BIO-RAD

LB002566revA

D-10
Hemoglobin Testing System

Technical Bulletin:
LIS Interface Requirements

For Use With Catalog Numbers:

220-0220, D-10 Hemoglobin Testing System, DJ series
12010405, D-10 Hemoglobin Testing System, DM series

Contents

1 Introduction

1.1 Purpose

This document defines the requirements for the communications interface between the Bio-Rad D-10 instrument and all Laboratory Information Systems (LIS).

1.2 Scope

This document is provided to the LIS vendor to aid in the design, maintenance and troubleshooting of a compatible interface between the Computer System and the Instrument. It is intended that all application-specific requirements of the interface be covered by this document. Selected generic requirements, that may be found within the LIS1-A and LIS2-A documents, are also covered.

The implementation follows LIS1-A or LIS2-A specifications.

1.3 References and Related Documents

a) LIS1-A (formerly ASTM E1381-02) Standard Specification for Low Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems. Maintained by CLSI (Clinical and Laboratory Standards Institute).

b) LIS2-A (formerly ASTM E1394-97) Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems. Maintained by CLSI.

1.4 Definitions and Abbreviations

a) Bidirectional interface - Either the Instrument or the LIS may be the Sender or Receiver. The Sender may initiate a message sequence that eventually causes message transmissions to be sent to the Receiver.

b) Instrument - Same as the D-10.

c) Host Computer System - Same as the LIS.

d) 1..n - Means one to many.

e) A1c - Hemoglobin A_{1c}.

f) A2/F - Hemoglobins A_2 and F.

2 LIS1-A Physical Layer

The mechanical and electrical connection for serial binary data bit transmission between the Instrument and LIS.

2.1 Communication Port Interface

The Instrument provides a standard DB9 male connector mounted on the back panel. The Instrument RS232 interface is configured as a DTE (Data Terminal Equipment, e.g., a terminal or PC). A DTE normally connects to a DCE (Data Communications Equipment, e.g., a modem). In this case, the Computer System is also configured as a DTE, thus a null modem cable or connector is required to hook up to the Computer System. The cable or connector may convert the 9-pin output to 25-pin male or female, as required, at the Computer System. Communication Port pin identification and communication settings are described in the Appendix.

3 LIS1-A Data Link Layer

The Data Link layer includes the message communication control characters sent to and from the D-10 and LIS (Sender to Receiver) to facilitate communication.

3.1 Control Characters

LIS1-A senders and receivers communicate via seven bit ASCII codes. Correct message transmission depends upon message text never including any of the below control characters.

STX	First character of any message frame.
ETX	Character immediately after the message text of a message frame. Signifies the last message frame of a group.
ETB	Character immediately after the message text of a message frame. Signifies that at least one more frame of a group is to be transmitted.
CR	Next to last character of any message frame.
LF	Last character of any message frame.
ACK	Receiver replies with ACK when it has successfully (no checksum error) received a message frame.
NAK	Receiver replies with NAK when it has unsuccessfully (checksum error or timeout) received a message frame.
ENQ	Sender sends to receiver to indicate ready to send message frame(s).
EOT	Sent by receiver to indicate that the last frame sent to receiver was received successfully, but also is a request to the sender to temporarily stop sending.

3.2 Communication Protocol Summary

3.2.1 Establishment Phase

- **The Sender notifies the receiver that a message is available:** The sender sends an <ENQ> to signal that it has a message to send; it waits 15 seconds for a response before retrying.
- **The Receiver notifies the sender it is ready for a message:** The Receiver responds with an <ACK> signaling that it is ready to receive a message. If the receiver is not ready to receive the message, it responds with a <NAK>. Upon receiving the <NAK>, the Sender will wait 10 seconds before sending another <ENQ>.
- **Contention:** If both Sender and Receiver send messages at the same time (both send an <ENQ> at the same time), the line is in contention. The instrument system has priority to transmit information when this occurs. The instrument waits 1 second before sending <ENQ> again. The LIS should wait 20 seconds. If it does not receive an <ENQ> from the instrument in that time, it assumes the line is in a neutral state and can retry sending another <ENQ> to the instrument.

3.2.2 Transfer Phase

- **Frames** – Messages are sent in frames. Multiple messages cannot be combined into a single frame. Every message must begin in a new frame.

  A frame is one of two types, Intermediate or End Frame. If the message is less than the maximum characters set per frame, the transmission is sent in a single End Frame terminated by the <ETX> End of Text control character. If the message is larger than the maximum characters set per frame, it is sent in one or more Intermediate frames (each intermediate frame contains the maximum characters set per frame) terminated with the <ETB> End of Block control character. The Intermediate Frame is followed by an End Frame containing the remainder of the message.

- **Intermediate Frames** – Terminate with **<ETB> End of Block control Character**, Checksum, <CR>, <LF>.
- **End Frames** – Terminate with **<ETX> End of Text control Character**, Checksum, <CR>, <LF>.

  Frame Structure:
  <STX> Frame # Message Text **<ETB>** Checksum <CR> <LF> **Intermediate Frame**
  <STX> Frame # Message Text **<ETX>** Checksum <CR> <LF> **End Frame**

- **Acknowledgments –** After a frame is sent, the Sender stops transmitting until the receiver replies. When it is ready to receive the next frame, the Receiver sends one of three replies to acknowledge the last frame:

  <ACK> The last frame was received, prepared to receive the next frame.
  <NAK> The last frame was not successfully received, prepared to receive the frame again.
  <EOT> The last frame was received successfully.

Example of a Transmitted Message with low level communication

HCS – Host Computer System (LIS)

LMS – LIS Management System (D-10 Instrument)

LIS1A control characters are in bold.

LMS->**<ENQ>**
HCS->**<ACK>**

LMS->**<STX>1**H|\^&|||D10^07^3.00|||||||||20040223090354<CR>**<ETX><CHK1><CHK2><CR><LF>**

HCS->**<ACK>**

LMS->**<STX>2**P|1<CR>**<ETX><CHK1><CHK2><CR><LF>**

HCS->**<ACK>**

LMS->**<STX>3**O|1|123456|123456-02-032-20031209-

07|^^^4||||||||||||||||||||||F<CR>

<ETX><CHK1><CHK2><CR><LF>

HCS->**<ACK>**

LMS->**<STX>4**R|1|^^^Unknown^AREA|0.9|||||||||20031209132023<CR>

<ETX><CHK1><CHK2><CR><LF>

HCS->**<ACK>**

LMS->**<STX>5**R|2|^^^Unknown^TIME|0.15|||||||||20031209132023<CR>

<ETX><CHK1><CHK2><CR><LF>

HCS->**<ACK>**

LMS->**<STX>6**R|3|^^^A1b^AREA|3.5|||||||||20031209132023<CR>**<ETX><CHK1><CHK2><CR><LF>**

HCS->**<ACK>**

LMS->**<STX>7**R|4|^^^A1b^TIME|0.28|||||||||20031209132023<CR>

<ETX><CHK1><CHK2><CR><LF>
HCS->**<ACK>**

LMS->**<STX>0**R|5|^^^F^AREA|0.9|||||||||20031209132023<CR>**<ETX><CHK1><CHK2><CR><LF>**

HCS->**<ACK>**

LMS->**<STX>1**R|6|^^^F^TIME|0.55|||||||||20031209132023<CR>**<ETX><CHK1><CHK2><CR><LF>**

HCS->**<ACK>**

LMS->**<STX>2**R|7|^^^A1c^AREA|4.6|||||||||20031209132023<CR>**<ETX><CHK1><CHK2><CR><LF>**

HCS->**<ACK>**

LMS->**<STX>3**R|8|^^^A1c^TIME|0.82|||||||||20031209132023<CR>

<ETX><CHK1><CHK2><CR><LF>

HCS->**<ACK>**

LMS->**<STX>4**R|9|^^^A0^AREA|88.8|||||||||20031209132023<CR>

<ETX><CHK1><CHK2><CR><LF>

HCS->**<ACK>**

LMS->**<STX>5**R|10|^^^A0^TIME|1.44|||||||||20031209132023<CR>

<ETX><CHK1><CHK2><CR><LF>

HCS->**<ACK>**

LMS->**<STX>6**R|11|^^^TOTAL^AREA|3335057|||||||||20031209132023<CR>

<ETX><CHK1><CHK2><CR><LF>

HCS->**<ACK>**

LMS->**<STX>7**L|1|N<CR>**<ETX><CHK1><CHK2><CR><LF>**

HCS->**<ACK>**

LMS->**<EOT>**

4 LIS2-A LAYER

The LIS2-A layer defines the structure of messages exchanged between the D-10 and LIS.

4.1 Field Delimiters Used by the D-10

Delimiter Type	Delimiter	Description
Field	|	Separates fields within a record
Repeat	\	Separates multiple sets of the same information within a field
Component	^	Divides one field into several subfields
Escape	&	Used to embed a special character in the data

4.2 Record Types

Each LIS2-A message is composed of a group of Record types. Each Record Type includes one or more record fields. Fields are separated by the (|) delimiter. Record types within a message are separated by a carriage return.

Fields may contain more than one component. In this case the (^) component delimiter is used to define the component within the field. Unused components within a field are skipped by inserting the (^) delimiter.

Field data within a record should not contain embedded spaces or blanks. The following characters are reserved delimiter characters used by the LIS2-A protocol: \, /, :, *, ?, “, <, >, |, ^, &

The following are record types used by the D-10.

Record Type	Record ID	Description
Message Header	H	Record Type Header includes delimiters used within the message transmission, Senders name, date and time.
Patient Information	P	Record Type Patient and Sequence Number fields.
Query Results	Q	Record Type Query including sort information for result retrieval. Used only to Query the D-10 for previously run sample results.
Test Order	O	Record Type Order, Specimen ID (defines Chromatogram file name), Instrument and Test ID.
Sample Result	R	Record Type Result includes Test Results.
Message Termination	L	Record Type Terminator, the last record of a message.

4.3 D-10 Instrument to LIS Transmission

Sample result Transmission messages are sent to the LIS Computer System after each injection, after the run, or by manual selection. Selection screens are shown in the Appendix and defined in detail in the D-10 Operation Manual.

The tables in the following sections list the Record Types within a Message transmitted or received by the D-10, and the supported fields contained within each. Refer to the following tables for a detailed description of each record type. **ASTM fields not supported by the D-10 are not referenced in this document.**

Record Type	Record Format
Message Header H	H|Delimiter|||SenderName||||||||DateTime<CR>
Patient P	P|SeqNo<CR>
Test Order O	O|SeqNo|SpecimenID|InstSpecID|UnivTestID||||||||||||||||||||RptType<CR>
Result R	R|SeqNo|UnivTestID|MeasVal||||||||DateTime<CR>
Terminator L	L|SeqNo|TermCode<CR>

4.3.1 Header Record Fields

Field Number	Field Name	Description	Example
1	Record Type	Header - Always “H”	H
2	D-10 Included Delimiters	Defines delimiters used by the D-10: Field, Repeat, Component, Escape	| \ ^ &
5	Sender Name	There are three components used in this field: Senders Name - 1 to 16 characters Instrument Number - Specified on D-10 LIS settings screen XX Software Version – 1 to 6 characters defining the software version of the sending system	D10^01^5.00
14	Date and Time	The Date and Time of the transmission in format YYYMMDDHHMMSS	20190925142132

Example

```
H|\^&|||D10^01^5.00|||||||||20190925142132
```

4.3.2 Patient Record Fields

Field Number	Field Name	Description	Example
1	Record Type	Patient – Always “P”	P
2	Sequence Number	Patient line number	1

Example

```
P|1
```

4.3.3 Order Record

Field Number	Field Name	Description	Example
1	Record Type	Order - Always “O”	O
2	Sequence Number	Order line number	1
3	Specimen ID	Barcoded or manually entered Sample ID – 1 to 24 characters. If Instrument assigned it would follow the format: Rack ID-Tube Position-Injection Number-Date (day-month-year)	BR2229 Instrument Assigned: RackA1-1-20-9-25-2019
4	Instrument Specimen ID	Instrument Specimen ID: Specimen ID-Tube Position-Injection Number-Date (YYYMMDD)-LIS ID This field is also used as the file name of the Chromatogram. See section A.3 and A.4	BR2229-1-20-20190925-01 Chromatogram Files Created: BR2229-1-20-20190925-01.png BR2229-1-20-20190925-01.pdf File if Instrument Assigned ID: RackA1-1-20-9-25-2019-1-20-20190925-01.pdf
5	Universal Test ID	Universal Test ID This field includes 4 sections; the first 3 are not used. The test selections are: A1c – “4” A2/F – “1”	^^^4 ^^^1
26	Report Type	Report Type: F – Results during run or manual export Q – Results sent in response to a query	F Q

Example

```
O|1|BR2229|BR2229-1-20-20190925-01|^^^4||||||||||||||||||||F
```

4.3.4 Results Record Fields

<table>
<tr><th>Field Number</th><th>Field Name</th><th>Description</th><th>Example</th></tr>
<tr><td>1</td><td>Record Type</td><td>Result – Always “R”</td><td>R</td></tr>
<tr><td>2</td><td>Sequence Number</td><td>Result line number</td><td>1 for the first record for this folder, 2 for the second, etc.</td></tr>
<tr><td>3</td><td>Universal Test ID</td><td>This field contains 5 components; the D-10 uses components 4 and 5.
Component 4 includes the peak identifier (name) except in the last Result line which is always “Total” used to define the Total Area.
Component 5 defines the type of measurement value in the next transmission line as either “Area” or “Time”.</td><td>Component 4 Values:<table><tr><td>Unknown</td><td>A2</td></tr><tr><td>A1a</td><td>Variant-Window</td></tr><tr><td>A1b</td><td>E-Window</td></tr><tr><td>F</td><td>S-Window</td></tr><tr><td>LA1c/CHb-1</td><td>D,S-Window</td></tr><tr><td>LA1c/CHb-2</td><td>C-Window</td></tr><tr><td>A1c</td><td>P1, P2, …etc.
Unnamed Hemoglobin</td></tr><tr><td>A0</td><td>Total</td></tr></table>Component 5 Values:<table><tr><td>Area</td><td>Time</td></tr></table>^^^A1a^Area^
^^^A1c^Time
^^^Total^Area</td></tr>
<tr><td>4</td><td>Data or Measurement Value</td><td>Measurement Value in Time (seconds) or Area (mmol/mol or %). See section A.5.</td><td>5.3</td></tr>
<tr><td>13</td><td>Date and Time Test Completed</td><td>Date and Time in format
YYYYMMDDHHMMSS</td><td>20191006163000</td></tr>
</table>

Example

```
R|7|^^^A1c^Area|5.3|||||||||20191006163000
R|8|^^^A1c^Time|.89|||||||||20191006163000
```

4.3.5 Terminator Record Fields

Field Number	Field Name	Description	Example
1	Record Type	Always “L”	L
2	Sequence Number	Always 1	1
3	Termination Code	N – Normal termination F – Last request for information processed I – No information available from last query E – Unknown internal error Q – Error in last request for information	N

Example

```
L|1|N
```

4.4 Sample Result LIS Transmission Examples

4.4.1 Example of A1c Result with “Variant-Window” Identified

```
H|\^&|||D10^01^3.00||||||||20191021095121
P|1
O|1|presample|presample-06-049-20180322-01|^^^4||||||||||||||||||||F
R|1|^^^Unknown^AREA|0.3|||||||20180322140541
R|2|^^^Unknown^TIME|0.13|||||||20180322140541
R|3|^^^A1a^AREA|0.8|||||||20180322140541
R|4|^^^A1a^TIME|0.20|||||||20180322140541
R|5|^^^A1b^AREA|0.9|||||||20180322140541
R|6|^^^A1b^TIME|0.28|||||||20180322140541
R|7|^^^F^AREA|0.6|||||||20180322140541
R|8|^^^F^TIME|0.42|||||||20180322140541
R|9|^^^LA1c/CHb-1^AREA|1.1|||||||20180322140541
R|10|^^^LA1c/CHb-1^TIME|0.67|||||||20180322140541
R|11|^^^A1c^AREA|6.8|||||||20180322140541
R|12|^^^A1c^TIME|0.85|||||||20180322140541
R|13|^^^P3^AREA|3.9|||||||20180322140541
R|14|^^^P3^TIME|1.36|||||||20180322140541
R|15|^^^Unknown^AREA|3.4|||||||20180322140541
R|16|^^^Unknown^TIME|1.40|||||||20180322140541
R|17|^^^A0^AREA|48.9|||||||20180322140541
R|18|^^^A0^TIME|1.44|||||||20180322140541
R|19|^^^Variant-Window^AREA|37.0|||||||20180322140541
R|20|^^^Variant-Window^TIME|1.60|||||||20180322140541
R|21|^^^TOTAL^AREA|2630967|||||||20180322140541
L|1|N
```

4.4.2 Example of A1c Result with “C Window” Identified

```
H|\^&|||D10^01^3.00||||||||20191021101833
P|1
O|1|RACKG2-5-85-20-3-2018|RACKG2-5-85-20-3-2018-05-085-20180320-01|^^^4||||||||||||||||||||F
R|1|^^^Unknown^AREA|0.3||||||||20180320161315
R|2|^^^Unknown^TIME|0.14||||||||20180320161315
R|3|^^^A1a^AREA|0.6||||||||20180320161315
R|4|^^^A1a^TIME|0.20||||||||20180320161315
R|5|^^^A1b^AREA|0.5||||||||20180320161315
R|6|^^^A1b^TIME|0.28||||||||20180320161315
R|7|^^^Unknown^AREA|0.2||||||||20180320161315
R|8|^^^Unknown^TIME|0.36||||||||20180320161315
R|9|^^^F^AREA|0.6||||||||20180320161315
R|10|^^^F^TIME|0.42||||||||20180320161315
R|11|^^^LA1c/CHb-1^AREA|0.9||||||||20180320161315
R|12|^^^LA1c/CHb-1^TIME|0.65||||||||20180320161315
R|13|^^^A1c^AREA|7.6||||||||20180320161315
R|14|^^^A1c^TIME|0.85||||||||20180320161315
R|15|^^^P3^AREA|3.6||||||||20180320161315
R|16|^^^P3^TIME|1.38||||||||20180320161315
R|17|^^^A0^AREA|55.3||||||||20180320161315
R|18|^^^A0^TIME|1.47||||||||20180320161315
R|19|^^^C-Window^AREA|34.3||||||||20180320161315
R|20|^^^C-Window^TIME|1.78||||||||20180320161315
R|21|^^^TOTAL^AREA|2245198||||||||20180320161315
L|1|N
```

4.4.3 Example of A1c Result with “D,S-window” Identified

```
H|\^&|||D10^01^3.00||||||||20191021102211
P|1
O|1|RACK04-3-47-18-6-2018|RACK04-3-47-18-6-2018-03-047-20180618-01|^^^4||||||||||||||||||||F
R|1|^^^Unknown^AREA|0.3||||||||20180618105747
R|2|^^^Unknown^TIME|0.14||||||||20180618105747
R|3|^^^A1a^AREA|0.6||||||||20180618105747
R|4|^^^A1a^TIME|0.20||||||||20180618105747
R|5|^^^A1b^AREA|0.7||||||||20180618105747
R|6|^^^A1b^TIME|0.28||||||||20180618105747
R|7|^^^F^AREA|0.9||||||||20180618105747
R|8|^^^F^TIME|0.43||||||||20180618105747
R|9|^^^LA1c/CHb-1^AREA|0.6||||||||20180618105747
R|10|^^^LA1c/CHb-1^TIME|0.66||||||||20180618105747
R|11|^^^A1c^AREA|6.7||||||||20180618105747
R|12|^^^A1c^TIME|0.84||||||||20180618105747
R|13|^^^P3^AREA|3.2||||||||20180618105747
R|14|^^^P3^TIME|1.39||||||||20180618105747
R|15|^^^A0^AREA|48.1||||||||20180618105747
R|16|^^^A0^TIME|1.48||||||||20180618105747
R|17|^^^D,S-window^AREA|42.5||||||||20180618105747
R|18|^^^D,S-window^TIME|1.66||||||||20180618105747
R|19|^^^TOTAL^AREA|2409852||||||||20180618105747
L|1|N
```

4.4.4 Example of A1c Result with "S-Window" Identified

```
H|\^&|||D10^01^3.00||||||||20191021101648
P|1
O|1|RACK03-6-45-20-3-2018|RACK03-6-45-20-3-2018-06-045-20180320-01|^^^4||||||||||||||||||||F
R|1|^^^Unknown^AREA|0.3||||||||20180320135551
R|2|^^^Unknown^TIME|0.14||||||||20180320135551
R|3|^^^A1a^AREA|0.5||||||||20180320135551
R|4|^^^A1a^TIME|0.21||||||||20180320135551
R|5|^^^A1b^AREA|1.1||||||||20180320135551
R|6|^^^A1b^TIME|0.28||||||||20180320135551
R|7|^^^Unknown^AREA|0.9||||||||20180320135551
R|8|^^^Unknown^TIME|0.37||||||||20180320135551
R|9|^^^LA1c/CHb-1^AREA|0.6||||||||20180320135551
R|10|^^^LA1c/CHb-1^TIME|0.70||||||||20180320135551
R|11|^^^A1c^AREA|5.0||||||||20180320135551
R|12|^^^A1c^TIME|0.85||||||||20180320135551
R|13|^^^P3^AREA|5.5||||||||20180320135551
R|14|^^^P3^TIME|1.36||||||||20180320135551
R|15|^^^A0^AREA|52.3||||||||20180320135551
R|16|^^^A0^TIME|1.47||||||||20180320135551
R|17|^^^S-Window^AREA|36.6||||||||20180320135551
R|18|^^^S-Window^TIME|1.65||||||||20180320135551
R|19|^^^TOTAL^AREA|2969414||||||||20180320135551
L|1|N
```

4.5 Test Results Query Message: LIS Computer → D-10 Instrument

The purpose of the Test Results Query Message is to request that the instrument send a specific set of results stored on the instrument.

The following table lists the possible ways a Computer System may query the Instrument. Any combinations used beyond those specified in the following table will return zero results.

NOTE: *The "✓" indicates that the field contains data specified by the user. **"All"** indicates that the characters "ALL" are entered in the field. **"Not Included"** indicates that the field in the message transmission is blank or the field itself is not included in the transmission.*

Starting Range ID Number	Universal Test ID	Beginning Results Date and Time	Ending Results Date and Time	Query Results
✓	✓	Not Included	Not Included	Returns all A1c **or** A2/F test results for a specified sample
"ALL"	✓	Not Included	Not Included	Returns all A1c **or** A2/F test results for all samples
✓	"ALL"	Not Included	Not Included	Returns all A1c **and** A2/F test results for a specified sample
"ALL"	"ALL"	Not Included	Not Included	Returns all A1c **and** A2/F test results for all samples
✓	✓	✓	✓	Returns all A1c **or** A2/F test results generated between the specified date range for a specified sample

Starting Range ID Number	Universal Test ID	Beginning Results Date and Time	Ending Results Date and Time	Query Results
"ALL"	✓	✓	✓	Returns all A1c **or** A2/F test results generated between the specified date range for all samples
✓	"ALL"	✓	✓	Returns all A1c **and** A2/F test results generated between the specified date range for a specified sample
"ALL"	"ALL"	✓	✓	Returns all A1c **and** A2/F test results generated between the specified date range for all samples

The following table shows the D-10 supported fields used in a query.

Record Type & ID	Record Format
Message Header H	H|Delimiter|||SenderName||||||||DateTime<CR>
Request Information Q	Q|SeqNo|StRngID||UnivTestID||BegDate|EndDate<CR>
Terminator L	L|SeqNo|TermCode<CR>

4.5.1 Header Record Fields

Field Number	Field Name	Description	Example
1	Record Type	Header - Always "H"	H
2	D-10 Included Delimiters	Defines delimiters used by the D-10: Field, Repeat, Component, Escape	| \ ^ &
5	Sender Name	There are three components used in this field: Senders Name - 1 to 16 characters Instrument Number – LIS ID Configured on the Senders instrument Software Version – 1 to 6 characters defining the software version of the sending system	Sysmex^01^5.00
14	Date and Time	The Date and Time of the transmission in format YYYMMDDHHMMSS	20190925142132

Example

```
H|\^&|||Sysmex^01^5.10|||||||||20190925142132
```

4.5.2 Query Record Fields

Field Number	Field Name	Description	Example
1	Record Type	Always Q	Q
2	Sequence Number	Query line number	1
3	Starting Range ID Number	The Second component is used. The second component is the specimen ID or the characters “ALL”. The field is not case sensitive. The specimen ID is the Barcode from the sample tube or the computer generated sample ID in the case of an unread sample tube. (1 to 24 characters) The characters “ALL” are used to select all results stored on the C: drive, listed in the Data tab. The Query cannot be used to return results that have been Archived to the D: drive.	^ALL
5	Universal Test ID	The Fourth component is used to define the test: A1c – 4 A2/F – 1	^^^4 ^^^1
7	Beginning Request Results Date and Time	The start date in format YYYYMMDD. When no Beginning Date is included in the Query, it is assumed All dates are selected.	
8	Ending Request Results Date and Time	The end date in format YYYYMMDD. When no Ending Date is included in the Query, it is assumed All dates are selected.	

Example

```
Q|1|^ALL||^^^4|20191006|20191008
```

4.5.3 Terminator Record Fields

Field Number	Field Name	Description	Example
1	Record Type	Always L	L
2	Sequence Number	Always 1	1
3	Termination Code	N – Normal termination F – Last request for information processed I – No information available from last query E – Unknown internal error Q – Error in last request for information	F

Example

```
L|1|F
```

Results of a successful query may contain zero, one, or many records. Review the termination code for the status of the query. A transmission with no test order or result records can have a code of “N” indicating that the query was successful with no records found.

4.6 Examples - Test Results Query Message

HCS – Host Computer System (LIS)

LMS – LIS Management System (Instrument)

LIS1A control characters are in bold.

4.6.1 Query for all A1c test results for the specified sample

HCS->**<ENQ>**

LMS->**<ACK>**

HCS->**<STX>1**H|\^&|||LIS^01^5.0|||||||||20030530121314<CR>**<ETX><CHK1><CHK2>**

<CR><LF>

LMS->**<ACK>**

HCS->**<STX>2**Q|1|^12345||^^^4<CR>**<ETX><CHK1><CHK2><CR><LF>**

LMS->**<ACK>**

HCS->**<STX>3**L|1|N<CR>**<ETX><CHK1><CHK2><CR><LF>**

LMS->**<ACK>**

HCS->**<EOT>**

NOTE: *Returns all A1c test results for sample 12345.*

4.6.2 Query for all A2/F results for all samples

HCS->**<ENQ>**

LMS->**<ACK>**

HCS->**<STX>1**H|\^&|||LIS^01^5.0|||||||||20030530121314<CR>**<ETX><CHK1><CHK2>**

<CR><LF>

LMS->**<ACK>**

HCS->**<STX>2**Q|1|^ALL||^^^1<CR>**<ETX><CHK1><CHK2><CR><LF>**

LMS->**<ACK>**

HCS->**<STX>3**L|1|N<CR>**<ETX><CHK1><CHK2><CR><LF>**

LMS->**<ACK>**

HCS->**<EOT>**

NOTE: *Returns all A2/F results on the instrument.*

4.6.3 Query for all A1c and A2/F results generated between the specified date range for the specified sample

HCS->**<ENQ>**

LMS->**<ACK>**

HCS->**<STX>1**H|\^&|||LIS^01^5.0|||||||||20030530121314<CR>**<ETX><CHK1><CHK2>**

<CR><LF>

LMS->**<ACK>**

HCS->**<STX>2**Q|1|^12345||^^^ALL||20030101|20031231<CR>**<ETX><CHK1><CHK2>**

<CR><LF>

LMS->**<ACK>**

HCS->**<STX>3**L|1|N<CR>**<ETX><CHK1><CHK2><CR><LF>**

LMS->**<ACK>**

HCS->**<EOT>**

NOTE: *Returns all A1c and A2/F results for sample 12345 generated between 01/01/2003 and 12/31/2003.*

4.6.4 Query for all results stored on the instrument

HCS->**<ENQ>**

LMS->**<ACK>**

HCS->**<STX>1**H|\^&|||LIS^01^5.0|||||||||20030530121314<CR>**<ETX><CHK1><CHK2>**

<CR><LF>

LMS->**<ACK>**

HCS->**<STX>2**Q|1|^ALL||^^^ALL<CR>**<ETX><CHK1><CHK2><CR><LF>**

LMS->**<ACK>**

HCS->**<STX>3**L|1|N<CR>**<ETX><CHK1><CHK2><CR><LF>**

LMS->**<ACK>**

HCS->**<EOT>**

NOTE: *Returns all test results stored on the instrument.*

4.6.5 Test Results Message in response to a query with no results

LMS->**<ENQ>**

HCS->**<ACK>**

LMS->**<STX>1**H|\^&|||D10^02^3.0|||||||||20030530121314<CR>**<ETX><CHK1><CHK2>**

<CR><LF>

HCS->**<ACK>**

LMS->**<STX>2**L|1|I<CR>**<ETX><CHK1><CHK2><CR><LF>**

HCS->**<ACK>**

LMS->**<EOT>**

NOTE: *Terminator Record's Termination Code field set to "I" indicates no results were found that match Host Computer query.*

4.6.6 Test Results Message indicating instrument query processing error

LMS->**<ENQ>**

HCS->**<ACK>**

LMS->**<STX>1**H|\^&|||D10^02^3.0|||||||||20030530121314<CR>**<ETX><CHK1><CHK2>**

<CR><LF>

HCS->**<ACK>**

LMS->**<STX>2**L|1|E<CR>**<ETX><CHK1><CHK2><CR><LF>**

HCS->**<ACK>**

LMS->**<EOT>**

NOTE: *Terminator Record's Termination Code field set to "E" indicates that there was an error on the instrument when processing the query.*

4.6.7 Test Results Message indicating Host Computer malformed query

LMS->**<ENQ>**

HCS->**<ACK>**

LMS->**<STX>1**H|\^&|||D10^2^000001|||||||||20030530121314<CR>**<ETX><CHK1>**
<CHK2>

<CR><LF>

HCS->**<ACK>**

LMS->**<STX>2**L|1|Q<CR><**ETX><CHK1><CHK2><CR><LF>**

HCS->**<ACK>**

LMS->**<EOT>**

NOTE: *Terminator Record's Termination Code field set to "Q" indicates that the host computer sent a valid LIS2-A message, but a data element inside the query did not conform to specifications. For example, a Specimen ID field (barcode) greater than 24 characters.*

Appendix

A.1 LIS1-A Physical Layer for Serial Data Exchange

The output port on the D-10 includes the signals in the following table. Required connection is DB9 Null Modem cable using pins 2, 3, and 5. The null Modem cable crosses pins 2 and 3 within the cable connecting Transmit to Receive and Receive to Transmit at either end of the cable.

Pins on the DB9 connector:

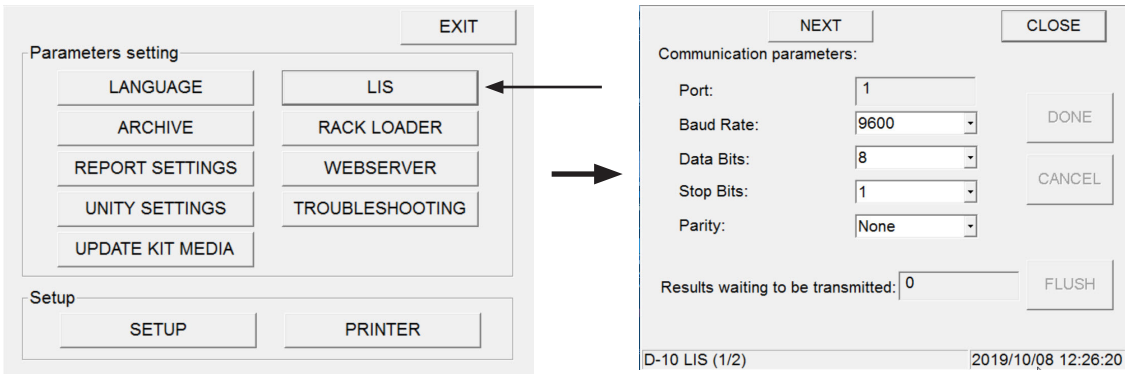
Pin Number	Name	Description
1	DCD	Data Carrier Detect (not used).
2	RD	Receive Data (an input).
3	TD	Transmit Data (an output).
4	DTR	Data Terminal Ready (an output).
5	SGND	Ground
6	DSR	Data Set Ready (an input, not used).
7	RTS	Request to Send (an output).
8	CTS	Clear to Send (an input).
9	RI	Ring Indicator (an input, not used).

The following communication port settings are available on the D-10. Bold values are the defaults.

Baud rate	1200, 2400, 4800, **9600** baud
Data length	7 bit, **8 bit**
Stop bit	**1 bit**, 2 bit
Parity	**None**, Even, Odd

This section describes features included in software version 5.0 and later. This is a summary of these features. Detailed information can be found in the D-10 Operation Manual LB002485.

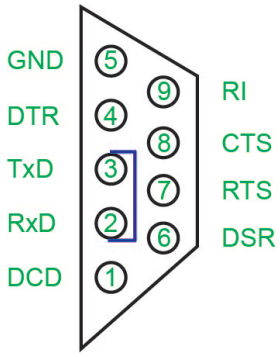
LIS RS232 Communications Port settings can be assigned within the Service Software using the Password “D-10setup”. Press the LIS button then assign port specifications using the drop-down lists in the LIS (1/2) screen.



A.2 Testing the D-10 LIS RS232 Port

In Software Version 5.0 and later there is an application to test the port's ability to Transmit and Receive.

In order to test the communication port, the Transmit and Receive lines must be connected together. Follow the drawing below to create a loop-back connector. This is simply a test connector which shorts pins 2 and 3 together. This allows the port to essentially communicate with itself. Plug the loop-back connector into the LIS port of the D-10.

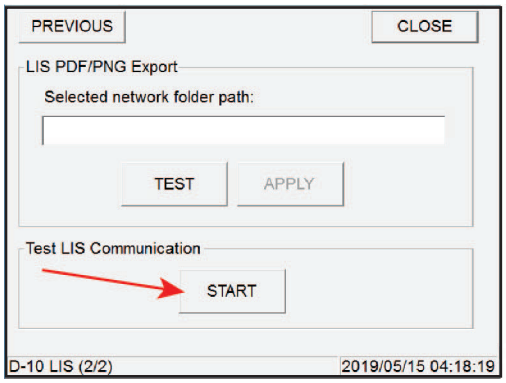


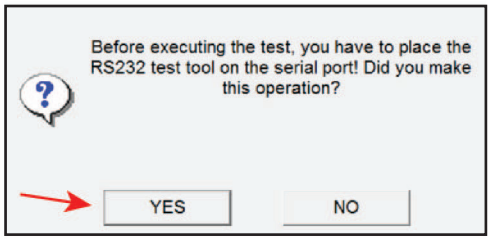
Install a wire jumper to connect the following signals:

RxD (pin 2) to TxD (pin 3)

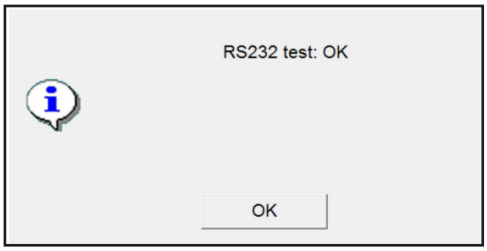
Navigate to the Service Software LIS (2/2) screen by selecting the Next button in the LIS (1/2) screen.

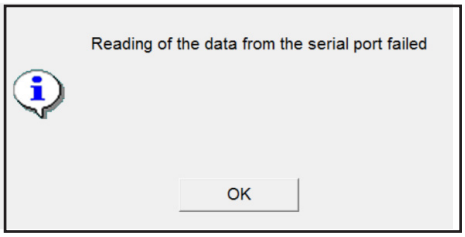
Press the Start button in the Test LIS Communication field. Press YES in the dialog box after attaching the loop-back connector.





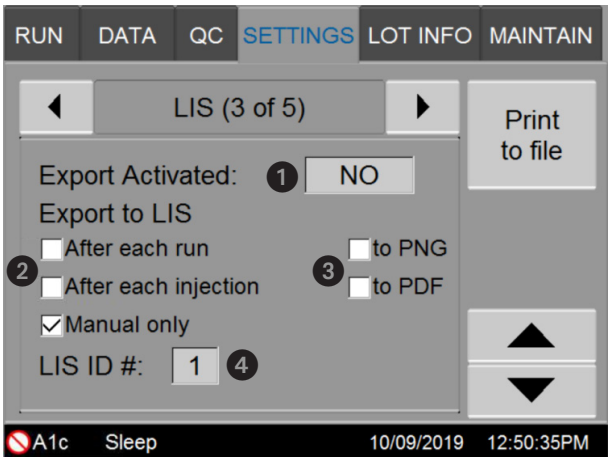
The test will pass if the test pattern transmitted matches what is received. The test will fail if there is a problem with the port or the test connecter.





A.3 Activating the D-10 Result Transmission to LIS

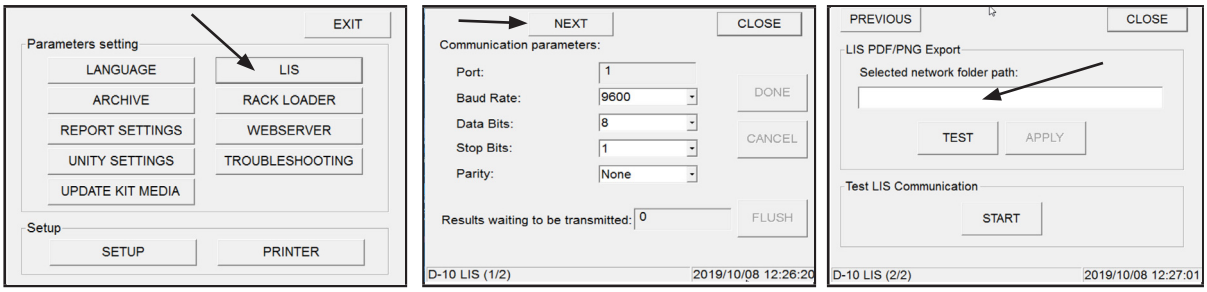
The Settings/LIS screen activates the transmission of patient results, defines the LIS ID number, and defines the type of result format (png or pdf or both) to export to a defined network folder. The png file includes only the chromatogram; the pdf file includes the entire result report.



1. Select YES to activate LIS output. Changes to options 2, 3, or 4 can be made only when Export Activated is “NO”.
2. Select when the D-10 will transmit result messages.
3. Select the type of Sample Result file (PNG or PDF or both) that will be exported to the defined Network folder.
4. Enter the LIS ID number which will be included in the “Instrument Specimen ID” field, the 4th field of the Order Record.

A.4 Setting the Output Location of the Sample Result File for LIS

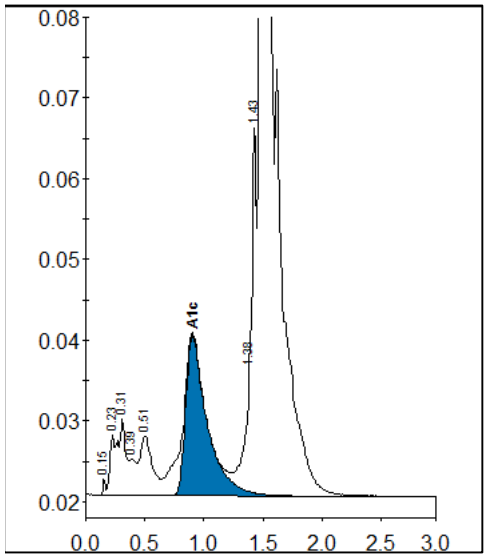
A copy of the sample result will be sent to the network location defined in the “Selected Network Folder Path” field of the LIS (2/2) screen. The name of the file will be the same as the Instrument Specimen ID, the 4th field in the Order Record.



The following is an example of a CAL2 sample transmission with the Instrument Specimen ID field highlighted. If selected, the two accompanying files will be sent to the defined network location. The name of the files will be identical to the Instrument Specimen ID in the Order Record.

H|\^&|||D10^01^3.00|||||||||20191023092314
P|1
O|1|CAL2|**CAL2-02-006-20190606-01**|^^^4|||||||||||||||||||||F
R|1|^^^Unknown^AREA|0.1|||||||||20190606144311
R|2|^^^Unknown^TIME|0.15|||||||||20190606144311
R|3|^^^A1a^AREA|0.7|||||||||20190606144311
R|4|^^^A1a^TIME|0.23|||||||||20190606144311
R|5|^^^A1b^AREA|1.4|||||||||20190606144311
R|6|^^^A1b^TIME|0.31|||||||||20190606144311
R|7|^^^Unknown^AREA|0.5|||||||||20190606144311
R|8|^^^Unknown^TIME|0.39|||||||||20190606144311
R|9|^^^F^AREA|1.6|||||||||20190606144311
R|10|^^^F^TIME|0.51|||||||||20190606144311
R|11|^^^A1c^AREA|10.3|||||||||20190606144311
R|12|^^^A1c^TIME|0.90|||||||||20190606144311
R|13|^^^P3^AREA|2.2|||||||||20190606144311
R|14|^^^P3^TIME|1.38|||||||||20190606144311
R|15|^^^Unknown^AREA|3.4|||||||||20190606144311
R|16|^^^Unknown^TIME|1.43|||||||||20190606144311
R|17|^^^A0^AREA|82.7|||||||||20190606144311
R|18|^^^A0^TIME|1.49|||||||||20190606144311
R|19|^^^TOTAL^AREA|3359520|||||||||20190606144311
L|1|N

CAL2-02-006-20190606-01.png

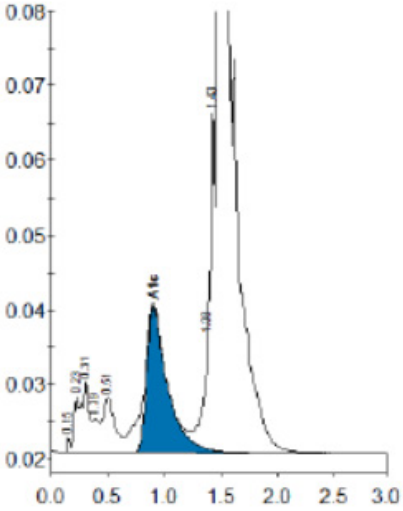


CAL2-02-006-20190606-01.pdf

Bio-Rad Laboratories
Hercules, CA 94547

Calibration report

Calibrator ID:	AA80265
Injection date	06/06/2019 02:43 PM
Injection #: 6	D-10 Method: HbA1c
Rack #: ---	Rack position: 2
Bio-Rad v: 5.00-2	S/N: #DJ2I000406



Peak table - ID: CAL2

Peak	R.time	Height	Area	Area %
Unknown	0.15	2121	3208	0.1
A1a	0.23	7475	21875	0.7
A1b	0.31	9439	45561	1.4
Unknown	0.39	4563	17282	0.5
F	0.51	7381	54701	1.6
A1c	0.90	19766	253002	10.3
P3	1.38	15641	72479	2.2
Unknown	1.43	45875	114167	3.4
A0	1.49	675276	2777245	82.7
Total Area:		3359520		

Concentration:	%
A1c	10.3

Calibration Passed

A.5 A1c Reported Measurement Value – Patient Record

With the release of Dia 3.60, it is possible to export the A1c measurement value in NGSP (%) or IFCC (mmol/mol) units. **No unit identifier is sent with the output string**. The output included in the A1c result string is defined during instrument installation and is not customer-selectable. The selection is displayed in the DATA screen and also included on the settings report. All other Area values are exported as % values. The A1c value is the only value that is selectable.

"Current unit for HbA1c is: % (NGSP)" indicates A1c area value is exported in units of percent.


```
1H|\^&|||D10^01^3.00||||||||20100824101323
2P|1
3O|1|A1CTRH|A1CTRH-04-014-20100823-01|^^^4|||||||||||||||||||||F
4R|1|^^^A1a^AREA|0.8||||||||20100823150835
5R|2|^^^A1a^TIME|0.20||||||||20100823150835
6R|3|^^^A1b^AREA|1.6||||||||20100823150835
7R|4|^^^A1b^TIME|0.28||||||||20100823150835
0R|5|^^^F^AREA|0.6||||||||20100823150835
1R|6|^^^F^TIME|0.43||||||||20100823150835
2R|7|^^^LA1c/CHb-1^AREA|0.9||||||||20100823150835
3R|8|^^^LA1c/CHb-1^TIME|0.68||||||||20100823150835
4R|9|^^^A1c^AREA|9.8||||||||20100823150835
5R|10|^^^A1c^TIME|0.80||||||||20100823150835
6R|11|^^^P3^AREA|4.9||||||||20100823150835
7R|12|^^^P3^TIME|1.39||||||||20100823150835
0R|13|^^^A0^AREA|84.2||||||||20100823150835
1R|14|^^^A0^TIME|1.47||||||||20100823150835
2R|15|^^^TOTAL^AREA|2210855||||||||20100823150835
3L|1|N
```

A1c result value exported in NGSP units (9.8%).

"Current unit for HbA1c is: mmol/mol (IFCC)" indicates A1c area value is exported in mmol/mol units.

A1c result value exported in IFCC units (82 mmol/mol).

```
1H|\^&|||D10^01^3.00||||||||20100824151847
2P|1
3O|1|A1CTRH|A1CTRH-04-034-20100824-01|^^^4|||||||||||||||||||||F
4R|1|^^^A1a^AREA|0.7||||||||20100824144612
5R|2|^^^A1a^TIME|0.20||||||||20100824144612
6R|3|^^^A1b^AREA|2.3||||||||20100824144612
7R|4|^^^A1b^TIME|0.28||||||||20100824144612
0R|5|^^^LA1c/CHb-1^AREA|1.0||||||||20100824144612
1R|6|^^^LA1c/CHb-1^TIME|0.67||||||||20100824144612
2R|7|^^^A1c^AREA|82||||||||20100824144612
3R|8|^^^A1c^TIME|0.79||||||||20100824144612
4R|9|^^^P3^AREA|4.7||||||||20100824144612
5R|10|^^^P3^TIME|1.39||||||||20100824144612
6R|11|^^^A0^AREA|84.1||||||||20100824144612
7R|12|^^^A0^TIME|1.47||||||||20100824144612
0R|13|^^^TOTAL^AREA|2235171||||||||20100824144612
1L|1|N
```

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