HL7 LIMS Interface Specifications

Introduction

This document is intended for use by Host Interface programmers and the QIAGEN Field Service Specialists supporting the system and describes the HL7 interface between LIMS and QIAGEN® instruments. QIAGEN instruments are managed by a middleware called QIAlink™ that is provided by QIAGEN.

Document revision history

Version	Revision date	Changes
1.0	April 2013	First version

This document applies to QIAlink Software version 1.0.0.

HL7 interface description

Reference to standard

The interface is based on version 2.4 of the Health Level Seven (HL7) Standard for electronic data exchange in all healthcare environments.

This interface implements only a small subset of the HL7 Standard, namely the OML message for ordering of tests and the OUL message for results transmission. The contents of both of these messages as used by this interface are described in detail in the following sections.

Transport layer

Message transfer is based on the TCP/IP protocol. The Minimal Lower Layer Protocol (MLLP) is used to separate the messages:

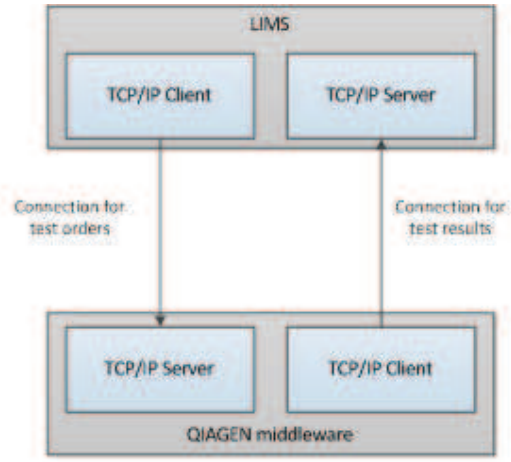
Header	Payload	Trailer
0x0B	HL7 message	0x1C 0x0D

For the transmission of test orders from LIMS to the middleware, the middleware acts as server and the LIMS acts as client.

For the transmission of results from the middleware to LIMS, the LIMS acts as server and the middleware acts as client.

This means that two TCP/IP connections are required, see figure below.

It is possible that multiple clients may connect to the LIMS TCP/IP server. This depends on the number of connected instrument types.



Message structure

The following sections explain the details of the messages that are used for test ordering and results transmission.

The following abbreviations are used in the tables describing the message structure:

Abbreviation	Description
M	Mandatory For messages from LIMS to the middleware, this means that the component must be included in the message. For messages from the middleware to LIMS, this means that the component will always be present.
O	Optional For messages from LIMS to the middleware, this means that the component is not required by the middleware, but will be evaluated, if present. For messages from the middleware to LIMS, this means that the component will only be present under certain circumstances.
N	Not supported For messages from LIMS to the middleware, this means that the component will be ignored by the middleware if present. For messages from the middleware to LIMS, this means that the component will never be used.

Request

The LIMS uses the OML^O21 message to order tests to be performed on QIAGEN instruments.

The message complies with the following structure:

MSH { SAC { ORC OBR } }

All additional components that comply with the message structure defined in HL7 2.4 will be ignored by the middleware.

The tables below specify the details of each message component.

Table.1 MSH for OML messages

Seq.	M/O/N	Element name	Content
1	M	Field separator	Shall be defined by the LIMS in accordance with HL7 2.4
2	M	Encoding characters	Shall be defined by the LIMS in accordance with HL7 2.4
3	O	Sending application	Can be used to identify the sending system
4	O	Sending facility	Can be used to identify the sending system
5	M	Receiving application	Shall be set to QIAlink Messages with a different or no receiving application will be ignored.
6	N	Receiving facility	Not used
7	M	Date/time of message	Timestamp of when the message was created by the sending system. Format: YYYYMMDDHHMMSS
8	N	Security	Not used
9	M	Message type	Always OML^O21
10	M	Message control ID	Unique identifier for each message
11	M	Processing ID	<processing ID>^<processing mode> Only messages with the processing ID P will be processed, all other messages will be ignored. The processing mode is not evaluated by the middleware.

Table continued on next page.

Table 1. Continued

Seq.	M/O/N	Element name	Content
12	M	Version ID	<version ID (ID)> ^ <internationalization code (CE)> ^ <internal version ID (CE)> Only the version ID is evaluated by the middleware, the internationalization code and internal version ID are ignored. The only supported version ID is 2.4.
13–17	N	Misc.	Not used
18	O	Character set	The following character sets are supported: • ASCII • UNICODE If no character set is defined, UNICODE is assumed
19–21	O	Misc.	Not used

Table 2. SAC for OML messages

Seq.	M/O/N	Element name	Content
1	N	External accession identifier	Not used
2	N	Accession identifier	Not used
3	M	Container identifier	ID corresponding to barcode on the sample
4	N	Primary (parent) container identifier	Not used
5	N	Equipment container identifier	Not used
6	M	Specimen source	Specifies the specimen either by using one of the predefined codes from the HL7 2.4 specification or a customer defined string
7–44	N	Misc.	Not used

Table 3. ORC for OML messages

Seq.	M/O/N	Element name	Content
1	M	Order control	Only NW (New order) is supported, all others will be ignored.
2	O	Placer order number	Will not be evaluated by the middleware.
3	O	Filler order number	Will not be evaluated by the middleware.
4–25	N	Misc.	Not used

Table 4. OBR for OML messages

Seq.	M/O/N	Element name	Content
1–3	N	Misc.	Not used
4	M	Universal service identifier	Identifier of required test
5–47	N	Misc.	Not used

The middleware will acknowledge each OML^O21 message by sending a corresponding ORL^O22 message.

The acknowledgement confirms receipt of the message; it does not imply that the message will be processed successfully.

Results

Message structure

The middleware uses the OUL^R21 message to report results to LIMS.

The message complies with the following structure:

MSH { SAC OBR {[OBX]} }

Note: the OBX component can be repeated to report results in different units.

Table 5. MSH for OUL messages

Seq.	M/O/N	Element name	Content
1	M	Field separator	Always |
2	M	Encoding characters	Always ^~\&
3	M	Sending application	Always QIAlink
4	N	Sending facility	Not used
5	M	Receiving application	Always LIMS
6	N	Receiving facility	Not used

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Table. 5 Continued

Seq.	M/O/N	Element name	Content
7	M	Date/time of message	Timestamp of when the message was created by the sending system Format: YYYYMMDDHHMMSS
8	N	Security	Not used
9	M	Message type	Always OUL^R21
10	M	Message control ID	Unique identifier for each message
11	M	Processing ID	Always P
12	M	Version ID	Always 2.4
13–17	N	Misc.	Not used
18	M	Character set	Always UNICODE
19–21	N	Misc.	Not used

Table 6. SAC for OUL messages

Seq.	M/O/N	Element name	Content
1	N	External accession identifier	Not used
2	N	Accession identifier	Not used
3	M	Container identifier	ID corresponding to barcode on the sample
4–44	N	Misc.	Not used

Table 7. OBR for OUL messages

Seq.	M/O/N	Element name	Content
1	M	Set ID - OBR	Ascending IDs starting with 1
2–3	N	Misc.	Not used
4	M	Universal service identifier	Target identifier
5–6	N	Misc.	Not used
7	M	Observation date/time	Date when result was released from the instrument software Format: YYYYMMDDHHMMSS
8–24	N	Misc.	Not used
25	M	Result status	Supported values: F — Analysis was successful; valid results are available. X — A problem or error occurred during analysis; no valid results could be produced.
26–33	N	Misc.	Not used
34	O	Technician	Contains the identification of the user who released the results. This field is only used if operator identification is supported by the software of the instrument used.
35–47	N	Misc.	Not used

Table. 8 OBX for OUL messages

Seq.	M/O/N	Element name	Content
1	M	Set ID - OBX	Ascending IDs starting with 1
2	M	Value type	Supported values: NM — Numeric result for quantitative analyses ST – String result for qualitative analyses
3	M	Observation identifier	Target identifier
4	N	Observation Sub-ID	Not used
5	M	Observation value	Result of the analysis. For possible values, refer to the "Result values" section.
6	O	Units	Unit of result value. Only used if the result is numeric, otherwise the unit field is left empty.
7–10	N	Misc.	Not used
11	M	Observation result status	Always F If the analysis was not successful, the complete OBX section will be omitted.
12–19	N	Misc.	Not used

After each result message, the LIMS acknowledges receipt with an ACK message.

Result values

This section describes the possible values that can occur as OBX Observation value.

Quantitative analyses

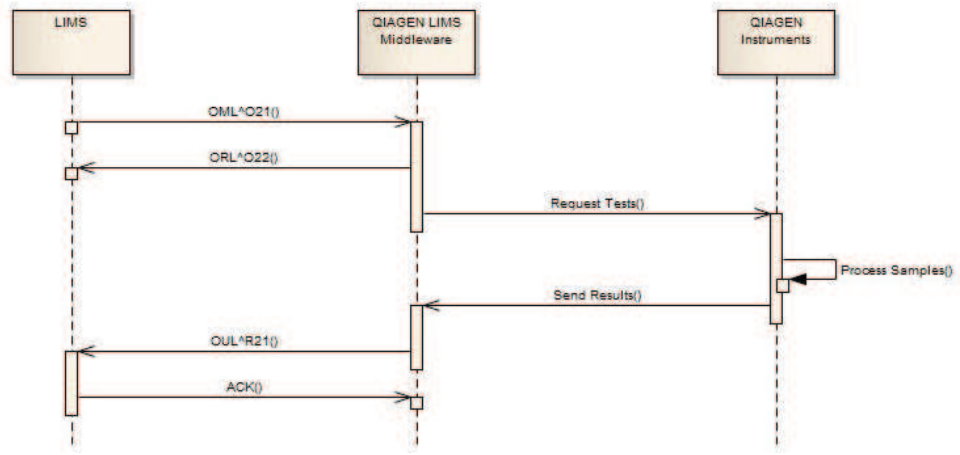
- String "TargetNotDetected": No viral load could be defined.
- Numeric value in scientific format (e.g., 1.23E+02): viral load represented in scientific format. Decimal separator is always ".".
- Numeric value in decimal format (e.g., 123.456): viral load represented in decimal format. Decimal separator is always ".".

Qualitative analyses

- String “TargetNotDetected”: No PCR reaction took place.
- String “TargetDetected”: A PCR reaction took place.

Dynamic behavior

The figure below shows the message flow from test order to transmission of results.



Examples

Two quantitative HCV/HIV assays for same sample

Request (LIMS → middleware)

MSH|^~\&|LIMS||QIAlink||20121101152100||OML^O21|555|P|2.4||||||UNICODE|

SAC|||123|||BLD|

ORC|NW|

OBR||||HIV|

ORC|NW|

OBR||||HCV|

Results (middleware → LIMS)

MSH|^~\&|QIAlink||LIMS||20121101171000||OUL^R21|476|P|2.4||||||UNICODE|

SAC|||123|||BLD|

OBR|1|||HIV|||20121101165505|||||||||||||||||F|||||||||testuser|

OBX|1|NM|HIV||5.00E-01|copies/ml|||||F|

SAC|||123|||BLD|

OBR|1|||HCV|||20121101165505|||||||||||||||||F|||||||||testuser|

OBX|1|NM|HCV||4.00E+02|copies/ml|||||F|

Qualitative multiplex influenza A and B assays for same sample

Request (LIMS → middleware)

MSH|^~\&|LIMS||QIAlink||20121101152100||OML^O21|555|P|2.4||||||UNICODE|

SAC|||123|||BLD|b

ORC|NW|

OBR||||Influenza|

Results (middleware → LIMS)

MSH|^~\&|QIAlink||LIMS||20121101171000||OUL^R21|476|P|2.4||||||UNICODE|

SAC|||123|||BLD|

OBR|1|||INA|||20121101165505|||||||||||||||||F|||||||||testuser|

OBX|1|ST|INA||TargetDetected||||||F|

SAC|||123||||blood|

OBR|1|||INB|||20121101165505|||||||||||||||||F|||||||||testuser|

OBX|1|ST|INB||TargetNotDetected||||||F|

Single HCV assay with only one target HCV

Request (LIMS → middleware)

MSH|^~\&|LIMS||QIAlink||20121101152100||OML^O21|555|P|2.4||||||UNICODE|

SAC|||123|||BLD|

ORC|NW|

OBR||||HCV|

SAC|||124|||BLD|

ORC|NW|

OBR||||HCV|

Results (middleware → LIMS)

MSH|^~\&|QIAlink||LIMS||20121101171000||OUL^R21|476|P|2.4||||||UNICODE|

SAC|||123|||BLD|

OBR|1|||HCV|||20121101165505|||||||||||||||||F|||||||||testuser|

OBX|1|NM|HCV||2.5E-02|copies/ml|||||F|

SAC|||124|||BLD|

OBR|1|||HCV|||20121101165505|||||||||||||||||F|||||||||testuser|

OBX|1|ST|HCV||TargetNotDetected||||||F|

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