BIO-RAD

CDM™ Software

L70217200

CDM 5.1 LIS Requirements

1 Introduction

A laboratory information management system (LIMS or LIS) stores and manages information regarding patients, tests ordered for patients, and the results of tests which have already been performed. When a patient sample is collected, or when it arrives at the laboratory, it is assigned a sample identification. The sample ID is associated with the patient and with tests to be performed on the sample. The LIS assembles a list of test orders for each assay that the lab performs, and sends these lists to CDM. The tests are performed on the VARIANT II/VARIANT II TURBO instruments which are controlled by CDM. Results associated with the orders for the test are transferred from CDM to the LIS.

To establish this connection for the CDM and the LIS, both systems must have compatible hardware and software. A correctly configured cable must connect the two systems.

To reduce the risk of incompatibility between the CDM and the LIS, the ASTM standard for the transfer protocols was followed during development. The Standard Specification for the Low-Level Protocol to Transfer Messages between Clinical Instruments and Computer Systems is under the jurisdiction of the Clinical Laboratory Standards Institute (CLSI, formerly NCCLS).

The low-level protocol is specified in LIS1-A (formerly ASTM standard E1381). Additionally, a high-level protocol is also implemented in the CDM, LIS2-A2 (formerly ASTM standard E1394). To receive copies of these standards, contact the CLSI (http://www.clsi.org).

1.1 New LIS Output Features for CDM 5.1

With the release of CDM version 5.1, there are three new **optional** features that can change what information is exported to the LIS:

(1) HbA_{1c} results can be exported to the LIS in up to 3 different reporting units.

(2) HbA_{1c} reporting unit names can be exported.

(3) The date and time that the sample was analyzed can be exported.

These features are described in more detail below.

1.1.1 Reporting units for HbA_{1c} results are selected in the CDM **Setup/Configuration/ HbA1c Units Settings** dialog box. The LIS outputs will match the selection in the Sample Reports column of the dialog box. The customer may select 1–3 of the supported units (i.e., NGSP, IFCC, Mono-S, and JDS). If a customer chooses to export their HbA_{1c} results in any unit other than NGSP, one or more new codes will need to be created in the customer's LIS system, as shown in the following table:

Unit	LIS Code	LIS Results to Report
IFCC	A1cIFCC	^^^A1cIFCC^AREA
Mono-S	A1cMono-S	^^^A1cMono-S^AREA
JDS	A1cJDS	^^^A1cJDS^AREA

These codes are also listed in Section 9, LIS Test ID Codes. For examples of HbA_{1c} results being transmitted in the optional units, see Sections 6.6–6.9.

NOTE: *If NGSP is the only unit selected, no new LIS codes are needed.*

1.1.2 The option “Export HbA1c Unit Names to LIS” is set in the CDM **Setup/ Configuration/LIS Setup** dialog box. For an example of HbA_{1c} unit names being exported to an LIS, see Section 6.8.

1.1.3 The option ”Export Date/Time of sample injection to LIS” is set in the CDM **Setup/ Configuration/LIS Setup** dialog box. For examples of results with the date and time of sample analysis being exported to an LIS, see Sections 6.7 and 6.9.

2 Supported Workflow Scenarios

Options and Settings for Workflow Scenarios

Item	Where Set	Options
LIS Communication Port	Setup/Configuration - System	Integer
AUTO Import From LIS	Setup/Configuration/LIS Setup - System	On/Off
Automatic LIS Export	Setup/Configuration - Instrument	On/Off
Export Unknown Peaks to LIS	Setup/Configuration/LIS Setup - System	On/Off

CAUTION: LIS provider must be contacted for supportability if the “Export Unknown Peaks to LIS” option is set to On.

NOTE: *The Reset LIS database button on the Setup/Configuration screen allows the user to clear CDM’s LIS database; it is recommended that the LIS database be cleared periodically. See Section 10 for more information.*

2.1 Scenario 1: Get Sample ID, Retrieve Demographics from LIS, Export Results

Settings:
LIS Communication Port = 6 (or choose an unused port)
AUTO Import From LIS = On
Automatic LIS Export = On

LIS prepares a list of orders for tests to be performed by the CDM instrument.

This list may include:

- Only orders for the current test on the CDM instrument
- Orders for all tests which are run on the CDM instrument

In both these cases, CDM must be able to identify which orders are valid for the current test.

Whenever the Orders list arrives, CDM stores the list, adding the new orders to any existing orders in its orders collection.

The VARIANT II/VARIANT II TURBO automatically builds the worklist as the barcode is read.

As the worklist is built, the demographics received from the host computer will be automatically entered when the Specimen ID is entered.

The results are exported based upon the order in which the samples are analyzed by the VARIANT II/VARIANT II TURBO.

When CDM is controlling more than one instrument, LIS patient orders cannot be instrument specific.

2.2 Scenario 2: Export Only

Settings:
LIS Communication Port = 6 (or choose an unused port)
AUTO Import From LIS = Off
Automatic LIS Export = On

Worklist entry is independent of LIS.

CDM has no knowledge of LIS test orders.

All results are exported with or without Sample ID.

When a sample is identified as Unknown, CDM creates a sample ID based on instrument # and injection #.

Manual Export from the Data/View Run Screen

1. Data export is available at all times, regardless of instrument state. Any patient or control results can be exported.
2. In the Data/View Run screen, select the run whose data is to be exported to LIS. Select the start and end injection numbers to be exported to LIS. Click the Export to LIS button.

   NOTE: *After clicking the Export to LIS button, data starts to transmit, but there is no indication of transmission. Data is transmitting at about 5 seconds/sample.*

Manual Export from the Data/View Sample Screen

1. Data export is available at all times, regardless of instrument state. Any patient or control results can be exported.
2. In the Data/View Sample screen, select the sample to be exported. To export the results, click the Export to LIS button.

3 CLSI-LIS2-A2 or ASTM E1394 Protocol

Message Header Record (14 Fields):

No.	CLSI Field Name	Supported?	CDM Field Name	Format	Character No. Limit
1	Record Type ID	Yes	--	H	--
2	Delimiter Definition	Yes	--	|\^&	--
3	Message Control ID	No	--	--	--
4	Access Password	No	--	--	--
5	Sender Name or ID	Yes	--	SystemName^InstrumentName	--
5.1	System Name	Yes	--	--	40
5.2	Instrument Name	Yes	--	--	60
6	Sender Street Address	No	--	--	--
7	Reserved Field	No	--	--	--
8	Sender Telephone Number	No	--	--	--
9	Characteristics of Sender	No	--	--	--
10	Receiver ID	No	--	--	--
11	Comment or Special Instructions	No	--	--	--
12	Processing ID	Yes	--	P	--
13	Version No.	No	--	--	--
14	Date and Time of Message	Yes	--	YYYYMMDDhhmmss	--

Example:

H|\^&|||Bio-Rad CDM System^Bio-Rad Variant V-II Instrument|||||||P||20010118143621

Patient Information Record (35 Fields):

No.	CLSI Field Name	Support-ed?	CDM Field Name	Format	Character No. Limit
1	Record Type ID	Yes	--	P	--
2	Sequence Number	Yes	--	(1,2,3,...)	--
3	Practice Assigned Patient ID	Yes	Patient ID	--	--
4	Laboratory Assigned Patient ID	No	--	--	--
5	Patient ID No. 3	No	--	--	--
6	Patient Name	Yes	Patient Name	LastName^FirstName^MI	--
6.1	Last Name	Yes	Last Name	--	--
6.2	First Name	Yes	First Name	--	--
6.3	Middle Initial	Yes	Middle Initial	--	--
7	Mother's Maiden Name	No	--	--	--
8	Birthdate	Yes	Date	--	--
9	Patient Sex	Yes	Sex	(M or F)	--
10	Patient Race-Ethnic Origin	No	--	--	--
11	Patient Address	No	--	--	--
12	Reserved Field	No	--	--	--
13	Patient Telephone Number	No	--	--	--
14	Attending Physician ID	Yes	Physician Name	--	31
15	Special Field 1	No	--	--	--
16	Special Field 2	No	--	--	--
17	Patient Height	No	--	--	--
18	Patient Weight	No	--	--	--
19	Patient's Known or Suspected Diagnosis	No	--	--	--
20	Patient Active Medications	No	--	--	--
21	Patient's Diet	No	--	--	--
22	Practice Field No. 1	No	--	--	--
23	Practice Field No. 2	No	--	--	--
24	Admission and Discharge Dates	No	--	--	--
25	Admission Status	No	--	--	--
26	Location	No	--	--	--
27	Nature of Alternative Diagnostic	No	--	--	--
28	Alternative Diagnostic Code and Classification	No	--	--	--
29	Patient Religion	No	--	--	--
30	Marital Status	No	--	--	--
31	Isolation Status	No	--	--	--
32	Language	No	--	--	--
33	Hospital Service	No	--	--	--
34	Hospital Institution	No	--	--	--
35	Dosage Category	No	--	--	--

Example:

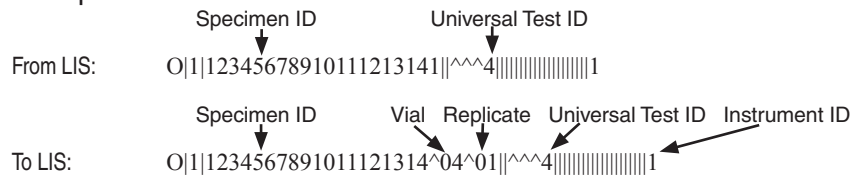
P|1|10000000000-001|||Smith^John^M.||19501201|M|||||Dr. Fred

NOTE: Patient Name and Physician Name can be composed of 3 parts separated by component delimiters (^). Example: LastName^FirstName^MI

Test Order Record (31 Fields):

No.	CLSI Field Name	Supported?	CDM Field Name	Format	Character No. Limit
1	Record Type ID	Yes	--	O	--
2	Sequence Number	Yes	--	(1,2,3,...)	--
3	Specimen ID	Yes	Sample ID	Part1^Part2^Part3	--
3.1	Part 1 Sample ID	Yes	--	Sample ID	20
3.2	Part 2 Vial/Tube #	Yes	--	Vial/Tube No.	2
3.3	Part 3 Replicate #	Yes	--	Replicate	2
4	Instrument Specimen ID	No	--	--	--
5	Universal Test ID	Yes	LIMS Test ID	^^^Part4	--
5.1	Empty	Yes	--	--	--
5.2	Empty	Yes	--	--	--
5.3	Empty	Yes	--	--	--
5.4	4 or 1	Yes	--	1 = β-Thal 4 = A1c	--
6	Priority	No	--	--	--
7	Requested/Ordered Date and Time	No	--	--	--
8	Specimen Collection Date and Time	No	--	--	--
9	Collection End Time	No	--	--	--
10	Collection Volume	No	--	--	--
11	Collector ID	No	--	--	--
12	Action Code	No	--	--	--
13	Danger Code	No	--	--	--
14	Relevant Clinical Information	No	--	--	--
15	Date/Time Specimen Received	No	--	--	--
16	Specimen Descriptor (Specimen Type^Specimen Source)	No	--	--	--
17	Ordering Physician	No	--	--	--
18	Physician's Telephone Number	No	--	--	--
19	User Field No. 1	No	--	--	--
20	User Field No. 2	No	--	--	--
21	Laboratory Field No. 1	No	--	--	--
22	Laboratory Field No. 2	No	--	--	--
23	Date/Time Results Reported or Last Modified	No	--	--	--
24	Instrument Charge to Computer System	No	--	--	--
25	Instrument Section ID	Yes	--	(1 or 2)	--
26	Report Types	No	--	--	--
27	Reserved Field	No	--	--	--
28	Location or Ward of Specimen Collection	No	--	--	--
29	Nosocomial Infection Flag	No	--	--	--
30	Specimen Service	No	--	--	--
31	Specimen Institution	No	--	--	--

Example:



Message Terminator Record (3 Fields):

No.	CLSI Field Name	Supported?	CDM Field Name	Format	Character No. Limit
1	Record Type ID	Yes	--	L	--
2	Sequence Number	Yes	--	1	--
3	Termination Code*	Yes	--	N	--

***NOTE:** CDM will only send an "N" character for termination code. When receiving, this field cannot be blank. CDM will ignore any character received in this field.

Example:

L|1|N

Message Result Record (14 Fields):

No.	CLSI Field Name	Supported?	CDM Field Name	Format	Character No. Limit
1	Record Type ID	Yes	--	(R)	--
2	Sequence Number	Yes	--	(1,2,3,...)	--
3	Universal Test ID	Yes	--	^^^Part4^Part5*	49
3.1	Component 1	Yes	Empty	--	--
3.2	Component 2	Yes	Empty	--	--
3.3	Component 3	Yes	Empty	--	--
3.4	Component 4	Yes	Peak Name	--	--
3.5	Component 5	Yes	("Area" or "Time")	--	--
4	Data or Measurement Value	Yes	--	--	255
5	Units	Yes	--	--	--
6	Reference Ranges	No	--	--	--
7	Result Abnormal Flags	No	--	--	--
8	Nature of Abnormality Testing	No	--	--	--
9	Results Status	No	--	--	--
10	Date of Change in Instrument Normative Values or Units	No	--	--	--
11	Operator Identification	No	--	--	--
12	Date/Time Test Started	No	--	--	--
13	Date/Time Test Completed	Yes	--	--	--
14	Instrument Identification	Yes	--	(1 or 2)	--

Examples:

R|1|^^^A1b^AREA|0.336|||||||||1
R|2|^^^A1b^TIME|0.258|||||||||1

*Examples of Field No. 3 =

^^^A1c^AREA
^^^Unknown5^AREA
^^^Total^AREA
^^^A1c^TIME

NOTE:

1) All fields accept any characters, including special characters. However, characters reserved for Delimiter Definition (|\^&) should not be used within fields as text.
2) Date/Time Stamps are exported to LIS as YYYYMMDDhhmmss.

4 CLSI-LIS1-A2 or ASTM E1380 Low-Level Protocols

4.1 Message Header Record (14 Fields): Same as the LIS2 Protocol

4.2 Patient Information Record (35 Fields): Same as the LIS2 Protocol

4.3 Test Order Record (31 Fields): Same as the LIS2 Protocol

4.4 Message Termination Record (3 Fields): Same as the LIS2 Protocol

5 Receiving Orders/Demographics from an LIS

The information below illustrates the format of a sample list that is to be sent using the CLSI communication protocols. The following is an example of a sample list transmission. For information regarding low-level transmission errors, refer to CLSI standards.

5.1 Sample List Example

The data below is an example of the format of the fields in a CDM sample list. This list is organized by the host computer according to the high-level protocol, and is then transmitted to CDM using the low-level protocol.

	Practice Assigned Patient ID	Specimen ID	Universal Test ID (Part 4)	Instrument Section ID
1	10000000000-001	12345678910111213141	4	1
2	10000000000-002	14131211101987654321	4	1

Patient Name (Part 1, 2, 3)	Birthdate	Sex	Doctor
Smith, John, M.	19501201	M	Dr. Fred
Jones, Mary, Q.	19501201	F	Dr. Bob

5.2 Example of a High-Level Message

The following example illustrates the formatting of the sample list using the high-level protocol specified in CLSI LIS2-A2.

Header —— H|\^&|||||||||P||20010118143621

First sample tube —— P|1|10000000000-001|||Smith^John^M.||19501201|M|||||Dr. Fred

First sample ID —— O|1|12345678910111213141||^^^4|||||||||||||||||1

Second sample tube —— P|2|10000000000-002|||Jones^Mary^Q.|Smith|19501201|F|||||Dr. Bob

Second sample ID —— O|1|14131211101987654321||^^^4|||||||||||||||||1

Termination Sequence —— L|1|N

5.3 Example of a Low-Level Message

CDM 5.1 supports the Single Record Per Frame Transmission Protocol model and the Multiple Records Per Frame Transmission Protocol model when receiving orders. When transmitting results, only the Single Record Per Frame Transmission Protocol model is used (see Section 6 for more information).

The following example illustrates the LIS2-A2 message from Section 5.2 being transmitted from the LIS to the CDM using the Single Record Per Frame model.

	LIS	CDM
	<ENQ>	<ACK>
Header	<STX>1H|\^&||||||||P||20010118143621<CR><ETX>C0<CR><LF>	<ACK>
First sample tube	<STX>2P|1|10000000000-001|||Smith^John^M.||19501201|M||||Dr. Fred<CR><ETX>3B<CR><LF>	<ACK>
First sample ID	<STX>3O|1|12345678910111213141||^^^4<CR><ETX>3B<CR><LF>	<ACK>
Second sample tube	<STX>4P|2|10000000000-002|||Jones^Mary^Q.||19501201|F||||Dr. Bob<CR><ETX>3E<CR><LF>	<ACK>
Second sample ID	<STX>5O|1|14131211101987654321||^^^4<CR><ETX>3E<CR><LF>	<ACK>
Termination Sequence	<STX>6L|1|N<CR><ETX>03<CR><LF> <EOT>	<ACK>

Checksum

Communication examples with codes enclosed in brackets are ASCII codes; refer to CLSI standard LIS1-A2. For example, the <ACK> character is 06 hexadecimal.

The following example illustrates the LIS2-A2 message from Section 5.2 being transmitted from the LIS to the CDM using the Multiple Records Per Frame model.

	LIS	CDM
	<ENQ>	<ACK>
Header	<STX>1H|\^&||||||||P||20010118143621<CR>	
First sample tube	2P|1|10000000000-001|||Smith^John^M.||19501201|M||||Dr. Fred<CR>	
First sample ID	3O|1|12345678910111213141||^^^4<CR>	
Second sample tube	4P|2|10000000000-002|||Jones^Mary^Q.||19501201|F||||Dr. Bob<CR>	
Second sample ID	5O|1|14131211101987654321||^^^4<CR>	
Termination Sequence	6L|1|N<CR><ETX>3B<CR><LF> <EOT>	<ACK>

Checksum

VARIANT II and VARIANT II TURBO will receive orders with demographics but not worklists with rack position or implied order of running.

6 Transmitting Results from CDM to an LIS

The examples below show sample information from an order that was received by CDM. The order contains the following data:

Sample ID (part 1)	Universal Test ID (part 4)
12345678910111213141	4

6.1 Examples of CLSI-LIS1-A2 Communication

CDM 5.1 supports the Single Record Per Frame model when sending results to an LIS.

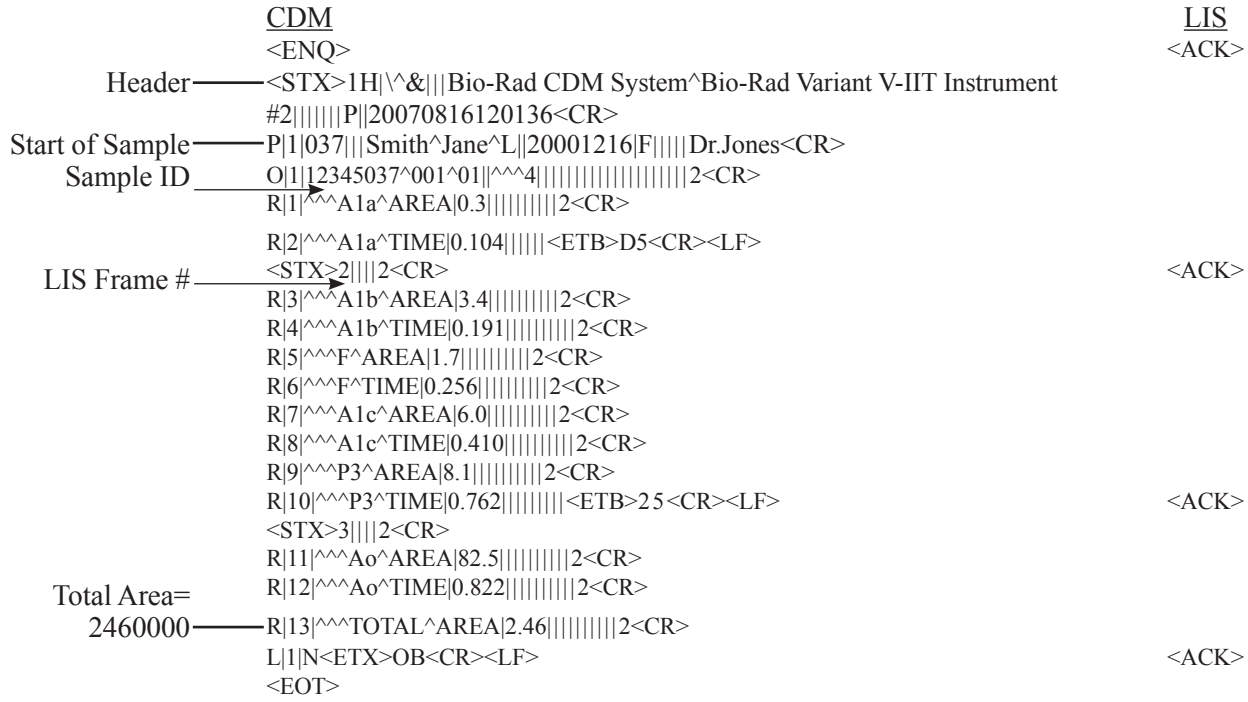
The following examples illustrate patient results transmitted to the LIS using the LIS1-A2 and LIS2-A2 communication protocols.

NOTE: *The LIS computer sends an <ACK> character after the successful receipt of each frame.*

6.1.1 Example of Single Record Low-Level Protocol

	CDM	LIS
	<ENQ>	<ACK>
Header	<STX>1H|\^&|||BIO-RAD CDM System^Bio-Rad Variant V-IIT	
	Instrument#1|||||||P||20070906103749<CR><ETX>33<CR><LF>	<ACK>
Start of Sample	<STX>2P|1|001|1|2|Smith^Jane^L.||19670116|F|||||Dr.Jones||||||||||Hercules||||M<CR><ETX>CC<CR>	
	<LF>	<ACK>
Sample ID	<STX>3O|1|12345678910111213141^001^01||^^^4||||||||||||||||1<CR><ETX>8D<CR><LF>	<ACK>
	<STX>4R|1|^^^A1a^AREA|0.5|||||||||1<CR><ETX>3B<CR><LF>	<ACK>
	<STX>5R|2|^^^A1a^TIME|0.10|||||||||1<CR><ETX>7F<CR><LF>	<ACK>
	<STX>6R|3|^^^A1b^AREA|13.9|||||||||1<CR><ETX>78<CR><LF>	<ACK>
	<STX>7R|4|^^^A1b^TIME|0.19|||||||||1<CR><ETX>8D<CR><LF>	<ACK>
	<STX>0R|5|^^^A1c^AREA|7.1|||||||||1<CR><ETX>40<CR><LF>	<ACK>
	<STX>1R|6|^^^A1c^TIME|0.35|||||||||1<CR><ETX>88<CR><LF>	<ACK>
	<STX>2R|7|^^^Ao^AREA|80.8|||||||||1<CR><ETX>57<CR><LF>	<ACK>
Total Area=	<STX>3R|8|^^^Ao^TIME|0.83|||||||||1<CR><ETX>6A<CR><LF>	<ACK>
1910000	<STX>4R|9|^^^TOTAL^AREA|1.91|||||||||1<CR><ETX>2A<CR><LF>	<ACK>
	<STX>5L|1|N<CR><ETX>08<CR><LF>	<ACK>
	<EOT>	<ACK>

6.1.2 Example of Multiple Records Low-Level Protocol



6.2 Example of High-Level Communication

The following example illustrates patient results embedded into the high-level protocol, CLSI LIS2-A2, after the low-level protocol has been removed.

NOTE: *If demographic information is entered and sent from LIS to CDM, then it will be transmitted back to LIS and appear in the patient field.*

H|\^&|||Bio-Rad CDM System^Bio-Rad Variant V-IIT Instrument #2|||||||P||20070816120136
P|1|037|||Smith^Jane^L|20001216|F|||||Dr.Jones
O|1|12345037^001^01||^^^4|||||||||||||||||||2
R|1|^^^A1a^AREA|0.3|||||||||2
R|2|^^^A1a^TIME|0.104|||||2||||2
R|3|^^^A1b^AREA|3.4|||||||||2
R|4|^^^A1b^TIME|0.191|||||||||2
R|5|^^^F^AREA|1.7|||||||||2
R|6|^^^F^TIME|0.256|||||||||2
R|7|^^^A1c^AREA|6.0|||||||||2
R|8|^^^A1c^TIME|0.410|||||||||2
R|9|^^^P3^AREA|8.1|||||||||2
R|10|^^^P3^TIME|0.762|||||||||2
R|11|^^^Ao^AREA|82.5|||||||||2
R|12|^^^Ao^TIME|0.822|||||||||2
R|13|^^^TOTAL^AREA|2.46|||||||||2
L|1|N

6.3 Example of "Unknown" Patient Result and Instrument ID Number Transmitted to LIS

The following example illustrates patient results transmitted from CDM to the LIS when the patient sample does not have a barcode label.

The "Unknown" sample ID is generated by CDM in the format "Unkown-instrument #-injection #", with the instrument # = 1 or 2 and the injection # being 1–4 digits.

```
H|\^&|||Bio-Rad CDM System^Bio-Rad Variant V-II Instrument|||||||P||200011061706231
P|1        [Inst.#, Inj.#, Tube#, Rep.#,Universal Test ID#]

O|1|Unknown-2-3^003^01||^^^4|||||||||||||||||||2
R|1|^^^A1a^AREA|0.7|||||||||2
R|2|^^^A1a^TIME|0.09|||||||||2                          Instrument ID#
R|3|^^^A1b^AREA|1.9|||||||||2
R|4|^^^A1b^TIME|0.31|||||||||2
R|5|^^^A1c^AREA|5.7|||||||||2
R|6|^^^A1c^TIME|0.91|||||||||2
R|7|^^^Ao^AREA|68.3|||||||||2
R|8|^^^Ao^TIME|1.79|||||||||2
R|9|^^^E, D^AREA|4.7|||||||||2
R|10|^^^E, D^TIME|1.88|||||||||2
R|11|^^^S^AREA|32.7|||||||||2
R|12|^^^S^TIME|1.94|||||||||2
R|13|^^^TOTAL^AREA|1.82|||||||||2
L|1|N
```

6.4 Example of Control Values Transmitted to LIS

The following example illustrates control values that were transmitted from CDM to the LIS. The example is for a VARIANT II HbA_{1c} NU control.

After control barcodes are read, CDM generates the sample ID in the format "Control name-instrument #-lot #", with the Control name = LC or HC and the instrument # = 1 or 2.

```
H|\^&|||Bio-Rad CDM System^VAR2_06|||||||P||20100120095811
P|1 [Low Control,Inst.#, Lot #, Vial or Tube #, Rep.#]

O|1|LC-1-33791^004^01||^^^4|||||||||||||||||||1
R|1|^^^A1b^AREA|2.0|||||||||1
R|2|^^^A1b^TIME|0.312|||||||||1
R|3|^^^F^AREA|0.5|||||||||1
R|4|^^^F^TIME|0.598|||||||||1
R|5|^^^Unknown1^AREA|0.8|||||||||1
R|6|^^^Unknown1^TIME|0.848|||||||||1
R|7|^^^A1c^AREA|5.7|||||||||1
R|8|^^^A1c^TIME|0.994|||||||||1
R|9|^^^P4^AREA|3.6|||||||||1
R|10|^^^P4^TIME|1.637|||||||||1
R|11|^^^Ao^AREA|89.6|||||||||1
R|12|^^^Ao^TIME|1.751|||||||||1
R|13|^^^TOTAL^AREA|2.26|||||||||1
L|1|N
```

6.5 Example of Unknown Peak Results Transmitted to LIS

The following example illustrates transmission of unknown peaks from CDM to LIS. The example is for an A_{1c} test on a VARIANT II TURBO instrument.

CAUTION: LIS provider must be contacted to support transmission of unknown peaks.

NOTE: *The "Export Unknown Peaks to LIS" option must be selected on the Setup/ Configuration/LIS Setup screen in order to transmit unknown peaks.*

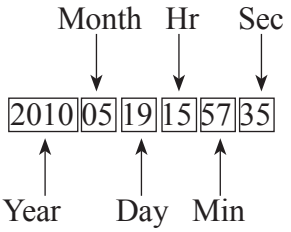
```
H|\^&|||Bio-Rad CDM System^Bio-Rad Variant V-IIT Instrument #2||||||P||20060718151700
P|1
O|1|12345001^010^01||^^^4||||||||||||||||||2
R|1|^^^A1a^AREA|0.9|||||||||2
R|2|^^^A1a^TIME|0.099|||||||||2
R|3|^^^A1b^AREA|11.8|||||||||2
R|4|^^^A1b^TIME|0.171|||||||||2
R|5|^^^LA1c^AREA|0.9|||||||||2
R|6|^^^LA1c^TIME|0.356|||||||||2
R|7|^^^A1c^AREA|5.7|||||||||2
R|8|^^^A1c^TIME|0.417|||||||||2
R|9|^^^Unknown1^AREA|7.1|||||||||2
R|10|^^^Unknown1^TIME|0.630|||||||||2
R|11|^^^P3^AREA|4.3|||||||||2
R|12|^^^P3^TIME|0.771|||||||||2
R|13|^^^Ao^AREA|75.7|||||||||2
R|14|^^^Ao^TIME|0.810|||||||||2
R|15|^^^TOTAL^AREA|2.07|||||||||2
L|1|N
```

6.6 Example of A1c Results Reported in NGSP and IFCC Units

```
H|\^&|||Bio-Rad CDM System^CDM 5.1 VII Instrument||||||P||20100623103823
P|1
O|1|Unknown-2-28^004^01||^^^4||||||||||||||||||2
R|1|^^^A1a^AREA|0.7|||||||||2
R|2|^^^A1a^TIME|0.195|||||||||2
R|3|^^^A1b^AREA|1.1|||||||||2
R|4|^^^A1b^TIME|0.229|||||||||2
R|5|^^^F^AREA|1.0|||||||||2
R|6|^^^F^TIME|0.281|||||||||2
R|7|^^^LA1c^AREA|1.8|||||||||2
R|8|^^^LA1c^TIME|0.414|||||||||2
R|9|^^^A1cIFCC^AREA|37|||||||||2          ← A1c result reported in IFCC Units
R|10|^^^A1c^AREA|5.5|||||||||2            ← A1c result reported in NGSP Units
R|11|^^^A1c^TIME|0.509|||||||||2
R|12|^^^P3^AREA|2.9|||||||||2
R|13|^^^P3^TIME|0.761|||||||||2
R|14|^^^P4^AREA|1.5|||||||||2
R|15|^^^P4^TIME|0.853|||||||||2
R|16|^^^Ao^AREA|86.4|||||||||2
R|17|^^^Ao^TIME|1.009|||||||||2
R|18|^^^TOTAL^AREA|1.99|||||||||2
L|1|N
```

6.7 Example of A1c Results Reported in NGSP, IFCC, and JDS Units with Date-Time

The ability to report the Date/Time that the test started is a user optional feature. It is a 14-digit number generated by CDM, which is illustrated below:



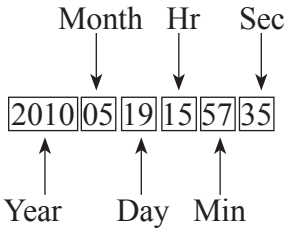

```
H|\^&|||Bio-Rad CDM System^CDM 5.1 VII Instrument||||||P||20100623104313
P|1
O|1|Unknown-2-28^004^01||^^^4||||||||||||||||||2
R|1|^^^Unknown1^AREA|0.6|||||||20100519155735||2
R|2|^^^Unknown1^TIME|0.163|||||||20100519155735||2
R|3|^^^A1a^AREA|0.7|||||||20100519155735||2
R|4|^^^A1a^TIME|0.195|||||||20100519155735||2
R|5|^^^A1b^AREA|1.1|||||||20100519155735||2
R|6|^^^A1b^TIME|0.229|||||||20100519155735||2
R|7|^^^F^AREA|1.0|||||||20100519155735||2
R|8|^^^F^TIME|0.281|||||||20100519155735||2
R|9|^^^LA1c^AREA|1.8|||||||20100519155735||2
R|10|^^^LA1c^TIME|0.414|||||||20100519155735||2
R|11|^^^A1cIFCC^AREA|37|||||||20100519155735||2      ← A1c result reported in IFCC Units
R|12|^^^A1c^AREA|5.5|||||||20100519155735||2         ← A1c result reported in NGSP Units
R|13|^^^A1cJDS^AREA|5.1|||||||20100519155735||2      ← A1c result reported in JDS Units
R|14|^^^A1c^TIME|0.509|||||||20100519155735||2
R|15|^^^P3^AREA|2.9|||||||20100519155735||2
R|16|^^^P3^TIME|0.761|||||||20100519155735||2
R|17|^^^P4^AREA|1.5|||||||20100519155735||2
R|18|^^^P4^TIME|0.853|||||||20100519155735||2
R|19|^^^Ao^AREA|86.4|||||||20100519155735||2
R|20|^^^Ao^TIME|1.009|||||||20100519155735||2
R|21|^^^TOTAL^AREA|1.99|||||||20100519155735||2
L|1|N
                                  Example of Date/Time Number
```

6.8 Example of A1c Results Reported in NGSP and IFCC Units with Unit Names Indicated

```
H|\^&|||Bio-Rad CDM System^CDM 5.1 V-II Instrument|||||||P||20100811084419
P|1
O|1|100034538705^006^01||^^^4||||||||||||||||||2
R|1|^^^A1a^AREA|0.7|||||||||2
R|2|^^^A1a^TIME|0.148|||||||||2
R|3|^^^A1b^AREA|1.5|||||||||2
R|4|^^^A1b^TIME|0.181|||||||||2
R|5|^^^F^AREA|0.7|||||||||2
R|6|^^^F^TIME|0.247|||||||||2
R|7|^^^LA1c^AREA|1.4|||||||||2
R|8|^^^LA1c^TIME|0.366|||||||||2
R|9|^^^A1c^AREA|7.2|NGSP|||||||||2          ← A1c result reported in NGSP Units
R|10|^^^A1cIFCC^AREA|55|mmol/mol|||||||||2  ← A1c result reported in IFCC Units
R|11|^^^A1c^TIME|0.475|||||||||2
R|12|^^^Ao^AREA|90.6|||||||||2
R|13|^^^Ao^TIME|0.811|||||||||2
R|14|^^^TOTAL^AREA|1.49|||||||||2
L|1|N
```

6.9 Example of A1c Results Reported in NGSP, IFCC, and Mono-S Units with Date-Time that Test Started

The ability to report the Date/Time that the test started is a user optional feature. It is a 14-digit number Generated by CDM, which is illustrated below:




```
H|\^&|||Bio-Rad CDM System^CDM 5.1 VII Instrument||||||P||20100623104420
P|1
O|1|Unknown-2-28^004^01||^^^4||||||||||||||||||2
R|1|^^^Unknown1^AREA|0.6|||||||20100519155735||2
R|2|^^^Unknown1^TIME|0.163|||||||20100519155735||2
R|3|^^^A1a^AREA|0.7|||||||20100519155735||2
R|4|^^^A1a^TIME|0.195|||||||20100519155735||2
R|5|^^^A1b^AREA|1.1|||||||20100519155735||2
R|6|^^^A1b^TIME|0.229|||||||20100519155735||2
R|7|^^^F^AREA|1.0|||||||20100519155735||2
R|8|^^^F^TIME|0.281|||||||20100519155735||2
R|9|^^^LA1c^AREA|1.8|||||||20100519155735||2
R|10|^^^LA1c^TIME|0.414|||||||20100519155735||2
R|11|^^^A1cIFCC^AREA|37|||||||20100519155735||2      ← A1c result reported in IFCC Units
R|12|^^^A1c^AREA|5.5|||||||20100519155735||2        ←A1c result reported in NGSP Units
R|13|^^^A1cMono-S^AREA|4.5|||||||20100519155735||2  ←A1c result reported in Mono-S
R|14|^^^A1c^TIME|0.509|||||||20100519155735||2
R|15|^^^P3^AREA|2.9|||||||20100519155735||2
R|16|^^^P3^TIME|0.761|||||||20100519155735||2
R|17|^^^P4^AREA|1.5|||||||20100519155735||2
R|18|^^^P4^TIME|0.853|||||||20100519155735||2
R|19|^^^Ao^AREA|86.4|||||||20100519155735||2
R|20|^^^Ao^TIME|1.009|||||||20100519155735||2
R|21|^^^TOTAL^AREA|1.99|||||||20100519155735||2
L|1|N
                                        Example of Date/Time Number
```

7 Limitations

Chromatograms are not exported via LIS communication.

The last LIS results will not export when the system is in a fault condition or the database is at its maximum capacity.

CDM will communicate with an LIS using CLSI Standard LIS2-A2. A subset of the standard is supported. In particular:

- An order must correspond to a single CDM test. It cannot specify a battery of tests.
- Queries are not supported. CDM does not query the LIS, and does not respond to queries from the LIS.
- CDM ignores existing Result records that it receives with an order. All results will be returned in new Result records constructed by CDM.

8 Communications Port Pin Out Information

(V2) PC-AT DB-9 Pin Number	Signal Name	Signal Description (as seen by DTE)
5	SGND	Signal Ground
3	TxD*	Transmitted Data
2	RxD*	Received Data

* logical 1 is low

This is the PC-AT to Modem standard

9 LIS Test ID Codes

The following tables contain the peak names and LIS test ID codes for the various Bio-Rad tests that use CDM software.

NOTE: *Peak tables can change depending on the instrument and/or method or if updates to the method have occurred. LIS output peak tables can be found in the CDM software under the Setup/ Test/Peak Table screen.*

Method	Test ID	Peaks	LIS Code	LIS Results to Report
VARIANT II β-thal Short	1	Unknown*	UnknownN	^^^UnknownN^AREA
		P1	P1	^^^P1^AREA
		F	F	^^^F^AREA
		P2	P2	^^^P2^AREA
		P3	P3	^^^P3^AREA
		Ao	Ao	^^^Ao^AREA
		A2	A2	^^^A2^AREA
		D-Window	D-Window	^^^D-window^AREA
		S-Window	S-Window	^^^S-window^AREA
		C-Window	C-Window	^^^C-window^AREA

Method	Test ID	Peaks	LIS Code	LIS Results to Report
VARIANT II HbA_{1c} (Original Kit)	4	A1a	A1a	^^^A1a^AREA
		A1b	A1b	^^^A1b^AREA
		F	F	^^^F^AREA
		LA1c/CHb	LA1c/CHb	^^^LA1c/CHb ^AREA
		A1c	A1c	^^^A1c^AREA
		P3	P3	^^^P3^AREA
		Ao	Ao	^^^Ao^AREA
		E, D	E, D	^^^E, D^AREA
		S	S	^^^S^AREA
		C	C	^^^C^AREA

Method	Test ID	Peaks	LIS Code	LIS Results to Report
VARIANT II HbA_{1c} (VII A_{1c} NU)	4	Unknown*	UnknownN	^^^UnknownN^AREA
		A1a	A1a	^^^A1a^AREA
		A1b	A1b	^^^A1b^AREA
		F	F	^^^F^AREA
		LA1c	LA1c	^^^LA1c ^AREA
		A1c	A1c	^^^A1c^AREA
		A1c**	A1cIFCC	^^^A1cIFCC^AREA
		A1c**	A1cMono-S	^^^A1cMono-S^AREA
		A1c**	A1cJDS	^^^A1cJDS^AREA
		P3	P3	^^^P3^AREA
		P4	P4	^^^P4^AREA
		Ao	Ao	^^^Ao^AREA
		E, D	E, D	^^^E, D^AREA
		S	S	^^^S^AREA
		C	C	^^^C^AREA

Method	Test ID	Peaks	LIS Code	LIS Results to Report
VARIANT II TURBO HbA_{1c} (Original Kit)	4	Unknown*	UnknownN	^^^UnknownN^AREA
		A1a	A1a	^^^A1a^AREA
		A1b	A1b	^^^A1b^AREA
		F	F	^^^F^AREA
		LA1c	LA1c	^^^LA1c^AREA
		CHb	CHb	^^^CHb^AREA
		A1c	A1c	^^^A1c^AREA
		A1c**	A1cIFCC	^^^A1cIFCC^AREA
		A1c**	A1cMono-S	^^^A1cMono-S^AREA
		A1c**	A1cJDS	^^^A1cJDS^AREA
		P3	P3	^^^P3^AREA
		Ao	Ao	^^^Ao^AREA
		Variant Window	Variant Window	^^^Variant Window^AREA
		S-Window	S-Window	^^^S-Window^AREA
		C-Window	C-Window	^^^C-Window^AREA

Method	Test ID	Peaks	LIS Code	LIS Results to Report
VARIANT II TURBO HbA_{1c} Kit - 2.0	4	Unknown*	UnknownN	^^^UnknownN^AREA
		A1a	A1a	^^^A1a^AREA
		A1b	A1b	^^^A1b^AREA
		F	F	^^^F^AREA
		LA1c	LA1c	^^^LA1c^AREA
		A1c	A1c	^^^A1c^AREA
		A1c**	A1cIFCC	^^^A1cIFCC^AREA
		A1c**	A1cMono-S	^^^A1cMono-S^AREA
		A1c**	A1cJDS	^^^A1cJDS^AREA
		P3	P3	^^^P3^AREA
		P4	P4	^^^P4^AREA
		Ao	Ao	^^^Ao^AREA
		Variant Window	Variant Window	^^^Variant Window^AREA
		C	C	^^^C^AREA

Method	Test ID	Peaks	LIS Code	LIS Results to Report
VARIANT II HbA_{1c} (T)	4	A1a	A1a	^^^A1a^AREA
		A1b	A1b	^^^A1b^AREA
		F	F	^^^F^AREA
		LA1c	LA1c	^^^LA1c^AREA
		CHb	CHb	^^^CHb^AREA
		A1c	A1c	^^^A1c^AREA
		A1c**	A1cIFCC	^^^A1cIFCC^AREA
		A1c**	A1cMono-S	^^^A1cMono-S^AREA
		A1c**	A1cJDS	^^^A1cJDS^AREA
		A0	A0	^^^Ao^AREA
		E,D-Window	E,D-Window	^^^ E,D-Window ^AREA
		S-Window	S-Window	^^^S-Window^AREA
		C-Window	C-Window	^^^C-Window^AREA

Method	Test ID	Peaks	LIS Code	LIS Results to Report
VARIANT II Dual HbA_{1c}	4	Unknown*	UnknownN	^^^UnknownN^AREA
		A1a	A1a	^^^A1a^AREA
		A1b	A1b	^^^A1b^AREA
		F	F	^^^F^AREA
		LA1c	LA1c	^^^LA1c^AREA
		A1c	A1c	^^^A1c^AREA
		A1c**	A1cIFCC	^^^A1cIFCC^AREA
		A1c**	A1cMono-S	^^^A1cMono-S^AREA
		A1c**	A1cJDS	^^^A1cJDS^AREA
		P3	P3	^^^P3^AREA
		Ao	Ao	^^^Ao^AREA
		E-Window	E-Window	^^^E-Window^AREA
		S-Window	S-Window	^^^S-Window^AREA
		C-Window	C-Window	^^^C-Window^AREA

Method	Test ID	Peaks	LIS Code	LIS Results to Report
VARIANT II Dual β-thal	4	Unknown*	UnknownN	^^^UnknownN^AREA
		A1a	A1a	^^^A1a^AREA
		A1b	A1b	^^^A1b^AREA
		F	F	^^^F^AREA
		LA1c	LA1c	^^^LA1c^AREA
		A1c	A1c	^^^A1c^AREA
		A1c**	A1cIFCC	^^^A1cIFCC^AREA
		A1c**	A1cMono-S	^^^A1cMono-S^AREA
		A1c**	A1cJDS	^^^A1cJDS^AREA
		P3	P3	^^^P3^AREA
		Ao	Ao	^^^Ao^AREA
		A2	A2	^^^A2^AREA
		S-Window	S-Window	^^^S-Window^AREA
		C-Window	C-Window	^^^C-Window^AREA

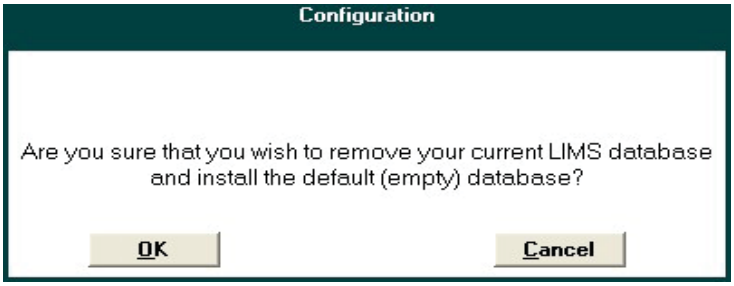
* For the actual LIS Code and LIS Results, N = 1 for the first unknown peak detected (i.e., Unknown1), N = 2 for the second unknown peak detected (i.e., Unknown2), etc.

** There is only one A1c peak. It is listed four times in the table due to the fact that three additional LIS codes have been created to allow for A1c results to be reported in IFCC, Mono-S, and JDS units. Reporting in units other than NGSP is a customer option, and not all customers will choose to report results in all optional units (IFCC, Mono-S, and JDS).

10 Clearing LIS Outqueue and Resetting LIS Database

Use of the Reset LIS database button is necessary only if the LIS is bi-directional (i.e., sends orders/demographic data to CDM). Downloaded demographic data for a sample is stored in CDM's LIS database until a matching barcode is read. If the sample is never run on the instrument, its demographic data will remain in the LIS database. In cases where sample IDs are reused by the lab, a new sample may be incorrectly matched with the demographic data from a previous sample. Therefore, it is recommended that the LIS database be cleared periodically. Click this button only after a run is completed and before the LIS sends more demographic data.

1. Select the Setup/Configuration screen.
2. Click the Reset LIS database button. A message will be displayed, prompting you to confirm the removal of the current LIS database and installation of the empty database.



3. Click the OK button.
4. The OutQueue sample data and the LIS Database pointer are now reset. Now data can be transferred into the OutQueue to test the LIS transfer.

NOTE: *The LIS database (LIMS.mdb) contains only test orders and demographics sent by the LIS. The orders and demographics information is copied to the CDM results database (Zephyr.db) as each sample is run.*

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