thermoscientific

LIS Interface Gallery - Indiko

Version 6.0

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ThermoFisher SCIENTIFIC

Manufactured by
Thermo Fisher Scientific Oy
Ratastie 2, P.O.Box 100
FI-01621 Vantaa
Finland
Tel: +358 10 329 200
E-mail: system.support.fi@thermofisher.com

Notices

When the system is delivered to you, it meets the pertinent electromagnetic compatibility (EMC) and safety standards as described below.

Standards

Table 1. Conformity with the following international standards and regulations for Indiko analyzers

Standard	Title
• EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes.
• EN ISO 14971	Medical devices - Application of risk management to medical devices.
• EN 61010-1 • IEC 61010-1 • UL 61010-1 • CAN/CSA-C22.2 No. 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements.
• EN 61010-2-010 • IEC 61010-2-010 • CAN/CSA-C22.2 No. 61010-2-010	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of material.
• EN 61010-2-081+A1 • IEC 61010-2-081+A1 • CAN/CSA-C22.2 No. 61010.2.081	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes.
• EN 61010-2-101 • IEC 61010-2-101 • CAN/CSA-C22.2 No. 61010.2.101	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.
• EN 61326-1	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements.

Standard	Title
• EN 61326-2-6	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements - *In vitro* diagnostic (IVD) medical equipment.
• FCC CFR 47 Part 15	Subpart B, Class B. EMC Requirements for US.
• EN 62304 • IEC 62304	Medical device software - Software life-cycle processes.
• EN 50581	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.
• CLSI LIS01-A2 (2nd edition)	Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems; Approved Standard.
• CLSI LIS02-A2 (2nd edition)	Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems; Approved Standard.

Table 2. Conformity with the following international standards and regulations for Gallery analyzers

Standard	Title
• EN ISO 12100	Safety of machinery – General principles for design – Risk assessment and risk reduction.
• EN 61010-1 • IEC 61010-1 • UL 61010-1 • CAN/CSA-C22.2 No. 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements.
• EN 61010-2-010 • IEC 61010-2-010 • CAN/CSA-C22.2 No. 61010-2-010	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of material.
• EN 61010-2-081+A1 • IEC 61010-2-081+A1 • CAN/CSA-C22.2 No. 61010.2.081	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes.
• EN 61326-1	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements.

Standard	Title
• EN 61000-6-2	Electromagnetic compatibility (EMC) – Part 6-2: Generic standards – Immunity for industrial environments.
• EN 61000-6-3	Electromagnetic compatibility (EMC) – Part 6-3: Generic standards – Emission standard for residential, commercial and light-industrial environments.
• FCC CFR 47 Part 15	Subpart B, Class B. EMC Requirements for US.
• EN 50581	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances.
• CLSI LIS01-A2 (2nd edition)	Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems; Approved Standard.
• CLSI LIS02-A2 (2nd edition)	Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems; Approved Standard.

CE

CE	The CE mark attached on Indiko (clinical chemistry analyzer, type 863) indicates the conformity with the IVD (in vitro diagnostic medical devices) directive 98/79/EC and RoHS directive (Restriction of the use of certain hazardous substances in electrical and electronic equipment) 2011/65/EU.
	The CE mark attached on Gallery (chemistry analyzer, type 861) indicates the conformity with the EMC (electromagnetic compatibility) directive 2004/108/EC and Machinery Directive 2006/42/EC and RoHS directive (Restriction of the use of certain hazardous substances in electrical and electronic equipment) 2011/65/EU. Changes that you make to your system may void compliance with one or more of these EMC and safety standards. Changes to your system include replacing a part or adding components, options, or peripherals not specifically authorized and qualified by Thermo Fisher Scientific. To ensure continued compliance with EMC and safety standards, replacement parts

and additional components, options, and peripherals must be ordered from Thermo Fisher Scientific or one of its authorized representatives.

FCC Notice

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

WEEE Compliance

This product is required to comply with the European Union's Waste Electrical & Electronic Equipment (WEEE) Directive 2012/19/EU. It is marked with the following symbol:

Thermo Fisher Scientific has contracted with one or more recycling/disposal companies in each EU Member State, and these companies should dispose of or recycle this product. For further information on Thermo Fisher Scientific's compliance with these directives, the recyclers in your country, and information on Thermo Fisher Scientific products which may assist the detection of substances subject to the RoHS Directive contact us by e-mail: weee.recycle@thermofisher.com.

Contents

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Preface

LIS Interface contains instructions on how to integrate the analyzer into the laboratory information system (LIS). This manual describes the communication between the analyzer and the host.

Intended use

Thermo Scientific Indiko Clinical Chemistry Analyzers are fully automated random access analyzers for routine and special chemistries, including specific proteins, therapeutic drugs, drugs of abuse.

Indiko Clinical Chemistry Analyzer(s) are intended to be used in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat or prevent a disease. Indiko, and all of the reagents included in this test system are for in vitro diagnostic use only.

Thermo Scientific Gallery is a discrete, automated chemistry analyzer. In addition to photometric measurement, the analyzer supports electrochemical measurement (ECM) technique.

Gallery is specifically designed e.g. for food, beverages, water, environmental and different bioprocess applications. Thermo Scientific Gallery is offered with various system applications. Furthermore, the analyzer supports user definable application setup.

Gallery Plus *Beermaster* model is dedicated for beer and wort quality control and analysis.

Intended audience

This manual is addressed to the personnel responsible for integrating the analyzer into the laboratory information system (LIS). The personnel must be trained in and should have a knowledge of handling the analyzer.

Note It is recommended to follow good laboratory practices (GLP).

Product documentation

The product documentation consists of the following manuals:

- Operation Manual contains instructions on how to operate the analyzer during normal operation once it has been installed. The manual can be used to find out what needs to be done before running analyses and how to run analyses. The manual also contains daily maintenance task descriptions and a troubleshooting guide.
- Reference Manual contains operational and analysis principle descriptions and lists test parameters per test.
- Installation Manual contains instructions on how to install the analyzer. The manual describes procedures for mechanical and electrical installation. The chapters are organized in the chronological order in which the analyzer should be installed.
- Service Manual contains instructions on how to service and maintain the analyzer. The manual also describes procedures for adjusting the analyzer and information about the analyzer parts. The manual also lists spare parts and accessories. Service Manual is provided only to the trained service engineers.
- The LIS Interface manual contains instructions on how to integrate the analyzer into the Laboratory Information System (LIS). The manual describes the communication between the analyzer and the host, using the RS-232 or TCP/IP interface.

Document revision history

Document version and date	Document code	Software version	History
A/December 2010	N12027	2.0	Document created.
A/July 2011	N12027	3.0	Additional information added about CLSI LIS2-A message structure.
A/February 2012	N12027	4.0	Examples about communication between analyzer and host computer updated.
A/January 2013	N12027	4.1	Information about PC configuration and checksum calculation updated.
A/June 2013	N12027	5.0	Birth date and reference ranges support added. Error flags updated.
A/October 2013	N12027	5.1	Support for quality control sending added. Examples about communication between analyzer and host computer updated.
A/July 2014	N12027	5.2	Additional information added about CLSI LIS2-A message structure.

Document version and date	Document code	Software version	History
A/June 2015	N12027	5.3	Updated CLSI LIS2-A message structure and contact information. Updated contact information.
A/October 2016	N12027	6.0	Updated CLSI LIS2-A message structure.

The original language of these instructions is English.

Document symbols and conventions

Symbols in manual

This manual uses notes that point out important information related to the correct and safe operation of the analyzer. Therefore, comply fully with all notices.

Note The note icon informs the operator of relevant facts and conditions.

CAUTION The caution icon indicates important information or warnings related to the concept discussed in the text. It might indicate the presence of a hazard which could result in the corruption of software or damage to equipment or property.

Document conventions

- Important abbreviations and terms in this manual are spelled out in Glossary.
- The last command of the user interface menu path is presented in bold, for example: Select F2 > Samples > **New**.
- Menu names in the user interface are shown in bold, for example: Select the correct test from the **Test name** drop-down menu in the Results view.
- Parameter names are shown in italics, for example: The test can be taken into or out of use with the *In use* parameter.
- Parameter values are indicated with quotation marks, for example: The values of the *In use* parameter are “Yes” and “No”.
- The statuses and messages are shown in Courier font, for example `No valid calibration`.

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Hardware interface

The analyzer LIS hardware interface works through a serial communication channel or an ethernet interface. The ethernet connector and the connector for serial communication are at the back of the analyzer workstation. An ethernet cable is used for the TCP/IP connection. The connector for the serial communication channel is a 9-pin male D-connector.

Note Do not use network cable connection for the internet or other LAN connections.

Figure 1. Connectors

1 - Serial connector
2 - Ethernet connector

Table 3. The signals needed at the analyzer end of cable

Pin	Description
Pin 2	Receive Data
Pin 3	Transmit Data
Pin 5	Ground

Note Configure the cable according to the documentation of LIS system in use.

Table 4. Example of cabling between analyzer and LIS

Analyzer	PC (RS-232)
Pin 2 RxD	Pin 3 TxD
Pin 3 TxD	Pin 2 RxD
Pin 5 Gnd	Pin 5 Gnd

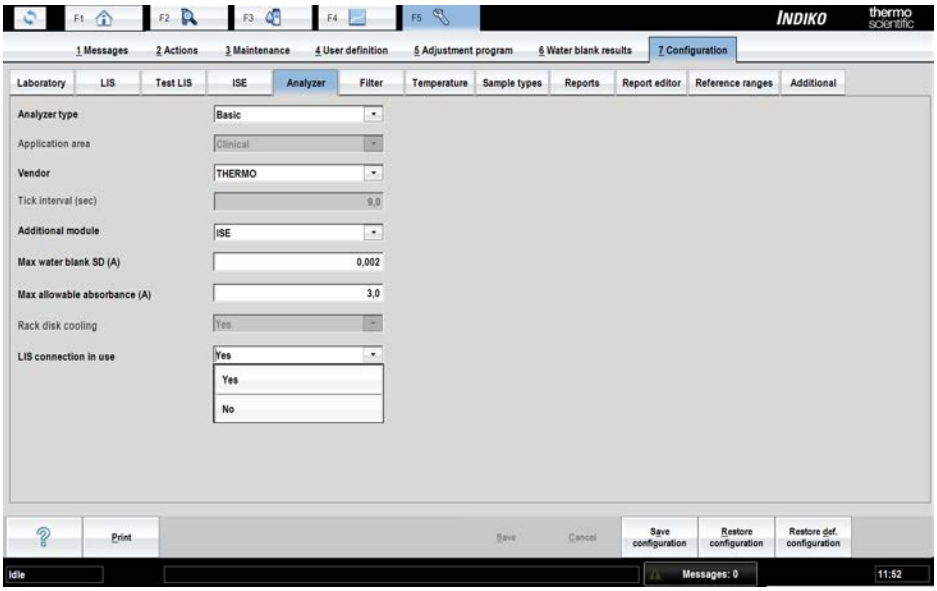
Note This example describes the minimum cable connections needed. Some computer systems may require some additional signals connected locally within connector. For more information about requirements, refer to the LIS documentation (Standards CLSI LIS01-A2 and CLSI LIS2-A 2).

Configuring ASTM software

To configure ASTM software:

1. Before configuration, take LIS into use.
   a) Select F5 > Configuration > **Analyzer**.
   b) Select **Yes** from the **LIS connection in use** drop-down menu.

Figure 2. Selecting LIS connection in use



2. Select F5 > Configuration > **LIS** to configure parameters shown in Configuration modifications on page 3. The ASTM software has additional configurations comparing to the analyzer online software. The configuration file is saved into the database.

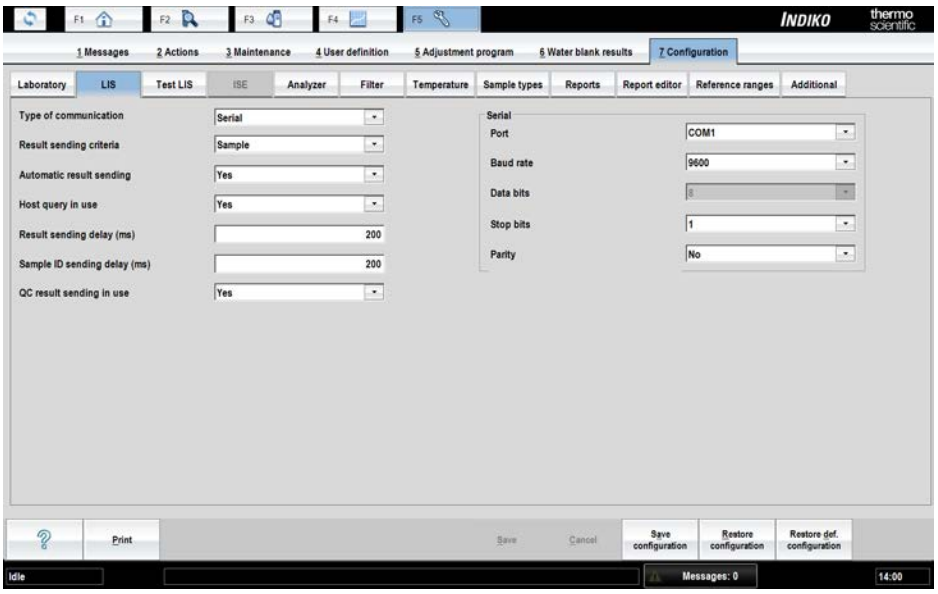
> **Note** The ASTM software supports sending results on ready sample or ready request basis. The sending of results on ready request basis loads the interface heavily. It is recommended to send results by ready sample. The selection can be done through the analyzer configuration function.

Table 5. Configuring parameters

Parameter	Value to be used	Description
Type of communication	TCP/IP, Serial	Select a connection type
Result sending criteria	Request, Sample	Define whether the sample results are sent according to the request or sample.

Parameter	Value to be used	Description
Automatic result sending	Yes	If the value is set to "Yes", new sample results and QC results (if defined) are automatically sent to the laboratory computer.
Host query in use	Yes	If the value is set to "Yes", the analyzer software sends a query for sample information and requests when new sample is introduced into the analyzer.
Multiple host query	Yes/No	If the value is set to "Yes", the analyzer sends the host query every time the barcode of the sample is read. If the value is set to "No", the analyzer sends the host query only for new samples.
Sample ID sending delay (ms)	0	If the value is not set to "0", the analyzer uses the delay between successive sending of new sample IDs. The sending delay can be used to ease the burden on laboratory computer, for example, when a full rack is introduced. The value is expressed in milliseconds.
Result sending delay (ms)	0	If the value is not set to "0", the analyzer uses the delay between successive sending of new sample results. The sending delay can be used to ease the burden on laboratory computer. The value is expressed in milliseconds.
QC result sending in use	Yes	If the value is set to "Yes", QC results are sent to the laboratory computer. The program also supports requests for archived QC results.

Figure 3. LIS Configuration



- Configuring serial connection

Configuring serial connection

If the **Type of communication** is set to **Serial**, configure parameters for serial interface.

Table 6. Serial interface parameters

Parameter	Values	Description
Serial port	COM1, COM3, COM4, COM5, COM6	Select the serial port.
Baud rate	2400, 4800, 9600, 19200	Select the baud rate between 2400 and 19200.
Data bits	8	The number of data bits is set to 8.
Stop bits	1, 2	The number of stop bits can be set to 1 or 2.
Parity	Even, Odd, No, Space, mark	Select the type of parity checking. If the value is set to "No", the parity checking is not performed.

Configuring TCP/IP connection

Socket Communication

Analyzer's socket communication is based on Windows Sockets which uses TCP/IP connection oriented sockets. A connection is needed between two parts, which are able to communicate, before information transmission can occur. After the communication, the connection can be terminated. The connection remains open until the session is closed, a request to clear the daily files is initiated or an error is occurred.

Analyzer can act as a client or a server in a socket communication. If the analyzer is run as a client, the analyzer tries to establish a connection to a given port at the given IP address. If the analyzer is run as a server, the analyzer creates a listening socket for a given port at given IP address and accepts client connection requests.

Communication requires a server at one end and a client at another end. Furthermore, the analyzer server mode can serve only one connection at a time and any attempt to create more connections may lead to malfunction. When the Windows firewall is in use, allow the `ArcASTM.exe` process to pass the firewall. It is allowed to disable the firewall only for testing purposes.

Communication protocol

Analyzer uses the ASTM protocol in socket communication. The serial channel is replaced with the socket communication. All interactions and message structures are similar when using a serial channel.

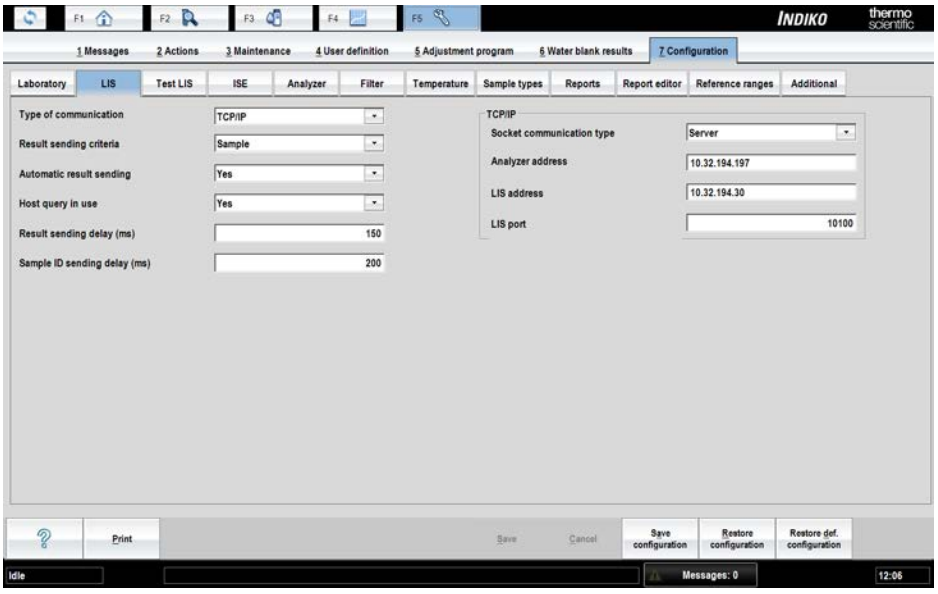
Configuration

Configure a new network card to use the specific TCP/IP address that is reserved for the communication. First, configure the new card using **Network Connections** in **Windows Control Panel**. After card configuration, define the settings for routes. If an address for a new card is 172.16.0.11 and the address for other end communication is 172.16.0.XXX, type the following command lines in **Windows Command Prompt**:

```
Route ADD -P 193.94.136.0 MASK 255.255.255.0 193.94.136.60
Route ADD -P 172.16.0.0 MASK 255.255.255.0 172.16.0.11
```

Commands create permanent entries to the route table and the Windows Sockets can tell which card to use for communicating with a certain IP address. If the address of the new card is not 172.16.0.11, change the last command line to match the used address.

Figure 4. LIS configuration



Furthermore, define the connection parameters for socket communication. Select **TCP/IP** from the **Type of communication** drop-down menu and configure parameters shown in TCP/P connection parameters on page 6. For successful communication, both ends must use same port number and matching IP addresses.

Table 7. TCP/IP connection parameters

Parameter	Values	Description
Socket communication type	Server, Client	Analyzer software can be socket server or socket client

Parameter	Values	Description
Analyzer address		IP address configured to a new network card
LIS address		IP address for LIS system
LIS port		A communication port which is opened to ASTM communication

Connection management

Analyzer tries to connect when possible. In client mode, the analyzer tries to create a connection once in every 20 milliseconds. In server mode, the analyzer waits for a connection. After the connection has been established, the analyzer does not disconnect until the application is closed, a request to clear the daily files is initiated or an unrecoverable error condition is occurred in communication.

Furthermore, clearing daily files and changing the LIS connection communication parameters disconnects the analyzer, but the connection is restored after the operation has been performed. The analyzer waits for a few seconds before accepting any new data through the LIS connection. This ensures that the analyzer is internally stable before starting a new session. Error messages are not shown when the connection is terminated due to the clearing of daily files. If a communication error occurs, analyzer disconnects and one of the following error messages is shown:

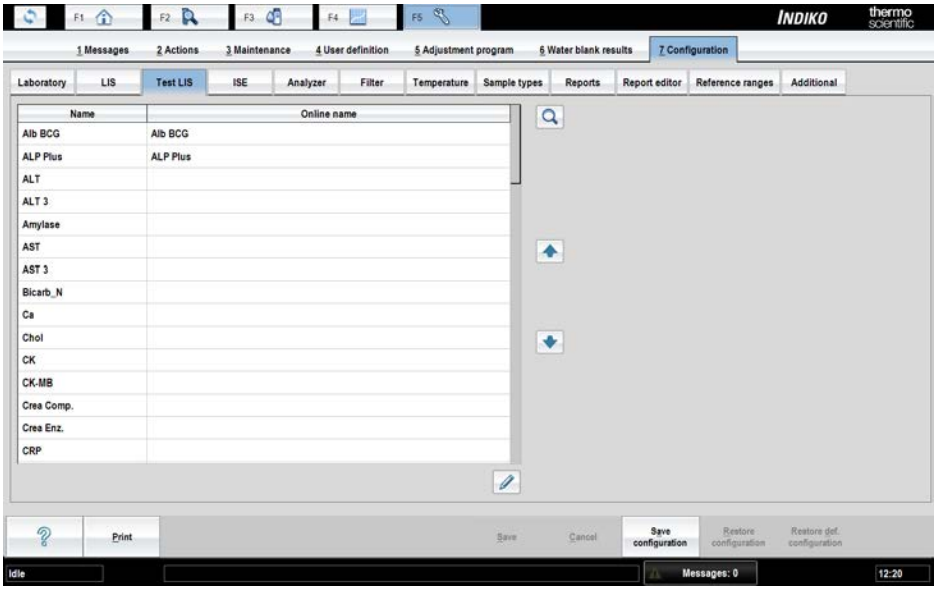
```
4403 Write error (LIMS)
4404 Read error (LIMS)
4406 Communication time-out (LIMS)
4407 Transmit error (LIMS)
```

Error messages indicate the problems in communication. Analyzer tries to restore the connection immediately after it is disconnected. A flashing yellow signal on workstation screen indicates a communication trial is going on, but it does not indicate a successful communication.

Configuring test online names

Each test must have a test online name defined, if results or requests need to be transferred into the LIS system through the ASTM protocol. The test online name must match with the LIS test name, otherwise an error message is shown. The test online name must be unique for each test. If the online name is invalid, a comment message is sent to the LIS server.

Figure 5. Configuring test online names



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ASTM protocol

The ASTM laboratory information management system interface is based on the following standards:

- CLSI LIS1-A: Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems
- CLSI LIS2-A: Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems

Features

The physical transmission layer is implemented according to CLSI LIS1-A. The connection can be established through the serial communication channel or the ethernet interface. The logical layer contains selected portions of CLSI LIS2-A. The detailed record structure is described in CLSI LIS2-A message structure on page 10.

Main features:

- automatic request for sample information when new sample is introduced to the analyzer (configurable ON/OFF)
- automatic sending of results either on ready sample or ready request basis (configurable reporting basis and ON/OFF)
- automatic sending of quality control results (configurable ON/OFF)
- response to sample information requests from the laboratory computer
- response to sample information received from the laboratory computer
- response to quality control information requested from the laboratory computer
- error situation management

Signal	Pin
RxD (received data)	2
TxD (transmitted data)	3
GND (ground)	5

Default communication parameters:

- 9600 baud
- 8 bit
- 1 start bit
- 1 stop bit
- no parity

No hardware or software flow control is used.

CLSI LIS2-A message structure

Following sections describe the ASTM records used by the analyzer.

The tables include:

- field name
- field number
- information about the field usage by the host
- information about the field usage by the analyzer
- description about the field usage

Optional fields have the usage information in brackets (X). The host can send data filled in all the fields, but only the marked fields are processed. The maximum length of the record is 247 characters without control characters and checksum. The ASTM software uses windows 1252 character encoding that supports characters 128-255 in ASCII table.

Header record (level 0)

The checksum is initialized to zero with the <STX> character. The first character used in computing the checksum is the frame number. Each character in the message text is added to the checksum (modulo 256). The computation for the checksum does not include <STX>, the checksum characters, or the trailing <CR> and <LF>.

Field name	No.	Host	Analyzer	Description
Record type ID	1	X	X	Always H. Starts every message. Do not use delimiter between the first and the second field
Delimiter definition	2	X	X	Field, repeat, component and escape delimiters
Message control ID	3	-		
Access password	4	-		
Sender name or ID	5	-	X	Analyzer type [1]
		-	X	Analyzer ID
		-	X	Database version

Field name	No.	Host	Analyzer	Description
Sender street address	6	-	-	
Reserved field	7	-	-	
Sender telephone number	8	-	-	
Characteristics of sender	9	-	-	
Receiver ID	10	-	-	
Comment or special instructions	11	-	-	
Processing ID	12	X	X	P (production)
		X	X	T (training)
		X	X	D (debugging)
		X	X	Q (QC)
Version No. Date and time of message	13	-	-	
Date and time of message	14	-	(X)	Form YYYYMMDDHHMMSS. Only in debug mode.

Message terminator record (level 0)

Field name	No.	Host	Analyzer	Description
Record type ID	1	X	X	Always L. Ends every message.
Sequence number	2	X	X	Always 1. One terminator per message.
Termination code	3	(X)	(X)	N or missing (normal termination)
		X	X	T (sender aborted)
		X	X	R (receiver requested abort)
		X	X	E (unknown error)
		-	X	Q (error in last request for information)
		-	X	I (no information available from last query)
		-	X	F (last request for information processed)

Patient information record (level 1)

If patient information is used, the patient name field is required.

Field name	No.	Host	Analyzer	Description
Record type ID	1	X	X	Always P.
Sequence number	2	X	X	Running number within Message. Starts with 1.
Practice assigned patient ID	3	(X)	(X)	If no code is given, this gets the value of Patient name.
Laboratory assigned patient ID	4	-	-	
Patient ID No. 3	5	-	-	
Patient name	6	(X)	(X)	Last name. Only one text field. Type the whole name. Optional if no patient relates to sample.
		-	-	First name
		-	-	Middle name or initials
Mothers maiden name	7	-	-	
Date of birth	8	(X)	(X)	Form YYYYMMDD.
Patient sex	9	(X)	(X)	Used as a reference range name. The field is case-sensitive.
Patient race-ethnic origin	10	-	-	
Patient address	11	-	-	
Reserved field	12	-	-	
Patient telephone number	13	-	-	
Attending physician ID	14	-	-	
Special field 1	15	-	-	
Special field 2	16	-	-	
Patient height	17	-	-	
Patient weight	18	-	-	
Patient's known or suspected diagnosis	19	-	-	
Patient active medications	20	-	-	

Field name	No.	Host	Analyzer	Description
Patient's diet	21	-	-	
Practice field 1	22	-	-	
Practice field 2	23	-	-	
Admission or discharge dates	24	-	-	
Admission status	25	-	-	
Sender	26	(X)	(X)	Ordering doctor
Native of alternative diagnostic code and classifiers	27	-	-	
Alternative diagnostic code and classification	28	-	-	
Patient religion	29	-	-	
Marital status	30	-	-	
Isolation status	31	-	-	
Language	32	-	-	
Hospital service	33	-	-	
Hospital institution	34	-	-	
Dosage category	35	-	-	

Test order record (level 2)

Field name	No.	Host	Analyzer	Description
Record type ID	1	X	X	Always O.
Sequence number	2	X	X	Running number within Patient information. Starts with 1.
Sample ID	3	(X)	(X)	SampleID or ControlID/ManualDilution/Rack/Position
		Optional, if there is no sample or control in the order. If manual dilution, rack and position information is omitted, the value 0 is set for each. Rack value "0" with position value "0" refer to a virtual collection and must be used, when no actual position is known.		

Field name	No.	Host	Analyzer	Description
Analyzer Sample ID	4	-	-	
Universal test ID	5	-	-	Universal test ID
		-	-	Universal test name
		-	-	Universal test ID type
		X	X	Manufacturer defined test code
		-	X	Auto-dilution factor
		Multiple tests can be ordered separated by repeat delimiter		
Priority	6	(X)	(X)	S (stat)
		(X)	(X)	A (asap)
		(X)	(X)	R (routine)
		-	-	C (callback)
		-	-	P (preoperative)
		Optional, if there is no sample or sample is calibrator or control.		
Requested/ordered date and time	7	-	-	
Sample collection date and time	8	(X)	(X)	Form YYYYMMDDHHMMSS
Collection end time	9	-	-	
Collection volume	10	-	-	
Collector ID	11	-	-	
Action code	12	X	-	A (add test requests to existing sample)
		X	-	N (new test requests + new sample)
		-	X	P (pending sample)
		-	-	L (reserved)
		-	X	X (sample or test in process)
		-	X	Q (QC sample)
		-	X	C (comment)
		Multiple action codes can be typed separated by repeat delimiter. For example X\Q.		

Field name	No.	Host	Analyzer	Description
Danger code	13	-	-	
Relevant clinical information	14	(X)	(X)	Sample information field
Date/time sample received	15	-	-	
Sample descriptor (type and source)	16	X	X	Type
		-	-	Source
		Type coding: 1 - serum 2- Plasma 3- Urine, 4 - CSF, 5 - Oral fluid, 6 - Whole blood, 7 - Hemol. Blood, 8 - Other		
Ordering physician	17	-	-	
Physicians telephone number	18	-	-	
User field No.1	19	-	-	
User field No.2	20	-	-	
Laboratory field No.1	21	-	(X)	Control lot ID
		-	(X)	Concentration
		-	(X)	Control lot standard deviation
Laboratory field No.2	22	-	-	
Date/time results reported or last modified	23	-	-	
Instrument charge to computer system	24	-	-	
Instrument section ID	25	(X)	(X)	Optional if no sample, Indiko always 1
Report types	26	X	-	O (order)
		-	-	P (preliminary results)
		-	-	C (correction to previously transmitted results)
		-	X	F (final results)
		X	X	X (requests cancelled)
		X	X	I (in analyzer pending)
		-	X	Y (no order for test (response to query))
		-	X	Z (no record of this patient (response to query))

Field name	No.	Host	Analyzer	Description
		X	X	Q (response to query (info))
		Multiple report types can be typed separated by repeat delimiter. For example Y\Z.		
Reserved field	27	-	-	
Location or ward of sample collection	28	-	-	
Nosocomial infection flag	29	-	-	
Sample service	30	-	-	
Sample institution	31	-	-	

Note If even one test is requested as STAT, the priority of test order record is set to stat (S) when results are reported by samples. When results are reported by requests, the right test priority is always seen.

Result record (level 3)

Field name	No.	Host	Analyzer	Description
Record type ID	1	-	X	Always R.
Sequence number	2	-	X	Running number within Test order. Starts with 1.
Universal test ID	3	-	-	Universal test ID
		-	-	universal test name
		-	-	universal test ID type
		-	X	manufacturer defined test code
		-	X	dilution factor used in calculation
Data or measurement value	4	-	(X)	If the result status is X (cancelled) or result is UNSTABLE, no result is given. The range of result will be [99999.9 … 0.00000] and [-0.00000 … -99999.9]. If the actual result exceeds the values, the nearest value is shown.
Units	5	-	(X)	Text field. All special characters (e.g. µ) are not supported. Unsupported characters are replaced with "?" character.
Reference ranges	6			Components:

Field name	No.	Host	Analyzer	Description
		-	X	Low limit
		-	X	High limit
		-	-	Description
Result abnormal flags	7	-	X	L/N/H (below lower limit/normal/above higher limit)
Nature of abnormality testing	8	-	-	
Result status	9	-	-	C (correction)
		-	X	P (preliminary)
		-	X	F (final)
		-	X	X (cancelled)
		-	X	I (pending)
		-	-	S (partial)
		-	-	M (MIC level)
		-	X	R (reported)
		-	-	N (contains necessary information to run a new order)
		-	X	Q (response to query)
		-	-	V (verified)
		-	-	S (result from pretreated sample)
		Multiple status flags can be given separated by repeat delimiter. For example F\Q.		
Date of change in analyzer normative values or units	10	-	-	
Operator identification	11	-	X	User login name if User levels have been set on. When a result is manually accepted, current user's login name is sent with the result. If the result is automatically accepted the text is "Automatic".
Date/time test started	12	-	-	
Date/time test completed	13	-	(X)	Form YYYYMMDDHHMMSS. No value if test is not completed.

Field name	No.	Host	Analyzer	Description
Analyzer identification	14	-	X	Analyzer ID is defined in the configuration parameter AnalyzerName.

Comment record (level 4) used with result record

Field name	No.	Host	Analyzer	Description
Record type ID	1	-	X	Always C. Used to transfer analyzer flags after Result record.
Sequence Number	2	-	X	Always 1, because of the use.
Comment source	3	-	-	P (practice)
		-	-	L (computer system)
		-	X	I (clinical analyzer system)
Comment text	4	-	X	Error condition identified with a number and a text in English. When the text in a comment record differs from the text in the Measurement Errors chapter in Operation Manual, the Operation Manual text is shown in parentheses.

Field name	No.	Host	Analyzer	Description
				2 - Addl. meas. error 3 - Instrument abs. limit (Abs. high) 4 - Init abs. low 5 - Init abs. high 6 - Bichr. net abs. 7 - Linearity 8 - Point(s) out of curve 9 - Reaction direction 10 - Blank init abs. low 11 - Blank init abs. high 12 - Blank resp. low 13 - Blank resp. high 14 - Unstable 15 - Unstable cal. 16 - Liquid movement 18 - Dil. limit low 19 - Dil. limit high 20 - Test limit low 21 - Test limit high 22 - Crit. limit low 23 - Crit. limit high 24 - Antigen limit low 25 - Antigen limit high 27 - QC (Batch incomplite) 28 - Calc. error 30 - Outside of cal. 31 - Square limit low (Coeff. of det. limit) 32 - Factor limit low (Slope limit min) 33 - Factor limit high (Slope limit max) 34 - Bias limit low 35 - Bias limit high 38 - Reference range low 39 - Reference range high
		Multiple flags can be given separated with repeat delimiter.		
Comment type	5	-	(X)	G (result approval comment)
		-	-	T (test name comment)
		-	-	P (positive test comment)
		-	-	N (negative test comment)
		-	X	I (analyzer flag(s) comment)

Comment record (level 3) used with transmission error conditions

Field name	No.	Host	Analyzer	Description
Record type ID	1	-	X	Always C. Used to transfer analyzer flags after Result record.
Sequence Number	2	-	X	Always 1, because of the use.
Comment source	3	-	-	P (practice)
		-	-	L (computer system)
		-	X	I (clinical analyzer system)
Comment text	4	-	X	Error condition identified by 'E' followed by a number E3 - wrong initializing character in record E4 - wrong termination code or request code in record E5 - records found in wrong order E104 - invalid sample plate position, sample position already reserved in analyzer by another sample or calibrator or control. The new sample was wrongly positioned by LIS. Use position 0^0 for any sample when the position is defined at a later moment with sample insertion into the analyzer. E105 - problems with analysis request, request could not be created E201 sample rack position is reserved E210 - problems with updating patient information E211 - patient information could not be found E220 - sample already exists E221 - problems with sample information E222 - Invalid test online name
Comment type	5	-	X	G (generic/free text document)
		-	-	T (test name comment)
		-	-	P (positive test comment)
		-	-	N (negative test comment)

Field name	No.	Host	Analyzer	Description
		-	-	I (analyzer flag(s) comment)

Request information record (level 1)

Field name	No.	Host	Analyzer	Description
Record type ID	1	X	X	Always Q. Analyzer requests external test results or orders new samples. Host requests sample and/or control results and monitors that results are in analyzer's database.
Sequence number	2	X	X	Always 1. Only one request can be outstanding at a time.
Starting range ID number	3	-	-	Patient ID or ALL
		(X)	(X)	Sample ID or ALL
		(X)	(X)	Rack
		(X)	(X)	Position
		Patient ID and sample ID are text fields, so field is not used as range. Multiple patients or samples can be requested separated by repeat delimiter.		
Ending range ID number	4	-	-	
Universal test ID	5	-	-	Universal test ID
		-	-	Universal test name
		-	-	Universal test ID type
		(X)	(X)	Manufacturer defined test code or ALL
		-	-	Auto-dilution factor
		Multiple tests can be requested separated by repeat delimiter.		
Nature of request time limits	6	-	-	S (sample collect date)
		(X)	(X)	R (result test date)
		According to standard R is taken as default, so it is optional.		
Beginning request results date and time	7	(X)	(X)	Form YYYYMMDDHHMMSS

Field name	No.	Host	Analyzer	Description
Ending request results date and time	8	(X)	(X)	Form YYYYMMDDHHMMSS
Requesting physician name	9	-	-	
Requesting physician telephone number	10	-	-	
User field No.1	11	-	-	
User field No.2	12	-	-	
Request information status codes	13	-	-	C (correction)
		(X)	(X)	P (preliminary)
		(X)	(X)	F (final)
		(X)	(X)	X (cancelled)
		(X)	(X)	I (pending)
		-	-	S (unfinalized results)
		-	-	M (MIC level)
		(X)	(X)	R (previously transmitted)
		-	-	A (cancel last request criteria)
		(X)	(X)	N (requesting new or edited results only)
		(X)	(X)	O (requesting test orders only (no results)
		-	-	D (requesting demographics only)
		Note: not repeated.		

Field lengths

Field	Length in characters
Analyzer type	1
Analyzer ID	20
Date and time of message	14
Practice assigned test ID	20
Patient name	24
Sample ID / Control ID	20
Manufacturer defined test code	30
Sample collection date and time	20
Relevant clinical information	80
Data or measurement value	9
Units	10
Date/time test completed	14
Beginning request results date and time	14
Ending request results date and time	14

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5

Examples: communication between analyzer and host computer

Examples show transmissions between the analyzer and the host computer, when the analyzer is configured to use automatic sample ID Sending and automatic result Sending. The control characters are presented between '<>'. For example `<enq>` means an ASCII character ENQ which hexadecimal value is 05. Examples give only an overview, the actual communication may vary.

Before starting the communication, it is possible to turn on the debugging of communication by selecting F5 > **Actions**. Click **Change debug status** and select the debug level. The file `lsdebug.txt` in the folder `c:\ARC\tmp` includes the LIS communication messages sent between the analyzer and LIS.

Examples: communication between analyzer and host computer

New sample introduced to the analyzer

Send: <ENQ>
Read: <ACK>
Send: <STX>1H|\^&|||1^Analyzer_1^||||||P||20101118101825<CR><ETX>A1
Read: <ACK>
Send: <STX>2Q|1|^SampleID_03^^||^^^ALL^|||||||O<CR><ETX>FF
Read: <ACK>
Send: <STX>3L|1|N<CR><ETX>06
Read: <ACK>
Send: <EOT>

Read: <ENQ>
Send: <ACK>
Read: <STX>1H|\^&|||1^LIS host^1.0||||||P<CR><ETX>0D
Send: <ACK>
Read: <STX>2P|1|PatientID_03|||Patient Name_3|||U|||||||||||||||Doctor Name|<CR><ETX>60
Send: <ACK>
Read: <STX>3O|1|SampleID_03||^^^ISE_test|S||20101102100000|||||Test information field||3|||||||||O<CR><ETX>2E
Send: <ACK>
Read: <STX>4L|1|F<CR><ETX>FF
Send: <ACK>
Read: <EOT>

Send: <ENQ>
Read: <ACK>
Send: <STX>1H|\^&|||1^Analyzer_1^||||||P||20101118104132<CR><ETX>9B
Read: <ACK>
Send: <STX>2P|1|PatientID_03|||Patient Name_3|||||||||||||||||||Doctor Name|||||||<CR><ETX>F5
Read: <ACK>
Send: <STX>3O|1|SampleID_03^0.0^3^1||^^^ISE_test^0|R||20101102100000||||X||Test information field||3|||||||||1|F<CR><ETX>21
Read: <ACK>
Send: <STX>4R|1|^^^ISE_test^5|0.00830|µmol/l|||||||20101118104459|Analyzer_1<CR><ETX>D6
Read: <ACK>
Send: <STX>5L|1|N<CR><ETX>08
Read: <ACK>
Send: <EOT>

Query and several tests to single sample

Send: <ENQ>
Read: <ACK>
Send: <STX>1H|\^&|||1^Analyzer_1^||||||P||20101118143543<CR><ETX>A4
Read: <ACK>
Send: <STX>2Q|1|^SampleID_07^^||^^^ALL^|||||||O<CR><ETX>03
Read: <ACK>
Send: <STX>3L|1|N<CR><ETX>06
Read: <ACK>
Send: EOT

Read: <ENQ>
Send: <ACK>
Read: <STX>1H|\^&|||||||||P<CR><ETX>0D
Send: <ACK>
Read: <STX>2P|1|PatientID_07|||Patient Name_7|||U|||||||||||||||<CR><ETX>68
Send: <ACK>
Read: <STX>3O|1|SampleID_07^0.0^0^0||^^^ISE_test\^^^Photo_reflex_test\^^^Photometric_test|R|||||||||3|||||||||O<CR><ETX>31
Send: <ACK>
Read: <STX>4L|1|F<CR><ETX>FF
Send: <ACK>
Read: <EOT>

Send: ENQ
Read: <ACK>
Send: <STX>1H|\^&|||1^Analyzer_1^||||||P||20101118143705<CR><ETX>A4
Read: <ACK>
Send: <STX>2P|1|PatientID_07|||Patient Name_7|||||||||||||||||||||||||<CR><ETX>F3
Read: <ACK>
Send: <STX>3O|1|SampleID_07^0.0^5^1||^^^ISE_test^0|R|||||X||||3|||||||||1|F<CR><ETX>9E
Read: <ACK>
Send: <STX>4R|1|^^^ISE_test^5|0.00675|µmol/l|||||||20101118143620|Analyzer_1<CR><ETX>D6
Read: <ACK>
Send: <STX>5O|2|SampleID_07^0.0^5^1||^^^Photo_reflex_test^5|R|||||X||||3|||||||||1|F<CR><ETX>B4
Read: <ACK>
Send: <STX>6R|1|^^^Photo_reflex_test^0|0.74143|mmol/l|||||||20101118143621|Analyzer_1<CR><ETX>9C
Read: <ACK>
Send: <STX>7O|3|SampleID_07^0.0^5^1||^^^Photometric_test^5|R|||||X||||3|||||||||1|F<CR><ETX>56
Read: <ACK>
Send: <STX>0R|1|^^^Photometric_test^0|0.80626|nmol/l|||||||20101118143620|Analyzer_1<CR><ETX>39
Read: <ACK>
Send: <STX>1O|4|SampleID_07^0.0^5^1||^^^Reflex_test_done^5|S|||||X||||3|||||||||1|F<CR><ETX>2F
Read: <ACK>
Send: <STX>2R|1|^^^Reflex_test_done^5|0.18109|g/l|||||||20101118143705|Analyzer_1<CR><ETX>D0
Read: <ACK>
Send: <STX>3L|1|N<CR><ETX>06
Read: <ACK>
Send: EOT

Invalid test request

Read: <ENQ>
Send: <ACK>
Read: <STX>1H|\^&|||60^ASTM_Tester^5.0||||||P||<CR><ETX>C5
Send: <ACK>
Read: <STX>2P|1|PatientID_06|||Patient Name_6|||||||||||||||||||Doctor Name|||||||<CR><ETX>D7
Send: <ACK>
Read: <STX>3O|1|SampleID_06||^^^Invalid_test|S||20101102100000||||A||Test information field||1|||||||||1|Q\O<CR><ETX>78
Send: <ACK>
Read: <STX>4L|1|F<CR><ETX>FF
Send: <ACK>
Read: <EOT>

Send: <ENQ>
Read: <ACK>
Send: <STX>1H|\^&|||1^Analyzer_1^||||||P||20101118141519<CR><ETX>A5
Read: <ACK>
Send: <STX>2P|1|PatientID_06|||Patient Name_6|||||||||||||||||||Doctor Name|||||||<CR><ETX><CR><ETX>F1
Read: <ACK>
Send: <STX>3O|1|SampleID_06||^^^^0|S|||||C||Test information field||3|||||||||1|X<CR><ETX>8D
Read: <ACK>
Send: <STX>4C|1|I|E105|G<CR><ETX>21
Read: <ACK>
Send: <STX>5L|1|Q<CR><ETX>0B
Read: <ACK>
Send: <EOT>

Measurement error in result

Send: ENQ
Read: <ACK>
Send: <STX>1H|\^&|||1^Analyzer_1^||||||P||20101118151136<CR><ETX>A1
Read: <ACK>
Send: <STX>2Q|1|^SampleID_20^^||^^^ALL^|||||||O<CR><ETX>FE
Read: <ACK>
Send: <STX>3L|1|N<CR><ETX>06
Read: <ACK>
Send: EOT

Read: <ENQ>
Send: ACK
read: <STX>1H|\^&|||||||||P<CR><ETX>0D
Send: ACK
read: <STX>2P|1|PatientID_20|||Patient Name_20||20010101|M|||||||||||||||<CR><ETX>0B
Send: ACK
read: <STX>3O|1|SampleID_20^0.0^0^0||^^^Photometric_test|R|||||||||2|||||||||O<CR><ETX>31
Send: ACK
read: <STX>4L|1|F<CR><ETX>FF
Send: ACK
Read: <EOT>

Send: ENQ
Read: <ACK>
Send: <STX>1H|\^&|||1^Analyzer_1^||||||P||20101118151301<CR><ETX>9B
Read: <ACK>
Send: <STX>2P|1|PatientID_20|||Patient Name_20|||||||||||||||||||||||||<CR><ETX>19
Read: <ACK>
Send: <STX>3O|1|SampleID_20^0.0^4^1||^^^Photometric_test^0|R|||||X||||2|||||||||1|F<CR><ETX>44
Read: <ACK>
Send: <STX>4R|1|^^^Photometric_test^0|0.92129|nmol/l|||||||20101118151221|Analyzer_1<CR><ETX>38
Read: <ACK>
Send: <STX>5C|1|I|20 AE meas error|I<CR><ETX>55
Read: <ACK>
Send: <STX>6L|1|N<CR><ETX>09
Read: <ACK>
Send: EOT

Examples: communication between analyzer and host computer

Result with user comment

Send: ENQ
Read: <ACK>
Send: <STX>1H|\^&|||1^Analyzer_1^||||||P||20110706101620<CR><ETX>9E
Read: <ACK>
Send: <STX>2P|1|PatientID_001|||Patient Name_1|||||||||||||||||||||||||<CR><ETX>17
Read: <ACK>
Send: <STX>3O|1|SampleID_001^0.0^3^1||^^^Photometric_test^0.0|R|||||X||||3|||||||||1|F<CR><ETX>D4
Read: <ACK>
Send: <STX>4R|1|^^^Photometric_test^0.0|0.80496|nmol/l|||||||20110706101439|Analyzer_1<CR><ETX>A6
Read: <ACK>
Send: <STX>5C|1|I|21 Test limit high|I<CR><ETX>5F
Read: <ACK>
Send: <STX>6C|2|I|The result is commented|G<CR><ETX>FA
Read: <ACK>
Send: <STX>7L|1|N<CR><ETX>04
Read: <ACK>
Send: EOT

Sending control results

Send: ENQ
Read: <ACK>
Send: <STX>1H|\^&|||60^1^5.0|||||||Q||20010502130025<CR><ETX>94
Read: <ACK>
Send: <STX>2P|1|||||||||||||||||||||||||||||||<CR><ETX>BF
Read: <ACK>
Send: <STX>3O|1|Control_1||^^^Ca^0.0|R|||||Q||||1|||||||||1|<CR><ETX>C4
Read: <ACK>
Send: <STX>4R|1|^^^Ca^0.0|2.3|mmol/l|^^|N||F||||20010502130024|0<CR><ETX>D4
Read: <ACK>
Send: <STX>5L|1|N<CR><ETX>08
Read: <ACK>
Send: EOT

Glossary

A

ASTM American Society for Testing and Materials

C

CLSI Clinical and Laboratory Standards Institute

G

GLP Good Laboratory Practices

GND Ground

I

ID Identification

L

LAN Local Area Network

LIS Laboratory Information System

Q

QC Quality Control

R

RxD Received Data

S

STAT Statim; immediately

T

TxD Transmitted Data