Abbott

Alinity ci-series LIS Interface Manual (ASTM)

80000456-103

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Foreword

The Alinity ci-series LIS (Laboratory Information System) Interface Manual (ASTM) is a messaging specification intended to specify the electronic communication between the Alinity ci-series (instrument) and a Laboratory Information System based on CLSI LIS01-A2 (ASTM 1381) and CLSI LIS2-A2 (ASTM 1394). (CLSI: Clinical and Laboratory Standards Institute) (ASTM: American Society for Testing and Materials)

The intended audience is for developers and testers of laboratory information systems.

This manual assumes that the reader is familiar with the basics of the CLSI LIS01-A2 and LIS2-A2 standards.

The remainder of this manual specifies the dynamic and static aspects of the Alinity ci-series CLSI (ASTM) LIS interface in detail. The *dynamic* aspects of information interchange include discussions of the systems that participate in interchanges and the real-world events that trigger messaging. The *static* aspects of messaging include the structure and contents of the electronic messages that are exchanged.

Although this manual describes the elements of CLSI (ASTM) messages and messaging interactions as they relate to this specification, it does not constitute an introduction to CLSI LIS01-A2 and LIS2-A2 standards.

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Customer service

For questions about the Alinity ci-series, contact the local representative or find country-specific contact information at corelaboratory.abbott.

Related information…

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Proprietary statement

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Related information…

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Abbott's liability for all matters arising from the supply, installation, use, repair, and maintenance of the instrument, whether arising under this Warranty or otherwise, shall be limited solely to the repair or (at Abbott's sole discretion) replacement of the instrument or of components thereof. Replaced parts shall become the property of Abbott Laboratories. In no event shall Abbott be liable for injuries sustained by third parties.

The ICT module Warranty is 20,000 samples or three months post-installation, whichever occurs first.

The cuvette warranty is one year post-installation.

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Key to symbols

The following symbols are used on Alinity ci-series labels and labeling.

Harmonized symbols

Directive 2002/96/EC

Symbol	Description
	WEEE: Waste Electrical and Electronic Equipment **NOTE:** Indicates that the item needs to be disposed of in a separate waste collection for electrical and electronic equipment and must not be disposed of in the general waste or trash.

IEC 61010-1

Symbol	Description
	Caution: Consult accompanying documents
	Caution: Hot surface
	Caution: Possibility of electric shock
	Off
	On

IEC 61010-2-101

Symbol	Description
 	Caution: Biological RISKS

ISO 3287, ISO 3767-1, ISO 7296-1/Amd 1, ISO 11192

Symbol	Description
	Interior light

ISO 7010-W022

Symbol	Description
	Caution: Sharp element

ISO 15223-1

Symbol	Description
	Consult operating instructions
	Date of manufacture
	Manufacturer
	Temperature limitation
	Use by/Expiration date
EC REP	Authorized Representative in the European Community
LOT	Batch code/Lot number
REF	Catalog number/List number
IVD	*In Vitro* Diagnostic Medical Device
SN	Serial number

Nonharmonized symbols

Symbol	Description
	Caution: Probe stick hazard
	Disconnect Mains Plug
	Priority
	UL Recognized Component Mark
ACID WASH	Acid Wash
ALKALINE WASH	Alkaline Wash
ASSEMBLED BY	Assembled by
CONCENTRATED WASH BUFFER	Concentrated Wash Buffer
DETERGENT A	Detergent A
DETERGENT B	Detergent B
DISTRIBUTED BY	Distributed by
DISTRIBUTED IN THE USA BY	Distributed in the USA by
FOR USE WITH	For use with
ICT REFERENCE SOLUTION	ICT Reference Solution
KIT	Kit
MANUFACTURED BY	Manufactured by
MANUFACTURED FOR	Manufactured for
PRE-TRIGGER SOLUTION	Pre-Trigger Solution
PRODUCED BY	Produced by

Symbol	Description
PRODUCED FOR ABBOTT BY	Produced for Abbott by
PRODUCT OF JAPAN	Product of Japan
PRODUCT OF SINGAPORE	Product of Singapore
PRODUCT OF USA	Product of USA
QTY	Quantity
REACTION VESSELS	Reaction vessels
REV	Revision
SAMPLE CUPS	Sample cups
SEQUENCE NUMBER	Sequence number
TRIGGER SOLUTION	Trigger Solution
UNIT	Unit
WASH BUFFER	Wash buffer
WATER BATH ADDITIVE	Water Bath Additive

Related information…

Read me first, page 5

Comparison between available LIS interfaces: CLSI (ASTM) vs. HL7

The Alinity ci-series supports two types of LIS interfaces: CLSI (ASTM) and Health Level 7 (HL7). The instrument can be configured to use one or the other. This section compares and contrasts the interfaces to provide information to help select which interface type to use.

The HL7 interface is the recommended interface based on additional messaging capabilities, more robust messaging, and conformance with the most current *In Vitro* Diagnostic (IVD) industry standards [developed in partnership with Integrating the Healthcare Enterprise (IHE) Laboratory]. The CLSI (ASTM) interface is provided for legacy reasons to support LIS or host systems that do not have support for HL7-based interfaces. (CLSI: Clinical and Laboratory Standards Institute) (ASTM: American Society for Testing and Materials)

Capability	**HL7**	**CLSI (ASTM)**	**Comment**
Connections			
TCP/IP	X	X	Both types support connections over TCP/IP only
Dual TCP/IP Connection	X		Separate TCP/IP connections: One for incoming messages and one for outgoing messages
Single TCP/IP Connection		X	Single TCP/IP connection used for both incoming and outgoing messages
Baseline Standards			
CLSI LIS01, LIS2		X	Communication based on CLSI standards
HL7 Messaging Standard Version 2.5.1, IHE LAW	X		Communication based on HL7 v2.5.1 and the IHE LAW messaging profiles
Supported Messages			
Order Download	X	X	
Order Query	X	X	
Results Upload	X	X	HL7 supports specimen, control, and calibrator results CLSI supports specimen and control results only
Test Status Update	X		Test status update message triggered upon: • Test started • Test exception • Test pending transmission until other tests for the sample are completed (Collation)
Sample Status Update	X		Sample status update message triggered upon: • Sample scan by instrument • Sample processing started • Sample processing completed • Sample removal from instrument

Capability	**HL7**	**CLSI (ASTM)**	**Comment**
Assay Availability	X		Assay availability message triggered upon time interval.
Command/Response	X		Command/Response message triggered from the host system in support of Disable/Enable patient sample processing for an assay on a processing module.
Messaging Layer			
Application Level Acknowledgment	X		HL7 requires application level acknowledgment of received messages (for example, the message is valid and has been accepted by the receiving application). CLSI supports only transmission level acknowledgment (for example, a message transmission was received). There is no acknowledgment that the message is valid or has been accepted by the received application.
Message ID	X		Unique message ID for each sent message and included in the message acknowledgment.
Application Layer			
Test Management by AWOS ID	X		All tests are referenced by AWOS ID. AWOS ID (generated by the LIS) uniquely identifies each test requested on a specific specimen. (AWOS = IHE LAW term: Analytical Work Order Step) For orders: Unambiguous support for order cancel, order add-ons, order replicates, and detection of duplicate orders. For results: Identification of results for specific orders, reruns, reflex tests, and unsolicited results.
Test Management by Specimen ID and Assay ID		X	All tests are referenced by Specimen ID and Assay ID only. For orders: Using order action code, can support order cancel, order add-ons, order replicates, and detection of duplicate orders. For results: No association of results to specific orders, no identification of reruns and reflex tests, cannot distinguish unsolicited results from results for requested orders.
Asynchronous Queries	X		In HL7 LAW, multiple queries can be sent by the instrument before the LIS sends the orders for the queries. In ASTM, the instrument must wait for the query response before sending the next query (only one query at a time can be in process).

Capability	HL7	CLSI (ASTM)	Comment
Order Acceptance	X		In HL7 LAW, each individual test order or test cancel is accepted or rejected by the instrument in an application acknowledgment message. Not supported by CLSI.
Order Status with Results	X		In HL7 LAW, when the instrument sends a test result, the message indicates if the instrument considers the order request as completed or if reruns are still pending. Not supported by CLSI.
Run Identification with Results	X		In HL7 LAW, test result messages indicate a unique run number to distinguish reruns from initial runs of a test order request. Not supported by CLSI.
Identification of Instrument-Initiated Reflex Tests	X		In HL7 LAW, test result messages identify if the result is from a reflex test initiated by the instrument and identify the test orders that caused the reflex test. Not supported by CLSI.

Related information...

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References

This manual is based on the following standards:

- CLSI LIS01-A2: Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems
- CLSI LIS2-A2: Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems
- IHE Laboratory Technical Framework, Laboratory Analytical Workflow (LAW) profile

Related information…

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Introduction

This section specifies implementation notes related to the CLSI (ASTM) interface supported by the instrument.

Related information…

Low-level protocol (CLSI LIS01-A2), page 20

Messaging protocol (CLSI LIS2-A2), page 22

Low-level protocol (CLSI LIS01-A2)

The instrument uses the low-level protocol as defined in CLSI LIS01-A2.

This manual does not fully specify the CLSI LIS01-A2 protocol but provides only some important characteristics of the instrument's implementation.

Related information...

CLSI (ASTM) implementation notes, page 19
TCP/IP support only, page 20
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TCP/IP support only

The CLSI LIS01-A2 specification addresses the low-level protocol (physical layer and data link layer) used for both serial binary data exchange and TCP/IP data exchange. However, the instrument supports TCP/IP data exchange only.

Related information...

Low-level protocol (CLSI LIS01-A2), page 20

Network connection

Per CLSI LIS01-A2, section 8.2.1.1, the instrument is defined to be the "client" and supports an active connection while the LIS/host system is defined as the "server" and offers a socket for connection. The instrument is configurable for both the port and IP address of the LIS and is defined to be the "client" to request a connection to the LIS offered socket. The instrument supports an active persistent connection as described below.

Active persistent connection

The following steps are performed by the instrument for an active persistent network connection.

1. At startup, attempt to connect to the configured IP address and port of the LIS.
2. If connection is unsuccessful, wait for a short time period and retry one or more times.
3. Keep the connection open at all times, even if no more messages remain to be exchanged.
4. If a disconnection is detected outside of a data exchange, retry the connection.

Related information...

Low-level protocol (CLSI LIS01-A2), page 20

Receiver interrupts

The instrument does not support receiver interrupts specified in section 8.3.5 of the CLSI LIS01-A2 specification. During the Transfer Phase the instrument does the following:

- When acting as a receiver during the Transfer Phase, the instrument does not issue a receiver interrupt request (that is, send an <EOT> in place of the usual <ACK>).
- When acting as a sender during the Transfer Phase, the instrument ignores receiver interrupt requests and processes the <EOT> character the same as a received <ACK> character.

Related information...

Low-level protocol (CLSI LIS01-A2), page 20

Frames

Per the CLSI LIS01-A2 section 8.3.1.1 and section 3.3.2, each LIS01-A2 frame transmitted by the instrument contains only a single LIS2-A2 record, and each frame received by the instrument must contain only a single LIS2-A2 record.

Related information...

Low-level protocol (CLSI LIS01-A2), page 20

Character set

Per section 4.3 of CLSI LIS2-A2, the standard does not define transmission of character encodings that require greater than 8 bits; however, character encodings greater than 8 bits can be transmitted through the use of appropriate algorithmic transformations.

The instrument transmits and receives characters using one of the following encodings (instrument configuration setting):

- Windows-1252
- UTF-8
- Shift-JIS
- ASCII

Related information...

Low-level protocol (CLSI LIS01-A2), page 20

Messaging protocol (CLSI LIS2-A2)

The instrument supports the messaging protocol defined in CLSI LIS2-A2. This manual does not attempt to fully specify the CLSI LIS2-A2 protocol, but only provides some important key characteristics of the instrument implementation.

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Logical information storage and transmission error recovery requirements, page 22
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Message buffering, page 26

Logical information storage and transmission error recovery requirements

Per CLSI LIS2-A2 section 4.2, data is presumed to be saved by the receiver whenever a decremental change in the hierarchical level is observed. According to the hierarchical record level requirements, all logical records necessary to reach the point where the transmission failure occurred must be retransmitted.

Related information…

Messaging protocol (CLSI LIS2-A2), page 22

Outgoing messages

For outgoing messages, the instrument supports these requirements as follows:

- For Order Query messages, each message contains data for only a single specimen. The only decremental change in the hierarchical level is achieved only when the Terminator record is successfully sent. Therefore, if a transmission failure occurs within a message, all records in the message must be retransmitted.
- For Test Results Upload, the message contains only a single specimen but can contain multiple results for that single specimen. The instrument presumes data to be saved according to the following criteria:

  At successful receipt of a test order record or terminator record, any unsaved test order record and associated result and comment records prior to this order record are saved.

NOTE: A new Order record marks the end of the complete set of records needed for result information for a single run of a test request (also indicates the beginning of the result information for the next test run).

An example result message, showing presumed save points, is provided below. In addition, a list of which records are resent, in the case of transmission failure, is provided.

Example: Initial segments of a Message Structure

Line #	Record Type	Level	Increment	Action of Instrument
A	Header	Level 0	0	
B	Patient	Level 1	+1	
C	Order	Level 2	+1	
D	Result	Level 3	+1	
E	Comment	Level 4	+1	
F	Manufacturer	Level 4	0	
G	Result	Level 3	-1	
H	Result	Level 3	0	
I	Order	Level 2	-1	◀ at this point, saves A through H (test result)
J	Result	Level 3	+1	
K	Order	Level 2	-1	◀ at this point, saves I through J (test exception)
L	Result	Level 3	+1	
M	Comment	Level 4	+1	
N	Manufacturer	Level 4	0	
O	Result	Level 3	-1	
P	Result	Level 3	-0	
Q	Terminator	Level 0	-3	◀ at this point, saves K through P

Records requiring retransmission

Line # where failure occurred	Instrument would require retransmission of:
A	A
B	AB
C	ABC
D	ABCD
E	ABCDE
F	ABCDEF
G	ABCDEFG
H	ABCDEFGH
I	ABCDEFGHI

Line # where failure occurred	Instrument would require retransmission of:
J	ABIJ
K	ABIJK
L	ABKL
M	ABKLM
N	ABKLMN
O	ABKLMNO
P	ABKLMNOP
Q	ABKLMNOPQ

Related information…

Messaging protocol (CLSI LIS2-A2), page 22

Incoming messages

For incoming messages, the instrument supports these requirements as follows:

- For Negative Order Query messages, each message contains data for only a single specimen. The only decremental change in the hierarchical level is achieved only when the Terminator record is successfully sent. Therefore, if a transmission failure occurs within a message (Message Header record through Message Terminator record), all records in the message must be retransmitted.
- For Test Order downloads, the instrument stores segments of the message as received, according to the following criteria:
  - At successful receipt of a record that is a decremental change in the hierarchical level, all unsaved data is saved prior to this record (per CLSI LIS2-A2).
  - At successful receipt of a test order record, any unsaved test order record and associated comment record prior to this order record are saved.

An example result order message, showing save points, is provided below. In addition, a list of which records would need to be resent in the case of transmission failure is provided.

Example: Test Order Message with Save Points

Line #	Record Type	Level	Increment	Action of Instrument
A	Header	Level 0	0	
B	Patient	Level 1	+1	
C	Order	Level 2	+1	
D	Order	Level 2	0	◀ at this point, saves A through C
E	Comment	Level 3	+1	
F	Order	Level 2	-1	◀ at this point, saves D through E

Line #	Record Type	Level	Increment	Action of Instrument
G	Comment	Level 3	+1	
H	Patient	Level 1	-2	◀ at this point, saves F through G
I	Order	Level 2	+1	
J	Order	Level 2	0	◀ at this point, saves H through I
K	Comment	Level 3	+1	
L	Terminator	Level 0	-3	◀ at this point, saves J through K

Records requiring retransmission

Line # where failure occurred	Instrument would require retransmission of:
A	A
B	AB
C	ABC
D	ABCD
E	ABDE
F	ABDEF
G	ABFG
H	ABFGH
I	AHI
J	AHIJ
K	AHJK
L	AHJKL

Related information…

Messaging protocol (CLSI LIS2-A2), page 22

Delimiters

For outgoing messages, the delimiters used are:

Delimiter Type	Character	Description
Field	|	Separates fields within records.
Repeat	\	Separates multiple occurrences for the same type of information within a field.
Component	^	Separates data elements within a field.
Escape	&	Allows embedding of special characters within the data.

For incoming messages, any characters defined in the header record and transmitted by the external system are used as the delimiters for that message.

Related information…

Messaging protocol (CLSI LIS2-A2), page 22

Record construction

When generating outgoing messages, the instrument only transmits each record, up to and including the last populated field of the record and then the trailing carriage return. All empty fields subsequent to the last populated field of the record are suppressed from transmission to the LIS. For example, when transmitting a Patient record, the instrument does not populate any fields beyond the Sequence Number, so the record is transmitted as P|1.

Related information…

Messaging protocol (CLSI LIS2-A2), page 22

Dates and times

All date and time fields are transmitted by the instrument in the local time as set in the instrument application. Indication of the time zone is provided only in the Message Header Record (H), Date and Time of Message field. All other time stamps in the message do not have the time zone specified and can be assumed to be in the same time zone indicated in the Message Header Record, Date and Time of Message field.

Related information…

Messaging protocol (CLSI LIS2-A2), page 22

Message buffering

Because of sample-processing requirements, Order Query messages take priority over any other outgoing messages. However, it will not interrupt a message that is in progress (for example, waiting for an acknowledgment to a results upload message).

For outgoing messages (for example, Result Upload), the instrument supports the queuing of multiple messages. As an example, the operator can request that results for N samples be sent to the LIS. This results in N result messages being queued for transmission. For situations like this that allow for multiple message transactions to be queued for processing in the background, the instrument supports a message buffer to hold outgoing messages. This message buffering also accounts for times when the network connection cannot be made to the LIS. This message buffer operates as a FIFO queue that allows new Order Query messages to go to the front of the queue. If the FIFO reaches its maximum capacity, no more messages, including query messages, are queued for transmission. A buffer-full indication is generated on the instrument user interface, and the instrument disables the connection.

Related information…

Messaging protocol (CLSI LIS2-A2), page 22

Introduction

Transmission of Specimen test results, Quality control results, and Order Query Requests use the high-level CLSI records and fields described in this section. Unused fields are not listed.

Related information…

Order query, page 28

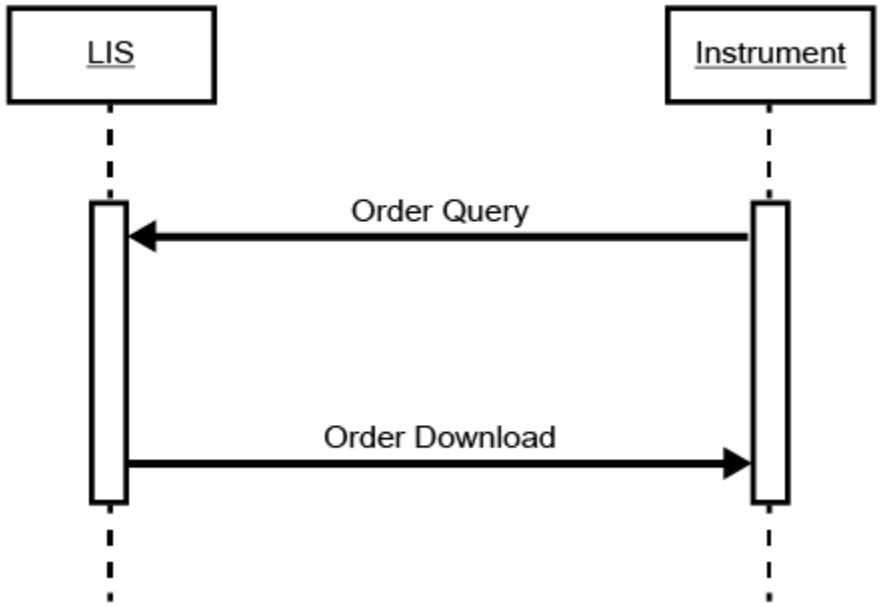
Specimen and QC results upload, page 30

Outgoing record format, page 33

Order query

When the instrument identifies a specimen (bar code read) and finds no existing orders for that specimen in its database, the instrument queries the LIS for orders against the specimen. The LIS responds with any test orders for that specimen.

Figure 1: Interaction diagram



Interaction model

Trigger event	The query is sent by the instrument when all the following conditions are met: • A specimen is recognized (bar code read) as being introduced to the instrument [will not query based on Sample location, but only based on Specimen Identification (ID)]. • There are no existing test orders found in its database for that specimen. • The sample is not configured as a Control or Calibrator sample on the instrument. • A batch is not In Progress on the system. • Query mode is enabled for the instrument. Only one Order Query is issued by the instrument to the LIS at any given time. An existing Order Query must complete prior to initiating a new request. Order Query requests are only made for a single sample. An Order Query request is considered complete under any of the following conditions: • receipt of a negative query response • receipt of test orders for the specimen • time-out waiting for a response (and retry attempts exhausted) • error in transmission of query (and retry attempts exhausted)

	When an Order Query message is transmitted to the host, no other outgoing messages are sent until the Order Query Request is completed. This allows the LIS the opportunity to download Test Orders to the instrument in response to the query.
Direction	Instrument to LIS

Related information...

Outgoing messages, page 27

Message structure, page 29

Notes on message structure, page 29

Message granularity, page 29

Message structure

The record hierarchy for an Order Query is as follows:

Message Header Record
Request Information Record
Message Termination Record

Related information...

Order query, page 28

Notes on message structure

1. All records are required and always provided.
2. The query parameter in the Request Information record is the Specimen ID as identified on the specimen bar code.

Related information...

Order query, page 28

Message granularity

Each unique message contains one specimen (therefore, only one Request Information record).

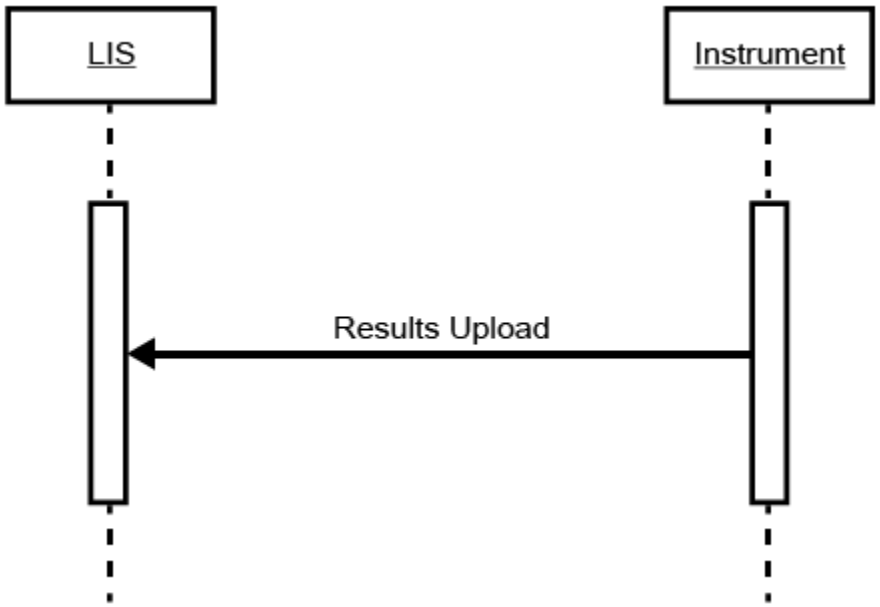
Related information...

Order query, page 28

Specimen and QC results upload

The instrument provides the ability to transmit the outcome (result or exception) of Specimen and Control test orders to the LIS.

Figure 2: Interaction diagram



Interaction model

Trigger event	The results are sent when the results are completed and released by the instrument. A completed result can either be a successfully completed test or a test that was attempted to be run but did not produce a result due to some condition (test exception).
Direction	Instrument to LIS

Related information…

Outgoing messages, page 27
Message structure: Specimen results, page 30
Message structure: QC results, page 31
Notes on message structure, page 32
Message granularity, page 32

Message structure: Specimen results

The record hierarchy for Specimen results is as follows:

Message Header Record
- **Patient Information Record**
  - **Test Order Record (Result - Test #1)**
    - **Result Record (Final)**
      - **Manufacturer Information Record(s)**
      - **Comment Record (optional)**
    - **Result Record (Interpretation)**
    - **Result Record (Preliminary)**
    - **Result Record (GUID)**
  - **Test Order Record (Exception - Test #2)**
    - **Result Record (Exception)**
      - **Manufacturer Information Record(s)**
    - **Result Record (GUID)**
  - **Test Order Record (Result - Test #3)**
    - **Result Record (Final)**
      - **Manufacturer Information Record(s)**
      - **Comment Record (optional)**
    - **Result Record (Interpretation)**
    - **Result Record (Preliminary)**
    - **Result Record (GUID)**

Message Termination Record

Related information...

Specimen and QC results upload, page 30

Message structure: QC results

The record hierarchy for QC results is as follows:

Message Header Record
- **Patient Information Record**
  - **Test Order Record (Result - Test #1)**
    - **Manufacturer Information Record (Control Material Info)**
    - **Result Record (Final)**
      - **Manufacturer Information Record(s)**
      - **Comment Record (optional)**
    - **Result Record (Interpretation)**
    - **Result Record (Preliminary)**
    - **Result Record (GUID)**
  - **Test Order Record (Exception - Test #2)**
    - **Manufacturer Information Record (Control Material Info)**
    - **Result Record (Exception)**
      - **Manufacturer Information Record(s)**
    - **Result Record (GUID)**
  - **Test Order Record (Result - Test #3)**
    - **Manufacturer Information Record (Control Material Info)**
    - **Result Record (Final)**

Manufacturer Information Record(s)
Comment Record (optional)
Result Record (Interpretation)
Result Record (Preliminary)
Result Record (GUID)
Message Termination Record

Related information…

Specimen and QC results upload, page 30

Notes on message structure

1. A Test Order record is included for each test (assay) result being reported in the message.
2. If the test outcome is a result, multiple result records are sent underneath the Test Order record, each for a different part of the result. The different parts of a result include the final numeric result value, the interpretation, the raw instrument response value, and the result Globally Unique Identifier (GUID).
3. If the test outcome is an exception, a Result record containing the exception code and text, is sent underneath the Test Order record. There will also be a result record for the GUID.
4. The Manufacturer record underneath the Test Order record is sent only for Control results and contains information about the control material (for example, lot number).
5. The Manufacturer records underneath the Result record contain information on each contributing item used to produce the result. Contributing items can include assay-specific reagents and assay calibration information. Calculated results are transmitted without contributing item information.
6. The Comment record underneath a Result record is sent only when there is a result comment for the test result.
7. With multiple Result records being sent for a result (each for a different part of the result), the Comment and Manufacturer records, if any, are included only after the first result record.

Related information…

Specimen and QC results upload, page 30

Message granularity

Each unique result message can contain:

1. one specimen.
2. one or more results (or exceptions) for the one specimen.

Related information…

Specimen and QC results upload, page 30

Outgoing record format

The following topics detail the outgoing CLSI record formats.

Related information…

Outgoing messages, page 27
Message Header record (H), page 33
Patient Information record (P), page 34
Test Order record (O), page 35
Result record (R), page 36
Comment record (C), page 39
Request Information record (Q), page 39
Message Terminator record (L), page 39
Manufacturer Information record (M), page 40

Message Header record (H)

The Message Header record is always the first record in a transmission.

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
6.1	Record Type ID	1	H	Header record
6.2	Delimiter Definition	4	| \ ^ &	Field delimiter: vertical bar Repeat delimiter: backslash Component delimiter: caret Escape delimiter: ampersand
6.5	Sender Name or ID	20	Alinity ci-series	Instrument Name
		10	^Version Number (string)	Instrument Software Version Number
		11	^Serial Number	Instrument Serial Number
6.12	Processing ID	1	P	Production: Treat message as an active message to be completed according to standard processing.
6.13	Version Number	7	LIS2-A2	Version level of the CLSI specification
6.14	Date and Time of Message	19	YYYYMMDDHHMMSS+/-HHMM	Date and Time of Message in CLSI date format. Indication of time zone is provided and represents the configured time zone in the instrument application. All other time stamps in the message do not have the time zone specified and can be assumed to be in the same time zone indicated in this field. The

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
				time zone (+/-HHMM) is represented as +/-HHMM offset from Coordinated Universal Time (UTC) [formerly Greenwich Mean Time (GMT), where +0000 or -0000 both represent UTC (without offset)].

Related information…

Outgoing record format, page 33

Patient Information record (P)

The Patient record contains information about the Patient associated with the test results.

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
7.1	Record Type	1	P	Patient record
7.2	Sequence Number	5	1 to 65536	Consistent with sequence number rules described in CLSI LIS2-A2
7.4	Laboratory Assigned Patient ID	20	Patient ID (string)	Patient ID (PID) Optional for Specimen results Empty for Control results
7.6	Patient Name	20	Last name (string)	Last, first, and middle patient names Optional for Specimen results Empty for Control results
		20	First name (string)	
		12	Middle name (string)	
7.8	Birth Date	8	YYYYMMDDHH	Patient date of birth Optional for Specimen results Empty for Control results
7.9	Patient Gender	1	M, F, U	Patient Gender (Male, Female, Unknown) Optional for Specimen results Empty for Control results
7.14	Doctor	20	String	Patient Doctor's name Optional for Specimen results Empty for Control results
7.26	Location	20	String	The patient general clinic location or nursing unit, or ward, or bed, or both. Optional for Specimen results Empty for Control results

Related information...

Outgoing record format, page 33

Test Order record (O)

The Test Order record contains information about the Specimen and test order requested when transmitting results.

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
8.4.1	Record Type	1	O	Test Order record
8.4.2	Sequence Number	5	1 to 65536	Consistent with sequence number rules described in CLSI LIS2-A2
8.4.3	Specimen ID	20	Specimen ID (string)	Specimen ID downloaded from the host, for host-originated orders, or entered on the system for user-originated orders.
8.4.4	Instrument Specimen ID	20	Specimen ID (string)	Same field as 8.4.3 above
		5	^Rack ID (string)	Sample Rack Bar Code ID for samples loaded on a sample rack. "LAS" (without quotes) for samples introduced from a Lab Automation track. LAS: Laboratory Automation System
		1	^Position (numeric)	Position in sample rack for sample loaded on a sample rack. LAS sampling position for samples introduced from a Lab Automation track (always 1).
		1	^Module (numeric)	Module section where the sample rack was loaded. Blank for samples introduced from a Lab Automation track, or samples in onboard storage area.
		2	^Position (numeric)	Reagent and sample manager (RSM) Position within Module section where the sample rack was loaded. Blank for samples introduced from a Lab Automation track, or samples in onboard storage area.
8.4.5	Universal Test ID	0	Empty	Universal Test ID (part 1) - not used
		0	^Empty	Universal Test ID (part 2) - not used
		0	^Empty	Universal Test ID (part 3) - not used
		4	^Assay Number (numeric)	Assay number that identifies the test.
		15	^Assay Name (string)	Assay name of the test.

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
		10	^Dilution (string)	Sample Dilution protocol name used for the test.
8.4.6	Priority	1	R or S	R = Routine S = Stat Priority
8.4.8	Collection Date and Time	14	YYYYMMDDHH MMSS	Date and time of sample collection Optional for Specimen results Empty for Control results
8.4.12	Action Code	1	Q or (Empty)	Q = Quality Control Sample (Empty) = Specimen Sample
8.4.26	Report Type	1	F or X	F = Final Result X = Test could not be performed (Exception)

Related information…

Outgoing record format, page 33

Result record (R)

The Result record contains the actual test results for Specimen and QC results. Results include the final result numeric value (Result type "F"), result interpretation (Result type "I"), result GUID (Result type "G"), and raw instrument response value used to calculate the result value (Result type "P").

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
9.1	Record Type	1	R	Result record
9.2	Sequence Number	5	1 to 65536	Consistent with the sequence number rules described in CLSI LIS2-A2
9.3	Universal Test ID	0	Empty	Universal Test ID (part 1) - not used
		0	^Empty	Universal Test ID (part 2) - not used
		0	^Empty	Universal Test ID (part 3) - not used
		4	^Assay Number (numeric)	Assay number that identifies the test
		15	^Assay Name (string)	Assay name of the test
		10	^Dilution (string)	Sample Dilution protocol name used for the test
		1	^Result Type	F = final numeric result value I = interpretation result P = raw preliminary result value G = result GUID X = exception code and text

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
9.4	Data Value	260	String	For result type "F", numeric value - may include "<" or ">", as well as decimal and thousands separators. For result type "I", interpretation string For result type "P", numeric instrument response For result type "G", GUID string For result type "X", Exception code (four digits) and an optional subcode (four characters) separated by a dash (for example, 1234-B001), a component delimiter, and an exception string of up to 250 characters (for example, 1234-B001^TestExceptionString).
9.5	Unit	8	String	For result type "F", result units For result type "I", empty For result type "P", [relative light unit (RLU), Abs, or mV] For result type "G", empty For result type "X", empty
9.6	Reference Ranges	60	String	For result type "F" (for QC results), populated with control min-max range as configured on the instrument For result type "F" (for Specimen results), populated with normal min-max range as configured on the instrument, if defined For result type "I", empty For result type "P", empty For result type "G", empty For result type "X", empty
9.7	Result Abnormal Flags	20	String	For result type "F", this field can be blank or contain one or more of the following flags: • IUO = Investigational Use Only • RUO = Research Use Only • EDIT = result has been edited or recalculated • EXP = Expired material • EXPC = Expired calibration or expired calibrator lot • A#1 = only 1 read within Absorbance limit • A#2 = only 2 reads within Absorbance limit • CNTL = Result produced after a control had a Westgard failure rating, or control result outside range • < = result below assay dynamic range • > = result above assay dynamic range

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
				• INDX = interfering substances • FLEX = flexible read time data used • LL = result below extreme range • HH = result above extreme range • PSHH = previous sample extreme high • LOW = result below normal range • HIGH = result above normal range • CORR = Correlation Assay version • 1-2s = control result fails Westgard rule • 1-3s = control result fails Westgard rule • 2-2s1R1M = control result fails Westgard rule • 2-2s1RxM = control result fails Westgard rule • 2-2sxR1M = control result fails Westgard rule • R-4s = control result fails Westgard rule • 4-1s1M = control result fails Westgard rule • 4-1sxM = control result fails Westgard rule • 10-x1M = control result fails Westgard rule • 10-xxM = control result fails Westgard rule **NOTE:** Multiple flags can be sent and are separated by a repeat delimiter. For result type "I", empty For result type "P", empty For result type "G", empty For result type "X", empty
9.9	Result Status	1	F or R	F = Final Result, initial transmission R = Previously transmitted final result
9.11	Operator Identification	12	String	Username of user logged into the instrument at the time the result was produced
		12	String	Username of user logged into the instrument at the time the result was released
9.13	Date/Time Test Completed	14	YYYYMMDDHHMMSS	Date and time the test processing completed (in CLSI date format)
9.14	Instrument Identification	11	String	Serial Number of the module which performed the test. For calculated test results (and some test exceptions), contains the System Control Module serial number.

Related information…

Outgoing record format, page 33

Comment record (C)

A Comment record follows a Result record if a result comment was entered for the test result.

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
10.1	Record Type	1	C	Comment record
10.2	Sequence Number	5	1 to 65536	Consistent with sequence number rules described in CLSI LIS2-A2
10.3	Comment Source	1	I	I = Instrument
10.4	Comment Text	50	String	Result comment
10.5	Comment Type	1	G	G = Generic comment for the result

Related information...

Outgoing record format, page 33

Request Information record (Q)

A Request Information record is used to request the LIS to send any outstanding orders for a single specified Specimen ID.

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
11.1	Record Type	1	Q	Request Information record
11.2	Sequence Number	1	1	Sequence number is always 1. Only one Request Information record is sent at any one time.
11.3	ID Number	0	Empty	LIS Patient ID - not supported
		20	^Specimen ID	Specimen ID read from the bar code label on the specimen container (for example, tube).
11.5	Universal Test ID	3	^^^ALL	Instrument always requests that ALL outstanding orders are sent (as the fourth component of the field).
11.13	Status Code	1	O	Instrument only requests Orders.

Related information...

Outgoing record format, page 33

Message Terminator record (L)

The Message Terminator record is always the last record in a transmission.

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
12.1	Record Type	1	L	Terminator (last) record
12.2	Sequence Number	1	1	Always set as 1

Related information…

Outgoing record format, page 33

Manufacturer Information record (M)

The Manufacturer Information record is used to send contributing item information for the test result or exception. It carries:

- substance information for assay-specific reagent material used.
- assay calibration information.
- substance information for QC material used only for QC results.

NOTE: CLSI-LIS2 does not define fields after CLSI field number 14.2. The notation *.N in the table below indicates the field number in the record defined for use in the interface.

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
14.1	Record Type	1	M	Manufacturer record
14.2	Sequence Number	5	1 to 65536	Consistent with the sequence number rules described in CLSI LIS2-A2
*.3	Record Type Sub ID	3	INV	Record containing contributing item information. Modeled after fields in the HL7 v2.5.1 INV segment.
*.4	Substance Identifier	20	String	The identifier of the contributing item varies based on Substance Type (see the table below).
*.5	Substance Type	2	String	The type of contributing item is one of: • SR = Assay-specific Reagent information • CO = Control specimen information • CA = Assay Calibration information
*.6	Inventory Container Identifier	20	String	The serial number of the reagent. Only present for Substance Type: SR. Blank for all other Substance Types.
*.7	Expiration Date/Time	14	YYYYMMDD[HHMMSS]	Calibration Expiration Date and time (may be blank) for Substance Type: CA. Lot Expiration Date (may be blank) for all other Substance Types.

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
*.8	Calibration Date/Time	14	YYYYMMDDHH MMSS	Date and time the assay was calibrated (in CLSI date format). Only present for Substance Type: CA. Blank for all other Substance Types.
*.9	Lot Number	20	String	The lot number of the contributing substance. For assay calibration information, this is the lot number of the calibrated reagent. Present for all Substance Types.

Substance Identifiers for Substance Types

Substance Type	Substance Identifier Field Contents	Example	Field Description
SR	Reagent ID - Version	165-1	For assay-specific reagents, the Reagent Configuration ID and version, separated by a dash (-), of the reagent as defined on the system.
CO	Control Name	HCV_Positive	For assay controls, the name of the control as defined on the instrument. This is the concatenation of a Control Set Name and a Control Name.
CA	Assay Number	165	For assay calibration, the assay number for the test.

Related information...

Outgoing record format, page 33

NOTES

Introduction

This section outlines the messages, records, and field contents for communications from the LIS host computer to the Alinity ci-series. Unsupported fields are not listed.

Related information…

Order download, page 44

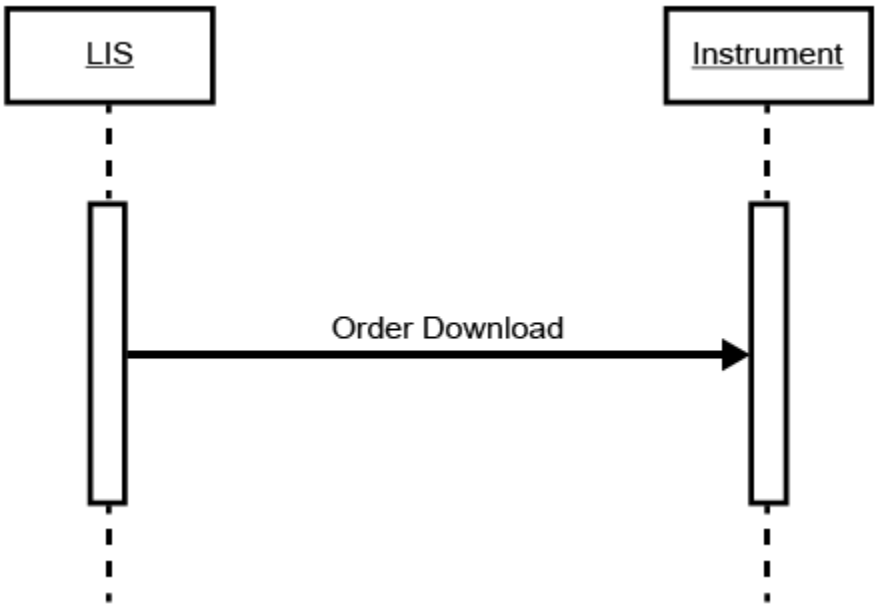
Negative query response, page 47

Incoming record format, page 49

Order download

This message is used to issue a new order to the instrument or to cancel an existing order previously sent.

Figure 3: Interaction diagram



Interaction model

Trigger event	Any change to an order which then causes the order to be allocated or scheduled on the instrument by the LIS. Such changes include submission of new orders, cancellations, and updates where multiple orders are associated with a single sample. The message can also be sent from the LIS in response to an order query from the instrument. The response can contain orders to be performed by the instrument. The instrument accepts unsolicited test orders from the LIS, regardless of whether the Host Query option is enabled or not. This message also covers the case where a previously downloaded order will need to be canceled or modified on the instrument. To affect an order modification, the combination of an order cancel and a new order must be used.
Direction	LIS to Instrument

Related information…

Incoming messages, page 43

Message structure, page 45

Notes on message structure, page 45

Message granularity, page 45
Order processing rules, page 46

Message structure

The record hierarchy for an Order Download is as follows:

Message Header Record
Patient Information Record
Test Order Record
Patient Information Record
Test Order Record
Test Order Record
Comment Order Record (optional)
Patient Information Record
Test Order Record
Test Order Record
Test Order Record
Message Termination Record

Related information...

Order download, page 44

Notes on message structure

1. Multiple tests can be ordered for a specimen using either of the following methods:
   a. Use of a Repeat Delimiter in the Universal Test ID field of the Test Order Record.
   b. Use of multiple Test Order records beneath a Patient Information Record.
2. An optional Comment record, containing a test order comment, may be included after a Test Order record. The comment text is limited to 50 characters. If multiple Comment records are received under the same Test Order record, only the first Comment record is processed.

Related information...

Order download, page 44

Message granularity

Each unique message can contain:

1. one or more specimens.
2. one or more test orders against each specimen.

Related information...

Order download, page 44

Order processing rules

Each individual test ordered (or canceled) is further processed and validated as described below:

1. A test on the instrument is fully specified as an "Assay Number" plus an optional sample dilution.
2. A sample dilution is specified by a dilution protocol name. If a sample dilution is not specified in the message, it defaults to the default (dilution) protocol configured for the assay.
3. If the test order request specifies an assay that is not defined (or is not enabled) on the instrument, the instrument ignores the test order request and notifies the user.
4. If the test order request specifies a dilution protocol name (protocol names are case sensitive), or that protocol is a hidden calibration dilution protocol, the instrument ignores the test order request and notifies the user.
5. If the test order request indicates a new order (Test Order Record, Action Code field = N) but that same test order for the sample ID already exists (Pending, Onboard, Scheduled, Running), the instrument ignores the test order request and notifies the user. If the test order does not already exist for the specified sample ID, then the test order is created.
6. If the test order request indicates an add order (Test Order Record, Action Code field = A), the test order is processed as a mandatory added test order. It is added to the test order regardless of whether or not the same test order already exists (Pending, Onboard, Scheduled, Running) for the sample ID.
7. If the test order request indicates a cancel order (Test Order Record, Action Code field = C), the test order is processed as a cancel request. The instrument cancels the first Pending test order found from its pending test order list that has the same Specimen ID and Assay Number. If no test is found or if the test order is already in progress or complete, the cancel request is ignored.

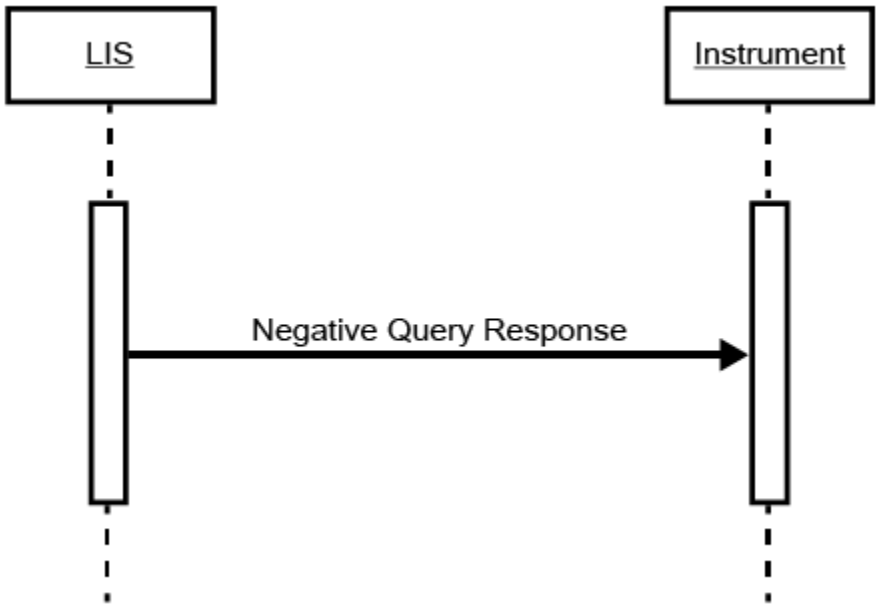
Related information...

Order download, page 44

Negative query response

This message is used in response to an order query to indicate there are no test orders to perform.

Figure 4: Interaction diagram



Interaction model

Trigger event	The message is sent from the LIS in response to an order query from the instrument. The response indicates that there are no outstanding orders for the requested Specimen ID.
Direction	LIS to Instrument

Related information…

Incoming messages, page 43
Message structure, page 47
Notes on message structure, page 48
Message granularity, page 48

Message structure

The record hierarchy for a Negative Query Response is as follows:

Message Header Record

Request Information Record
Message Termination Record

Related information...

Negative query response, page 47

Notes on message structure

The Request Information record is a copy of the original record sent from the instrument with the Status Code field set to X.

Related information...

Negative query response, page 47

Message granularity

Each unique message can contain a negative query response for one specimen.

Related information...

Negative query response, page 47

Incoming record format

For all record formats described in this section, any field not specified is ignored if present in an incoming record.

Related information...

Incoming messages, page 43
Message Header record (H), page 49
Patient Information record (P), page 49
Test Order record (O), page 50
Comment record (C), page 52
Request Information record (Q), page 52
Message Terminator record (L), page 53

Message Header record (H)

The Message Header record is always the first record in a transmission.

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
6.1	Record Type	1	H or h	Header record
6.2	Delimiter Definition	4		Characters 2 and 6 of the record must be the same and characters 2, 3, 4, and 5 must be different.
6.12	Processing ID	1	P	Production: Treat message as an active message to be completed according to standard processing.

Note

Processing ID must be P (or p) in the incoming message or the message "Message Header Record to Terminator Record" is ignored.

Related information...

Incoming record format, page 49

Patient Information record (P)

The Patient record contains information about the Patient associated with the test orders.

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
7.1	Record Type	1	P or p	Patient record

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
7.2	Sequence Number	5	1 to 65536	Consistent with sequence number rules described in CLSI LIS2-A2
7.4	Laboratory Assigned Patient ID	20	Patient ID (string)	Patient ID (PID) Optional for Specimen test orders
7.6	Patient Name	20	Last name (string)	Last, first, and middle patient names Optional for Specimen test orders
		20	First name (string)	
		12	Middle name (string)	
7.8	Birth Date	8	YYYYMMDDHH	Patient date of birth Optional for Specimen test orders
7.9	Patient Gender	1	M, F, U	Patient Gender (Male, Female, Unknown) Optional for Specimen test orders
7.14	Doctor	20	String	Patient Doctor's name Optional for Specimen test orders
7.26	Location	20	String	The patient general clinic location or nursing unit, or ward, or bed, or both. Optional for Specimen test orders

Related information...

Incoming record format, page 49

Test Order record (O)

The Test Order record contains information about the Specimen and test order requested when downloading test order requests.

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
8.4.1	Record Type	1	O or o	Test Order record
8.4.2	Sequence Number	5	1 to 65536	Consistent with sequence number rules described in CLSI LIS2-A2
8.4.3	Specimen ID	20	Specimen ID (string)	Specimen ID downloaded from the host. Valid characters include byte codes 32 through 126 (decimal), excluding 124 (vertical pipe "|"). It is recommended that the Specimen ID field does not contain any trailing or leading white space characters, as they are not easily discernible as part of the Specimen ID when displayed on the instrument user interface.

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
8.4.4	Instrument Specimen ID	N/A	N/A	Field ignored on input
8.4.5	Universal Test ID	0	Empty	Universal Test ID (part 1) - not used
		0	^Empty	Universal Test ID (part 2) - not used
		0	^Empty	Universal Test ID (part 3) - not used
		4	^Assay Number (numeric)	Assay number that identifies the test.
		15	^Assay Name (string)	Assay name of the test - optional for all test orders. The instrument ignores the assay name sent with test orders and creates the order according to the assay number. This field can be blank.
		10	^Dilution (string)	Sample Dilution protocol name (case sensitive) - optional for all test orders. If left blank, the instrument creates the test order using the default dilution.
8.4.6	Priority	1	S	S = Stat Priority **NOTE:** Blank or any other character = Routine
8.4.8	Collection Date and Time	14	YYYYMMDDHHMMSS	Date and time of sample collection Optional for Specimen test orders
8.4.12	Action Code	1	N, A, or C	N = New order for a specimen - only create new order if the specified assay in 8.4.5 does not already exist for the specimen A = Add (unconditional) order for a specimen - create order for the specified assay in 8.4.5, even if an order already exists for that assay C - Cancel (delete) pending order for the assay specified in 8.4.5
8.4.26	Report Type	1	O or Q	O = Order record; asking that analysis be performed Q = response to Query (this record is a response to an order query request)

Notes:

1. The instrument supports repeat delimiters in the Universal Test ID field on incoming requests in support of ordering multiple tests for a specimen. (In addition, multiple tests may be ordered by sending multiple Order records, each with a single Universal Test ID specified.)
2. Replicates for an assay may be ordered using one of these two methods:
   a. Use of Repeat Delimiters in Universal Test ID field of Test Order Record
   b. Multiple Order records containing Action Code "A"

Related information...

Incoming record format, page 49

Comment record (C)

For incoming test order requests, a Comment record following an Order contains the optional test order comment for the test requests in the preceding Order record.

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
10.1	Record Type	1	C or c	Comment record
10.2	Sequence Number	5	1 to 65536	Consistent with sequence number rules described in CLSI LIS2-A2
10.3	Comment Source	1	L	L = information system (LIS)
10.4	Comment Text	50	String	Order comment text. Instrument truncates any text in excess of 50 characters.
10.5	Comment Type	1	G	G = Generic comment for the test order

Related information...

Incoming record format, page 49

Request Information record (Q)

A Request Information record is used to send a negative query response from the LIS. The negative query response is used to indicate that an earlier Query Request from the instrument resulted in no orders to send.

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
11.1	Record Type	1	Q or q	Request Information record.
11.2	Sequence Number	1	1	Sequence number is always 1. Only one Request Information record is sent at any one time.
11.3	ID Number	0	Empty	LIS Patient ID - not supported.
		20	^Specimen ID	Specimen ID read from the bar code label on the specimen container (for example, tube) originally sent by the instrument with the query request.
11.5	Universal Test ID	3	^^^ALL	Field contents originally sent by the instrument with the query request.
11.13	Status Code	1	X	X = Negative query response - Indicates that either the Specimen ID is unknown to the LIS

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
				or there are no outstanding orders for the specified Specimen ID.

Related information...

Incoming record format, page 49

Message Terminator record (L)

The Message Terminator record is always the last record in a transmission.

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
12.1	Record Type	1	L or l	Terminator (last) record
12.2	Sequence Number	1	1	Always set as 1

Related information...

Incoming record format, page 49

NOTES

Introduction

This appendix contains example messages for outgoing and incoming messages.

Related information…

Outgoing messages, page 56
Incoming messages, page 58

Outgoing messages

Order Query

```
H|\^&|||Alinity ci-series^1.0^s00123|||||||P|LIS2-A2|20151103103758-0600
Q|1|^002111522041500||^^ALL||||||||O
L|1
```

Specimen result

```
H|\^&|||Alinity ci-series^1.0^s00123|||||||P|LIS2-A2|20151103110207-0600
P|1
O|1|002231522041700|002231522041700^F5678^3^1^10|^^^25^Anti-HCV^UNDILUTED|
R|||||||||||||||||||F
R|1|^^^25^Anti-HCV^UNDILUTED^F|0.21|S/CO||RUO||F||Admin^Admin||
20151103104756|i12345
M|1|INV|25|CA|||20151030110131|21544MU52
M|2|INV|25-0|SR|42514|20241231||21544MU52
R|2|^^^25^Anti-HCV^UNDILUTED^I|NonReactive|||||F||Admin^Admin||
20151103104756|i12345
R|3|^^^25^Anti-HCV^UNDILUTED^P|15000|RLU||||F||Admin^Admin||20151103104756|
i12345
R|4|^^^25^Anti-HCV^UNDILUTED^G|6d9fc45f-1512-4141-8a82-3a90fa63f542|||||F||
Admin^Admin||20151103104756|i12345
L|1
```

Specimen exception

```
H|\^&|||Alinity ci-series^1.0^s00123|||||||P|LIS2-A2|20151103112259-0600
P|1
O|1|00256114041500|00256114041500^H8878^1^1^8|^^^25^Anti-HCV^UNDILUTED|
R|||||||||||||||||||X
R|1|^^^25^Anti-HCV^UNDILUTED^X|1401^TestException - Unable to process
test. Background read failure.|||||F||Admin^Admin||20151103112204|i12345
M|1|INV|25|CA|||20151030110024|21544MU52
M|2|INV|25-0|SR|42514|20241231||21544MU52
C|1|I|Example comment.|G
R|2|^^^25^Anti-HCV^UNDILUTED^G|4fd3f19f-0052-441f-963f-a314c8c123ba|||||F||
Admin^Admin||20151103112204|i12345
L|1
```

Control result

```
H|\^&|||Alinity ci-series^1.0^s00123|||||||P|LIS2-A2|20151103110348-0600
P|1
```

```
O|1|CMV IgG Neg|CMV IgG Neg^X5459^1^1^3|^^^65^CMV IgG^UNDILUTED|R||||||
Q|||||||||||||F
M|1|INV|CMV IgG Neg|CO||20300730||22549OI33
R|1|^^^65^CMV IgG^UNDILUTED^F|8.00|S/CO|0 - 30.3|RUO||F||Admin^Admin||
20151103110348|i12345
M|1|INV|65|CA|||20151030105800|58965KF25
M|2|INV|65-0|SR|08547|20230910||58965KF25
R|2|^^^65^CMV IgG^UNDILUTED^P|248|RLU||||F||Admin^Admin||20151103110348|
i12345
R|3|^^^65^CMV IgG^UNDILUTED^G|f66ee4d3-3867-4233-8005-dc75adf05aa8|||||F||
Admin^Admin||20151103110348|i12345
L|1
```

Related information...

Example messages, page 55

Incoming messages

Order Download for Single Specimen

```
H|\^&|||||||||||P
P|1|||PID0001|Doe^John^Q||19610722|M|||||Dr. Smith||||||||||||ParkClinic
O|1|0021115220415OO||^^^65|||||||A|||||||||||||O
C|1|L|Order comment.|G
L|1
```

Order Download for Multiple Specimens with Multiple Orders per Specimen

```
H|\^&|||||||||||P
P|1
O|1|009986522317500||^^^65|||||||A|||||||||||||O
O|2|009986522317500||^^^85|||||||A|||||||||||||O
O|3|009986522317500||^^^25|||||||A|||||||||||||O
P|2
O|1|009986522317600||^^^65|||||||A|||||||||||||O
O|2|009986522317600||^^^85|||||||A|||||||||||||O
O|3|009986522317600||^^^25|||||||A|||||||||||||O
P|3
O|1|009986522317700||^^^65|||||||A|||||||||||||O
O|2|009986522317700||^^^85|||||||A|||||||||||||O
O|3|009986522317700||^^^25|||||||A|||||||||||||O
P|4
O|1|009986522317800||^^^65|||||||A|||||||||||||O
O|2|009986522317800||^^^85|||||||A|||||||||||||O
O|3|009986522317800||^^^25|||||||A|||||||||||||O
L|1
```

Order Cancel for Single Specimen

```
H|\^&|||||||||||P
P|1
O|1|0021115220415OO||^^^65|||||||C|||||||||||||O
L|1
```

Negative Query Response

```
H|\^&|||||||||||P
Q|1|^44576114055699||^^^ALL||||||||X
```

```
L|1
```

Related information…

Example messages, page 55

NOTES

Introduction

This appendix contains a functional comparison and a message record comparison of the Alinity ci-series and the ARCHITECT system.

Related information…

Functional comparison, page 62

Message record comparison, page 64

Functional comparison

The following is a brief description of the major functional differences between the LIS (ASTM/CLSI) interfaces of the Alinity ci-series and ARCHITECT System. This comparison is provided in support of customers that are replacing an ARCHITECT System with an Alinity ci-series.

Capability	Alinity ci-series	ARCHITECT
Physical Layer		
Data Exchange	TCP/IP	RS-232
Data Link Layer		
Maximum Frame Size	64,000 characters	247 characters
Message Content Layer		
Character Encoding Options	• ASCII (English characters only) • Windows-1252 • Windows-932 (Shift-JIS) • UTF-8	• ASI - Abbott Standard Interface (Abbott only encoding scheme dating back to Abbott AxSYM instrument system) • Windows-1252 • Windows-932 (Shift-JIS) • Windows-936 (Simplified Chinese GBK) • UTF-8
Patient Demographic Data Transmission	Sends all available patient demographic data	Enable/disable feature for transmission of select patient demographic data (Collection Date/Time, Patient Location, Doctor)
Control Orders	Does not accept Control orders	Accepts Control orders
Error Code and Text for Test Exceptions Transmission	Sends both Code and Text. (If LIS cannot handle non-English characters, use ASCII.)	Enable/disable feature for transmission of the Error Text in support of LIS (that cannot accept non-English characters)
Sending Test Exceptions	Sent within Result record under Order record	Sent within Comment record under Order record
Test Order Comments	Single comment up to 50 characters: Comment record under Order record	Concatenation of multiple optional ASTM fields to form a single comment up to 50 characters: • Comment record under Patient record • Danger Code field • Clinical information field • Specimen type field • Specimen source field • Comment record under Order record
Multiple Result Flags	Flags separated by repeat delimiter	Flags separated by component delimiter

Capability	Alinity ci-series	ARCHITECT
Multiple PIDs per Patient	Single PID field	Three different PID fields; complex rules for mapping
Location of Sample Rack in RSM	Sent within Test Results/Exceptions	Not sent
Contributing Substances		
Calibration Date/ Time	Sent with Test Results/Exceptions in M record (identifies what calibration was used to produce the result)	Not sent
Reagent Information	Sent using M record in Test Results	Sent in R record of Test Results (in component of Universal Test ID field)
Control Lot Number	Sent using M record of Control Test Results	Sent in R record of Control Test Results (in component of Universal Test ID field)

Related information...

Alinity ci-series to ARCHITECT comparison, page 61

Message record comparison

The following includes a comparison of the fields within message records which contain differences between the LIS (ASTM/CLSI) interfaces of the Alinity ci-series and ARCHITECT System. This comparison is provided in support of customers that are replacing an ARCHITECT System with an Alinity ci-series.

Related information...

Alinity ci-series to ARCHITECT comparison, page 61
System-specific outgoing messages, page 64
System-specific incoming messages, page 69

System-specific outgoing messages

Differences are provided regarding the format of the records sent by the Alinity ci-series or the ARCHITECT System to the host.

Related information...

Message record comparison, page 64
Message Header record, page 64
Patient Information record (P), page 65
Test Order record, page 65
Results record, page 66
Comment record, page 68
Request Information record (Q), Alinity ci-series, page 68
Manufacturer Information record (Alinity ci-series only), page 68

Message Header record

The following table details the differences in format of the Message Header record sent by the Alinity ci-series or ARCHITECT System to the host.

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
6.5	Sender Name or ID	Alinity ci-series 20 ARCHITECT 9	Instrument Name	Instrument Model Name
	Software Version	Alinity ci-series 10 ARCHITECT 4	^Version Number	Instrument Software Version Number
	Serial Number	Alinity ci-series 11 ARCHITECT 25	^Serial Number	System Control Serial Number
	Interface Version	Alinity ci-series (Not Supported)	^Interface Version	Record types the system supports

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
		ARCHITECT 16		**NOTE:** Not supported or provided in Alinity ci-series.
6.13	Version Number	Alinity ci-series 7	LIS2-A2	Version level of the CLSI specification
		ARCHITECT 14	1	ARCHITECT LIS Interface Version
6.14	Date and Time of Message	Alinity ci-series 19	YYYYMMDD HHMMSS+/- HHMM	Date and Time of Message in CLSI date format. **NOTE:** Alinity ci-series provides the time zone.
		ARCHITECT 14	YYYYMMDDHH MM SS	

Related information...

System-specific outgoing messages, page 64

Patient Information record (P)

The following table details the differences in the format of the Patient Information sent by the Alinity ci-series or ARCHITECT System to the host.

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
7.3	Practice-Assigned Patient ID	Alinity ci-series (Not Supported)	Patient ID	Patient ID
		ARCHITECT 20		
7.5	Patient ID No.3	Alinity ci-series (Not Supported)	Patient ID No. 3	Patient ID No. 3
		ARCHITECT 20		

Related information...

System-specific outgoing messages, page 64

Test Order record

The following table details the differences in the format of the Test Order record sent by the Alinity ci-series or ARCHITECT System to the host.

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
8.4.4	Instrument Specimen ID	20	Specimen ID	Specimen ID
	Rack ID	Alinity ci-series 5	^Rack ID	Sample Rack Bar Code ID for samples loaded on a sample rack
		ARCHITECT 4		

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
	Position	Alinity ci-series 1 ARCHITECT 2	^Position	Position in sample rack for sample loaded on a sample rack
	Module	Alinity ci-series 1 ARCHITECT (Not Supported)	^Module	Module section where the sample rack was loaded
	Position	Alinity ci-series 2 ARCHITECT (Not Supported)	^Position	RSM Position within Module section where the sample rack was loaded
8.4.5	Universal Test ID	0	Empty	Universal Test ID (part 1) - not used
		0	^Empty	Universal Test ID (part 2) - not used
		0	^Empty	Universal Test ID (part 3) - not used
		4	^Assay Number	Assay number that identifies the test
		Alinity ci-series 15 ARCHITECT 10	^Assay Name	Assay name of the test
		10	^Dilution	Sample Dilution protocol name used for the test.
		Alinity ci-series (Not supported) ARCHITECT 1	^Status (P or C)	Assay status: P if assay is installed as the primary version; C if the assay is installed as the correlation version **NOTE:** Alinity ci-series does not support Assay Status component.

Related information...

System-specific outgoing messages, page 64

Results record

The following table details the differences in the format of the Results record sent by the Alinity ci-series or ARCHITECT System to the host.

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
9.3	Alinity ci-series Universal Test ID	0	Empty	Universal Test ID (part 1) - not used
		0	^Empty	Universal Test ID (part 2) - not used
		0	^Empty	Universal Test ID (part 3) - not used
		4	^Assay Number	Assay number that identifies the test.
		Alinity ci-series 15	^Assay Name	Assay name of the test.

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
		ARCHITECT 10		
		10	^Dilution	Sample Dilution protocol name used for the test.
		Alinity ci-series (Not supported)	^Status (P or C)	Assay status: P if assay is installed as the primary version; C if the assay is installed as the correlation version
		ARCHITECT 1		
		Alinity ci-series (Not supported)	^Reagent Lot	Reagent Master Lot Number
		ARCHITECT 15		
		Alinity ci-series (Not supported)	^Reagent serial number	Serial number of reagent kit used to process the test result
		ARCHITECT 5		
		Alinity ci-series (Not supported)	^Control lot number	Lot number of the control material
		ARCHITECT 20		
		1	^Result Type	F = final numeric result value I = interpretation result P = raw preliminary result value **NOTE:** Additional in Alinity ci-series: G = result GUID X = exception code and text
9.4	Data Value	Alinity ci-series 260	Result	Result Value
		ARCHITECT 20		
9.5	Unit	Alinity ci-series 8	Units	Result Units
		ARCHITECT 7		
9.6	Reference Ranges	Alinity ci-series 60	Reference Range	Reference Range
		ARCHITECT At least 35		
9.7	Result Abnormal Flags	Alinity ci-series 20	Result Flags	Result Flags Alinity ci-series uses repeat delimiter to separate multiple result flags; ARCHITECT uses component delimiter.
		ARCHITECT At least 35		
9.11	Operator Identification	12	Order Operator ID	ID of operator logged into system at time of order **NOTE:** Different in Alinity ci-series: Username of user logged into the

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
				instrument at the time the result was produced.
		12	^Release Operator ID	Username of user logged into the instrument at the time the result was released.
9.14	Instrument Identification	Alinity ci-series 11 ARCHITECT 25	Instrument ID	Serial Number of the module which performed the test.

Related information...

System-specific outgoing messages, page 64

Comment record

The following table details the differences in the format of the Comment record sent by the Alinity ci-series or ARCHITECT System to the host.

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
10.4	Comment Text	Alinity ci-series 50 ARCHITECT At least 260	Comment	Result Comment or Exception String
10.5	Comment Type	1	Alinity ci-series G ARCHITECT G or I	Result Comment or Exception String

Related information...

System-specific outgoing messages, page 64

Request Information record (Q), Alinity ci-series

Negative Query Response record, ARCHITECT

There are no differences in the Request Information record sent by the Alinity ci-series to the host and the Negative Query Response record sent by the ARCHITECT System to the host.

Related information...

System-specific outgoing messages, page 64

Manufacturer Information record (Alinity ci-series only)

The Manufacturing Information record is included in Alinity ci-series; ARCHITECT does not support this record. Record sent by the Alinity ci-series to the host.

Related information...

System-specific outgoing messages, page 64

System-specific incoming messages

Differences are provided regarding the format of the records sent by the Alinity ci-series or the ARCHITECT System to the host.

Related information...

Message record comparison, page 64
Message Header record, page 69
Patient Information record (P), page 69
Test Order record, page 70
Comment record, page 72
Request Information record (Q), Alinity ci-series, page 72
Message Terminator record, page 72

Message Header record

The following table details the differences in the format of the Message Header record sent by the host to the Alinity ci-series or ARCHITECT System.

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
6.12	Processing ID	1	Alinity ci-series P	Production: Treat message as an active message to be completed according to standard processing.
			ARCHITECT P or p	
6.13	Version Number	Alinity ci-series (Not Supported)	1	Must be 1
		ARCHITECT 1		

Related information...

System-specific incoming messages, page 69

Patient Information record (P)

The following table details the differences in the format of the Patient Information record sent by the host to the Alinity ci-series or ARCHITECT System.

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
7.3	Practice-Assigned Patient ID	Alinity ci-series (Not Supported)	Practice-Assigned Patient ID	Returned unchanged during transmission to the host
		ARCHITECT 20		

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
				Optional for Patient test orders Default = empty field The system does not use contents of this field for Control test orders.
7.5	Patient ID No. 3	Alinity ci-series (Not Supported) ARCHITECT 20	Patient ID No. 3	Optional for Patient test orders Empty for Control test orders

Related information...

System-specific incoming messages, page 69

Test Order record

The following table details the differences in the format of the Test Order record sent by the host to the Alinity ci-series or ARCHITECT System.

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
8.4.5	Universal Test ID	0	Empty	Universal Test ID (part 1) - not used
		0	^Empty	Universal Test ID (part 2) - not used
		0	^Empty	Universal Test ID (part 3) - not used
		4	^Assay Number	Assay number that identifies the test
		Alinity ci-series 15 ARCHITECT 10	^Assay Name	Assay name of the test
		10	^Dilution	Sample Dilution protocol name used for the test
		Alinity ci-series (Not Supported) ARCHITECT 1	^Status (P, p, C, or c)	Assay status: P or p if assay is installed as the primary version. C or c if the assay is installed as the correlation version (optional for all test orders. If left blank, the system places the test order for the primary version of the assay). **NOTE:** Alinity ci-series does not support Assay Status component.
8.4.6	Priority	1	Alinity ci-series S ARCHITECT	S or s = Stat Priority Blank or any other character = Routine

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
			S or s	**NOTE:** Alinity ci-series does not support "s".
8.4.12	Action Code	1	Alinity ci-series N, A, or C ARCHITECT N, A, C or Q	N = New order for a specimen - only create new order if the specified assay in 8.4.5 does not already exist for the specimen A = Add (unconditional) order for a specimen - create order for the specified assay in 8.4.5 even if an order already exists for that assay C - Cancel (delete) pending order for the assay specified in 8.4.5 **NOTE:** Alinity ci-series does not support "Q" = Control Sample.
8.4.13	Danger Code	Alinity ci-series (Not Supported) ARCHITECT 15	Danger Code	Part of the Test Order Comment Field (optional)
8.4.14	Clinical Information	Alinity ci-series (Not Supported) ARCHITECT 15	Clinical Information	Part of the Test Order Comment Field (optional)
8.4.16	Specimen Type	Alinity ci-series (Not Supported) 5	Specimen Type	Part of the Test Order Comment Field (optional)
	Specimen Source	Alinity ci-series (Not Supported) 15	^Specimen Source	
8.4.26	Report Types	1	Alinity ci-series O or Q ARCHITECT O or o Q or q	O (or o) = Order record; asking that analysis be performed. Q (or q) = response to Query. (This record is a response to an order query request.) **NOTE:** Alinity ci-series does not support "o" or "q".

Related information...

System-specific incoming messages, page 69

Comment record

The following table details the differences in the format of the Comment record sent by the host to the Alinity ci-series or ARCHITECT System.

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
10.4	Comment Text	50	Alinity ci-series String	Order comment text.
			ARCHITECT Printable characters	**NOTE:** Alinity ci-series truncates any text in excess of 50 characters.

Related information...

System-specific incoming messages, page 69

Request Information record (Q), Alinity ci-series

There are no differences in the Request Information record sent by the host to the Alinity ci-series and a Negative Query Response record sent by the host to the ARCHITECT System.

Related information...

System-specific incoming messages, page 69

Message Terminator record

There are no differences between the fields in the message terminator record.

Related information...

System-specific incoming messages, page 69

Revision history

Document control numbers	Revision date	Content revised
80000456-101	2016-12-12	Original release
80000456-102	2018-05-21	• Read me first: Updated the copyright information for Proprietary statement. • Read me first: Updated the text for Disclaimers. • Read me first: Updated the biological risk graphics, date of manufacture graphic, manufacturer graphic, temperature limitation graphic, and WEEE description for Key to symbols. • Read me first: Added the interior light symbol and description for Key to symbols. • Read me first: Added the Assay Availability row for Comparison between available LIS interfaces: CLSI (ASTM) vs. HL7.
80000456-103	2022-02-14	• Read me first: Added intended user statement to Foreword. • Read me first: Revised the uniform resource locator for Customer service. • Read me first: Revised the current copyright date for Proprietary statement. • Read me first: Revised the content for Disclaimers. • Read me first: Removed the Alinity ci-series agency approvals topic. • Read me first: Added symbols and revised the layout for Key to symbols. • Read me first: Added row for Command/Response to Comparison between available LIS interfaces: CLSI (ASTM) vs. HL7. • Section 2, Outgoing messages: Revised content for Message granularity. • Section 3, Incoming messages: Revised Trigger event content for Order download.

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