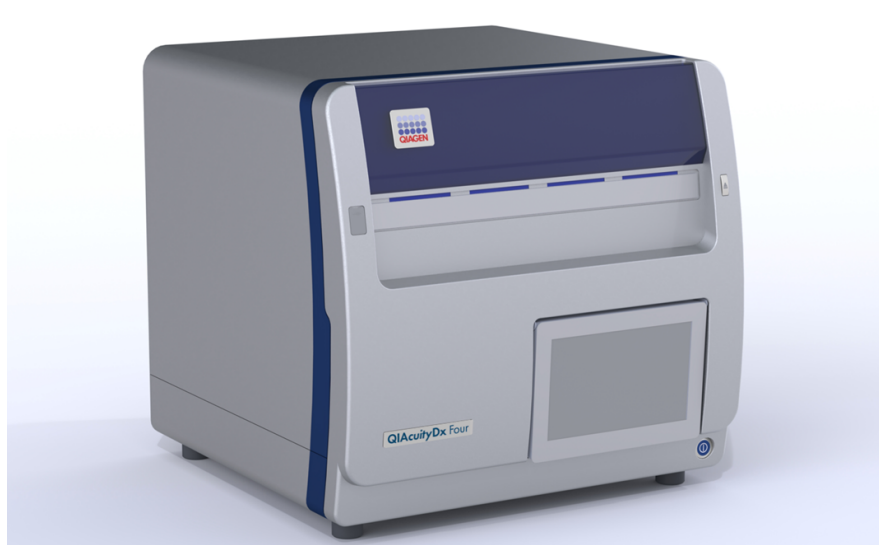


QIAcuityDx[®] LIMS Interface Protocols

For QIAcuityDx Software Suite, version 1.1.0 or later



IVD

For in vitro diagnostic use



REF

911060



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Purpose and Scope

Purpose

The purpose of this document is to specify the interface protocols of the QIAcuityDx System that exchange information between the instrument and an external computer system.

This external system, which plays the role of the Automation Manager, is typically a laboratory information management system (LIMS) or a Laboratory Data Manager computer system. In this document, the external system will be generically referred to as LIMS.

This document details all data exchanged between the QIAcuityDx System and the LIMS, guiding the implementation of the HL7 protocol mode supported by QIAcuityDx Four communications.

Scope

This document describes the LIMS interface specification for the QIAcuityDx Software Suite version 1.1.0.

References

External documents

1. HL7 Transport Specification: MLLP, release 1, based on: HL7 Implementation Guide for HL7, version 2.3.1, Appendix C “Lower Layer Protocols”, section C.4.3.
2. HL7, Health Level 7 Messaging Standard, version 2.5, approved June 26, 2003
3. Clinical and Laboratory Standards Institute (CLSI), Point-of-Care Connectivity; Approved Standard—Second Edition, CLSI document POCT1-A2.
4. IHE, Laboratory Technical Framework (LAB TF), vol. 1, 2a, 2b, 2x, revision 6.0
5. IHE IT Infrastructure Technical Framework, volume 2x, revision 12.0

Table 1 provides a list of acronyms and definitions used in this document.

Table 1. Definitions and acronyms

Word or acronym	Definition
ACK	Acknowledgment message
AR	Application reject, application error
Assay	As a standalone term, “assay” is a synonym to “test” or “application”, and contains the whole procedure to gain a defined diagnostic insight from a sample from a system's/customer's view. An assay plugin is the software component of each QIAGEN Assay, dedicated to QIAcuityDx instrument, assay metadata, and other non-functional elements.
CLSI	Clinical and Laboratory Standards Institute
HL7	Health Level 7
IHE	Healthcare Enterprise, non-profit organization, https://www.ihe.net/
LIMS application	Software-based system supporting a modern laboratory's operations concerning patient sample, test, and result handling with standardized interface to different platforms.
MSH	Message header
OBX	Observation result segment including the test result of a single pathogen
OUL	Unsolicited laboratory observation message
SPM	Specimen message
Standard PC	The PC on which the QIAcuityDx Software Suite runs
System, QIAcuityDx System	QIAcuityDx System, comprised of QIAcuityDx Software Suite, the Software Assay Plugins, and QIAcuityDx Four, which includes QIAcuityDx Control Software.
QAK	Query acknowledgement
QIAcuityDx Four	QIAcuityDx digital PCR instrument with four drawer positions to load up to four Nanoplates simultaneously.
QIAGEN LIMS Connector	Reusable software component developed by QIAGEN for providing communication capabilities with LIMS systems.
USI	Universal service identifier
User	A person who operates the QIAcuityDx System in the intended way
WOS	Work order step

Hardware Interface and Lower Layer Protocol

Physical layer

For better performance, it is recommended to connect the device where QIAcuityDx Software Suite is installed through a standard RJ45 10/100 ethernet port for networked computer communications.

Transport layer

The QIAcuityDx interface uses the TCP/IP standard.

Lower-layer transport protocol

The lower-layer protocol supported by the QIAcuityDx System at the session level is the Minimal Lower Layer Protocol (MLLP), V1 (1).

MLLP is a commonly used protocol and is based on a minimalistic layer framing. It is recommended by Integrating the Healthcare Enterprise (IHE) for the HL7 V2.x protocol messaging (3). MLLP adds header and trailer characters to the message to identify the beginning and end of the message, as TCP/IP is a continuous stream of bytes.

It is assumed that MLLP will be used only in a network environment and the details of error detection and correction are handled by the lower levels of the TCP/IP transport protocol and do not require supplementation.

Message content is enclosed by special single-byte characters to form a block. The framed MLLP block format is as follows:

<SB>data<EB><CR>

The items used in the lower-level frame are listed in Table 2.

Table 2. Lower-layer frame items

Item	Description	Content	Size (bytes)	Hexadecimal value
<SB>	Start block character	<VT> (ASCII vertical tab character)	1	<0x0B>
data	This is the message content of the block	UTF-8 character values	Variable number of bytes	Characters greater than <0x1F> and the carriage return character, <CR>
<EB>	End block character	<FS> (ASCII field separator character)	1	<0x1C>
<CR>	Carriage return	<CR> (ASCII carriage return character)	1	<0x0D>

The block data item may support all single-byte character encodings (e.g., iso-8859-x, cp1252) as well as some multiple-byte encodings (e.g., UTF-8 and Shift_JIS).

QIAcuityDx Software Suite interface supports UTF-8 encoding, which is a character encoding capable of encoding all possible characters, or code points, in Unicode.

HL7 Protocol

The QIAcuityDx Software Suite supports connectivity to a LIMS in a central-laboratory scenario through the HL7 protocol over TCP/IP.

The LIMS is responsible for translating a laboratory work order into a series of work order steps (WOSs) related to a specimen assigned to the QIAcuityDx System. By definition, a WOS is related to a single specimen.

The specimen is identified in the QIAcuityDx System by the LIMS with a unique identifier, which is usually printed on the barcode label stuck to the specimen container.

HL7 messaging

HL7 messages consist of a hierarchy of records, which are named segments of various types in HL7, and a message is the atomic unit of data transferred between systems. 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 refine the basic attribute.

For more information, please see vol. 2x, C.2: HL7 Implementation Notes (4).

Message elements

HL7 messages are broken down into a hierarchy of the following entities.

- **Message:** A message is the entire unit of data transferred between systems in a single transmission. It is a series of segments, the sequence of which is defined by the message specifications. For instance, the QIAcuityDx System uses observation results (OUL) messages to report results and ACK messages to provide acknowledgment of receipt or failure to the sender.
- **Segment:** A segment is a logical grouping of data fields. Segments within a defined message may be required or, optional, may occur only once or may be allowed to repeat. Each segment is named and contains a segment identifier, which is a unique three-character code.
- **Field:** A field is a string of characters and is of a specific data type. Each field is identified by the segment that contains it and its position within the segment (e.g., SPM-4 is the fourth field of the specimen segment). The maximum length of the field is stated as normative information. Exceeding the listed length should not be considered an error. A field is bounded by the field delimiter character.
- **Data types:** A data type restricts the contents and format of the data field. Data types are given a two- or three-letter code. Some data types are coded or composite types with several components. The applicable data type is listed and defined in each field definition.
- **Component:** A component is one of a logical grouping of items that comprise the contents of a coded or composite field. Within a field having several components, not all components are required to have a value.
- **Delimiter:** Delimiter characters are used to separate segments, fields, and components in an HL7 message. The delimiter values are given in MSH-2 and used throughout the message. Applications must use agreed upon delimiters to parse the message.

Message syntax

The abstract message is defined in special notation that lists the three-letter segment identifiers in the order they will appear in the message. Braces, { }, indicate that one or more of the enclosed group of segments may repeat, and brackets, [], indicate that the enclosed group of segments is optional.

The conventions in Table 3 are used to describe the syntax of the protocol.

Table 3. Protocol syntax conventions

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.

Message identification

Within HL7, the following two components identify a message:

- **Message type:** A message type is an identifier of the purpose of a message. Every message must contain a message type to declare the purpose of the message.
- **Triggering event:** The triggering event is the real-world circumstance causing the message to be sent. These events (represented by a three-letter code) represent values such as "A patient is admitted" or "An order event occurred". A message type may be associated with more than one trigger event, but the same trigger event code may not be associated with more than one message type.

Messaging length

There is no maximum record length. Outgoing messages can be of any size.

Segment specifications

The “HL7 Protocol” section of this document describes the definition of HL7 messages. The subsequent sections describe element details and contain tables listing the HL7 message elements communicated within the segment. These definition tables describe the data elements in the segments and characteristics of their use.

The information in Table 4 is specified for each data element that appears in the table format.

Table 4. Data element format

Column	Description
Seg	Indicates the segment code.
F.C	Element sequence number: the ordinal position of the data within the segment. Format: <Field #>[[.R<repeat #>].<Component #>][.<Subcomponent #>]] These elements are not always consecutive because the interface does not use or support all possible elements in the standard. However, following HL7 rules, the gaps do not diminish the number of separators within the segment.
Element name	HL7 name for the field. This is a globally unique descriptive name for the field.
Description	Field or component definition in the context of the specific service and the associated instrument or host.
LEN	Length of the element. This is the maximum number of characters that one occurrence of the data field may occupy.
DT	Data type. This is the HL7 data type of the element. These restrict the contents of the element as defined by the HL7 standard.
RQ	Optionality of the element: whether the element is required, optional, or conditional in a segment. The designations are as follows: R = required RE = required if available O = optional C = conditionally required. X = not supported or ignored in the current version, it may be used in the future
Allowed values	May include allowed or required values.
Comment, example	Comments about the element, including whether it may repeat, reference a table of values that may be defined by HL7 (TBL#), or negotiated between the instrument and the LIMS.

Field structure

A field can be seen as a specific attribute of a record that may contain aggregates of data elements further refining the basic attribute. There are two kinds of aggregates within a message:

- **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 the data elements that precede it.

Field length

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

Example: For a 10-character length field, only 10 characters can be used.

Character codes

All data are represented using UTF-8 encoding. UTF-8 is a multibyte character encoding for Unicode that can represent every character in the Unicode character set and is backward-compatible with the ASCII standard (ANSI X3.4-1986).

- Disallowed characters in the message: 0–8, 10–12, 14–31, 127, 255
- The ASCII standard character 13 is reserved as the record terminator

Data types

Data types specify the format and type of data used. A data type may be as simple as a numeric data type, which allows a number. It may be a more complex coded entry that requires a specific set of code values and the name of the code system. Data types may contain subcomponents that are further specified by additional data types (e.g., data type CE — “coded element” — may be composed of three different data types).

Delimiters

Types

Delimiters are used to establish separate sections within a message. There are five different delimiters.

- **Record delimiter** signals the end of the defined record types. This delimiter is always the carriage return character: Latin-1 (13) (ASCII 13).
- **Field delimiter** is used to separate adjacent fields. It is configurable and is specified in the message header record. The field delimiter must be a single character, excluding the record delimiter.
- **Repeat delimiter** 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. The repeat delimiter must be a single character, excluding the record and field delimiters.
- **Component delimiter** 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. The component delimiter must be a single character, excluding the record, field, and repeat delimiters.
- **Subcomponent delimiter** is used to separate adjacent subcomponents of data fields where allowed. If there are no subcomponents, this character may be omitted.
- **Escape delimiter** 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 generally uses a single character. The escape delimiter must be different from the record, field, repeat, and component delimiter.

Message transmission control

The HL7 protocol describes an exchange of messages in terms of two entities: the initiating and responding systems. Each is both a sender and a receiver of messages. The initiating system sends first and then receives, while the responding system receives and then sends.

Network guidelines

Following IHE recommendation, the QIAcuityDx Software Suite initiates a transaction (to send a message) by initiating a network connection. Thus, the QIAcuityDx System attempts to establish a socket connection as a client to support the WOS query and WOS status change transactions with the LIMS, and QIAcuityDx System expects to receive the response to the query or acknowledgement messages through this open connection. After this response, the initiating application initiates a new transaction on the same connection. This process is illustrated in Figure 1.

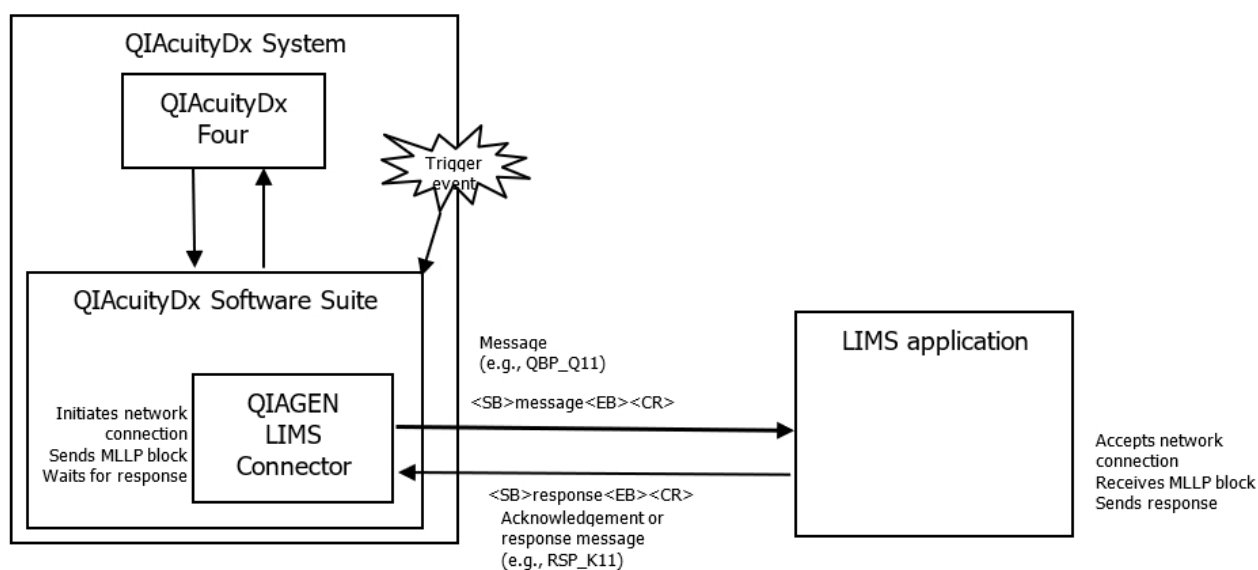


Figure 1. Trigger events and use of network connections.

From a transactional viewpoint, an MLLP network connection is unidirectional. Event-triggered messages flow in one direction, and acknowledgement messages related to those event-triggered messages flow in the other direction. Transactions between two applications that contain trigger events on both sides require at least two network connections between the initiating systems, one for each direction.

Message initiation

According to the HL7 standard, each message must begin with the message header (MSH) segment, as outlined in Table 5.

Table 5. Message header segments

Seg	F.C	Element name	Description	DT	LEN	RQ	Allowed values	Comment, example
MSH	1	Field separator		SI	1	R		ASCII 124
MSH	2	Encoding characters		ST	4	R	^~\&	ASCII 94, ASCII 126, ASCII 92 and ASCII 38, respectively
MSH	3	Sending application		HD		R		Type of device
MSH	4	Sending facility		HD		RE		
MSH	5	Receiving application		HD		R		
MSH	6	Receiving facility		HD		RE		
MSH	7	Date and time of message	Date and time the message was generated	TS	26	R		
MSH	9	Message type		MSG	15	R		
MSH	10	Message control identifier	Unique message identifier	ST	36	R		
MSH	11	Processing identifier		PT	3	R	P	Production
MSH	12	Version identifier	Version of protocol	VID	60	R	2.5	
MSH	18	Character set	The character set specified in this field is used for the encoding of all characters within the message.	ID	16	C	ASCII UNICODE UTF-8	

The sending application populates the MSH fields in the following manner:

- MSH-1 and MSH-2 use HL7-recommended values.
- MSH-3, MSH-4, MSH-5, MSH-6 are filled with data as defined in the appropriate section.
- MSH-7 is filled with the date and time of the message.
- MSH-9 is filled with the defined message type and event.
- MSH-10 is populated with a unique identifier for the message. Acknowledgements in response to this message must refer to this identifier.
- MSH-11 and MSH-12 are filled with the supported processing identifier and version, respectively.

Acknowledge mode

The HL7 standard describes two acknowledge modes, original and enhanced. The QIAcuityDx System uses the original acknowledgement mode. See the original mode processing rules in (1), 2.9.2, and (4), C.2.3.

To keep the dialog logic simple, the original mode ensures there is always one and only one acknowledgement message coming back to the sending application, the application-level acknowledgement message (also called the application ACK message). The original mode is adequate for point-to-point interfaces and is the mode that IHE Laboratory transactions based on HL7 messages use. See more details in (3), vol. 2a, 2.4.4.

Create response message

Upon receipt of the message, the receiving application validates whether the message can be accepted by the receiver according to the contents of the following fields: MSH-9 (message type and event code), MSH-11 (processing identifier), and MSH-12 (version identifier). If the contents of any of these fields fail validation, the system creates an ACK message with an application reject (AR) code in MSA-1.

If the message passes the initial validation, the responding system then passes the message to the receiving application, which processes the message. If the processing of the message is successful, the receiving application generates an ACK message containing acknowledgment code "AA" in MSA-1. Otherwise, the MSA-1 contains the AR code "AE". The receiving application passes the response message back to the responding system.

This applies to WOS messages. The acknowledgement codes that can be included in MSA-1 of the acknowledgment are listed in Table 6.

Table 6. Acknowledgment codes

Value	Description	Comment
AA	Application accept	The message has been accepted and processed successfully by the receiving application.
AE	Application error	A message error occurs when malformed HL7 messages are received. Examples include missing or out-of-order segments, incorrect data types, or unsupported table values. It shall not be sent again without correcting the error.
AR	Application reject	The message has been rejected by the receiving application. In this case, failure to process the message is unrelated to its content or format (e.g., analyzer busy, system down, internal error, etc.). If the rejection is not related to an invalid value in the MSH segment, the sender may try to send the message again later. It is likely that the responding system will accept the message the second time.

Send response message

Upon receiving the response message, the responding system transmits it to the initiating system.

ACK message

In general, the simple general acknowledgment (ACK) message can be used as a response if there is no custom acknowledgement message used or if there has been an error that prohibits processing.

Note that the message type (Field MSH-9) for the simple general acknowledgement message is constructed as follows:

- The value of MSH-9.1 (Message Code) is always ACK.
- The value of MSH-9.2 (Trigger Event) is equal to the value of MSH-9.2 (Trigger Event) in the message being acknowledged.
- The value of MSH-9.3 (Message Structure) is always ACK.

See Table 1 for application-specific details.

Table 7. ACK message segments

Segment	Meaning	Use
MSH	Message header	R
MSA	Message acknowledgement	R
[{ERR}]	Error message	O

Error segment

The error segment is used to add error information and comments to acknowledgment messages, as described in Table 8, Table 9, and Table 10.

Table 8. Error segment

Seg	F.C	Element name	Description	DT	LEN	RQ	Allowed values	Comment, example
ERR	2	Error location	Indicates the location in a message related to the identified error, warning, or message	ERL		C		Issued in case the application does not recognize either the message type (MSH-9.1) or the trigger event (MSH-9.2)
ERR	3	HL7 error code	Indicates the HL7 (communication) error code	CWE		R		From HL7 Table 0357. See the supported values below.
ERR	4	Severity	Indicates the severity of an application error	ID		R		From HL7 Table 0516. See the supported values below.
ERR	8	User message	Contains the message description from the application	TX		O		

Table 9. HL7 error codes

Value	Description	Comment
0	Message accepted	Success. Optional, as the AA conveys success. Used for systems that must always return a status code.
100	Segment sequence error	Error. Message segments were not in proper order or required segments are missing.
101	Required field missing	Error. A required field is missing from a segment.
102	Data type error	Error. A field contains data of the wrong data type.
103	Table value not found	Error. A field data identifier was compared, and no match was found.
200	Unsupported message type	Rejection. The message type is not supported.
201	Unsupported event code	Rejection. The event code is not supported.
202	Unsupported processing identifier	Rejection. The processing identifier is not supported.
203	Unsupported version identifier	Rejection. The version identifier is not supported.
204	Unknown key identifier	Rejection. The identifier of the patient, order, etc., was not found. Used for transactions other than additions (e.g., transfer of a non-existent patient).
205	Duplicate key identifier	Rejection. The order already exists, and it is being processed.
206	Application record locked	Rejection. The transaction could not be performed at the application storage level (e.g., database locked).

Table 10. Severity code

Value	Description	Comment
W	Warning	Transaction successful, but there may be issues.
E	Error	Transaction was unsuccessful.

Error recovery

When the initiating application (i.e., QIAcuityDx System) wants to send a message (initiate a transaction), it uses the current open network connection if available. Otherwise, it will initiate a new network connection to start the transaction.

The initiating application must be able to handle cases where the connection has been closed due to possible timeout by the accepting application or a communication failure (broken connection).

For example, if the initiating application does not submit a request over the connection in a timely manner, the accepting application has the right to close the connection. When this condition is detected, the initiating application needs to open a new connection for subsequent requests.

If the initiating application does not receive a response to the query or an acknowledgement message in a defined time (response time should be a few seconds or less), then the QIAcuityDx System will consider the message undelivered and terminates the transaction. The QIAcuityDx System may initiate a new transaction to resend the message or send another message.

Transmission scenarios

The QIAcuityDx System protocol supports the following communication scenarios (as illustrated in Figure 2):

- WOS query at specimen is recognized (query mode or “host query”).
- Results are reported through WOS status-change messages.

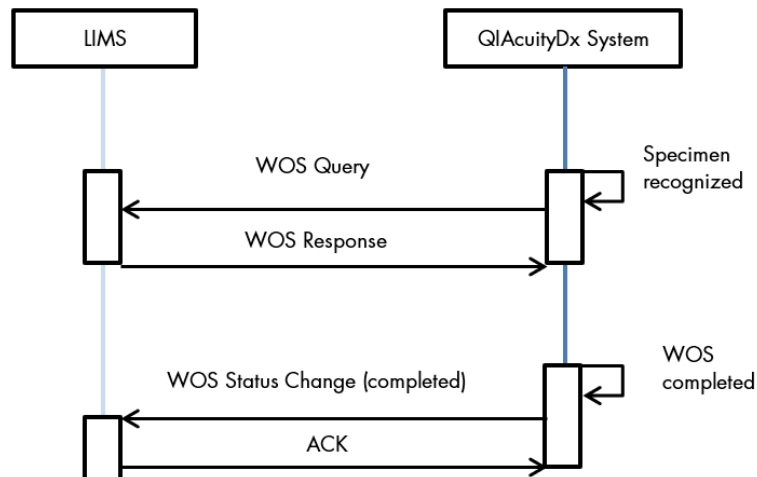


Figure 2. Process with QIAcuityDx System process working in query mode.

Work order step query

After the QIAcuityDx System recognizes a specimen while working in query mode, it sends a WOS query message (QBP^Q11) with the specimen identifier to the LIMS. The LIMS replies with the response message (RSP^K11) containing either one or more WOSs for the specimen identified in the query or an unknown specimen in the case that the specimen is unknown to the LIMS or there is no WOS for the specimen to be executed on the QIAcuityDx System. The transaction model is based on IHE LAB-22 (3) (Figure 3).

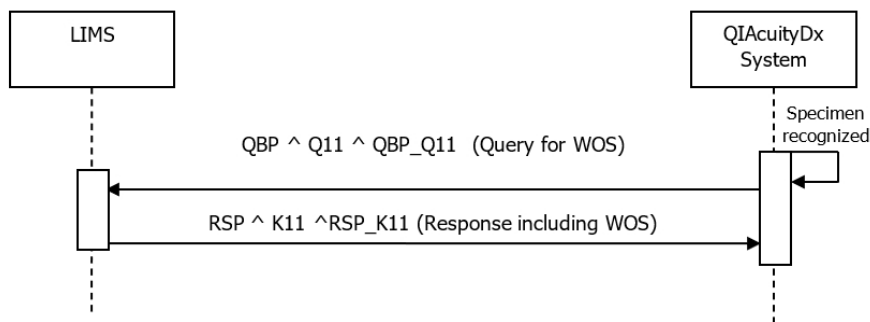


Figure 3. WOS query transaction.

WOS status change (WOS complete)

The WOS status-change transaction is initiated when the QIAcuityDx System reports the status of a WOS related to a specimen. The QIAcuityDx System generates a WOS status-change message and sends it to the LIMS to transfer the tests results when the WOS is complete. The LIMS should respond to the QIAcuityDx System using the ACK message. This transaction is based on IHE LAB-23 and is illustrated in Figure 4.

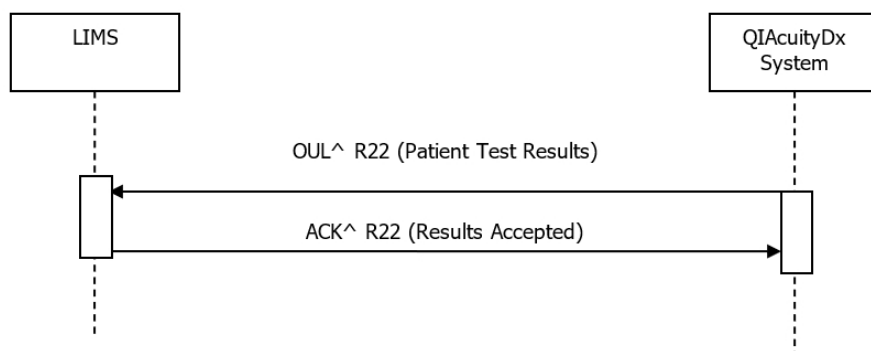


Figure 4. Unsolicited WOS status-change transaction.

Messages description

WOS query message (QBP^Q11)

The WOS query message is based on the HL7 QBP^Q11 message and is used to send the information concerning the specimen identification from the QIAcuityDx System to the LIMS (see Table 14 and Table 15).

Table 11. QIAcuityDx System message structure

Segment	Meaning	Use, comments
MSH	Message header	R (required)
[{SFT}]	Software segment	Not used by the current QIAcuityDx System
QPD	Query parameter definition	R
RCP	Response control parameter	R
[DSC]	Continuation pointer	Not used by the current QIAcuityDx System

Table 12. Segments details

Seg	F.C	Element name	Description	DT	LEN	RQ	Allowed values	Comment, example
MSH	1	Field separator		ST	1	R		ASCII 124
MSH	2	Encoding characters		ST		R	^~\&	ASCII 94, ASCII 126, ASCII 9, and ASCII 38, respectively
MSH	3	Sending application		HD	50	R		
MSH	3.1	Sending application name		ST		R	QIAcuityDx	QIAcuityDx Four name
MSH	4	Sending facility		HD	50	RE		
MSH	4.1	Sending facility name		ST		RE		Sending facility name; not used by the current QIAcuityDx System
MSH	5	Receiving application		HD		R		
MSH	5.1	Receiving application		HD		R		The host or LIMS name. Defined by user.
MSH	6	Receiving facility		HD		RE		
MSH	6.1	Receiving facility name		ST	50	RE		Receiving department or service Not used by the current QIAcuityDx System
MSH	7	Date and time of message	Date and time the message was generated	TS	26	R		
MSH	9	Message type		MSG		R	QBP^Q11^QBP_Q11	
MSH	10	Message control identifier	Unique message identifier	ST	36	R		
MSH	11	Processing identifier				R	P	"P" stands for "Production"
MSH	12	Version identifier	Version of protocol			R	2.5	
MSH	18	Character set	The character set specified in this field is used to encode for the encoding of all the characters in within the message.	ID	16	C	ASCII UNICODE UTF-8	
MSH	21	Message profile identifier	IHE laboratory profile	EI		O		Not used by the current QIAcuityDx System
QPD	1	Message query						
QPD	1.1	Message query identifier	Query identifier	ID	3	R	WOS	Always set to WOS
QPD	1.2	Message query text	Query text name	ST	100	R	Work Order Step	Always set to Work Order Step
QPD	1.3	Message query name of coding system	Query name of coding system	ID	20	R	IHELAW	Always set to IHELAW

Table 12. Segments details (continued)

Seg	F.C	Element name	Description	DT	LEN	RQ	Allowed values	Comment, example
QPD	3	Specimen identification	Specimen identifier entered or obtained from the sample-container bar code	VARIES	256	O		e.g., 9988776655
RCP	1	Query priority		ID	1	R	I	Always set to "I", indicating "immediate"
RCP	3	Response modality		CE	60	R	R	Always set to R, indicating real time

Example

MSH|^~\&|QIAcuityDx||ExternalSystem||20250109165823.4098||QBP^Q11^QBP_Q11|bde89d79- 5068-4034-8c1a-70d8c52aed5b|P|2.5|||||UNICODE UTF-8

QPD|WOS^Work Order Step^IHELAW|SampleTestIVD

RCP|I||R

WOS query response (RSP^K11)

The WOS query response message is based on the HL7 RSP_K11 message and is used to send information concerning the test to be performed from the LIMS to the QIAcuityDx System in response to the previous request (see Table 13 and Table 14).

In case of an unknown specimen or no order for the specimen, the LIMS sends a response with "NF" as content in QAK-2 as well as a no specimen section. Otherwise, QAK-2 is set to "OK", and the response includes the specimen section, which includes the WOS information.

Table 13. WOS query response message structure

Segment	Meaning	Use, comments
MSH	Message header	R
[{SFT}]	Software segment	Not used by the current QIAcuityDx System
MSA	Message acknowledgement	R
[ERR]	Error	Not used by the current QIAcuityDx System
QAK	Query acknowledgement	R
QPD	Query parameter definition	R; this segment echoes the query parameter definition segment sent in the requesting query
{	Specimen beginning	
SPM	Specimen	C [1..1]; only one specimen is supported
[{OBX}]	Observation related to specimen	Not used by the current QIAcuityDx System
[{SAC}]	Specimen container	Not used by the current QIAcuityDx System
[	Patient beginning	
PID	Patient identification	Not used by the current QIAcuityDx System
[{OBX}]	Observation related to the patient	Not used by the current QIAcuityDx System
]	Patient end	

Table 13. WOS query response message structure (continued)

Segment	Meaning	Use, comments
{	Order beginning	
ORC	Common order	R
{TQ1}	Timing or quantity	Not used by the current QIAcuityDx System
	Observation request beginning	
OBR	Observation request	R
[TCD]	Test code details	Not used by the current QIAcuityDx System
[{	Observation beginning	Not used by the current QIAcuityDx System
OBX	Observation result	
[TCD]	Test code details	
[{ NTE }]	Notes and comments (for results)	
}]	Observation end	
	Observation request end	
[{	Previous result beginning	Not used by the current QIAcuityDx System
[PV1]	Patient visit, previous result	Not used by the current QIAcuityDx System
{	Previous Order beginning	
ORC	Common order, previous result	
OBR	Order detail, previous result	
{	Previous Observation beginning	Not used by the current QIAcuityDx System
OBX	Observation, result, previous result	
[{NTE}]	Comment of the result	Not used by the current QIAcuityDx System
}	Previous Order end	
}	Previous Order end	
}]	Previous result end	
}	Order end	
}	Specimen end	

Table 14. Segments details

Seg	F.C	Element name	Description	DT	LEN	RQ	Allowed values	Comment, example
MSH	1	Field separator		ST	1	R		ASCII 124
MSH	2	Encoding characters		ST		R	^~\&	ASCII 94, ASCII 126, ASCII 92 and ASCII 38, respectively
MSH	3	Sending application		HD		R		
MSH	3.1	Sending application name		ST	50	R		The host or LIMS name
MSH	4	Sending facility		HD		X		
MSH	4.1	Sending facility name		ST	50	X		Sending department or service
MSH	5	Receiving application		ST	20	R		
MSH	5.1	Receiving application name		ST	20	R		Received QIAcuityDx Four name; must match the sending application value in the acknowledged message (MSH, Field 3.1)
MSH	6	Receiving facility		HD		X		
MSH	6.1	Receiving facility name		ST	50	X		Receiving department or service
MSH	7	Date and time of message	Date and time the message was generated	TS	26	R		20130201174531
MSH	9	Message type		MSG		R	RSP^K11^RSP_K11	
MSH	10	Message control identifier	Unique message identifier	ST	32	R		
MSH	11	Processing identifier				R	P	Production
MSH	12	Version identifier	Version of protocol			R	2.5	
MSH	18	Character set	The character set specified in this field is used for encoding the characters within the message	ID	16	C	UNICODE UTF-8	
MSH	21	Message profile identifier	IHE laboratory profile	EI		O		Not used by the current QIAcuityDx System
MSA	1	Acknowledgment code		ID	2	R	AA	AA = accept AE = error AR = reject
MSA	2	Message control identifier	From MSH-10 of associated message	ST	20	R		
QAK	2	Query response status		ID	2	R	OK or NF	OK = data found NF = no data found
QPD	1	Message query						

Table 14. Segments details (continued)

Seg	F.C	Element name	Description	DT	LEN	RQ	Allowed values	Comment, example
QPD	1.1	Message query identifier	Query identifier	ID	3	R	WOS	
QPD	1.2	Message query text	Query text name	ST	100	O	Work Order Step	
QPD	3	Specimen identification	Specimen identifier obtained from the sample container bar code	ST	20	R		9988776655
SPM	1	Set identifier	Identifies SPM segment instances in messages where the SPM segment repeats	SID		R	1	Only one specimen is supported
SPM	2	Specimen identifier	Unique identifier for the specimen	EIP		R		
SPM	2.1.1	Specimen identifier	Entity identifier	ST	20	R		9988776655
SPM	4	Specimen type	Describes the precise nature of the entity that will be the source material for the observation	CWE		R		
SPM	4.1	Specimen type identifier		ST	20	R		See "HL7 Protocol" (e.g., WB)
SPM	4.2	Specimen type text		ST	199	O		WB, PLAS
SPM	11	Specimen role	This field indicates the role of the sample	CWE		R	P	P = patient
SPM	17	Specimen collection date and time	The date and time when the specimen was acquired from the source	DR		X		Not used by the current QIAcuityDx Software Suite version
ORC	1	Order control	Determines the function of the order segment	ID		R	NW	Reference 1, chapter 4.23.1. NW = new order
ORC	2	Placer order number	Placer application's order number that identifies the individual order	EI		R		
ORC	4	Order group number	Placer or filler order group number identifies the set of closely related orders for this specimen by the application.	EIP		X		Not used by the current QIAcuityDx Software Suite version
ORC	9	Date and time of transaction	Date and time of the event that initiated the current transaction	TS		R		Required by the current QIAcuityDx Software Suite version
OBR	1	Sequence number	Defines the i'th occurrence of the associated record type	SI		R	1	

Table 14. Segments details (continued)

Seg	F.C	Element name	Description	DT	LEN	RQ	Allowed values	Comment, example
OBR	2	Placer order number	Identifies an individual order. This is a permanent identifier for an order and its associated observations	EI		O		Same as ORC-2
OBR	2.1	Identifier		ST	16	O		Not used by the current QIAcuityDx Software Suite version
OBR	4	Universal service identifier	System-defined identifier for the requested observation, test or battery	ID		R		
OBR	4.1	Universal service identifier, code	USI code	ST	20	R (required if 4.4, 4.5 & 4.6 are empty)		This field contains the code of the test panel to be performed (ordered) on the specimen by the QIAcuityDx System. These are defined in LOINC.
OBR	4.2	Universal service identifier, text	USI text	ST	199	R (required if 4.4, 4.5 & 4.6 are empty)		This field contains the text of the test panel to be performed (ordered) on the specimen by the QIAcuityDx System. These are defined in LOINC.
OBR	4.3	Universal service identifier, coding system	USI coding system	ID	20	R (required if 4.4, 4.5 & 4.6 are empty)	LN	This field contains the coding system of the test panel to be performed (ordered) on the specimen by the QIAcuityDx System. These are defined in LOINC.
OBR	4.4	Universal service identifier, alternate code	USI alternate code	ST	20	R (required if 4.1, 4.2 & 4.3 are empty)		This field contains the code of the test panel to be performed (ordered) on the specimen by the QIAcuityDx System. These codes are defined by QIAGEN.
OBR	4.5	Universal service identifier, alternate text	USI alternate text	ST	199	R (required if 4.1, 4.2 & 4.3 are empty)		This field contains the text of the test panel to be performed (ordered) on the specimen by the QIAcuityDx System. These codes are defined by QIAGEN.

Table 14. Segments details (continued)

Seg	F.C	Element name	Description	DT	LEN	RQ	Allowed values	Comment, example
OBR	4.6	Universal service identifier, alternate coding system	USI alternate coding system	ID	20	R (required if 4.1, 4.2 & 4.3 are empty)	99QIA	This field contains the coding system of the test panel to be performed (ordered) on the specimen by the QIAcuityDx System. This is only applicable for IVD Software Assay Plugins. These codes are defined by QIAGEN.
OBR	11	Specimen action code	Action to be taken with respect to the specimen that accompanies or precedes this order	ID		R	A	Add ordered tests to the existing specimen; from reference 1 chapter 4.5.3.11,
OBR	16	Ordering provider	Identity of the person who is responsible for creating the request (i.e., the ordering physician)	XCN		O		Not used by the current QIAcuityDx Software Suite version

The QIAcuityDx System supports only one specimen (specimen group) per message.

The message shall include only one order related to the specimen. Only one assay shall be ordered per specimen.

Example: Specimen known and WOS reported, IVD Mode Plugin

```
MSH|^~\&|MYLIS||QIAcuityDx||202311292005||RSP^K11^RSP_ K11|d5527358- 405c- 4847- 8cab-a9bc23fc2942|P|2.5|||||UNICODE UTF-8<CR>
```

```
MSA|AA|bd159431-a7cc-41b9-af0a-10e3a55d6f21<CR>
```

```
QAK||OK<CR>
```

```
QPD|WOS^work Order Step|Q2015042115324601|9988776655<CR>
```

```
SPM|1|sample 03||WB|||||P|||||202311292005<CR>
```

```
ORC|NW|2342343325|||CM|||202311292005<CR>
```

```
OBR|1|2342343325||^E^ESR1^ASSAY^ESR1 Assay^99QIA||||202311292005|A<CR>
```

Note that the LIMS may send fields that are not required by the instrument.

Example: Specimen known and WOS reported, Utility Mode Plugin

MSH|^~\&|ExternalSystem||QIAcuityDx||202311292005||RSP^K11^RSP_K11|d5527358-405c-4847-8cab-a9bc23fc2942|P|2.5|||||UNICODE UTF-8<CR>

MSA|AA|bd159431-a7cc-41b9-af0a-10e3a55d6f21<CR>

QAK||OK<CR>

QPD|WOS^work Order Step||sample1-UTL1106<CR>

SPM|1|sample1-UTL1106|null|WB^WB|||||P|||||202311292005<CR>

ORC|NW|2342343325|||CM|||202311292005<CR>

OBR|1|2342343325||^utl Plugin 1.1.0.6||||202311292005||A<CR>

Note that the LIMS may send fields that are not required by the instrument.

Example: Specimen sample1 unknown or no WOS for the specimen sample1 (IVD Mode/UTL Mode)

MSH|^~\&|ExternalSystem||QIAcuityDx||202501141022||RSP^K11^RSP_K11|e8a63394-eed3-4542-820c-83d61601ee3c|P|2.5|||||UNICODE UTF-8

MSA|AA|e8a63394-eed3-4542-820c-83d61601ee3c

QAK||NF

QPD|WOS^work Order Step||sample1

Observation results message (OUL^R22)

This message is based on the HL7 OUL^R22 message. The message is used to send information concerning the patient, specimen, status, and test results of the WOS from the QIAcuityDx to the LIS (see Table 15 and Table 16).

Table 15. The QIAcuityDx message structure

Segment	Meaning	Use
MSH	Message header	R
PID	Patient identification	R
{	Specimen begin	
SPM	Specimen information	R
SAC	Specimen container detail	X
{	Order begin	
OBR	Observation order information	R
ORC	Common order information	R
{	Result begin	
OBX	Observation result	R
{		
{ [INV] }	Inventory detail	R/X (Required in IVD mode, not supported in UTL mode)
{ [NTE] }	Notes and comments	O. Plate description field and/or flags
}	Result end	
}	Order end	
}	Specimen end	

Table 16. Segments details

Seg	F.C	Element name	Description	DT	LEN	RQ	Allowed values	Comment, example
MSH	1	Field separator		ST	1	R		ASCII 124
MSH	2	Encoding characters		ST		R	^~\&	ASCII 94, ASCII 126, ASCII 92 and ASCII 38, respectively
MSH	3	Sending application		HD		R		
MSH	3.1	Sending application name		ST	50	R	QIAcuityDx	QIAcuityDx Four name
MSH	4	Sending facility		HD		O		
MSH	4.1	Sending facility name		ST	50	O		Sending facility name, not used by the current QIAcuityDx Software Suite version
MSH	5	Receiving application		HD		R		
MSH	5.1	Receiving application name		ST	20	R		The host or LIMS name. Defined by user.
MSH	6	Receiving facility		HD		O		
MSH	6.1	Receiving facility name		ST	50	O		Receiving department or service; not used by the current QIAcuityDx Software Suite version
MSH	7	Date and time of message	Date and time the message was generated	TS	26	R		
MSH	9	Message type		MSG		R	OUL^R22^OUL_R22	
MSH	10	Message control identifier	Unique message identifier	ST	36	R		
MSH	11	Processing identifier				R	P	Production
MSH	12	Version identifier	Version of protocol			R	2.5	
MSH	18	Character set	The character set specified in this field is used to encode all the characters within the message.	ID	16	C	UNICODE UTF-8	
SPM	1	Set identifier	Identifies SPM segment instances in messages where the SPM segment repeats	SID		R	1	
SPM	2	Specimen identifier	Unique identifier for the specimen	EIP		R		
SPM	2.1	Specimen identifier	Entity identifier	ST	20	R		The specimen identifier (sample identifier)

Table 16. Segments details (continued)

Seg	F.C	Element name	Description	DT	LEN	RQ	Allowed values	Comment, example
SPM	4	Specimen type	Describes the precise nature of the entity that will be the source material for the observation	CWE		R		
SPM	4.1	Specimen type identifier		ST	20	R		Reference 1, chapter 7.c18.4 (e.g., WB)
SPM	4.2	Specimen type text		ST	199	O		E.g.: Whole blood
SAC	9	Carrier type	Used for the plate type name	CE		R		E.g.: QIAcuityDx Nanoplate 26k 24-well"
SAC	10	Carrier identifier	Used for the plate barcode	ST		R		
SAC	11	Position in carrier		ST		R	0	Always 0, not implemented in this version,
OBR	1	Sequence number	Defines the i'th occurrence of the associated record type	SI		R	1	
OBR	2	Placer order number	Identifies an individual order. This is a permanent identifier for an order and its associated observations	EI		O		Same as ORC-2
OBR	2.1	Identifier		ST	16	R		
OBR	4	Universal service identifier	System-defined identifier for the requested observation, test or battery	ID		R		
OBR	4.1	Universal service identifier, code	USI code	ST	20	R (required if 4.4, 4.5 & 4.6 are empty)		This field contains the code of the test panel to be performed (ordered) on the specimen by the QIAcuityDx System. These are defined in LOINC.
OBR	4.2	Universal service identifier, text	USI text	ST	199	R (required if 4.4, 4.5 & 4.6 are empty)		This field contains the text of the test panel to be performed (ordered) on the specimen by the QIAcuityDx System. These are defined in LOINC.
OBR	4.3	Universal service identifier, coding system	USI coding system	ID	20	R (required if 4.4, 4.5 & 4.6 are empty)	LN	This field contains the text of the test panel to be performed (ordered) on the specimen by the QIAcuityDx System. These are defined in LOINC.

Table 16. Segments details (continued)

Seg	F.C	Element name	Description	DT	LEN	RQ	Allowed values	Comment, example
OBR	4.4	Alternate Universal service identifier, code	Alternate USI code	ST	20	R (required if 4.1, 4.2 & 4.3 are empty)		This field contains the code of the test panel to be performed (ordered) on the specimen by the QIAcuityDx System.
OBR	4.5	Alternate Universal service identifier, text	Alternate USI text	ST	199	R (required if 4.1, 4.2 & 4.3 are empty)		This field contains the text of the test panel to be performed (ordered) on the specimen by the QIAcuityDx System.
OBR	4.6	Alternate Universal service identifier, coding system	Alternate USI coding system	ID	20	R (required if 4.1, 4.2 & 4.3 are empty)	99QIA	This field contains the text of the test panel to be performed (ordered) on the specimen by the QIAcuityDx System.
OBR	7	Observation Date/Time		DTM		R		E.g.: 20230731143656.457
ORC	1	Order control	Determines the function of the order segment	ID		R	NW	
ORC	2	Placer order number	Placer application's order number that identifies the individual order	EI		O		
OBX	1	Set identifier	Identifies OBX segment instances in messages where the OBX segment repeats	SID		R		
OBX	2	Value type	Value type of result	ID	2	R	"ST" (text), "NM" (numeric), or "CE" (coded element)	
OBX	3	Observation identifier	Identifies the service identifier	EIP		R		For IVD plugins-related results, see Specific assay's Observation identifier codes. For UTL plugins-related results, refer to HL7 Protocol section.
	3.1		Test identifier code (LOINC)	ST				
	3.2		The test name (LOINC)	ST				
	3.3		The coding system (LOINC)	ST			LN	
	3.4		The alternate test identifier	ST				
	3.5		The alternate test name	ST				
	3.6		The alternate coding system	ST			99QIA	
OBX	5	Observation value				R		

Table 16. Segments details (continued)

Seg	F.C	Element name	Description	DT	LEN	RQ	Allowed values	Comment, example
	5.1		Qualitative or quantitative result	ST		R	Numeric, text, "FAILED" or "INVALID"	
OBX	6	Units		ST		O		Used when quantitative results carry unit. E.g.: "copies/ μ L"
OBX	11	Observation result status	Current completion status of the process results	ID		R	F or X	F = final result (protocol execution completed successfully) X = results cannot be obtained for this observation (execution failed or invalid)
OBX	14	Date/Time of the observation		TS		R		
	14.1		Date/Time of the observation	DTM		R		E.g.: 20231129002433.5932
OBX	16	Responsible observer	The professional who performed the observation	XCN		R		
	16.1	Observer identifier		ST		R		Reports the identifier of the operator (user) who performed the test.
OBX	17	Observation method		CE		R		
	17.2	Observation method		ST		R		Reports the assay plugin used for the observation
OBX	18	Equipment instance identifier	Serial number of the QIAcuityDx Four instrument	ST		R		Instrument serial number
OBX	19	Date and time of analysis	Measurement date time	TS		R		
INV	1	Inventory detail	Identifies INV segment instances in messages where the INV segment repeats	SID		R		
INV	2	Substance identifier	Unique identifier for the substance that is in inventory.	CE		R		Reports the Kit's information.
	2.1		The Kit ID	ST		R		E.g.: 04053228049418
	2.2		The Kit name	ST		R		E.g.: QIAcuityDx Universal MasterMix Kit (1ml)
INV	4	Inventory container identifier	The Kit's Catalogue Number	ST		R		
INV	12	Expiration Date/Time		DTM		R		E.g.: 20231231235959
INV	16	Lot number	The Kit's lot number	ST		R		

Table 16. Segments details (continued)

Seg	F.C	Element name	Description	DT	LEN	RQ	Allowed values	Comment, example
NTE	3	Comment	User for comments	ST		○		Reports the Plate's Description field content. Reports the reason for invalidations or failure. E.g.: "Min. valid partition not reached."
NTE	4	Comment type		CE			RE	Fixed value: "RE"

Note: OBX-16, OBX-18, and OBX-19 may be reported only in the first OBX segment.

UTL mode observation identifier

The compounding of the Observation identifier for results obtained in UTL mode, follows a logic based on its well or hyperwell ID, imaging step, reaction mix name, target name or selected channel, and its plugin version.

Element Name	Description	Allowed values	Comment, example
Prefix	Indicates that the observation identifier is related to UTL mode	UTL	Fixed as "UTL"
Separator	Separator character	_	Fixed as "_" (Underscore)
Well or hyperwell ID	Indicates the well or hyperwell on the plate of the observation	The ones used in the plate	Examples: HW1, A1, A3, B4, HW5
Separator	Separator character	_	Fixed as "_" (Underscore)
Imaging step	Indicates the imaging step related to the observation. Represented as IS + the imaging step number (from 1 to 8)	IS1, IS2, IS3, IS4, IS5, IS6, IS7, IS8	
Separator	Separator character	_	Fixed as "_" (Underscore)
Reaction mix name	Indicates the name of the Reaction mix related to the observation	User defined	User defined
Separator	Separator character	_	Fixed as "_" (Underscore)
Target name or Channel	Indicates the name of the Target or the Channel related to the observation	Target: user defined. Channel: Green, Yellow, Orange, Red, Crimson	Target: user defined. Channel: Green, Yellow, Orange, Red, Crimson
Separator	Separator character	_	Fixed as "_" (Underscore)
Plugin version	Indicates the plugin version related to the observation		Example: 1.1.0.1

UTL_ + Well ID or Hyperwell ID + _ + Imaging step + _ + Reaction mix name + _ + target name or channel + _ + plugin version.

Example: UTL_A1_IS1_Reactionmix1_Target2_1.1.0.0

UTL OBX example

```
OBX|1|NM|^^^UTL_A1_IS1_Reactionmix1_Target2_
1.1.0.0^^QIA99||101|copies/μl||||F||20231129002433.5932||Operator|^UTL
Plugin|76431234|20220620054042.8074<CR>
```

IVD mode example

MSH|^~\&|QIAcuityDx||ExternalSystem||20240905175141.9581||OUL^R22^OUL_R22|9564a1d8-3c30-48b6-8b39-0aea64fdc375|P|2.5|||||UNICODE UTF-8<CR>

SPM|1|Sample2||WB|||||P<CR>

SAC|||||||Nanoplate 26K 24-well
GMP^99QIA|01515234100001291231000001|0|||||||<CR>

OBR||2342343325||^BCRABL1ASSAY^BCR:ABL1 Assay^99QIA||20230731143656.457<CR>

ORC|NW|2342343325||<CR>

OBX|1|NM|^MR^Molecular
Response^99QIA||2.10|||||F||20230731143656.457||operator|^bcr-
ab|1|SN123456789|20230731143656.457<CR>

INV|A2C45678901234^PRIMER_PROBE_KIT|""||260100||||||20240330000000|||2312244444|<CR>

INV|04053228049418^MASTERMIX_KIT|""||260101||||||20240331000000|||555555553<CR>

NTE|||comment/error/warning/flag example|RE<CR>

OBX|2|NM|^ISNCN^International Standard
NCN^99QIA||0.80|||||F||20230731143656.457||operator|^bcr-
ab|1|SN123456789|20230731143656.457<CR>

INV|A2C45678901234^PRIMER_PROBE_KIT|""||260100||||||20240330000000|||2312244444|<CR>

INV|04053228049418^MASTERMIX_KIT|""||260101||||||20240331000000|||555555553|<CR>

NTE|||comment/error/warning/flag example|RE<CR>

OBX|3|NM|^CNABL1^ABL1 copy
number^99QIA||3555|||||F||20230731143656.457||operator|^bcr-
ab|1|SN123456789|20230731143656.457<CR>

INV|A2C45678901234^PRIMER_PROBE_KIT|""||260100||||||20240330000000|||2312244444|<CR>

INV|04053228049418^MASTERMIX_KIT|""||260101||||||20240331000000|||555555553|<CR>

NTE|||comment/error/warning/flag example|RE<CR>

OBX|4|NM|^CNMBCR^Mbcr copy
number^99QIA||5333|||||F||20230731143656.457||operator|^bcr-
ab|1|SN123456789|20230731143656.457<CR>

INV|A2C45678901234^PRIMER_PROBE_KIT|""||260100||||||20240330000000|||2312244444|<CR>

INV|04053228049418^MASTERMIX_KIT|""||260101|||||||20240331000000|||555555553|<CR>

NTE|||comment/error/warning/flag example|RE<CR>

OBX|5|NM|^^^BCRABL1STATUS^BCR:ABL1
Status^99QIA||2.10|||||F|||20230731143656.457||operator|^bcr-
abl1|SN123456789|20230731143656.457<CR>

INV|A2C45678901234^PRIMER_PROBE_KIT|""||260100|||||||20240330000000|||2312244444|<CR>

INV|04053228049418^MASTERMIX_KIT|""||260101|||||||20240331000000|||555555553|<CR>

NTE|||comment/error/warning/flag example|RE<CR>

UTL mode example

MSH|^~\&|QIAcuityDx|ExternalSystem||20250109162118.7221||OUL^R22^OUL_R22|ffc67238-1d11-
4711-93f2-b3db5964d1b3|P|2.5|||||UNICODE UTF-8

SPM|1|Sample1-UTL1106||WB|||||P

SAC|||||||QIAcuity Nanoplate 8.5k 24-
well^99QIA|01035244742207250212726066|0|||||||||||||

OBR|""|^autl Plugin 1.1.0.6|||20250109113507

ORC|NW|""|

OBX|1|NM|^^^UTL_A1_IS1_REACTION MIX1_name11_
1.1.0.6^99QIA||662.94|copies/î%1||||F|||20250109113507||CMN_GLOBAL|^autl-
1.1.0.6|2.1.21|20250109113229

NTE|||test description1|RE

OBX|2|NM|^^^UTL_A1_IS1_REACTION MIX1_name12_
1.1.0.6^99QIA||681.46|copies/î%1||||F|||20250109113507||CMN_GLOBAL|^autl-
1.1.0.6|2.1.21|20250109113229

NTE|||test description1|RE

OBX|3|NM|^^^UTL_A1_IS1_REACTION MIX1_name13_
1.1.0.6^99QIA||0.48|copies/î%1||||F|||20250109113507||CMN_GLOBAL|^autl-
1.1.0.6|2.1.21|20250109113229

NTE|||test description1|RE

OBX|4|NM|^^^UTL_A1_IS1_REACTION MIX1_name14_
1.1.0.6^99QIA||0.0|copies/î%1||||F|||20250109113507||CMN_GLOBAL|^autl-
1.1.0.6|2.1.21|20250109113229

NTE|||test description1|RE

OBX|5|NM|^^^UTL_A1_IS1_REACTION MIX1_name15_
1.1.0.6^^99QIA||0.0|copies/î¼1|||F||20250109113507||CMN_GLOBAL|^ut1-
1.1.0.6|2.1.21|20250109113229

NTE|||test description1|RE

Acknowledgement message (ACK^R22)

The QIAcuityDx System expects to receive a general acknowledgement message (ACK^R22) from the LIS in response to the observation results message (see Table 17 and Table 18).

Table 17. LIMS message structure

Segment	Meaning	Use	Comment
MSH	Message header	R	
MSA	Message acknowledgement	R	
[ERR]	Error message	C	Required, if message acknowledgement is an error.

Table 18. Segments details

Seg	F.C	Element name	Description	DT	LEN	RQ	Allowed values	Comment, example
MSH	1	Field separator		ST	1	R		ASCII 124
MSH	2	Encoding characters		ST		R	^~\&	ASCII 94, ASCII 126, ASCII 92 and ASCII 38, respectively
MSH	3	Sending application		HD		R		
MSH	3.1	Sending application name		ST	50	R		The host or LIMS name
MSH	5	Receiving application		ST	20	R		
MSH	5.1	Receiving application name		ST	20	R		QIAcuityDx Four name, must match value "Sending application" of the acknowledged message (MSH, field 3.1)
MSH	7	Date and time of message	Date and time the message was generated	TS	26	R		
MSH	9	Message type		MSG		R	ACK^R22^ACK	
MSH	10	Message control identifier	Unique message identifier	ST	32	R		
MSH	11	Processing identifier				R	P	Production
MSH	12	Version identifier	Version of protocol			R	2.5	

Table 18. Segments details (continued)

Seg	F.C	Element name	Description	DT	LEN	RQ	Allowed values	Comment, example
MSH	18	Character set	The character set specified in this field is used for the encoding of all the characters within the message.	ID	16	C	UNICODE UTF-8	
MSH	21	Message profile identifier	IHE laboratory profile	EI		O		
MSA	1	Acknowledgment code		ID	2	R	AA	AA = accept AE = error AR = reject
MSA	2	Message control identifier	From MSH-10 of associated message	ST	20	R		
ERR	3	HL7 error code				C		Required, if Acknowledgment Code is "AE"
ERR	4	Severity				O		

Example

MSH|^~\&|MYLIS||QIAcuityDx||201301121548||ACK^R22^ACK|M2015042115324802|P|2.5|||||UNICODE UTF-8<CR>

MSA|AA|M2015042115324601<CR>

Appendix

Sample (specimen) type codes

Sample types are coded in the QIAcuityDx System messages using values defined in Table 0487 – Specimen Type of reference 1, chapter 7.18.4 (see Table 19).

Note: this table replaces Table 0070 – Specimen Source codes in reference 1, chapter 7.18.2.

Table 19. Specimen source codes

Value	Description	Value	Description	Value	Description
ABS	Abscess	HEV	Drain, hemovac	PPP	Plasma, platelet poor
PELVA	Abscess, pelvic	GTUBE	Drainage tube, drainage (gastrostomy)	PRP	Plasma, platelet rich
PERIA	Abscess, perianal	GASD	Drainage, gastric	POL	Polyps
RECTA	Abscess, rectal	ILEO	Drainage, ileostomy	PROST	Prosthetic device
SCROA	Abscess, scrotal	JP	Drainage, Jackson Pratt	PSC	Pseudocyst
SUBMA	Abscess, submandibular	JEJU	Drainage, jejunal	PUST	Pus
SUBMX	Abscess, submaxillary	NASDR	Drainage, nasal	PUS	Pus
TSTES	Abscess, testicular	NGAST	Drainage, nasogastric	PUSFR	Pustule
AIRS	Air sample	PND	Drainage, penile	QC3	Quality control
ALL	Allograft	DRNGP	Drainage, Penrose	RES	Respiratory
AMP	Amputation	RECT	Drainage, rectal	SAL	Saliva
GASAN	Antrum, gastric	SUMP	Drainage, sump	FSCLP	Scalp, fetal
ASP	Aspirate	DRNG	Drainage, tube	CSCR	Scratch, cat
ETA	Aspirate, endotrach	EARW	Ear wax (cerumen)	SECRE	Secretion(s)
GASA	Aspirate, gastric	EFFUS	Effusion	NSECR	Secretion, nasal
NGASP	Aspirate, nasogastric	ELT	Electrode	SER	Serum
TASP	Aspirate, tracheal	ATTE	Environmental, autoclave ampule	ASERU	Serum, acute
TTRA	Aspirate, transtracheal	AUTOC	Environmental, Autoclave Capsule	CSERU	Serum, convalescent
AUTP	Autopsy	EFF	Environmental, effluent	PLEVS	Serum, peak level
BX	Biopsy	EEYE	Environmental, eye wash	TSERU	Serum, trough
GSPEC	Biopsy, gastric	EFOD	Environmental, food	SHUNT	Shunt
SKBP	Biopsy, skin	EISO	Environmental, isolette	EXS	Shunt, external
CONE	Biopsy, cone	EOTH	Environmental, other substance	SITE	Site
BITE	Bite	ESOI	Environmental, soil	CVPS	Site, CVP
CBITE	Bite, cat	ESOS	Environmental, solution (sterile)	INCI	Site, incision or surgical
DBITE	Bite, dog	SPS	Environmental, spore strip	NGS	Site, naso or gastric
HBITE	Bite, human	STER	Environmental, Sterrad	NEPH	Site, nephrostomy
IBITE	Bite, insect	ENVIR	Environmental, unidentified substance	PIS	Site, pacemaker insertion

Table 19. Specimen source codes (continued)

Value	Description	Value	Description	Value	Description
RBITE	Bite, reptile	WWA	Environmental, water	PDSIT	Site, peritoneal dialysis
BLEB	Bleb	DEION	Environmental, water (deionized)	PDTS	Site, peritoneal dialysis tunnel
BLIST	Blister	WWT	Environmental, water (tap)	PINS	Site, pin
BBL	Blood bag	FAW	Environmental, water (well)	POPLV	Site, popliteal vein
BPU	Blood product unit	WWO	Environmental, water (ocean)	SHU	Site, shunt
HBLUD	Blood, autopsy	EWHI	Environmental, whirlpool	TRAC	Site, tracheostomy
CSVR	Blood, cell saver	EXUDTE	Exudate	SKN	Skin
FBLOOD	Blood, fetal	FLT	Filter	TZANC	Smear, Tzanck
MBLD	Blood, menstrual	FIST	Fistula	GSOL	Solution, gastrostomy
WB	Blood, whole	FLUID	Fluid	ILLEG	Source of specimen is illegible
BOIL	Boil	FGA	Fluid, abdomen	OTH	Source, other
BON	Bone	CSMY	Fluid, cystostomy tube	UDENT	Source, unidentified
BOWL	Bowel contents	ACNFLD	Fluid, acne	USPEC	Source, unspecified
BRTH	Breath (use EXHLD)	FLU	Fluid, body unsp	SPRM	Spermatozoa
BRSH	Brush	CST	Fluid, cyst	SPT	Sputum
EBRUSH	Brush, esophageal	HYDC	Fluid, hydrocele	SPTC	Sputum, coughed
BRUS	Brushing	IVFLD	Fluid, IV	SPTT	Sputum, tracheal aspirate
GASBR	Brushing, gastric	JNTFLD	Fluid, joint	DCS	Sputum, deep cough
BUB	Bubo	KIDFLD	Fluid, kidney	SPUTIN	Sputum, induced
BULLA	Bulla or bullae	LSAC	Fluid, lumbar sac	SPUT1	Sputum, simulated
BRN	Burn	FLD	Fluid, other	SPUTSP	Sputum, spontaneous
CALC	Calculus (stone)	PCFL	Fluid, pericardial	STONE	Stone, kidney
CARBU	Carbuncle	RENC	Fluid, renal cyst	STL	Stool, fecal
CAT	Catheter	FRS	Fluid, respiratory	SUP	Suprapubic tap
CSITE	Catheter insertion site	SHUNF	Fluid, shunt	SUTUR	Suture
CTP	Catheter tip	SNV	Fluid, synovial (joint fluid)	TISS	Tissue
ANGI	Catheter tip, angio	GAST	Fluid or contents, gastric	TISU	Tissue, ulcer
ARTC	Catheter tip, arterial	FUR	Furuncle	ACNE	Tissue, acne
CVPT	Catheter tip, CVP	GAS	Gas	HERNI	Tissue, herniated
ETTP	Catheter tip, endotracheal	EXG	Gas, exhaled (breath)	SCAR	Tissue, keloid (scar)
FOLEY	Catheter tip, Foley	IHG	Gas, inhaled	TRANS	Transudate
HEMAQ	Catheter tip, hemaquit	GENV	Genital vaginal	ETTUB	Tube, endotracheal
HEMO	Catheter tip, hemovac	GRAFT	Graft site	GT	Tube, gastric
IDC	Catheter tip, indwelling	POPGS	Graft site, popliteal	TUBES	Tubes
INTRD	Catheter tip, introducer	POPLG	Graft, popliteal	IVTIP	Tubing tip, IV

Table 19. Specimen source codes (continued)

Value	Description	Value	Description	Value	Description
IVCAT	Catheter tip, IV	GRANU	Granuloma	TUMOR	Tumor
MAHUR	Catheter tip, makurkour	IMP	Implant	DEC	Ulcer, decubitus
SCLV	Catheter tip, subclavian	INFIL	Infiltrate	UR	Urine
SPRP	Catheter tip, suprapubic	INS	Insect	URT	Urine catheter
SWGZ	Catheter tip, Swan-Gantz	IUD	Intrauterine device	URC	Urine clean catch
VASTIP	Catheter tip, vas	IT	Intubation tube	URINB	Urine, bladder washings
VENT	Catheter tip, ventricular	KELOI	Lavage	URINC	Urine, catheterized
GROSH	Catheter, Groshong	LAVG	Lavage, bronchial	USCOP	Urine, cystoscopy
HIC	Catheter, Hickman	LAVGG	Lavage, gastric	URINM	Urine, midstream
PORTA	Catheter, porta	LAVGP	Lavage, peritoneal	URINN	Urine, nephrostomy
SPRPB	Catheter tip, suprapubic	LAVPG	Lavage, pre-bronch	URINP	Urine, pedibag
TLC	Catheter tip, triple lumen	LESN	Lesion	RANDU	Urine, random
CLIPP	Clippings	ORL	Lesion, oral	VITF	Vitreous fluid
COL	Colostrum	PENIL	Lesion, penile	VOM	Vomit
CNJT	Conjunctiva	LIQO	Liquid, other	WRT	Wart
CNJT	Conjunctiva	LIQ	Liquid, unspecified	WASH	Wash
CNJT	Conjunctiva	MASS	Mass	WASI	Washing (e.g., bronchial washing)
LENS1	Contact lens	SMM	Mass, sub-mandibular	WAT	Water
LENS2	Contact lens case	MUCOS	Mucosa	WEN	Wen
CYST	Cyst	MUCUS	Mucus	WICK	Wick
BCYST	Cyst, Baker's	NEDL	Needle	WORM	Worm
ICYST	Cyst, inclusion	NODUL	Nodule(s)	WND	Wound
PILOC	Cyst, pilonidal	CYN	Nodule, cystic	WNDA	Wound abscess
RENALC	Cyst, renal	ORH	Other	WNDD	Wound drainage
DIA	Dialysate	PACEM	Pacemaker	WNDE	Wound exudate
DISCHG	Discharge	PLAN	Plant material	PUNCT	Wound, puncture

Data dictionary notes

Table 20. Data dictionary notes

#	Element	Type	Comments
0	control_id message control identifier		The message control identifier may be implemented by the software in different ways (counter, timestamp, globally unique identifier, etc.). Although this identifier should be unique in the conversation scope, it is recommended that the identifier to be unique for each device for traceability reasons. For instance, a current date and time stamp: "M2015042115324801".
1	device_id	Fixed by each device	This is the unique identifier as IEEE EUI-64 string-encoded format of the instrument address. Example: 3B-A7-94-FF-FE-07-CB-D0 The QIAcuityDx System gets this identifier from the network interface. The 64-bit extended unique identifier (EUI-64) format is defined by the Institute of Electrical and Electronics Engineers (IEEE) and is used by the IPv6 system to provide 64-bit MAC addresses. There is a conversion of the 48-bit IEEE 802 MAC address of ethernet interfaces to the modified EUI-64 identifier. For more details, see https://standards.ieee.org/develop/regauth/tut/eui64.pdf
2	vendor_id	Fixed	"QTY-DX" If a vendor identifier is supplied, it should be a registered identifier. Contact CLSI to register an identifier as a POCT1 vendor code identifier for QIAGEN. For more information, see http://clsi.org/ and standard@clsi.org
3	manufacturer_ name	Fixed	"QTY-DX"
4	model_id	Fixed	"QIAcuityDx", instrument model identifier.
5	serial_id	Fixed per device	QIAcuityDx Four instrument serial number (unique serial identifier).
6	hw_version	Fixed	Indicates the QIAcuityDx Four current hardware version (e.g., "QIACUITYDX_HW_A")
7	sw_version	Fixed	Indicates the current QIAcuityDx Control Software version (e.g., "1.0.00")
8	device_name	Configurable	This is a convenient name for the device (e.g., "QIAcuityDxLab4"). Parameter is set in the LIMS or instrument configuration.
9	LIMS application	Configurable	The identifier of the LIMS instance. Parameter is set in the LIMS configuration.
10	operator_id		The operator's username
11	password		
12	permission_ level_cd		Table 10 of reference 2 defines a default set of codes (see below). However, vendors may extend this set, following the rules for the CV data type.
13	Ordering phys- icians I.D.		

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