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# QIAstat-Dx LIS Interface Specification



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# Purpose and Scope

## Purpose

The purpose of this document is to specify the interface protocols of the QIAstat-Dx system to 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 System (LIS) or a laboratory Data Manager computer system. In this document, the external system will be generically referenced as LIS.

This document details information of all the data exchanged between the system and LIS, guiding the implementation of the HL7 protocol mode supported by the QIAstat-Dx instrument communications.

## Scope

This document describes the LIS interface specification for the QIAstat-Dx software version 1.2.x.

# References

## External documents

- [1] HL7, Health Level 7 Messaging Standard, Version 2.5, Approved June 26, 2003
- [2] Clinical and Laboratory Standards Institute (CLSI), Point-of-Care Connectivity; Approved Standard—Second Edition, CLSI document POCT1-A2.
- [3] IHE, Laboratory Technical Framework (LAB TF), Vol. 1, 2a, 2b, 2x, Rev. 6.0
- [4] IHE IT Infrastructure Technical Framework, Volume 2x, Rev. 12.0
- [5] 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.

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

**Table 1. Definitions and acronyms**

Word or acronym	Definition
/TBD/	To be defined
Analytical Module (AM)	The slave QIAstat-Dx hardware module. It is controlled by the Operational Module (master) and performs measurements. Several Analytical Modules can be connected to one Operational Module.
Assay	An assay is a file. The content of the file describes what can be measured, how to measure and how to evaluate the raw measurement results.  Assay files provide all the information required to perform a specific assay.  Assays are identifiable by a unique numeric assay identifier (“Assay ID”), which is assigned at factory.
GUI	Graphical user interface
n.a.	not applicable
Operational Instance (OI)	Either a dedicated QIAstat-Dx hardware module (Operational Module) with an embedded PC or a standard PC. The QIAstat-Dx Application Software can be executed on both hardware platforms.
Operational Module (OM)	The dedicated QIAstat-Dx hardware module with an embedded PC able to run the QIAstat-Dx Application Software. This module controls the Analytical Modules.
Software Product	The Application Software for the Operational Module and the standard PC.
Standard PC	The PC on which the QIAstat-Dx Application Software runs.
System	The Operational Module and one up to four Analytical Modules.
User	A person who operates the QIAstat-Dx system in the intended way.

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# Hardware Interface and Lower Layer Protocol

QIAstat-Dx system has a 10/100 Ethernet port supporting the host communication interface. The communication through this port is configurable for the HL7 protocol.

## Physical layer

The QIAstat-Dx analyzer includes a standard RJ45 10/100 Ethernet port for networked computer communications.

## Transport layer

The QIAstat-Dx interface uses the TCP/IP standard.

## Lower-layer transport protocol

The lower layer protocol supported by the QIAstat-Dx instrument at the session level is the *Minimal Lower Layer Protocol* (MLLP) V1 (see [5]).

MLLP is a commonly used protocol and based on a minimalistic layer framing. It is recommended by IHE as HL7 V2.x protocol messaging (see [3], 2a, 2x). MLLP adds header and trailer characters to the message to identify the beginning and ending of the message because 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 TCP/IP transport protocol and do not require any 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).

QIAstat-Dx interface supports the UTF-8\* encoding.

\* UTF-8 is a character encoding capable of encoding all possible characters, or code points, in **Unicode**.

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# HL7 Protocol

The QIAstat-Dx instrument supports the connectivity to a LIS in a Central Laboratory scenario through the HL7 protocol over TCP/IP.

The LIS is responsible for translating a laboratory Work Order into a series of Work Order Steps (WOS) related to a specimen assigned to the QIAstat-Dx. By definition, a WOS is related to a single specimen.

The specimen in QIAstat-Dx is identified by the LIS with a unique ID, which is usually printed on the bar code label stuck to the specimen container.

## HL7 messaging

HL7 messages consist of a hierarchy of records, named segments in HL7, of various types, 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 further refining the basic attribute.

[4], Vol. 2x, C.2: HL7 Implementation Notes

## 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 in a sequence defined by the message specifications. For instance, the QIAstat-Dx uses 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 is identified by a segment ID, which is a unique 3-character code.

- **Field**

A field is a string of characters and is of a specific data type. Each field is identified by the segment it is in and its position within the segment; e.g., SPM-4 is the fourth field of the Specimen segment. A 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 2- or 3-letter code. Some data types are coded or composite types with several components. The applicable data type is listed and defined in each field definition.

- **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 be valued.

- **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 3-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.



When describing the syntax of the protocol, the conventions in Table 3 shall be used.

**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, there are two components that identify a message:

- **Message type:** a message type is an identifier of the purpose of a message. Every message must contain a message type as way to declare the purpose of the message.
- **Triggering event:** the triggering event is considered to be 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 a maximum record length. Outgoing messages can be of any size.

## Segment specifications

Section "HL7 Protocol" of this document describes the definition of HL7 messages. Each *Element Details* section contains a table listing the HL7 message elements communicated within the segment. These definition tables describe the data elements in the segments and characteristics of their usage.

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

**Table 4. Date element format**

Column	Description
Seg	Indicates the Segment code.
F.C	<p>Element Sequence Number: the ordinal position of the data within the segment. Format.            &lt;Field #&gt;[[.R&lt;repeat #&gt;].&lt;Component #&gt;][.&lt;Subcomponent #&gt;]]</p> <p>These elements are not always consecutive since 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.</p>
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 instrument/host usage.
LEN	Length of the element. The maximum number of characters that one occurrence of the data field may occupy.
DT	Data Type. The HL7 data type of the element. These are restrictions on the contents of the element as defined by the HL7 Standard.
RQ	<p>Optionality. Whether the element is required, optional, or conditional in a segment.</p> <p>The designations are:</p> <p><b>R</b> - required</p> <p><b>RE</b>- required if available</p> <p><b>O</b> - optional</p> <p><b>C</b> - conditionally required.</p> <p><b>X</b> – not supported or ignored in current version, it may be used in the future.</p>
Allowed Values	May include allowed or required values.
Comment/example	Comments about the element, if it may repeat, reference to a table of values which may be defined by HL7 (TBL#) or negotiated between the instrument and the LIS.

## Field structure

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

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## Field 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 concrete 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 characters can be used

## Character codes

All data is represented using UTF-8 encoding. UTF-8 is a multibyte character encoding for Unicode. The main characteristics of UTF-8 are that it can represent every character in the Unicode character set and it is backward-compatible with 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 (for example data type CE — “coded element” — may be composed of 3 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 any of the defined record types. It is fixed to 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. It shall be a single character excluding Latin-1 (13) (ASCII 13).
- **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. It shall be a single character, excluding Latin-1 (13) (ASCII 13) and the value used by the field delimiter.
- **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. It shall 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** separates 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 mainly uses a single character. The chosen character shall be different from Latin-1 (13) (ASCII 13) and the field, repeat, and component delimiter values.

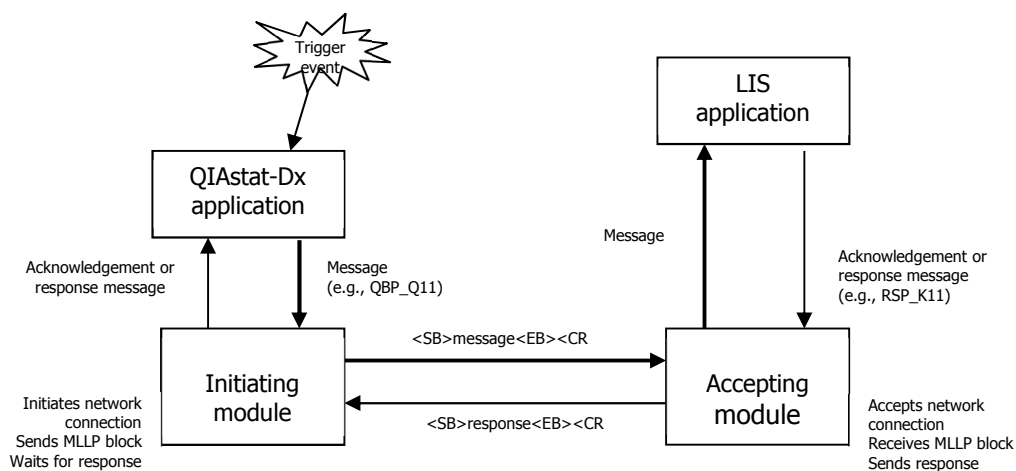
## Message transmission control

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

### Network guidelines

Following IHE recommendation, when QIAstat-Dx wants to initiate a transaction (to send a message) it will initiate the network connection. That is, QIAstat-Dx will try to establish a socket connection as a client to support the *WOS Query* and *WOS Status Change* transactions with the LIS, and QIAstat-Dx expects to receive the response to the query or acknowledgement messages through this open

connection. After this response, the initiating application can initiate a new transaction on the same connection. This process is illustrated in Figure 1.



**Figure 1. Trigger events and usage of network connections.**

From a transactional viewpoint a 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 which contain trigger events on both sides require at least two network connections between the Actors, one for each direction.

## Message initiation

According to the HL7 standard, each message shall begin with the MSH (message header) 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		
MSH	4	Sending Facility		HD		RE		
MSH	5	Receiving Application		HD		R		
MSH	6	Receiving Facility		HD		RE		
MSH	7	Date/Time Of Message	Date and time the message was generated	TS	26	R		
MSH	9	Message Type		MSG	15	R		
MSH	10	Message Control ID	Unique message identifier	ST	32	R		
MSH	11	Processing ID		PT	3	R	P	Production
MSH	12	Version ID	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 of the characters within the message.	ID	16	C	ASCII UNICODE UTF-8	
MSH	21	Message Profile Identifier	IHE Laboratory Profile	EI		O		

The sending application shall populate the MSH fields in the following manner:

- MSH-1 and MSH-2 use HL7-recommended values.
- MSH-3, MSH-4, MSH-5 and MSH-6 are filled with data as defined in the appropriate section.
- MSH-7 is filled with the date/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 shall refer to this ID.
- MSH-11 and MSH-12 are filled with the supported processing ID and version.

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## Acknowledge mode

The HL7 standard describes two acknowledge modes, Original and Enhanced. QIAstat-Dx interface 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 shall be always one and only one acknowledgement message coming back to the sending application, the *Application Level Acknowledgement Message* (called the Application ACK Message for short). The original mode is adequate for point-to-point interfaces, and it is the mode that IHE Laboratory transactions based on HL7 messages shall use. See more details in [3], Vol. 2a, 2.4.4.

## Create response message

Upon receipt of the message the receiving application makes an initial determination as to whether or not the message can be accepted by the receiver according to the following criteria: MSH-9 (message type and event code), MSH-11 (processing ID) and MSH-12 (version ID). If any of these checks fail, the system creates an ACK message with an Application Reject (AR) in MSA-1 acknowledgment code.

If the message passes the initial validation of the responding system then passes it to the receiving application, which processes the message. If the processing of the message is successful, then the receiving application generates an ACK message with a value of "AA" in MSA-1 acknowledgment code, otherwise the value included in the MSA-1 acknowledgment code is "AE" (Application Error) or AR. The receiving application passes the response message back to the responding system.

This applies to Work Order Status messages. The *Acknowledgement Code* (MSA-1) of the acknowledgment shall be one of the values listed in Table 6.

**Table 6. Acknowledgement Code values**

Value	Description	Comment
AA	Application Accept	The message has been accepted and processed successfully by the receiving application.
AE	Application Error	The message contains errors. It shall not be sent again without correcting the error. The response message shall provide additional error information.
AR	Application Reject	The message has been rejected by the receiving application. The failure to process the message is for reasons unrelated to its content or format (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 again to send the message later and, for most such problems, it is likely that the responding system will be able to accept the same message.

## Send response message

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

## ACK message

If the simple general acknowledgment (ACK) is used, there has been an error that precludes application processing, see Table 7. 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 for the general acknowledgment message, is always ACK.

**Table 7. ACK message segments**

Segment	Meaning	Usage
MSH	Message Header	R
MSA	Message Acknowledgement	R
[[ERR]]	Error	O

## Error segment

This segment is used to add error information and comments to acknowledgment messages, see 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	Identifies 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	Identifies the HL7 (communications) error code.	CWE		R		From HL7 Table 0357. See Supported values below
ERR	4	Severity	Identifies the severity of an application error.	ID		R		From HL Table 0516. See Supported values below.
ERR	8	User Message	Message description from 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 id	Rejection. The Processing ID is not supported.
203	Unsupported version id	Rejection. The Version ID is not supported.
204	Unknown key identifier	Rejection. The ID 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 codes

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., QIAstat-Dx) wants to send a message (initiate a transaction) it uses the current open network connection if available. Otherwise 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 the response to the query or the acknowledgement message in a defined time (response time should be a few seconds or less) then QIAstat-Dx will consider the message undelivered, and it terminates the transaction. QIAstat-Dx may initiate a new transaction to resend the message or send another message.

## Transmission scenarios

QIAstat-Dx protocol supports the following communication scenarios, as illustrated in

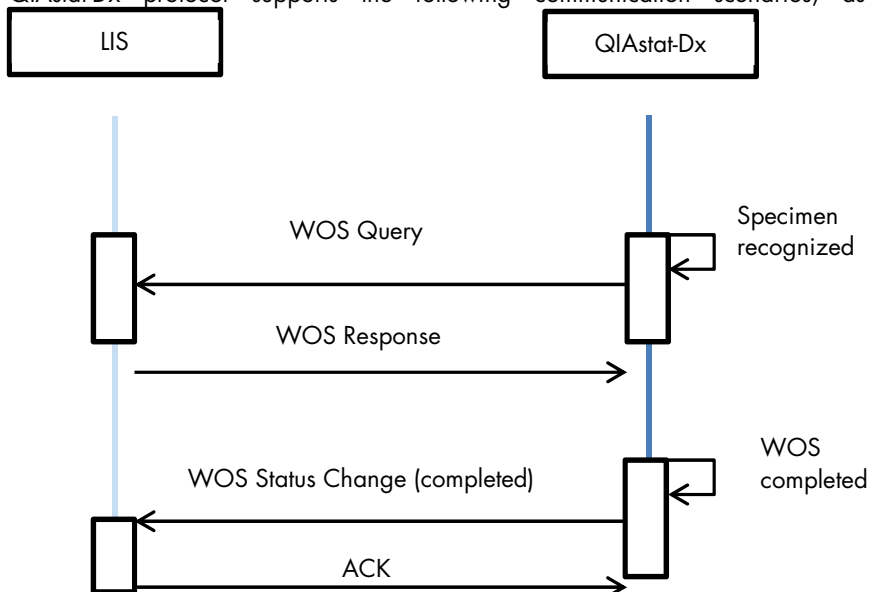


Figure 2.

- Work Order Step Query at specimen recognized (Query Mode or “Host Query”).
- Report of results through WOS Status Change messages.

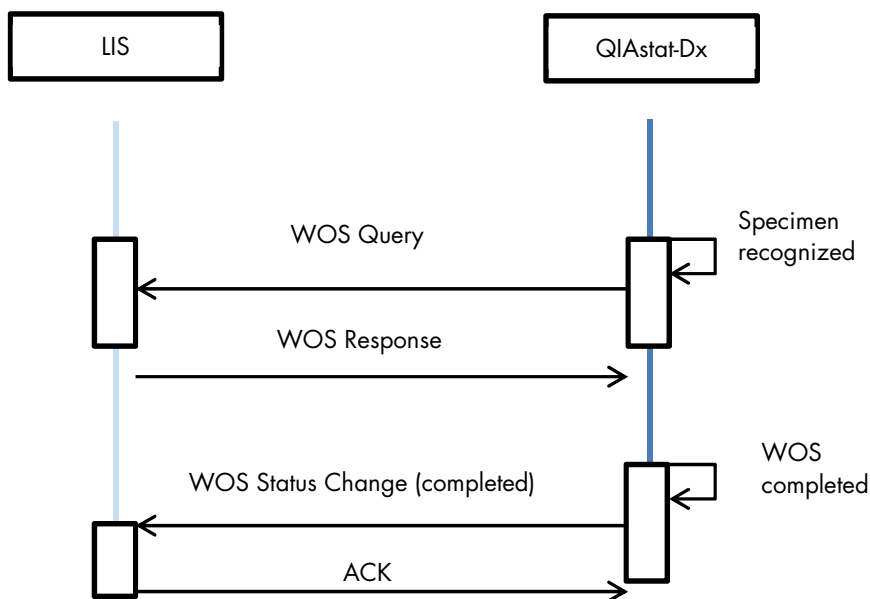


Figure 2. Process with QIAstat-Dx working in Query Mode.

## Work order step query

After the QIAstat-Dx working in query mode recognizes one specimen, it sends a “WOS Query Message”(QBP^Q11) with one Specimen ID to the LIS. The LIS replies with the response message (RSP^K11) containing one or more WOS for the specimen identified in the query, or an unknown specimen if the specimen is unknown to the LIS or there is no WOS for the specimen to be executed on the QIAstat-Dx. The transaction model is based on IHE LAB-22, see [3] and Figure 3.

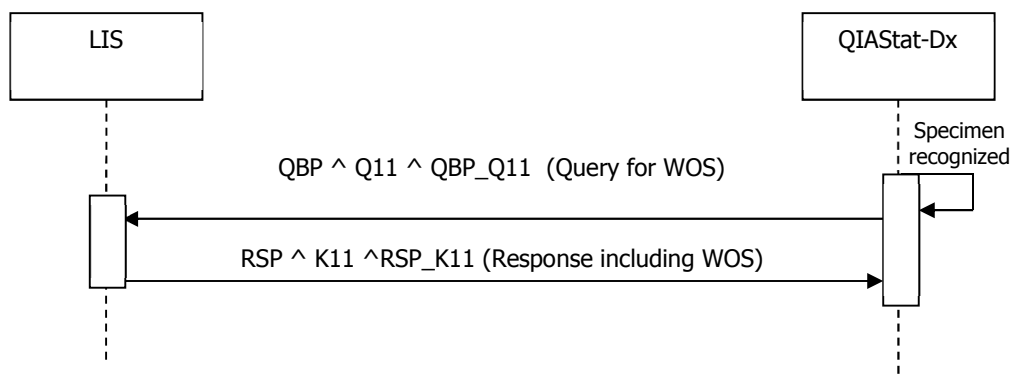


Figure 3. Work Order Step Query transaction.

### WOS status change (WOS complete)

This transaction is initiated when QIAstat-Dx reports the status of a WOS related to a specimen. The QIAstat-Dx generates and sends to the LIS a WOS Status Change message to send the tests results when the WOS is complete. The LIS should respond to the QIAstat-Dx using the acknowledgment message (ACK). This transaction is based on IHE LAB-23 and is illustrated in Figure 4.

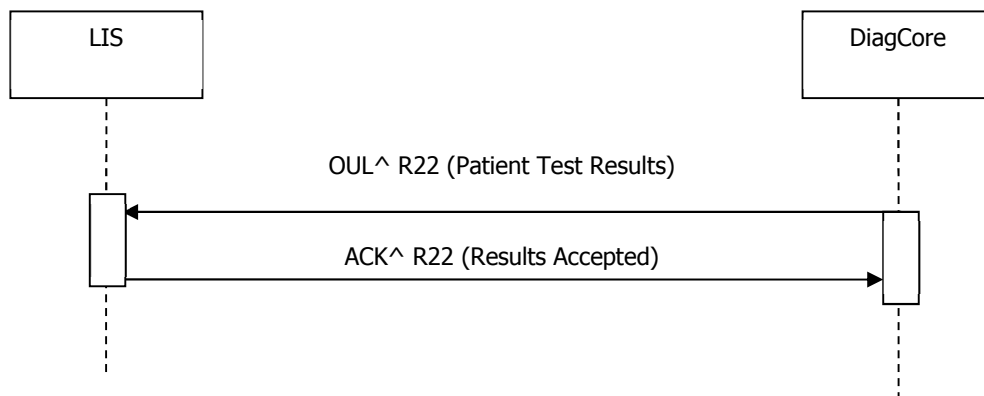


Figure 4. Unsolicited WOS Status Change transaction.

## Messages description

### WOS query message (QBP^Q11)

This message is based on the HL7 QBP^Q11 message and it is used to send from QIAstat-Dx to LIS the information concerning the specimen identification, see Table 11 and Table 12.

Table 11. QIAstat-Dx message structure

Segment	Meaning	Usage/comments
MSH	Message Header	R
[{SFT}]	Software Segment	Not used by QIAstat-Dx
QPD	Query Parameter Definition	R
RCP	Response Control Parameter	R
[DSC]	Continuation Pointer	Not used by QIAstat-Dx

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		R		
MSH	3.1	Sending Application Name		ST	50	R		QIAstat-Dx Device Name
MSH	4	Sending Facility		HD		RE		
MSH	4.1	Sending Facility Name		ST	50	RE		Sending Facility Name. Not used by the current version of QIAstat-Dx
MSH	5	Receiving Application		HD		R		
MSH	5.1	Receiving Application Name		ST	20	R		The host/LIS name.
MSH	6	Receiving Facility		HD		RE		
MSH	6.1	Receiving Facility Name		ST	50	RE		Receiving Dept. or Service. Not used by the current version of QIAstat-Dx .
MSH	7	Date/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 ID	Unique message identifier	ST	32	R		
MSH	11	Processing ID				R	P	(Production)
MSH	12	Version ID	Version of protocol			R	2.5	
MSH	18	Character Set	The character set specified in this field is used for the encoding of all of the characters within the message.	ID	16	C	ASCII UNICODE UTF-8	
MSH	21	Message Profile Identifier	IHE Laboratory Profile	EI		O		
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	2	Query Tag	Valued by the initiating system to identify the query, and used to match response messages to the originating query.	ST	32	R		Unique query identifier.
QPD	3	Specimen Identification	Specimen ID entered or obtained from the sample container bar code	ST	20	R		E.g., 9988776655
RCP	1	Query Priority		ID	1	R	I	Always set to I = Immediate
RCP	3	Response Modality		CE	60	R	R	Always set to R = Real time

## Example

```
MSH|^~\&|DiagCORE123456|MicroLab|MYLIS|Microbiology|20150421153246||  
QBP^Q11^QBP_Q11|M2015042115324601|P|2.5|||||UNICODE UTF-8<CR>  
QPD|WOS^Work Order Step|Q2015042115324601|9988776655<CR>  
RCP|I||R<CR>
```

## WOS query response (RSP^K11)

This message is based on the HL7 RSP\_K11 message and it is used to send from LIS to QIAstat-Dx the information concerning the test to perform 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 LIS will set in the response the "NF" flag in QAK-2 and no SPECIMEN section is required. Otherwise (QAK-2 is set "OK") the response shall include the SPECIMEN section including the WOS information.

Table 13. WOS query message structure

Segment	Meaning	Usage/comments
MSH	Message Header	R
[{SFT}]	Software Segment	Not used by QIAstat-Dx
MSA	Message Acknowledgement	R
[ERR]	Error	Not used by QIAstat-Dx
QAK	Query Acknowledgement	R
QPD	Query Parameter Definition	R. This segment echoes the Query Parameter Definition Segment sent in the requesting query.
{	--- SPECIMEN begin	
SPM	Specimen	C [1..1] Only one specimen is supported
[{OBX}]	Observation related to specimen	Not used by QIAstat-Dx
[{SAC}]	Specimen Container	Not used by QIAstat-Dx
[	--- PATIENT begin	
PID	Patient Identification	
[{OBX}]	Observation related to the patient	Not used by QIAstat-Dx
]	--- PATIENT end	
{	--- ORDER begin	
ORC	Common Order	R
{TQ1}	Timing/Quantity	R
	--- OBSERVATION REQUEST begin	
OBR	Observation Request	R

Segment	Meaning	Usage/comments
[ TCD ]	Test Code Details	Not used by QIAstat-Dx
[{	--- OBSERVATION begin	Not used by QIAstat-Dx
OBX	Observation/Result	
[ TCD ]	Test Code Detail	
[{ NTE }]	Notes and Comments (for Results)	
}]	--- OBSERVATION end	
	--- OBSERVATION REQUEST end	
[{	--- PRIOR RESULT begin	Not used by QIAstat-Dx
PV1	Patient Visit - previous result	
{	--- ORDER PRIOR begin	
ORC	Common order - previous result	
OBR	Order detail - previous result	
{	--- OBSERVATION PRIOR begin	
OBX	Observation/Result - previous result	
[{NTE}]	Comment of the result	
}	--- OBSERVATION PRIOR end	
}	--- ORDER PRIOR end	
}]	--- PRIOR RESULT end	
}	--- ORDER end	
}	--- SPECIMEN end	

**Table 14. Segments details**

Seg	F.C	Element name	Description	DT	LEN	RQ	Allowed values	Comment/ example	o
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/LIS name	
MSH	4	Sending Facility		HD		X			
MSH	4.1	Sending Facility Name		ST	50	X		Sending department or service	

Seg	F.C	Element name	Description	DT	LEN	RQ	Allowed values	Comment/ example
MSH	5	Receiving Application		ST	20	R		
MSH	5.1	Receiving Application Name		ST	20	R		Received QIAstat-Dx Device Name, must match value "Sending Application" 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/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 ID	Unique message identifier	ST	32	R		
MSH	11	Processing ID				R	P	Production
MSH	12	Version ID	Version of protocol			R	2.5	
MSH	18	Character Set	The character set specified in this field is used for the encoding of all of the characters within the message.	ID	16	C	ASCII 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 ID	From MSH-10 of associated message	ST	20	R		



Seg	F.C	Element name	Description	DT	LEN	RQ	Allowed values	Comment/ example
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 acknowledgement segment (QAK).	ST	32	R		Query Tag sent by the system in QPD-2. 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
QAK	2	Query Response Status		ID	2	R	OK or NF	OK = Data found NF = No data found
QPD	1	Message Query						
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	2	Query Tag	Valued by the initiating system to identify the query, and used to match response messages to the originating query	ST	32	R		Unique query identifier
QPD	3	Specimen Identification	Specimen ID obtained from the sample container bar code	ST	20	R		9988776655
SPM	1	Set ID	Identifies SPM segment instances in messages where the SPM segment repeats	SID		R	1	Only one specimen is supported
SPM	2	Specimen ID	Unique identifier for the specimen	EIP		R		
SPM	2.1.1	Specimen ID 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		

Seg	F.C	Element name	Description	DT	LEN	RQ	Allowed values	Comment/example
SPM	4.1	Specimen Type Identifier		ST	20	R		See "Sample (specimen) type codes". For instance, NASDR
SPM	4.2	Specimen Type Text		ST	199	O		Nasal Drainage
SPM	11	Specimen Role	This field indicates the role of the sample	CWE		R	P	P = Patient
SPM	17	Specimen Collection Date/Time	The date and time when the specimen was acquired from the source	DR		X		Not used by the current version of QIAstat-Dx
PID	1	Set ID	Identifies PID segment instances in messages where the PID segment repeats	SID		R	1	
PID	3	Patient Identifier List	Patient identification	ST		O		Patient I, if selected in QIAstat-Dx configuration
PID	5	Patient Name	Name of patient	CX		X		Not used by the current version of QIAstat-Dx
ORC	1	Order Control	Determines the function of the order segment	ID		R	N W	(1), Chapter 4.23.1. NW = New Order
ORC	2	Placer Order Number	Placer application's order number that identifies the individual order	EI		O		Not used by the current version of QIAstat-Dx
ORC	4	Order Group Number	Placer/filler order group number identifies the set of closely related orders for this specimen by the application.	EIP		X		Not used by the current version of QIAstat-Dx
ORC	9	Date/Time of Transaction	Date and time of the event that initiated the current transaction	TS		R		Required by the current version of QIAstat-Dx
TQ1	1	Set ID – TQ1	Sequence number. Defines the i'th occurrence of the associated record type	SI		R	1	
TQ1	9.1	Priority	Identifier of the urgency of the request	ID		R	R	R = Routine
OBR	1	Sequence Number	Defines the i'th occurrence of the associated record type	SI		R	1	

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 version of QIAstat-Dx
OBR	4	Universal Service Identifier	System defined identifier for the requested observation/test/battery	ID		R		
OBR	4.1	Universal Service Identifier, Code	USI Code	ST	20	R		This field contains the identification of the test panel to perform (ordered) on the specimen by QIAstat-Dx These codes are defined by QIAGEN.
OBR	11	Specimen action code	Action to be taken with respect to the specimen that accompany or precede this order	ID		R	A	Add ordered tests to the existing specimen. From (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 version of QIAstat-Dx

QIAstat-Dx supports only one specimen (SPECIMEN group) per message.

The message may include multiple orders (ORDER group) related to the specimen. All order requests for the specimen will be considered pertaining to a common order group, although the order group identification (ORC-4) is optional.

Each OBSERVATION REQUEST group defines the service request that match an QIAstat-Dx defined profile.

### Example: specimen know and WOS reported

```
MSH|^~\&|MYLIS|Microbiology|DiagCORE123456|MicroLab|20150421153248||  
RSP^K11^RSP_K11|M2015042115324802|P|2.5|||||UNICODE UTF-8<CR>  
MSA|AA|M2015042115324601<CR>  
QAK|Q2015042115324601|OK<CR>  
QPD|WOS^Work Order Step|Q2015042115324601|9988776655<CR>  
SPM|1|9988776655||NASDR^ Nasal  
Drainage|||||P|||||20150421141214<CR>  
PID|1||12345||SMITH^ADAM^^^^L|19800101|M<CR>  
ORC|NW|0123-1||0123|||||20150421141214<CR>  
TQ1|1|||||||R<CR>  
OBR|1|0123-1||DCPNEU01||||||A<CR>  
ORC|NW|0123-2||0123|||||20150421141214<CR>  
TQ1|1|||||||R<CR>  
OBR|1|0123-2||DCPNEU02||||||A <CR>
```

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

### Example: specimen unknown or no WOS for the specimen

```
MSH|^~\&|MYLIS|Microbiology|DiagCORE123456|MicroLab|201301121548||RS  
P^K11^RSP_K11|M2015042115324802|P|2.5|||||UNICODE UTF-8<CR>  
MSA|AA|M2015042115324601<CR>  
QAK|Q2015042115324601|NF<CR>  
QPD|WOS^Work Order Step|Q2015042115324601|9988776655<CR>
```

### Observation results message (OUL^R22)

This message is based on the HL7 OUL^R22 message and it is used to send information concerning the patient, specimen, status and test results of the WOS from QIAstat-Dx to LIS, see Table 15 and Table 16.

Table 15. QIAstat-Dx message structure

Segment	Meaning	Usage/comments
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
}	--- 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		QIAstat-Dx Device Name
MSH	4	Sending Facility		HD		O		
MSH	4.1	Sending Facility Name		ST	50	O		Sending Facility Name. Not used by the current version of QIAstat-Dx
MSH	5	Receiving Application		HD		R		
MSH	5.1	Receiving Application Name		ST	20	R		The host/LIS name
MSH	6	Receiving Facility		HD		O		

Seg	F.C	Element Name	Description	DT	LEN	RQ	Allowed values	Comment/Example
MSH	6.1	Receiving Facility Name		ST	50	O		Receiving Dept. or Service. Not used by the current version of QIAstat-Dx
MSH	7	Date/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 ID	Unique message identifier	ST	32	R		
MSH	11	Processing ID				R	P	Production
MSH	12	Version ID	Version of protocol			R	2.5	
MSH	18	Character Set	The character set specified in this field is used for the encoding of all of the characters within the message.	ID	16	C	ASCII UNICODE UTF-8	
MSH	21	Message Profile Identifier	IHE Laboratory Profile	EI		O		
PID	1	Set ID	Identifies PID segment instances in messages where the PID segment repeats	SID		R	1	
PID	3	Patient Identifier List	Patient identification	ST		O		Patient ID
PID	5	Patient Name	Name of patient			X		
SPM	1	Set ID	Identifies SPM segment instances in messages where the SPM segment repeats	SID		R	1	
SPM	2	Specimen ID	Unique identifier for the specimen	EIP		R		
SPM	2.1.1	Specimen ID	Entity Identifier	ST	20	R		The Specimen ID (Sample ID) assigned by the LIS
SPM	3	Specimen Parent ID	Unique identifier for the specimen	EIP		O		
SPM	3.1.1	Specimen Parent ID	Entity Identifier	ST	20	O		The Specimen ID internally generated by QIAstat-Dx, if available, known as "Instrument Specimen ID"

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		[1] Chapter 7.18.4 For instance, NASDR
SPM	4.2	Specimen Type Text		ST	199	O		For instance, Nasal Drainage
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/battery	ID		R		
OBR	4.1	Universal Service Identifier, Code	USI Code	ST	20	R		This field contains the identification of the test panel to perform (ordered) on the specimen by QIAstat-Dx.  These codes are defined by QIAGEN.
OBR	16	Ordering Provider	The provider who ordered the test	ID		O		
OBR	25	Result Status		ST	20	R	F	[1] Chapter 4.5.3.25. F = Final Results
ORC	1	Order Control	Determines the function of the order segment	ID		R	SC	[1] Chapter 4.23.1. SC = Status Changed
ORC	2	Placer Order Number	Placer application's order number that identifies the individual order	EI		O		
ORC	2.1	Identifier		ST	16	O		Not used by the current version of QIAstat-Dx

Seg	F.C	Element Name	Description	DT	LEN	RQ	Allowed values	Comment/Example
ORC	4	Order Group Number	Placer/filler order group number identifies the set of closely related orders for this specimen by the application.	EIP		X		Not used by the current version of QIAstat-Dx.
ORC	9	Date/Time of Transaction	Date and time of the event that initiated the current transaction	TS		R		
OBX	1	Set ID	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 ID	EIP		R		
	3.1		Test identifier code (LOINC)	ST				
	3.2		The test name (LOINC)	ST				
	3.3		The coding system (LOINC)	ST				
	3.4		The alternate test identifier	ST				
	3.5		The alternate test name	ST				
	3.6		The alternate coding system	ST				
OBX	4	Observation Sub-Identifier	Identifier of secondary results in OBX segments with the same observation ID	EIP		R		Allows OBX segments that contain information pertaining to the same identified microorganism to be distinguish
	4.1		Analyte/organism name	ST				Name of the analyte or organism
OBX	5	Observation Value				R		
	5.1		Qualitative or quantitative result	ST		R	Numeric, "POSITIVE", "NEGATIVE", "EQUIVOCAL", "NOT APPLICABLE", "UNDETERMINED"	Qualitative results use SNOMED coding system. See 5.2
OBX	6	Units		ST		O		If quantitative results carry unit



Seg	F.C	Element Name	Description	DT	LEN	RQ	Allowed values	Comment/Example
OBX	8	Abnormal Flags	Indicates the normalcy status of the result.	ST		X		
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)
OBX	16	Responsible Observer	The professional who performed the observation	XCN		R		
	16.1	Observer ID		ST		R		Reports the operator (user) ID that performed the test.
	16.2	Family Name		FN		R		Reports the operator (user) name that performed the test
OBX	18	Equipment Instance Identifier	Serial number of QIAstat-Dx analyzer	ST		R		Instrument serial number
OBX	19	Date/Time of Analysis	Measurement date time	TS		R		

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

## Example

```
MSH|^~\&|DiagCORE123456|MYLIS||20150421153246||OUL^R22^OUL_R22|M201
5042115324601|P|2.5|||||UNICODE UTF-8<CR>
PID|1||12345<CR>
SPM|1|9988776655||NASDR^Nasal
Drainage|||||P|||||20150421141214<CR>
OBR|1|0123-1|DCPNEU01|||||||||||||F<CR>
ORC|SC|0123-1||0123|||||20150421141214<CR>
OBX|1|CE|76078-5^Influenza virus A RNA^LN^FluAV^Influenza virus
A^STAT-DX
|FluAV|10828004^POSITIVE^SCT|||||F||||1201||Supervisor01^José
Hucha|20150421141234<CR>
OBX|2|NM|^^^FluAV.Ct^Influenza virus A Ct^STAT-
DX|FluAV|32.5|||||F<CR>
OBX|3|NM|^^^FluAV.EndPoint^Influenza virus A End Point^STAT-
DX|FluAV&EndPoint|325|||||F<CR>
OBX|4|CE|76087-6^Parainfluenza virus 4
RNA^LN^ParaFluV4^Parainfluenza virus^STAT-
DX|ParaFluV4|10828004^POSITIVE^SCT|||||F<CR>
OBX|5|NM|^^^ParaFluV4.Ct^Parainfluenza virus 4 Ct^STAT-
DX|ParaFluV4|28.1|||||F<CR>
OBX|6|NM|^^^ParaFluV4.EndPoint^Parainfluenza virus 4 EndPoint^STAT-
DX|ParaFluV4|401|||||F<CR>
OBX|7|CE|39528-5^Adenovirus DNA^LN^AdeV^Adenovirus^STAT-DX
|AdeV|260385009^NEGATIVE^SCT|||||F<CR>
OBX|8|NM|^^^AdeV.Ct^Adenovirus Ct^STAT-DX|AdeV|NA|||||F<CR>
OBX|9|NM|^^^AdeV.EndPoint^Adenovirus End Point^STAT-
DX|AdeV|1|||||F<CR>
```

## Acknowledgment message (ACK^R22)

QIAstat-Dx expects to receive from LIS a General Acknowledgment message (ACK^R22) as response to the Observation Results Message, see Table 17 and Table 18.

**Table 17. LIS message structure**

Segment	Meaning	Usage
MSH	Message Header	R
MSA	Message Acknowledgement	R
[ERR]	Error	O

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/LIS name
MSH	5	Receiving Application		ST	20	R		
MSH	5.1	Receiving Application Name		ST	20	R		QIAstat-Dx Device Name, must match value "Sending Application" of the acknowledged message (MSH, Field 3.1)
MSH	7	Date/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 ID	Unique message identifier	ST	32	R		
MSH	11	Processing ID				R	P	Production
MSH	12	Version ID	Version of protocol			R	2.5	
MSH	18	Character Set	The character set specified in this field is used for the encoding of all of the characters within the message.	ID	16	C	ASCII 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 ID	From MSH-10 of associated message	ST	20	R		
ERR	3	HL7 Error Code				O		
ERR	4	Severity				O		

---

### Example

```
MSH|^~\&|MYLIS|Microbiology|DiagCORE123456|MicroLab|201301121548||AC  
K^R22^ACK|M2015042115324802|P|2.5|||||UNICODE UTF-8<CR>  
MSA|AA|M2015042115324601<CR>
```

# Appendix

## Qualitative result codes

For laboratory-based reporting, SNOMED is recommended for OBX-5 when results are coded and CE data types are used. Table 19 provides a list of SNOMED codes for qualitative results ("Ordinal Results") related to the Presence (Positive)/Absence (Negative) findings.

Table 19. SNOMED codes

Code	Name	Code system	IsPositive
10828004	POSITIVE (qualifier value)	SNOMED	Y
260385009	NEGATIVE (qualifier value)	SNOMED	N
373068000	UNDETERMINED (qualifier value)	SNOMED	N
42425007	EQUIVOCAL (qualifier value)	SNOMED	N
385432009	NOT APPLICABLE (qualifier value)	SNOMED	N

See <http://www.snomedbrowser.com/Codes/Details/260245000>.

## Device status codes

Table 20 provides a list all the device status codes that QIAstat-Dx may report in the condition\_cdof the Device Status Object. QIAstat-Dx uses values from excerpted from [2], Table 25.

Table 20. Device status codes

Code	Value	Code system	Description
B	Busy	POCT1A	All analytical modules of QIAstat-Dx are in the process of running a test or otherwise occupied and unable to start a new test.
L	Locked	POCT1A	The Device has been locked so that it cannot be used to run tests (i.e., by a Device directive from the Observation Reviewer).
P	Partial Lock	POCT1A	One or more analytic modules have been disabled for this Device (i.e., by a Device directive from the Observation Reviewer).
R	Ready	POCT1A	The Device is ready to process tests.
E	Error	STAT-DX	The device is in an error condition and cannot process any test.

## Sample (specimen) type codes

Sample types are coded in QIAstat-Dx messages using values defined in *Table 0487 – Specimen Type* [1], Chapter 7.18.4; also see Table 21.

**Note:** this table replaces *Table 0070 – Specimen Source codes* in [1], Chapter 7.18.2.

**Table 21. 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	AUTOCL	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	Biospy, 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/Surgical
DBITE	Bite, Dog	SPS	Environmental, Spore Strip	NGS	Site, Naso/Gastric

Value	Description
HBITE	Bite, Human
IBITE	Bite, Insect
RBITE	Bite, Reptile
BLEB	Bleb
BLIST	Blister
BBL	Blood bag
BPU	Blood product unit
HBLUD	Blood, Autopsy
CSVR	Blood, Cell Saver
FBLOOD	Blood, Fetal
MBLD	Blood, Menstrual
WB	Blood, Whole
BOIL	Boil
BON	Bone
BOWL	Bowel contents
BRTH	Breath (use EXHLD)
BRSH	Brush
EBRUSH	Brush, Esophageal
BRUS	Brushing
GASBR	Brushing, Gastric
BUB	Bubo
BULLA	Bulla/Bullae
BRN	Burn
CALC	Calculus (=Stone)
CARBU	Carbuncle
CAT	Catheter
CSITE	Catheter Insertion Site
CTP	Catheter tip
ANGI	Catheter Tip, Angio
ARTC	Catheter Tip, Arterial
CVPT	Catheter Tip, CVP
ETTP	Catheter Tip, Endotracheal

Value	Description
STER	Environmental, Sterrad
ENVIR	Environmental, Unidentified Substance
WWA	Environmental, Water
DEION	Environmental, Water (Deionized)
WWT	Environmental, Water (Tap)
FAW	Environmental, Water (Well)
WWO	Environmental, Water (Ocean)
EWHI	Environmental, Whirlpool
EXUDE	Exudate
FLT	Filter
FIST	Fistula
FLUID	Fluid
FGA	Fluid, Abdomen
CSMY	Fluid, Cystostomy Tube
ACNFLD	Fluid, Acne
FLU	Fluid, Body unsp
CST	Fluid, Cyst
HYDC	Fluid, Hydrocele
IVFLD	Fluid, IV
JNTFLD	Fluid, Joint
KIDFLD	Fluid, Kidney
LSAC	Fluid, Lumbar Sac
FLD	Fluid, Other
PCFL	Fluid, Pericardial
RENC	Fluid, Renal Cyst
FRS	Fluid, Respiratory
SHUNF	Fluid, Shunt
SNV	Fluid, synovial (Joint fluid)
GAST	Fluid/contents, Gastric
FUR	Furuncle
GAS	Gas
EXG	Gas, exhaled (=breath)

Value	Description
NEPH	Site, Nephrostomy
PIS	Site, Pacemaker Insertion
PDSIT	Site, Peritoneal Dialysis
PDTS	Site, Peritoneal Dialysis Tunnel
PINS	Site, Pin
POPLV	Site, Popliteal Vein
SHU	Site, Shunt
TRAC	Site, Tracheostomy
SKN	Skin
TZANC	Smear, Tzanck
GSOL	Solution, Gastrostomy
ILLEG	Source of Specimen Is Illegible
OTH	Source, Other
UDENT	Source, Unidentified
USPEC	Source, Unspecified
SPRM	Spermatozoa
SPT	Sputum
SPTC	Sputum - coughed
SPTT	Sputum - tracheal aspirate
DCS	Sputum, Deep Cough
SPUTIN	Sputum, Inducted
SPUT1	Sputum, Simulated
SPUTSP	Sputum, Spontaneous
STONE	Stone, Kidney
STL	Stool = Fecal
SUP	Suprapubic Tap
SUTUR	Suture
TISS	Tissue
TISU	Tissue ulcer
ACNE	Tissue, Acne
HERNI	Tissue, Herniated
SCAR	Tissue, Keloid (Scar)



Value	Description
FOLEY	Catheter Tip, Foley
HEMAQ	Catheter Tip, Hemaquit
HEMO	Catheter Tip, Hemovac
IDC	Catheter Tip, Indwelling
INTRD	Catheter Tip, Introducer
IVCAT	Catheter Tip, IV
MAHUR	Catheter Tip, Makurkour
SCLV	Catheter Tip, Subclavian
SPRP	Catheter Tip, Suprapubic
SWGZ	Catheter Tip, Swan Gantz
VASTIP	Catheter Tip, Vas
VENT	Catheter Tip, Ventricular
GROSH	Catheter, Groshong
HIC	Catheter, Hickman
PORTA	Catheter, Porta
SPRPB	Catheter Tip, Suprapubic
TLC	Catheter Tip, Triple Lumen
CLIPP	Clippings
COL	Colostrum
CNJT	Conjunctiva
CNJT	Conjunctiva
CNJT	Conjunctiva
LENS1	Contact Lens
LENS2	Contact Lens Case
CYST	Cyst
BCYST	Cyst, Baker's
ICYST	Cyst, Inclusion
PILOC	Cyst, Pilonidal
RENALC	Cyst, Renal
DIA	Dialysate
DISCHG	Discharge

Value	Description
IHG	Gas, Inhaled
GENV	Genital vaginal
GRAFT	Graft Site
POPGS	Graft Site, Popliteal
POPLG	Graft, Popliteal
GRANU	Granuloma
IMP	Implant
INFIL	Infiltrate
INS	Insect
IUD	Intrauterine Device
IT	Intubation tube
KELOI	Lavage
LAVG	Lavage, Bronchial
LAVGG	Lavage, Gastric
LAVGP	Lavage, Peritoneal
LAVPG	Lavage, Pre-Bronch
LESN	Lesion
ORL	Lesion, Oral
PENIL	Lesion, Penile
LIQO	Liquid, Other
LIQ	Liquid, Unspecified
MASS	Mass
SMM	Mass, Sub-Mandibular
MUCOS	Mucosa
MUCUS	Mucus
NEDL	Needle
NODUL	Nodule(s)
CYN	Nodule, Cystic
ORH	Other
PACEM	Pacemaker
PLAN	Plant Material

Value	Description
TRANS	Transudate
ETTUB	Tube, Endotracheal
GT	Tube, Gastric
TUBES	Tubes
IVTIP	Tubing Tip, IV
TUMOR	Tumor
DEC	Ulcer, Decubitus
UR	Urine
URT	Urine catheter
URC	Urine clean catch
URINB	Urine, Bladder Washings
URINC	Urine, Catheterized
USCOP	Urine, Cystoscopy
URINM	Urine, Midstream
URINN	Urine, Nephrostomy
URINP	Urine, Pedibag
RANDU	Urine, Random
VITF	Vitreous Fluid
VOM	Vomitus
WRT	Wart
WASH	Wash
WASI	Washing; e.g., bronchial washing
WAT	Water
WEN	Wen
WICK	Wick
WORM	Worm
WND	Wound
WNDA	Wound abscess
WNDD	Wound drainage
WNDE	Wound exudate
PUNCT	Wound, Puncture

Value	Description
DIV	Diverticulum
DRN	Drain

Value	Description
PLAS	Plasma
PLB	Plasma bag

Value	Description

In addition the following sample types are used in the QIAstat-Dx and shall be coded according to the information in Table 22.

**Table 22. Sample type codes**

Code	Name
TBD	Swab
TBD	UTM
TBD	Stool

# [PROVISIONAL]

Table 23. Data dictionary notes

#	Element	Type	Comments
0	control_id Message Control ID		The message control IDF may be implemented by the Sw in different ways (counter, timestamp, globally unique identifier, etc.). Although this identifier should be unique in the conversation scope, for traceability reasons it is recommended that the identifier to be unique per device. For instance, a current date and time stamp: "M2015042115324801".
1	device_id	Fixed per 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 QIAstat-Dx 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. See <a href="https://standards.ieee.org/develop/regauth/tut/eui64.pdf">https://standards.ieee.org/develop/regauth/tut/eui64.pdf</a>
2	vendor_id	Fixed	"STAT-DX" If a vendor identifier is supplied then it should be a registered identifier. Contact CLSI to register an identifier as a POCT1 vendor code identifier for QIAGEN. See: <a href="http://clsi.org/">http://clsi.org/</a> and <a href="mailto:standard@clsi.org">standard@clsi.org</a>
3	manufacturer_name	Fixed	"STAT-DX"
4	model_id	Fixed	"QIAstat-Dx", instrument model identifier.
5	serial_id	Fixed per device	QIAstat-Dx instrument serial number (unique serial identifier).
6	hw_version	Fixed	Indicates the QIAstat-Dx current HW version; e.g., "QIASTAT-DX_HW_A"
7	sw_version	Fixed	Indicates the QIAstat-Dx current SW version; e.g., "1.0.00"
8	device_name	Configurable	This is a convenient name for the device; e.g., "QIAstat-DxLab4"). Parameter to be set in the LIS or instrument configuration.
9	LIS application	Configurable	The identifier of the LIS instance. Parameter to be set in the LIS configuration.
10	operator_id		The operator's user name
11	password		
12	permission_level_cd		[2] Table 10 defines a default set of codes (see below) but vendors may extend this set, following the rules for the CV data type.
13	Ordering physicians I.D.		

## Test report

<b>Sample ID:</b> ABC12345	
<b>Patient ID:</b> ABCD12345	
<b>Assay Name:</b> QIAstat-Dx Pneumonia 1	
<b>Sample Type:</b> Sputum	
<b>External Control:</b> NO	
<b>Controls:</b> Passed	
<b>Result Details</b>	<b>Ct/End Point Fluorescence</b>
Influenza A: Positive	32.5/325
Parainfluenza Virus 4: Positive	28.1/401
Adenovirus: Negative	NA/2
Coronavirus NL63: Negative	NA/1
Coronavirus 229E: Negative	NA/1
Coronavirus OC43: Negative	NA/3
Coronavirus HKU1: Negative	NA/2
Parainfluenza 1: Negative	NA/1
Parainfluenza 2: Negative	NA/1
Parainfluenza 3: Negative	NA/3
Human Metapneumovirus: Negative	NA/2
Mycoplasma Pneumoniae: Negative	NA/1
Respiratory Syncytial virus: Negative	NA/1
Chlamydia Pneumoniae: Negative	NA/3
Streptococcus pneumoniae: Negative	NA/3
Haemophilus influenzae: Negative	NA/3
Klebsiella pneumoniae: Negative	NA/3
<b>Controls</b>	
Internal process Control: Pass	33/350
Internal Control: Pass	31/360
<b>Test Details</b>	
<b>User:</b> John Smith	<b>Test Status:</b> Completed
<b>Cartridge S/N:</b> 12345566	<b>Error Code:</b> None
<b>Cartridge expiration date:</b> 20/12/2014	<b>Test Start Date:</b> 10/6/2014 09h00
<b>ANALYTICAL MODULE S/N:</b> AFGR45678	<b>Test End Date:</b> 10/6/2014 9h30
<b>User Notes:</b> AAA BBB CCC	



## QIAstat-Dx Respiratory Panel



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### TEST REPORT

Patient ID                      Sample ID 12                      Test Time                      2019-02-18 17:24

Detected                      + Influenza A H1N1 pdm09  
   + *Mycoplasma pneumoniae*

User                      administrator                      Test Status                      ✓ Completed  
   Internal Controls                      ✗ Failed

### RESULT DETAILS

Ct / EP

Viruses	Invalid	Adenovirus	- / -
	Invalid	Coronavirus 229E	- / -
	Invalid	Coronavirus HKU1	- / -
	Invalid	Coronavirus NL63	- / -
	Invalid	Coronavirus OC43	- / -
	Invalid	Human Metapneumovirus A+B	- / -
	Invalid	Influenza A H1	- / -
	+ Detected	Influenza A H1N1 pdm09	35.0 / 7,444
	Invalid	Influenza A H3	- / -
	Invalid	Influenza B	- / -
	Invalid	Parainfluenza virus 1	- / -
	Invalid	Parainfluenza virus 2	- / -
	Invalid	Parainfluenza virus 3	- / -
	Invalid	Parainfluenza virus 4	- / -
	Invalid	Respiratory Syncytial Virus A+B	- / -
	Invalid	Rhinovirus/Enterovirus	- / -
Bacteria	Invalid	<i>Bordetella pertussis</i>	- / -
	Invalid	<i>Chlamydia pneumoniae</i>	- / -
	+ Detected	<i>Mycoplasma pneumoniae</i>	36.9 / 2,841
Controls	Not detected	IC	- / -

### TEST DETAILS

User administrator                      Cartridge SN 180004016                      SN Operational module 0  
Assay RP                      Cartridge LOT 180004                      SN Analytical module 1004  
Sample UTM                      Expiration Date 2018-07-18                      Error code None

Figure 5. Example test report.

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**Notes**

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**Notes**

