

Gallery - Indiko

## **LIS Interface**

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## **Notices**

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

## **Standards**

Table 1. Indiko Standards

| Standard                                  | Title   |  |
|---|---|--|
| IEC 61010-1 (2 <sup>nd</sup> edition)     | Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements.   |  |
| UL 61010-1 (2 <sup>nd</sup> edition)      | Safety Requirements for Electrical Equipment for<br>Measurement, Control, and Laboratory Use - Part 1:<br>General Requirements.   |  |
| CAN/CSA C22.2<br>61010-1-04               | Safety Requirements for Electrical Equipment, Control, and Laboratory Use - Part 1: General Requirements.   |  |
| IEC 61010-2-010 (2 <sup>nd</sup> edition) | Safety Requirements for Electrical Equipment on Measurement, Control and Laboratory Use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials.  |  |
| IEC 61010-2-081                           | Safety Requirements for Electrical Equipment on<br>Measurement, Control and Laboratory Use - Part 2-081:<br>Particular requirements for automatic and semi-automatic<br>laboratory equipment for analysis and other purposes. |  |
| IEC 61010-2-101                           | Safety Requirements for Electrical Equipment on<br>Measurement, Control and Laboratory Use - Part 2-101:<br>Particular requirements for in vitro diagnostic (IVD)<br>medical equipment.                                       |  |
| IEC 61326-1 (1st edition)                 | Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements.   |  |
| IEC 61326-2-6 (1st edition)               | Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements - <i>In vitro</i> diagnostic (IVD) medical equipment.   |  |

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Table 2. Gallery Standards

| Standard                                  | Title   |  |
|---|---|--|
| IEC 61010-1 (2 <sup>nd</sup> edition)     | Safety Requirements for Electrical Equipment for<br>Measurement, Control, and Laboratory Use - Part 1:<br>General Requirements.   |  |
| UL 61010-1 (2 <sup>nd</sup> edition)      | Safety Requirements for Electrical Equipment for<br>Measurement, Control, and Laboratory Use - Part 1:<br>General Requirements  |  |
| CAN/CSA-C22.2<br>61010-1-04               | Safety Requirements for Electrical Equipment, Control, and Laboratory Use - Part 1: General Requirements.   |  |
| IEC 61010-2-010 (2 <sup>nd</sup> edition) | Safety Requirements for Electrical Equipment on Measurement, Control and Laboratory Use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials.  |  |
| IEC 61010-2-081                           | Safety Requirements for Electrical Equipment on<br>Measurement, Control and Laboratory Use - Part 2-081:<br>Particular requirements for automatic and semi-automatic<br>laboratory equipment for analysis and other purposes. |  |
| IEC 61326-1 (1st edition)                 | Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements.   |  |

#### 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.

The CE mark attached on Gallery (chemistry analyzer, type 861) indicates the conformity with the EMC (electromagnetic compatibility) directive 2004/108/EC and Low Voltage Directive 2006/95/EC.

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 2002/96/EC. 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. 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 are available online: go to <a href="http://www.thermoscientific.de">http://www.thermoscientific.de</a> and enter a search "RoHS/WEEE Thermo Fisher Scientific and the WEEE Directive" (use quatation marks).



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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. |

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 > **Add**.

- 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 *Test in use* parameter.
- Parameter values are indicated with quotation marks, for example: The values of the *Test in use* parameter are "Yes" and "No".
- The statuses and messages are shown in Courier font, for example Analyzing not allowed (Start-up not done).

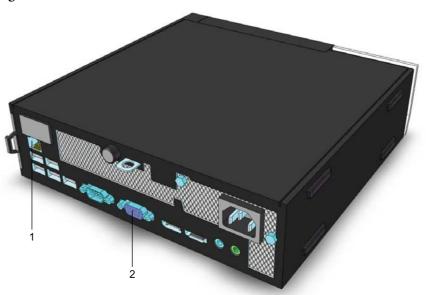


## Hardware interface

The analyzer LIS hardware interface works through the serial communication channel or the ethernet interface. The ethernet connector and connector serial communication channel is at the back of the analyzer workstation. The ethernet cable is used for the TCP/IP connection. The connector for 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 Ethernet connector
- 2 Serial 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 | TxD         |
| Pin 3 TxD | RxD         |
| Pin 5 Gnd | Gnd         |

#### 1 Hardware interface

Hardware interface

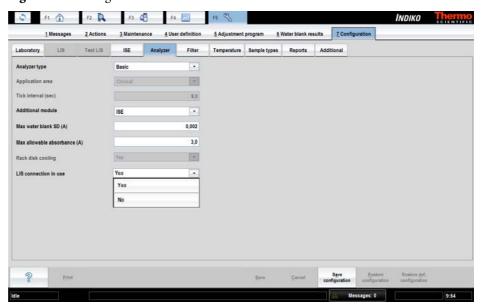
**Note** This example describes the minimum cable connections needed. Some computer systems may require some additional signals connected locally within connector. For more information about requirements, refer to the LIS documentation.

## **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 Table 5: Configuring parameters on page 3. The ASTM software has additional configurations comparing to the analyzer online software. The configuration file is saved into the database.

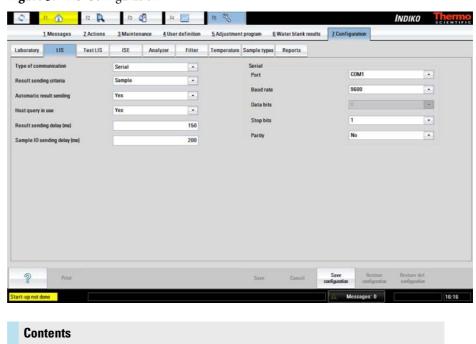
**Note** The ASTM software supports sending results on ready sample or ready request basis. The sending of results on ready request basis loads the interface heavily. It is recommended to send results by ready sample. The selection can be done through the analyzer configuration function.

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 results are sent according to the request or sample.  |
| Automatic result sending | Yes              | If the value is set to "Yes", new results are automatically send to the laboratory computer.   |
| Host query in use        | Yes              | If the value is set to "Yes", the analyzer software sends a query<br>for sample information and requests when new sample is<br>introduced into the analyzer. |

| Parameter                    | Value to be used | Description   |
|------------------------------|------------------|---|
| 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.  |

Figure 3. LIS Configuration



- Configuring serial connection
- Configuring TCP/IP connection
- Configuring test online names

## **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,<br>COM5, COM6 | Select the serial port.                      |
| Baud rate   | 2400, 4800, 9600, 19200         | Select the baud rate between 2400 and 19200. |

| Parameter | Values                     | Description  |
|-----------|----------------------------|--|
| 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.

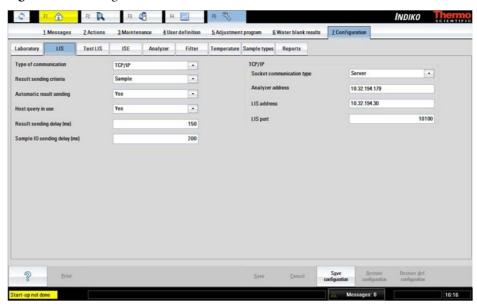
### **Configuration**

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 Table 7: TCP/IP 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    |
| 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:

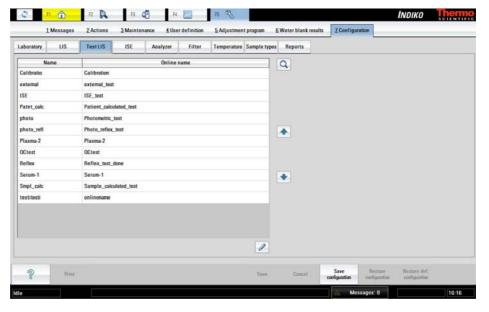
```
4403 Write error (LIMS)
4404 Read error (LIMS)
4406 Communication time-out (LIMS)
4407 Transmit error (LIMS)
```

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.

Figure 5. Configuring test online names





## **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

#### **Contents**

- Features
- CLSI LIS2-A message structure

#### **Features**

The physical transmission layer is implemented according to CLSI LIS1-A. The cable connector is a 9-pin male connector instead of the standard 25-pin male connector. The physical transmission layer uses TCP/IP connection. 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)
- response to sample information requests from the laboratory computer
- response to sample information received from the laboratory computer
- · error situation management

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

#### 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 calculation of checksum does not include the STX character, the checksum itself or the ETX character. The calculation starts by clearing the checksum. Every character of the message is added to the checksum (modulo 256) excluding the characters mentioned above. The result is an 8-bit checksum. For example, the characters in normal analyzer status record:

0x02 0x04 0x04 0x00 0x08 0x03

0x02 - STX character

0x04 - message length

0x04 - message ID

0x00 - status

0x08 - checksum

0x03 - ETX character

| 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   |
|                           |     |      | X        | Analyzer ID   |
|                           |     |      | X        | Software version  |
| Sender street address     | 6   | -    | -        |   |
| Reserved field            | 7   | -    | -        |   |
| Sender telephone number   | 8   | -    | -        |   |
| Characteristics of sender | 9   | -    | -        |   |
| Receiver ID               | 10  | -    | -        |   |

| Field name                           | No. | Host | Analyzer | Description                              |
|--------------------------------------|-----|------|----------|--|
| 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        | 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   |
|                                |     | -    | -        | First name  |
|                                |     | -    | -        | Middle name or initials                                   |

| Field name  | No. | Host | Analyzer | Description  |
|---|-----|------|----------|--|
|   |     | -    | -        | Only one text field. Type the whole name.<br>Optional if no patient relates to sample. |
|   |     | -    | -        | Only one text field. Type the whole name.<br>Optional if no patient relates to sample. |
| Mothers maiden name                                   | 7   | -    | -        |  |
| Date of birth   | 8   | -    | -        |  |
| Patient sex   | 9   | -    | -        |  |
| 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  | -    | -        |  |
| 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  | -    | -        |  |

| Field name      | No. | Host | Analyzer | Description |
|-----------------|-----|------|----------|-------------|
| 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/ManualDilution/Rack/Position  |
|                                 |     | position<br>with pos | information is | sample in the order. If manual dilution, rack and omitted, the value 0 is set for each. Rack value "0" refer to a virtual collection and can be used safely, n is known. |
| 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                    | X              | Auto-dilution factor   |
|                                 |     | -                    | X              | 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)   |

| Field name                                  | No. | Host   | Analyzer | Description  |  |  |
|---|-----|--|----------|--|--|--|
|   |     | -  | X        | X (sample or test in process)  |  |  |
|   |     | X  | X        | Q (QC sample)  |  |  |
|   |     | Multiple action codes can be typed separated by repeat delimiter. For example X\Q. |          |  |  |  |
| Danger code                                 | 13  | -  | -        |  |  |  |
| Relevant clinical information               | 14  | (X)  | (X)      |  |  |  |
| Date/time sample received                   | 15  | -  | -        |  |  |  |
| Sample descriptor (type and source)         | 16  | X  | X        | Туре   |  |  |
|   |     | -  | -        | Source   |  |  |
|   |     |  |          | 2- Plasma 3- Urine, 4 - CSF, 5 - Oral fluid, 6 -<br>ol. 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  | -  | -        |  |  |  |
| 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.   |  |  |
| 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))                        |  |  |
|   |     | X  | X        | Q (response to query (info))   |  |  |
|   |     | Multipl<br>example   |          | an be typed separated by repeat delimiter. For                           |  |  |
| Reserved field                              | 27  | -  | -        |  |  |  |

| Field name                            | No. | Host | Analyzer | Description |
|---------------------------------------|-----|------|----------|-------------|
| 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    | X        | Always R.  |
| Sequence number           | 2   | X    | X        | Running number within Test order. Starts with 1.   |
| Universal test ID         | 3   | -    | -        | Universal test ID  |
|                           |     | -    | -        | universal test name  |
|                           |     | -    | -        | universal test ID type   |
|                           |     | X    | X        | manufacturer defined test code   |
|                           |     | (X)  | X        | dilution factor used in calculation  |
| Data or measurement value | 4   | X    | (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 [-0.0000099999.9]. If the actual result exceeds the values, the nearest value is shown. |
| Units                     | 5   | X    | X        |  |
| Reference ranges          | 6   |      |          | Components:  |
|                           |     | -    | X        | Low  |
|                           |     | -    | X        | High   |
|                           |     | -    | -        | Description  |
| Result abnormal flags     | 7   | -    | X        | L/H (below/above normal)   |
|                           |     | -    | X        | LL/HH (below/above panic normal)   |
|                           |     | -    | X        | (below/above absolute low/high (off the scale of analyzer))  |
|                           |     | -    | X/-      | N/A (normal/abnormal)  |
|                           |     | -    | -        | U/D (significant change up/down (delta))   |

#### 3 ASTM protocol

Comment record (level 4) used with result record

| Field name   | No. | Host                | Analyzer                                      | Description  |
|--|-----|---------------------|---|--|
|  |     | -                   | -   | B/W (better/worse (used when direction is not relevant))         |
| Nature of abnormality testing                        | 8   | -                   | -   |  |
| Result status  | 9   | -                   | -   | C (correction)   |
|  |     | -                   | X   | P (preliminary)  |
|  |     | X                   | 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<br>example | n be given separated by repeat delimiter. For |  |
| Date of change in analyzer normative values or units | 10  | -                   | -   |  |
| Operator identification                              | 11  | -                   | (X)   | User login name if User levels have been set on                  |
| Date/time test started                               | 12  | -                   | -   |  |
| Date/time test completed                             | 13  | (X)                 | (X)   | Form YYYYMMDDHHMMSS. No value if test is not completed.          |
| Analyzer identification                              | 14  | -                   | X   | Analyzer ID is defined in konelab.ini in 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)                                   |

| Field name     | No. | Host       | Analyzer       | Description  |
|----------------|-----|------------|----------------|--|
| Comment text 4 | 4   | -          | X              | Error condition identified with a number and a text in English.  |
|                |     |            |                | 1 - Instr. error 2 - Addl. meas. error 3 - Instrument abs. limit 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. low 12 - Blank resp. low 13 - Blank resp. high 14 - Unstable 15 - Unstable cal. 16 - Liquid movement 17 - ISE dV 18 - Dil. limit Low 19 - Dil. limit high 20 - Test limit low 21 - Test limit high 22 - Crit. limit high 23 - Crit. limit high 24 - Antigen limit low 25 - Antige limit high 26 - Calibration 27 - QC 28 - Calc. error 29 - Not Measurable 30 - Outside of cal. |
|                |     | Multiple f | lags can be gi | iven separated with repeat delimiter.  |
| Comment type   | 5   | -          | -              | G (generic/free text document)   |
|                |     | -          | -              | T (test name comment)  |
|                |     | <u>-</u>   | -              | 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) |  |

#### 3 ASTM protocol

Request information record (level 1)

| Field name   | No. | Host | Analyzer | Description  |
|--------------|-----|------|----------|--|
|              |     | -    | 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  |
|              |     |      |          | E108 - maximum number of samples/ patient exceeded   |
|              |     |      |          | 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  |
| Comment type | 5   | -    | X        | G (generic/free text document)   |
|              |     | -    | -        | T (test name comment)  |
|              |     | -    | -        | P (positive test comment)  |
|              |     | -    | -        | N (negative test comment)  |
|              |     | -    | -        | 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 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  | 3   | -    | -        | Patient ID or ALL  |

| Field name                              | No. | Host   | Analyzer | Description                               |  |  |
|---|-----|--|----------|---|--|--|
| ID number                               |     | (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.<br>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            |  |  |
|   |     | -  | -        | 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                       |  |  |
| 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) |  |  |

#### 3 ASTM protocol

ASTM protocol

| Field name | No. | Host        | Analyzer | Description                                 |
|------------|-----|-------------|----------|---|
|            |     | (X)         | (X)      | O (requesting test orders only (no results) |
|            |     | -           | -        | D (requesting demographics only)            |
|            |     | Note: not r | epeated. |   |

## **Field lengths**

| Field                                   | Length in characters                     |
|---|--|
| Analyzer type                           | 3  |
| Analyzer ID                             | 2  |
| Software version                        | 16                                       |
| Date and time of message                | 14                                       |
| Laboratory assigned patient ID          | 16                                       |
| Patient name                            | 24                                       |
| Hospital institution                    | 24                                       |
| Sample ID                               | 20                                       |
| Analyzer sample ID                      | Rack, Position integers max 6 characters |
| Universal test ID                       | 30                                       |
| Sample collection date and time         | 14                                       |
| Relevant clinical information           | 30                                       |
| Analyzer section ID                     | 2  |
| Data or measurement value               | 8  |
| Units                                   | 10                                       |
| Date/time test completed                | 14                                       |
| Beginning request results date and time | 14                                       |
| Ending request results date and time    | 14                                       |



# **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.

#### 5 Examples: communication between analyzer and host computer

Examples: communication between analyzer and host computer

#### New sample introduced to the analyzer

```
Send: <ENQ>
Read: <ACK>
Send: <STX>1H|\^&|||1^Indiko Basic^|||||||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>
Send: <ACK>
Read: <STX>4L|1|F<CR><ETX>FF
Send: <ACK>
Read: <EOT>
Send: <ENQ>
Read: <ACK>
Send: <STX>1H|\^&|||1^Indiko Basic^|||||||P||20101118104132<CR><ETX>9B
Read: <ACK>
Send: <STX>2P|1|PatientID_02|||Patient Name_2||||||||||||Doctor Name||||||||<CR><ETX>F5
Read: <ACK>
Read: <ACK>
Send: <STX>4R|1|^^^ISE_test^5|0.00830|\text{\mool/I|||||||||20101118104459|Indiko Basic<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^Indiko Basic^|||||||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>
Send: <ACK>
Read: <STX>4L|1|F<CR><ETX>FF
Send: <ACK>
Read: <EOT>
Send: ENQ
Read: <ACK>
Send: <STX>1H|\^&|||1^Indiko Basic^|||||||P||20101118143705<CR><ETX>A4
Read: <ACK>
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|\text{\munol}/\l|||||||||20101118143620|Indiko Basic<CR><ETX>D6
Read: <ACK>
Send: <STX > 5O|2|SampleID\_07^0.0^5^1||^{\wedge \wedge}Photo\_reflex\_test^5|R||||||X||||3||||||1||F < CR > <ETX > B4
Read: <ACK>
Send: <STX>6R|2|^^Photo_reflex_test^0|0.74143|mmol/l||||||20101118143621|Indiko Basic<CR><ETX>9C
Read: <ACK>
Send: <STX > 7O|3|SampleID\_07^0.0^5^1||^{^n}Photometric\_test^5|R||||||X||||3||||||1||F<CR> <ETX>56
Read: <ACK>
Read: <ACK>
Read: <ACK>
Send: <STX>2R|4|^^Reflex_test_done^5|0.18109|g/I|||||||20101118143705|Indiko Basic<CR><ETX>D0
Read: <ACK>
Send: <STX>3L|1|N<CR><ETX>06
Read: <ACK>
Send: EOT
```

#### 5 Examples: communication between analyzer and host computer

Examples: communication between analyzer and host computer

#### 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>
Send: <ACK>
Read: <STX>4L|1|F<CR><ETX>FF
Send: <ACK>
Read: <EOT>
Send: <ENQ>
Read: <ACK>
Send: <STX>1H|\^&|||1^Indiko Basic^|||||||P||20101118141519<CR><ETX>A5
Read: <ACK>
Send: <STX>2P|1|PatientID_06|||Patient Name_6|||||||||||Doctor Name|||||||||CR><ETX><F1
Read: <ACK>
Send: <STX>3O|1|SampleID\_06||^{\wedge\wedge\wedge0}|S||||||C||Test\ information\ field||3||||||1|X<CR><ETX>8D
Read: <ACK>
Send: <STX>4C|2|I|E105|G<CR><ETX>21
Read: <ACK>
Send: \langle STX \rangle 5L|1|Q\langle CR \rangle \langle ETX \rangle 0B
Read: <ACK>
Send: <EOT>
```

#### Measurement error in result

```
Send: ENQ
Read: <ACK>
Send: <STX>1H|\^&|||1^Indiko Basic^|||||||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||^{\wedge \wedge} Photometric\_test \\ |R||||||||||||||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^Indiko Basic^|||||||P||20101118151301<CR><ETX>9B
Read: <ACK>
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/||||||||20101118151221|Indiko Basic<CR><ETX>38
Read: <ACK>
Send: <STX>5C|3|I|20 AE meas error|I<CR><ETX>55
Read: <ACK>
Send: <STX>6L|1|N<CR><ETX>09
Read: <ACK>
Send: EOT
```

#### 5 Examples: communication between analyzer and host computer

Examples: communication between analyzer and host computer

#### Result with user comment

Send: ENQ

Read: <ACK>

Send: <STX>1H|\^&|||1^Indiko Basic^|||||||P||20110706101620<CR><ETX>9E

Read: <ACK>

Read: <ACK>

 $Send: <STX > 3O|1|SampleID\_001^{0}.0^{3}1||^{\wedge \wedge}Photometric\_test^{\wedge}0.0|R||||||X||||3||||||1||F < CR > <ETX > D4$ 

Read: <ACK>

 $Send: <STX>4R|1|^{\wedge\wedge}Photometric\_test^{\wedge}0.0|0.80496|nmol/l|||||||20110706101439|Indiko~Basic< CR><ETX>A6$ 

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

## **Glossary**

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| 60-cell storage Sample prep block; intermediate storage for sample in the sample pretreatment procedure |
|---|
| В   |
| BCM Bitterness Column Module  |
| C   |
| CLRW Clinical Laboratory Reagent Water  |
| CLSI Clinical and Laboratory Standards Institute  |
| D   |
| DB Database   |
| DVM Digital Voltage Measurement   |
| G   |
| GLP Good Laboratory Practices   |
| I   |
| ID Identification   |
| L   |
| LIS Laboratory Information System   |
| Q   |
| QC Quality Control  |

S

SD Standard Deviation
STAT Statim; immediately

U

UPS Uninterruptable Power Supply