Technical Service Bulletin

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File Name: TB 2010.pdf   Author: Michael Spindeler

Product: Alegria
Model: N/A
Part No.:   ORG 308

Subject: Basic information on how to connect the Alegria to a laboratory information
                management system (LIMS)
Approval:

Basic Information for connecting Alegria to LIMS

This technical bulletin describes the two-way electronic transmission of digital
information (requests, results, etc.) between Alegria and laboratory information
management system (LIMS).

LIS1:

Low level communication protocol describes the physical layer for data exchange.

Data exchange:
It works only in serial binary way.

Character structure:
Start bit = 1, data bits = 8, parity bit = no, stop bit = 1
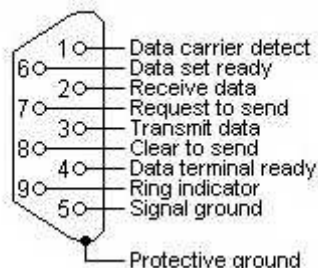
Baud rate:
9600

Interface connection:
Null modem cable with two female (9-pole) connectors on both ends (preferably with
suitable cable locking hardware) with the following pin configuration (1-7; 7-1; 2-3; 3-
2; 4-6,8; 6,8-4; 5-5; 9-9).

Pin configuration for the serial port of the Alegria:

Data link layer:
The data link mode of operation is one-way transfer of information. Information flows
in one direction at a time. Replies occur after information is sent, never at the same
time. It is a simplex stop-and-wait protocol.
For more detailed description of the different data link phases (establishment,
transfer and termination) please see LIS1AE.PDF pages 4, 5 and 6.

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LIS2:

High level communication protocol describes the structure of the messages transferred between Alegria and LIMS. The data fields available for communication are specified and interpreted.

Scenario of communication:

Origin	Type of message	Receiver	Comment
LIMS	Test Order Request	Alegria	Test orders are transmitted in batch mode.
Alegria	Response to Test Order with results included.	LIMS	Results can be exported automatic after the analyse or manual by the user.
LIMS	Request for transmission of already stored results	Alegria	Selection is done based on Patient ID or given Time Interval.

For sending a message to the LIMS, the message is made up of the following listed records:

1. Message header record:

This contains general information about the sender. It is always the first in a transmission.

E. G.: Header: H|\^&|||460213||||||||1|20100115155240

Field	Name – LIS2	Example	Comments
1	Record Type ID	H	Header record
2	Delimiter definition	|\^&	Delimiters used
3	Message control ID		Not used
4	Access password		Not used
5	Sender name	460213	Alegria Instrument ID = serial number
6	Sender street		Not used
7	Reserved		Not used
8	Sender telephone number		Not used
9	Characteristics of sender		Not used
10	Receiver ID		Not used
11	Comments or special instructions		Not used
12	Processing ID		Not used
13	Version number	1	LIS2-A2
14	Date and time of message	20100115155240	YYYYMMDDHHMMSS

2. Patient information record:
This contains general information about the patient, e.g. patient ID.

Patient info: P|1||6022007503|||||||||||||||||||||

Field	Name – LIS2	Example	Comments
1	Record type ID	P	Patient record
2	Sequence number	1	This is the first record
3	Practice assigned patient ID		Not used
4	Laboratory assigned patient ID	6022007503	Patient ID
5	Patient ID no. 3		Not used
6	Patient name		Not used
7	Mother's maiden name		Not used
8	Date of birth		Not used
9	Patient sex		Not used
10	Patient race		Not used
11	Patient address		Not used
12	Reserved		Not used
13	Patient telephone number		Not used
14	Attending physician ID		Not used
15	Special field 1		Not used
16	Special field 2		Not used
17	Patient height		Not used
18	Patient weight		Not used
19	Diagnosis		Not used
20	Medication		Not used
21	Diet		Not used
22	Practice field no 1		Not used
23	Practice field no 2		Not used
24	Admission date		Not used
25	Admission status		Not used
26	Location		Not used

⚠ Info:
The number you put in field P4 has to be printed as barcode on the sample tube. It
will be used for linking the barcode of the sample to the barcode of the test strip with
the external barcode reader.

3. Test order record:

This contains information about the particular test on a single patient.

Test order: O|1|1234567890|2241011443680277|^^^Elastase|||||||||||||||||||||F

Field	Name – LIS2	Example	Comments
1	Record type ID	O	Test order record
2	Sequence number	1	Sequence number generated by LIMS. If order is entered manually in instrument this field is left blank when exporting results.
3	Specimen ID – accession number	1234567890	Generated by LIMS. If order is entered manually in instrument this field will be contain the Patient ID.
4	Instrument specimen ID – sample number	2241011443680277	Barcode filled in by instrument when result is returned.
5	Universal test ID	^^^Elastase	Test name
6	Priority code		Not used
7	Ordered date/time		Not used
8	Sample draw time		Not used
9	Collection end time		Not used
10	Collection volume		Not used
11	Collector ID		Not used
12	Action code		Not used
13	Danger code		Not used
14	Relevant clinical information		Not used
15	Date/time specimen received		Not used
16	Specimen descriptor		Not used
17	Ordering physician		Not used
18	Physicians telephone number		Not used
19	User field no. 1		Not used
20	User field no. 2		Not used
21	Laboratory field no. 1		Not used
22	Labaratory field no. 2		Not used
23	Data/time result reported or last modified		Not used
24	Instrument charge to computer system		Not used
25	Instrument section ID		Not used
26	Report types	F	F = final results I = in instrument pending

⚠   Info:

Test order record has to be sent according to this description. In case not all requested information is provided to the Alegria subsequent errors in the data transmission can appear.

⚠   Info:

O3 is only filled with the Patient ID in case the "Add sample" function is used inside the LIMS protocol. It will not work when exporting already analyzed results done in touch screen or external barcode reader protocol from the archive.

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4. Result record:
This contains information and the result for a single request.

Result: R|1|^^^Elastase|37.4^U/ml^Pos|||||F||Test User||20100118160552

Field	Name – LIS2	Example	Comments
1	Record type ID	R	Result record
2	Sequence number	1	This is the first record
3	Universal Test ID	^^^Elastase	Name of the test performed
4	Measurement value	37.4^U/ml^Pos	<value>^ <unit>^ <interpretation>
5	Units		Not used
6	Reference ranges		Not Used
7	Result abnormal flag		Not Used
8	Nature of abnormality testing		Not used
9	Result status	F	F = final results R = previously transmitted
10	Date of change in instrument normative values or units		Not used
11	Operator identification	Test User	User ID
12	Date/time test started		Not used
13	Date/time test completed	20100118160552	YYYYMMDDHHMMSS

5. Query:
The request information record can be used by the LIMS to **request results of previously stored analyzes**. The two criteria's that can be used to query the instrument are Patient ID and Start and End Time. Either one criteria is used or they are combined. For Patient ID is no range available; instead one Patient ID shall be specified. If there is more than one Patient ID to query for, several queries must be sent. After each query the LIMS must wait for reply before sending the next query.

Query: Q|1|ALL||||20080801000000|20081308090005|||||

Field	Name – LIS2	Example	Comments
1	Record type ID	Q	Query record
2	Sequence number	1	This is first record
3	Starting Range Id Number	ALL	Patient ID, only one at the time allowed or value of ALL giving all results.
4	Ending Range Id Number		Not Used
5	Universal Test ID		Not Used
6	Nature of Request Time Limits		Not Used
7	Beginning Request Results Data and Time	20080801000000	YYYYMMDDHHMMSS
8	Ending Request Results Data and Time	20081308090005	YYYYMMDDHHMMSS
9	Requesting Physician Name		Not Used
10	Requesting Physician Telephone Number		Not used
11	User Field Number 1		Not Used
12	User Field number 2		Not used
13	Request Information Status Codes		Not Used

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6. Comment record:
This contains general information about the analyser or errors/flags on individual parameters.

Comment: C|1|I|QC Approved|I

Field	Name – LIS2	Example	Comments
1	Record type ID	C	Comment record
2	Sequence number	1	This is first record
3	Comment source	I	I = clinical instrument system
4	Comment text	QC Approved	QC Approved QC Not approved
5	Comment type	I	I = instrument flag(s) comment

7. Message terminator record:
This record ends the transmission. It is always the last in a transmission.

Message terminator: L|1|N

Field	Name – LIS2	Example	Comments
1	Record type ID	L	Message terminator record
2	Sequence number	1	This is first record
3	Termination code	N	N = normal termination

Test sample request:

```
H|\^&|||460213|||||||||1|20100115155240
P|1||6022007503|||||||||||||||||||||||
O|1|1234567890||^^^Elastase|||||||||||||||||||||F
O|2|1234567891||^^^Elastase|||||||||||||||||||||F
L|1|N
```

Test sample result:

```
H|\^&|||460213|||||||||1|20100118160555
P|1||6022007503|||||||||||||||||||||||
O|1|1234567890|2241011443680277|^^^Elastase|||||||||||||||||||||F
R|1|^^^Elastase|37.4^U/ml^Pos|||||F||Test User||20100118160552
C|1|I|QC Approved|I
L|1|N
H|\^&|||460213|||||||||1|20100118160556
P|1||6022007503|||||||||||||||||||||||
O|2|1234567891|2241011443680300|^^^Elastase|||||||||||||||||||||F
R|1|^^^Elastase|37.4^U/ml^Pos|||||F||Test User||20100118160552
C|1|I|QC Approved|I
L|1|N
```

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If you installed and configured the software on the host side you are just a few steps away from successfully connecting the Alegria to a LIMS. On the Alegria side you need to connect to LIMS. At the moment we only support to connect the Alegria serial to a LIMS. If you have enabled the connection you will see a yellow sign labelled with LIMS in the upper right corner of the screen.
Next step is that you have to choose the export mode of the results.
Last step is to set up the synonyms for the test names according to the names stored on the host side.
For more detailed description of the different menus please see the instruction for use manual.
For more detailed description of the LIMS protocol and how to start the analytical run please see the quick guide for use.