG	3	R	N	ORC
1	Order Control		1	ID	2	R	N	'OC': order canceled
2	Order Number		1	SI	4	R	N	1,2, 3...n
9	Date / Time of the order		1	TS	14	R	N	Date time of the order

Order Control

Order Control ORC.1	Description	HL7 Message Description
OC	Order Canceled	Instrument System Uploads Results (ORU^R01 – ACK^R01)
RE	Observations	Instrument System Uploads Results (ORU^R01 – ACK^R01)

9.4.1.9 Observation Request Segment (OBR) - (Upload Message)

This segment is used to transmit information specific to an order for a diagnostic study or observation. The primary use of this segment is to identify the test/analysis to be run by GX instrument system on the specimen.

Message*

```
OBR|Sequence Number|||Universal Test ID||||||||||||||||||||Order
Status
```

* Bold Red fields are required for the overall record.

Definition

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
0	Segment Name		1	MSG	3	R	N	OBR
1	Sequence Number	Defines the i'th occurrence of the associated segment type	1	SI	4	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		1	ID	1	R	N	Refer to table mapping below for a list of allowed values per type of message

Order Status

Order Status OBR.25.1	Description	HL7 Message Description
X	Order cannot be done, canceled	Instrument System Uploads Results (ORU^R01 – ACK^R01)
		Instrument System Returns Results Initiated by Result Request (ORF^R04)
F	Final results	Instrument System Uploads Results (ORU^R01 – ACK^R01)
		Instrument System Returns Results Initiated by Result Request (ORF^R04)
I	Test is Pending	Instrument System Uploads Results (ORU^R01 – ACK^R01)
		Instrument System Returns Results Initiated by Result Request (ORF^R04)
A	Some but not all results available	Instrument System Returns Results Initiated by Result Request (ORF^R04)
Y	Invalid Test ID	Instrument System Returns Results Responding to Request for an Unidentified Patient or Specimen (ORF^R04)
Z	Invalid Patient ID	
V	Invalid Specimen ID or Instrument Specimen ID	
E	The query has a bad format	

9.4.1.10 Comments (Notes) Segment (NTE) - (Upload Message)

The NTE segment is used for sending notes and comments.

Message*

NTE|Sequence Number|Source of Comment|Comment ID^Comment code^Comment description^Comment details^Comment timestamp

* **Bold Red** fields are required for the overall record.

Definition

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
0	Segment Name		1	MSG	3	R	N	NTE
1	Sequence Number	Defines the i'th occurrence of the associated segment type	1	SI	4	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"
		Comment code	2	ST	50	R	N	
		Comment description	3	ST	500	O	Y	Note text
		Comment details	4	ST	500	O	N	
		Comment timestamp	5	TS	14	O	N	

9.4.1.11 Comments (Error) Segment (NTE) - (Upload Message)

The NTE segment is used for sending notes and comments.

Message*

NTE|Sequence Number|Source of Comment|Comment ID^Comment code^Comment description

* **Bold Red** fields are required for the overall record.

Definition

Field No.	Field Name	Description	Component	Data Type	Max. Length	Req	Allow Repeat	Allowed values
0	Segment Name		1	MSG	3	R	N	NTE
1	Sequence Number	Defines the i'th occurrence of the associated segment type	1	SI	4	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	'InvalidSpecimenData'/ 'DuplicatedTest'/ 'InvalidTestData'/ 'InvalidPatientData'/ 'InvalidTransmissionInformation'
		Comment description	3	ST	500	O	N	'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'

9.4.1.12 Timing/Quantity (TQ1) - (Upload Message)

This segment is used to provide the priority of the service request.

Message*

Instrument System Rejects Test Order Initiated From Query For All Tests

Instrument System Rejects Test Order Initiated From Query For Specific Specimen

Instrument System Uploads Results (ORU^R01 – ACK^R01)

TQ1|||||||||Priority

OR

Instrument System Returns Results Initiated by Result Request (ORF^R04)

TQ1|||||||Start Date/Time|End Date/Time|Priority

* **Bold Red** fields are required for the overall record.

Definition

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
0	Segment Name		1	MSG	3	R	N	
7	Start Date/ Time	Date and time the system started the test	1	TS		O*	N	
8	End Date/ Time	Date and time the system completed the test	1	TS	14	O*	N	
9	Priority	Describes the urgency of the request	1	ID	1	R	N	S: Stat R: Normal

9.4.1.13 Specimen Segment (SPM) - (Upload Message)

The SPM segment is used to describe the characteristics of a single specimen. The SPM segment relays information about the type of specimen and the date/time the specimen was received. It differs from the intent of the OBR segment in that the OBR addresses order-specific information.

Message*

```
SPM|Sequence Number|Specimen ID^Instrument Specimen ID||Specimen
Type|||||||Specimen Role
```

* Bold Red fields are required for the overall record.

Definition

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
0	Segment Name		1	MSG	3	R	N	SPM
1	Sequence Number		1	SI	4	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		1	ID	5	R	N	'ORH' (Other) ('Other' according to POCT1-A standard)
11	Specimen Role		1	ID	1	R	N	Q: Quality Control
								P: Sample Patient

9.4.1.14 Equipment Detail Segment (EQU) - (Upload Message)

The equipment detail segment contains the data necessary to identify and maintain the equipment that is being used throughout the Laboratory Automation System.

Message*

EQU|Equipment Instance Identifier|Event Date/Time

* **Bold Red** fields are required for the overall record.

Definition

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
0	Segment Name		1	MSG	3	R	N	EQU
1	Equipment Instance Identifier		1	ST	50	R	N	N/D (Not defined)
2	Event Date/ Time		1	TS	14	R	N	Current datetime.

9.4.1.15 Observation Result Segment (OBX) - (Upload Message)

The OBX segment is used to transmit a single observation or observation fragment.

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 segment if the remainder of the result segment has the same information.

Message*

OBX|Sequence Number|Value Type|System defined Test Panel ID^**System defined Test ID**^System defined Test name^System defined Test version|Analyte Name^Complementary Result Name|Observed, calculated or implied result value (Qualitative)^Observed, calculated or implied result value (Quantitative)|Units|Reference Ranges|Abnormal Flags|||Result Status|||||Responsible Observer||Equipment Instance

* **Bold Red** fields are required for the overall record.

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

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

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

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

~~[CartridgeSerialNumber]~[ModuleSerialNumber]~[InstrumentSerialNumber]~
[ComputerSystemName]

Definition

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
0	Segment Name		1	MSG	3	R	N	OBX
1	Sequence Number	Defines the i'th occurrence of the associated segment type	1	SI	4	R	N	1,2, 3...n
2	Value Type	'ST' for String 'NM' for Numeric	1	ID	2	R	N	'ST'

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
3	Observation Identifier	System defined Test Panel ID	1	ST	32	O	N	Empty for a single result test. Assay panel ID for a multi-result test
		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 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 / Organism name	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/LOG' Empty for main result or analyte 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	20	O	N	Numeric value
6	Units		1	ST	20	O	N	* Refer to table mapping below for a list of allowed values per type of message.
7	Reference Ranges	When available reports the reference ranges	1	ST	60	O	N	Format: Lower limit - upper limit; example: “3.5 - 4.5” If no lower limit: “< 4.5” If no upper limit: “> 3.5” Only present if the result is the main one and there is a quantitative result.
8	Abnormal Flags	This field shall indicate the normalcy status of the result.	1	IS	2	O	N	* Refer to table mapping below for a list of allowed values per type of message.
11	Result Status		1	ID	1	O*	N	* Refer to table mapping below for a list of allowed values per type of message.
16	Responsible Observer	Family Name	2	ST	32	O*	N	Full Name. The rest of the components are ignored.

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
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 at start of this section.

*: 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

Test Units R.5.1:

Test Units R.5.1
Copies/mL
IU/mL
Copies
%
% (IS)
IU

Result Flag OBX.8.1

Result Flag OBX.8.1	Description
<	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

Result Status OBX.11.1	Description	Message Types
F	Final Result	Instrument System Uploads Results (ORU^R01 – ACK^R01)
		Instrument System Returns Results Initiated by Result Request (ORF^R04)
X	Result cannot be done	Instrument System Uploads Results (ORU^R01 – ACK^R01)
		Instrument System Returns Results Initiated by Result Request ORF^R04)
C	Correction of previous result	Instrument System Uploads Results (ORU^R01 – ACK^R01)
		Instrument System Returns Results Initiated by Result Request ORF^R04)

9.4.1.16 Query Definition Segment (QRD) - (Upload Message)

The QRD segment is used to define a query.

Message

QRD|**Query Date/Time**|**Query Format Code**|**Query Priority**|**Query ID**|||**Quantity Limited Request**|**Who Subject Filter**|**What Subject Filter**|**What Department Data Code**|Patient Identification- Patient ID 1^**Specimen identification**^Instrument Specimen ID^Test Id^Practice Patient ID - Patient ID 2

* **Bold Red** fields are required for the overall record.

Definition

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
0	Segment Name		1	MSG	3	R	N	QRD
1	Query Date/ Time	Contains the date the query was generated by the application program	1	TS	14	R	N	
2	Query Format Code	D/R/T	1	ID	1	R	N	'R'- Response is in segment-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

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
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-Patient ID 1	1	ST	32	O	N	
		Specimen identification	2	ST	25	R	N	
		Instrument Specimen ID	3	ST	32	O	N	This field is required if the “Use Instrument Specimen ID” option is enabled. This field will be ignored if the “Use Instrument Specimen ID” is disabled.
		Test Id	4	ST	15	O	N	
		Practice Patient ID - Patient ID 2	5	ST	32	O	N	

9.4.1.17 Specimen Container Detail Segment (SAC) - (Upload Message)

[Dummy segment, for HL7 compliance]

Message

```
SAC|External accession
```

Definition

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
0	Segment Name		1	MSG	3	R	N	SAC
1	External accession	This field identifies the laboratory accession	1	String	50	O	N	Not used

9.4.1.18 Inventory Detail Segment (INV) - (Upload Message)

[Dummy segment, for HL7 compliance; only supported by DX5.1 QC results]

Message

```
INV||||
```

Definition

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
0	Segment Name		1	MSG	3	R	N	INV

9.4.2 Download Message Mapping Format

The following download messages share the message mapping for each segment supported.

- Host Responds with No Available Test Order for Query for All (RSP^Z02)
- Host Responds with Test Orders for Query for All (RSP^Z02)
- Host Responds with Test Orders for Query for Specific Specimen (RSP^Z02)
- Host Responds with No Available Test Order for Query for Specific Specimen (RSP^Z02)
- Host Requests Test Result (QRY^R02)
- Host Downloads Unsolicited Test Orders (OML^O21-ORL^O22)
- Host Rejects Uploaded Test Result (no message is sent from LIS)
- LIS Host Acknowledgment(s)

9.4.2.1 Message Segment Header (MSH) - (Download Message)

The MSH segment defines the intent, source, destination, and some specifics of the syntax of the message.

Message*

MSH|Field SeparEncoding Characters| Receiver ID||System ID^System Name^Software Version ||Date and time of Message||Message Code^Trigger Event^Message Structure|Message ID|Processing ID|Version Number|||Accept Acknowledgment|Application Acknowledgment

* **Bold Red** fields are required for the overall record.

Definition

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
0	Segment Name		1	MSG	3	R	N	MSH
1	Field Separator		1	ST	1	R	N	'|'
2	Encoding Characters		1	ST	4	R	N	See Section 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

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
5	Receiver ID	System ID	1	HD	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	14	R	N	If empty, the current date and time is assumed
9	Message Type	Message Code	1	ID	3	R	N	Refer to table mapping below for a list of allowed values per type of message
		Trigger Event	2	ID	3	R	N	
		Message Structure	3	ID	3	R	N	
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 Acknowledgment		1	ID	2	O	N	Refer to table mapping below for a list of allowed values per type of message
16	Application Acknowledgment		1	ID	2	O	N	Refer to table mapping below for a list of allowed values per type of message

Message Type

Message Type MSH.9	HL7 Message Description
ACK^R01	LIS Host Acknowledgment
RSP^Z02	Host Responds with Test Orders for Query for All (RSP^Z02)
	Host Responds with No Available Test Order for Query for All (RSP^Z02)
	Host Responds to Query with Test Orders (RSP^Z02)
	Host Responds with No Available Test Order for Query for Specific Specimen (RSP^Z02)
QRY^R02^QRY_R02	Host Requests Test Result (QRY^R02)
OML^021^OML_021	Host Downloads Unsolicited Test Orders (OML^O21-ORL^O22)

Accept Acknowledgment

Accept Acknowledgment MSH.15	Description	HL7 Message Description
NE	Never	LIS Host Acknowledgment
		Host Responds with No Available Test Order for Query for Specific Specimen (RSP^Z02)
		Host Downloads Unsolicited Test Orders (OML^O21-ORL^O22) – Option II
		Host Responds with No Available Test Order for Query for All (RSP^Z02)
		Upload ACK of a Non-Expected Message
AL	Always	Host Downloads Unsolicited Test Orders (OML^O21-ORL^O22) – Option I

Application Acknowledgment

Application Acknowledgment MSH.16	Description	HL7 Message Description
NE	Never	LIS Host Acknowledgment
		Upload ACK of a Non-Expected Message
		Host Responds with No Available Test Order for Query for Specific Specimen (RSP^Z02)
		Host Downloads Unsolicited Test Orders (OML^O21-ORL^O22) – Option I
		Host Responds with No Available Test Order for Query for All (RSP^Z02)
AL	Always	Host Downloads Unsolicited Test Orders (OML^O21-ORL^O22) – Option II

9.4.2.2 ACK – Message Acknowledgment (MSA) - (Download Message)

The MSA segment contains information sent while acknowledging another message.

Message*

`MSA|Acknowledgment Code|Message Control ID`

* `Bold Red` fields are required for the overall record.

Definition

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
0	Segment Name		1	MSG	3	R	N	MSA
1	Acknowledgment Code	Acknowledgment Code	1	ID	2	R	N	Refer to table mapping below for a list of allowed values per type of message
2	Message Control ID	From MSH-10 of associated message	1	ST	32	R	N	

Acknowledgment Code

Acknowledgment Code MSA.1.1	HL7 Message Description
CA	LIS Host Acknowledgment(s) (ACK^J01, ACK^R01, ACK^U03)
	LIS Host Acknowledgment (ORL^022 Option I)
AA	Host Responds with Test Orders for Query for All (QCN^J01 / ACK^J01)
	Host Responds with No Available Test Order for Query for All (RSP^Z02)
CR	Upload ACK of a Non-Expected Message
AR	LIS Host Acknowledgment (ORL^022 Option II)

9.4.2.3 Query Acknowledgment (QAK) - (Download Message)

This segment contains information about the query response.

Message*

`QAK|Query Tag|Query Response Status|Message Query Name`

* `Bold Red` fields are required for the overall record.

Definition

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
0	Segment Name		1	MSG	3	R	N	QAK
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 acknowledgment 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)

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
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	Refer to table mapping below for a list of allowed values per type of message
			2	ST	100	R	N	Refer to table mapping below for a list of allowed values per type of message

Message Query Name

Message Query Name QAK.3	HL7 Message Description
Z01^REQUEST TEST ORDERS	Host Responds with No Available Test Order for Query for Specific Specimen (RSP^Z02)
Z03^HOST QUERY	Host Responds with No Available Test Order for Query for All (RSP^Z02)

9.4.2.4 Query Parameter Definition (QPD) - (Download Message)

This segment provides the specimen information for the query.

Message*

```
QPD|User defined trigger^Message Query Name|Query Tag|User Parameter
1
```

* **Bold Red** fields are required for the overall record.

Definition

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
0	Segment Name		1	MSG	3	R	N	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	Refer to table mapping below for a list of allowed values per type of message
			2	ST	100	R	N	Refer to table mapping below for a list of allowed values per type of message
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 acknowledgment 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 segments must be retrieved	1	ST	32	R	N	'ALL'

Message Query Name

Message Query Name QPD.1	HL7 Message Description
Z03^HOST QUERY	Host Responds with No Available Test Order for Query for Specific Specimen (RSP^Z02)
	Host Responds with No Available Test Order for Query for All (RSP^Z02)

9.4.2.5 Query Definition Segment (QRD) - (Download Message)

The QRD segment is used to define a query.

Message*

QRD|**Query Date/Time**|**Query Format Code**|**Query Priority**|**Query ID**||||**Quantity Limited Request**|**Who Subject Filter**|**What Subject Filter**|**What Department Data Code**|Patient Identification- Patient ID 1^**Specimen identification**^Instrument Specimen ID^Test Id^Practice Patient ID - Patient ID 2

* **Bold Red** fields are required for the overall record.

Definition

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
0	Segment Name		1	MSG	3	R	N	QRD
1	Query Date/ Time	Contains the date the query was generated by the application program.	1	TS	14	R	N	
2	Query Format Code	D/R/T	1	ID	1	R	N	'R'- Response is in segment-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

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
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'
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

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
11	What Data Code Value Qual.	Patient Identification-Patient ID 1	1	ST	32	O	Y	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
		Instrument Specimen ID	3	ST	32	O	Y	This field is required if the “Use Instrument Specimen ID” option is enabled. This field will be ignored if the “Use Instrument Specimen ID” is disabled.
		Test Id	4	ST	15	O	Y	
		Practice Patient ID - Patient ID 2	5	ST	32	O	Y	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.

9.4.2.6 Patient Identification Segment (PID) - (Download Message)

The PID segment is used by all applications as primary means of communicating patient identification information. This segment contains permanent patient identifying and demographic information that, for the most part, is not likely to change frequently.

Message*

```
PID|Sequence Number|Patient ID 2|Patient ID 1||Family Name^ Given
Name^ Second Given Name^Suffix^Prefix
```

* **Bold Red** fields are required for the overall record.

Definition

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
0	Segment Name		1	MSG	3	R	N	PID
1	Sequence Number	Defines the i'th occurrence of the associated segment type	1	SI	4	R	N	1,2,3 … n
2	Patient ID 2	Patient identification	1	ST	32	O	N	
3	Patient ID 1	Patient identification	1	ST	32	O	N	
5	Family Name	Patient last name	1	ST	194	O	N	
	Given Name	Patient first name	2	ST	30	O	N	
	Second Given Name	Middle name or initial	3	ST	30	O	N	
	Suffix	e.g. JR or III	4	ST	20	O	N	
	Prefix	e.g. DR	5	ST	20	O	N	

9.4.2.7 Common Order Segment (ORC) - (Download Message)

The Common Order segment (ORC) is used to transmit elements that are common to all of the tests ordered.

Message*

ORC|**Order Control**|**Order Number**|||||||Date/Time of the order

* **Bold Red** fields are required for the overall record.

Definition

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
0	Segment Name		1	MSG	3	R	N	ORC
1	Order Control		1	ID	2	R	N	* Refer to table mapping below for a list of allowed values per type of message
2	Order Number		1	SI	4	R	N	1,2, 3...n
9	Date / Time of the order		1	TS		O	N	If empty, current date and time is used

Order Control

Order Control ORC.1	Description	HL7 Message Description
NW	New Order	Host Requests Test Result (QRY^R02)
		Host Downloads Unsolicited Test Orders (OML^O21-ORL^O22)
RE	Observations	
OC	Order Canceled	Host Requests Test Result (QRY^R02)
		Host Downloads Unsolicited Test Orders (OML^O21-ORL^O22)

9.4.2.8 Observation Request Segment (OBR) - (Download Message)

This segment is used to transmit information specific to an order for a diagnostic study or observation. The primary use of this segment is to identify the test/analysis to be run by GX instrument system on the specimen.

Message*

Host Downloads Unsolicited Test Orders (OML^O21-ORL^O22)

OBR|Sequence Number|||Universal Test ID||||||||||||||||||||Order Status

OR

Host Responds with Test Orders for Query (RSP^Z02)

OBR|Sequence Number|||Universal Test ID||||||||||||||||||||Order Status

* **Bold Red** fields are required for the overall record.

Definition

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
0	Segment Name		1	MSG	3	R	N	OBR
1	Sequence Number	Defines the i'th occurrence of the associated segment type	1	SI	4	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		1	ID	1	R	N	'A' (Added in previous specimen or creates a new specimen following the rules of the sample life cycle)
25	Order Status		1	ID	1	R*	N	Refer to table mapping in Section 9.4.1.9, Observation Request Segment (OBR) - (Upload Message) for a list of allowed values per type of message

Specimen Action Code

Specimen Action Code OBR.11	Description	HL7 Message Description
A	Some but not all results available	Host Requests Test Result (QRY^R02)
	Added in previous specimen or creates a new specimen following the rules of the sample life cycle	Host Downloads Unsolicited Test Orders (OML^O21-ORL^O22)
		Host Responds with Test Orders for Query (RSP^Z02)
I	No results available	Host Requests Test Result (QRY^R02)
X	Result cannot be done, canceled	Host Requests Test Result (QRY^R02)
F	Final results	Host Requests Test Result (QRY^R02)

9.4.2.9 Timing/Quantity (TQ1) - (Download Message)

This segment is used to provide the priority of the service request.

Message*

Host Responds with Test Orders for Query (RSP^Z02)

Host Downloads Unsolicited Test Orders (OML^O21-ORL^O22)

```
TQ1|||||||Start Date/ Time|End Date/ Time|Priority
```

OR

```
TQ1|||||||Start Date/ Time|End Date/ Time|Priority
```

* **Bold Red** fields are required for the overall record.

Definition

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
0	Segment Name		1	MSG	3	R	N	TQ1
7	Start Date/ Time	Date and time the system started the test	1	TS	14	R*	N	
8	End Date/ Time	Date and time the system completed the test	1	TS	14	R*	N	
9	Priority	Describes the urgency of the request	1	ID	1	R	N	S: Stat R: Normal

9.4.2.10 Specimen Segment (SPM) - (Download Message)

The SPM segment is used to describe the characteristics of a single specimen. The SPM segment relays information about the type of specimen and the date/time the specimen was received. It differs from the intent of the OBR segment in that the OBR addresses order-specific information.

Message*

SPM|**Sequence Number**|**Specimen ID**^Instrument Specimen ID||**Specimen Type**||||||**Specimen Role**

* **Bold Red** fields are required for the overall record.

Definition

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
0	Segment Name		1	MSG	3	R	N	SPM 0
1	Sequence Number		1	SI	4	R	N	1,2, 3...n 1
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		1	ID	5	R	N	'ORH' (Other) ('Other' according to POCT1-A standard)
11	Specimen Role		1	ID	1	R	N	Q: Quality control P: Sample Patient

9.4.2.11 Observation Result Segment (OBX) - (Download Message)

The OBX segment is used to transmit a single observation or observation fragment.

Message*

OBX|**Sequence Number**|**Value Type**|System defined Test Panel ID^**System defined Test ID**^System defined Test name^System defined Test version|Analyte Name^Complementary Result Name|Observed, calculated or implied result value (Qualitative)^Observed, calculated or implied result value (Quantitative)|Units|Reference Ranges|Abnormal Flags|||Result Status|||||Responsible Observer||Equipment Instance

* **Bold Red** fields are required for the overall record.

Definition

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
0	Segment Name		1	MSG	3	R	N	OBX
1	Sequence Number	Defines the i'th occurrence of the associated segment type	1	SI	4	R	N	1,2, 3...n
2	Value Type	'ST' for String 'NM' for Numeric	1	ID	2	R	N	'ST', 'NM'
3	Observation Identifier	System defined Test Panel ID	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

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
4	Observation Sub-ID	Analyte Name / Organism name	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/ LOG'.
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	20	O	N	Numeric value
6	Units		1	ST	20	O	N	Refer to table mapping below for a list of allowed values per type of message.
7	Reference Ranges	When available reports the reference ranges	1	ST	60	O	N	Format: Lower limit - upper limit; example: "3.5 - 4.5" If no lower limit: "< 4.5" If no upper limit: "> 3.5" Only present if the result is the main one and there is a quantitative result.
8	Abnormal Flags	This field shall indicate the normalcy status of the result.	1	IS	2	O	N	Refer to table mapping below for a list of allowed values per type of message.
11	Result Status		1	ID	1	O*	N	Refer to table mapping below for a list of allowed values per type of message.

Field No.	Field Name	Description	Component	Data Type	Max Length	Req	Allow Repeat	Allowed Values
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 in Section 9.3.4.1.

Test Units

Test Units OBX.6.1
Copies/mL
IU/mL
Copies
%
% (IS)
IU

Result Flag

Result Flag OBX.8.1	Description
<	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

10 Troubleshooting the LIS Interface

This chapter describes common LIS problems and how to troubleshoot them.

10.1 System Configuration Problems

Table 10-1 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*, the *GeneXpert Xpress System User's Guide,* the *GeneXpert Infinity System Operator Manual* or the *GeneXpert Omni System Operator Manual* for the contact information.

Table 10-1. 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.

10.2 Order Management Problems

Table 10-2 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*, the *GeneXpert Xpress System User's Guide* or the *GeneXpert Infinity System Operator Manual* for the contact information.

Table 10-2. Order Management Problems

Problem	Cause	Solution
Multiple system receives same test order - both assign ISID.	Test order sent to multiple GX systems in parallel.	Operator to cancel test order. LIS Admin to switch to Host Query configuration instead of Query All. Prevent the LIS from downloading to multiple systems.

Table 10-2. Order Management Problems (Continued)

Problem	Cause	Solution
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 entering 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).

10.3 Result Management Problems

Table 10-3 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*, the *GeneXpert Xpress System User's Guide,* the *GeneXpert Infinity System Operator Manual* or the *GeneXpert Omni System Operator Manual* for the contact information.

Table 10-3. 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 uploads 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.

A List of Supported Assay Host Panel Names

ASSAY HOST PANEL NAME	RESULT NAME(S)	RESULT TEST CODE(S)	SAMPLE TYPE	LOINC
Xpert Carba-R Assay- Report Carba-R targets				
CARBA	IMP	IMP		
	KPC	KPC		
	NDM	NDM		
	OXA48	OXA48		
	VIM	VIM		
Xpert C.diff Epi Assay- Report C.diff Toxin and 027				
CDIFFEPI	027	027		
	Toxigenic C. diff	TOX		
Xpert C.difficile Assay- Report C.diff Toxin				
CDIFF	CDIFF	CDIFF		
Xpert CTNG Assay- Report CTNG Combo				
CTNG	CT	CT		
	NG	NG		
Xpert CTNG Assay- Report CT Only				
CT	CT	CT		
Xpert CTNG Assay- Report NG Only				
NG	NG	NG		
Xpert Entrovirus Assay- Report Entrovirus				
EV	EV	EV		
Xpert FluA Assay-Reports Flu A/B and 2009 H1N1				
FLUABH1N1	2009H1N1	H1N1		
	Flu A	FLUA		
	Flu B	FLUB		
Xpert FLU/RSV Assay- Report FLU Only				
FLUAB	Flu A	FLUA		
	Flu B	FLUB		
	QC Check	QC		
	RSV	NULL		

ASSAY HOST PANEL NAME	RESULT NAME(S)	RESULT TEST CODE(S)	SAMPLE TYPE	LOINC
Xpert FLU/RSV Assay- Report FLU/RSV Combo				
FLUABRSV	Flu A	FLUA		
	Flu B	FLUB		
	QC Check	QC		
	RSV	RSV		
Xpert FLU/RSV Assay- Report RSV Only				
FLURSV	Flu A	NULLA		
	Flu B	NULLB		
	QC Check	QC		
	RSV	RSV		
Xpert FII/FV Assay- Report FII/FV				
F2F5	FII	F2		
	FV	F5		
Xpert FII Assay- Report FII only				
F2	F2	F2		
Xpert FV Assay- Report FV only				
F5	F5	F5		
Xpert GBS Assay- Report GBS				
GBS	GBS	GBS		
Xpert GBS LB Assay- Report GBS LB				
GBSLB	GBSLB	GBSLB		
Xpert MRSA NxG				
MRSANXG	MRSANXG	MRSANXG		
Xpert MRSA				
MRSA	MRSA	MRSA		
Xpert MRSA Blood Culture Assay- Report MRSA or SA				
MRSASABC	MRSA	MRSA		
	SA	SA		
Xpert MRSA Skin and Soft Tissue Assay- Report MRSA or SA				
MRSASASSTI	MRSA	MRSA		
	SA	SA		
Xpert SA Complete-Report MRSA or SA				
MRSASANASAL	MRSA	MRSA		
	SA	SA		

ASSAY HOST PANEL NAME	RESULT NAME(S)	RESULT TEST CODE(S)	SAMPLE TYPE	LOINC
Xpert MTB/RIF Assay- Report MTB Complex and RIF Resistance				
MTBRIF	MTB	MTB		
	MTB Invalid	INV		
	QC Check	QC		
	Rif Resistance	RIF		
Xpert Norovirus Assay- Report Norovirus				
NORO	NORO GI	G1		
	NORO GII	G2		
	QC	QC		
Xpert Trichomonas Assay- Report Trichomonas				
TV	TV	TV		
Xpert Van A Assay- Report Van A				
VANA	VANA	VANA		
Xpert Xpress Step A Assay- Report Strep A				
STREPA	STREPA	STREPA		
Xpert Xpress SARS-CoV-2 Assay- Report SARS-CoV-2				
SARSCOV2	SARSCOV2	SARSCOV2	Nasopharyngeal (NP) swab Nasal wash / Aspirate	94500-6
Xpress Flu- Report FluA/B				
XFLUAB	Flu A	XFLUA		
	Flu B	XFLUB		
	QC Check	QC		
Xpress FLU/RSV Assay Combo				
XFLUABRSV	Flu A	XFLUA		
	Flu B	XFLUB		
	QC Check	QC		
	RSV	XRSV		
Xpress FLU/RSV Assay – Report FLU only				
XFLUAB	Flu A	XFLUA		
	Flu B	XFLUB		
	QC Check	QC		
	RSV	XNULL		
Xpress FLU/RSV Assay- Report RSV Only				

ASSAY HOST PANEL NAME	RESULT NAME(S)	RESULT TEST CODE(S)	SAMPLE TYPE	LOINC
XFLURSV	Flu A	XNULLA		
	Flu B	XNULLB		
	QC Check	QC		
	RSV	XRSV		