

Data Transmission

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Chapter 10 - Data Transmission/LIS Protocol

10.1 Premier Hb9210™ Data Transmission using ASTM E1394-97 Protocol

10.1.1 Introduction

Trinity Biotech's HbA1c analyzer, the Premier Hb9210™, has the ability to transmit data to a Laboratory Information System, (LIS). There are two modes of transmitting data to a LIS, ASCII data dump out of a "dumb" communication port and one that uses the ASTM E1394-97 and ASTM E1381-95 protocols.

10.1.2 General

Trinity Biotech's Premier Hb9210™ HbA1c software is written specifically for HbA1c analysis on Trinity Biotech's analyzer, the Premier Hb9210™. The laboratory runs any number of whole blood and hemolysate samples in a **batch** mode. After analysis of the samples in the batch, all sample identifications and results are sent to a host computer or a LIS in a **batch** mode, immediately after each sample, or both. Note: all control data is transmitted, but calibrator data is not.

During analysis of the batch of samples, each sample will yield a chromatogram, or graph, of the separated glycosylated and non-glycosylated hemoglobin proteins. The percentage area of the glycosylated hemoglobin protein peak is calculated and results of %HbA1c and millimoles HbA1c/mol Hb (mM A1c) are given. Laboratory (Operator) review of patient result chromatograms and QC recovery verification is required for quality assurance as required under the Laboratory's quality and GLP programs. The Premier Hb9210™ system software is sufficiently sophisticated to facilitate this process by detection of common "peak code" sample and system management errors and is designed to aid the operator in the detection and prompt resolution of basic operational needs and adjustments. If peak codes are received during the run and cause the run to stop after x occurrences, LIS transmission will stop immediately. A dash symbol (-) and no result will be transmitted to the LIS in the event of detected sample and system management errors.

Communication between the HbA1c software and the LIS is bi-directional, as prescribed by the ASTM E1394-97 protocol, meaning that acknowledgement and ready signals are transmitted between the GHb/HbA1c software and the LIS. But communication is uni-directional as to general data transfer, meaning that results are transmitted to the LIS and run lists, test orders, and patient information are not downloaded to the HbA1c software from the LIS.

Each patient set of results sent to the LIS will have a Header Record, a Patient Record, an Order Record, three (3) Result Records, and a Message Terminator Record.

10.1.3 Physical Connection & Communication

On the front panel of the CPU Module on the Premier Hb9210™ is an RS-232-C, male, 9-pin connector for interfacing the analyzer with a LIS; generally com port 2. A null modem cable is used to connect to this port to a LIS. Communication is user selectable baud rate, number of data bits, parity, and stop bits. The default is 9600 baud rate, 8 data bits, no parity, 1 stop bit.

10.2 ASTM E1394-97 Field Usage

10.2.1 Header Record

The Header Record starts with the “**H**” character (ASCII 72) and is followed by the characters used for the Field Delimiter, “**I**” (ASCII 124); Repeat Delimiter, “****” (ASCII 92); Component Delimiter, “**^**” (ASCII 94) and the Escape Character, “**&**” (ASCII 38). This first series of 5 characters constitute the 1st field of the Header Record and as all fields, is followed by the Field Delimiter, “**I**”. The rest of the Header Record fields are explained below:

#	Field	Value or Use
1	Control ID	Not used.
2	Access password	Not used.
3	Instrument Identity	ID of instrument in the format: “PREMIER^XXXXXX^TTTTTTTT” Component 1, PREMIER , is the instrument type; component 2, XXXXXX , is the user defined instrument number, a number 1 through 9; and component 3, TTTTTTTT , is the user defined common name of the instrument.
4	Sender name / ID	Not used.
5	Sender address	Not used.
6	Reserved	Not used.
7	Sender telephone #	Not used.
8	Sender characteristics	Not used.
9	Receiver Identity	ASTM RECVR
10	Receiver ID	Not used.
11	Comment / instructions	Not used.
12	Processing ID	P (stands for Production)
13	Specification version number	E 1394-97
14	Time stamp for message generation	Current date and time in the format: YYYYMMDDHHMMSS

As prescribed in the ASTM E1394-97 document that describes the protocol and fields of this usage, the fields are separated with a defined Field Delimiter, “**I**”; empty or Not used fields will only contain the Field Delimiter. The final field may or may not end with the Field Delimiter. The end of the Header Record will be indicated with a Carriage Return character (ASCII 13). Any ASTM E1394-97 prescribed fields following the Carriage Return character will not be used and therefore not sent.

10.2.2 Patient Record

The Patient Record is used with minimal information. In this situation, the Patient Record is used only to signal that new patient results are forthcoming. The Patient Record fields are explained below:

#	Field	Value or Use
1	Record type ID	P (Stands for Patient type record)
2	Sequence number	1 through 7 , then repeats.

The fields are separated with a defined Field Delimiter, “I”. The final field may or may not end with the Field Delimiter. The end of the Patient Record will be indicated with a Carriage Return character (ASCII 13). Any ASTM E1394-97 prescribed fields following the Carriage Return character will not be used and therefore not sent.

10.2.3 Order Record

The Order Record is also used with minimal information, as the GHb/HbA1c software does not accept order or assay commands from the LIS. The Order Record fields are explained below:

#	Field	Value or Use
1	Record type ID	0 (Stands for Order type record)
2	Sequence number	1 (Only one Order per patient.)
3	LIS assigned Specimen ID	Not used.
4	Instrument assigned Specimen ID field	User entered (may be by barcode scanner) identification or accession number of patient sample. If no ID or sample name is entered a single space, (ASCII 32), will be the entry.
5	Universal Test ID and Manufacturer's Code	^^^PREMIER GHB Parts 1 through 3 of the Universal Test ID are blank and thus only 3 Component Delimiters are given for them. The last component of this field is PREMIER GHB , which is the Manufacturer's Code.
6	Priority	R for Routine samples and S for Stat samples.
7	Requested / Ordered Priority	Not used.
8	Specimen Collection Date & 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 Info	Not used.
15	Date / Time Specimen Received	Not used.
16	Specimen Descriptor	Not used.
17	Ordering Physician	Not used.
18	Physician's Tel #	Not used.
19	User Field #1	Not used.
20	User Field #2	Not used.
21	Lab Field #1	Not used.
22	Lab Field #2	Not used.
23	Date/Time Results Reported	Not used.
24	Instrument Charge (billing)	Not used.
25	Instrument Section ID	Position=RXXX:YY R is the rack type identifier (W for whole blood, H for hemolysate sample and A for anemic sample) of the sample, XXX is the unique alphanumeric code for the rack and YY is a number from 01 to 10 indicating the position within the rack. Calibrators & controls will use 0000:00 for this field value.
26	Report Type	F (Stands for Final.)

The fields are separated with a defined Field Delimiter, “|”; empty or Not used fields will only contain the Field Delimiter. The final field may or may not end with the Field Delimiter. The end of the Order Record will be indicated with a Carriage Return character (ASCII 13). Any ASTM E1394-97 prescribed fields following the Carriage Return character will not be used and therefore not sent.

10.2.4 Result Number 1 Record ... Result Number 3 Record

The Result Records 1 through 4 are the actual results of the assay of each patient sample. The HbA1c software provides 2 results for each assay.

The Result Record 1 fields are explained below (legacy reporting units of %GHb):

#	Field	Value or Use
1	Record type ID	R (Stands for Results type record)
2	Sequence number	1 (Test result 1 of 4.)
3	Universal Test ID and Manufacturer's Code	^^^GHb Parts 1 through 3 of the Universal Test ID are blank and thus only 3 Component Delimiters are given for them. The last component of this field is GHb , which is the Manufacturer's Code.
4	Data Value	---
5	Units of data	% The percent character, (ASCII 37).
6	Reference Ranges	Not used.
7	Result Abnormal Flags	Not used.
8	Nature of Abnormality Testing	Not used.
9	Status	F (Stands for Final)
10	Date of Change in Instrument Normative Values field	Not used.
11	Operator Identification field	Not used.
12	Date/Time Test Started field	Not used.
13	Date/Time Test Completed	Date and time in the format: YYYYMMDDHHMMSS
14	Instrument Identification	Not used.

The fields are separated with a defined Field Delimiter, “|”; empty or Not used fields will only contain the Field Delimiter. The final field may or may not end with the Field Delimiter. The end of the Results Record will be indicated with a Carriage Return character (ASCII 13). Any ASTM E1394-97 prescribed fields following the Carriage Return character will not be used and therefore not sent.

The Result Record 2 fields are explained below:

#	Field	Value or Use
1	Record type ID	R (Stands for Results type record)
2	Sequence number	2 (Test result 2 of 4.)
3	Universal Test ID and Manufacturer's Code	^^^HbA1c Part 1 of the Universal Test ID are blank and thus 1 Component Delimiter are given.. The last component of this field is HbA1c , which is the Manufacturer's Code.
4	Data Value	Value of 0.0 through 100.0 , with one fixed decimal place.
5	Units of data	% The percent character, (ASCII 37).
6	Reference Ranges	Not used.
7	Result Abnormal Flags	Not used.
8	Nature of Abnormality Testing	Not used.
9	Status	F (Stands for Final)
10	Date of Change in Instrument Normative Values field	Not used.
11	Operator Identification field	Not used.
12	Date/Time Test Started field	Not used.
13	Date/Time Test Completed	Date and time in the format: YYYYMMDDHHMMSS
14	Instrument Identification	Not used.

The fields are separated with a defined Field Delimiter, “I”; empty or Not used fields will only contain the Field Delimiter. The end of the Results Record will be indicated with a Carriage Return character (ASCII 13). Any ASTM E1394-97 prescribed fields following the Carriage Return character will not be used and therefore not sent.

The Result Record 3 fields are explained below (legacy reporting units of AG):

#	Field	Value or Use
1	Record type ID	R (Stands for Results type record)
2	Sequence number	3 (Test result 3 of 4.)
3	Universal Test ID and Manufacturer's Code	^^^AG Parts 1 through 3 of the Universal Test ID are blank and thus only 3 Component Delimiters are given for them. The last component of this field is AG , which is the Manufacturer's Code.
4	Data Value	---
5	Units of data	mg/dl or mmol/l User selectable. For milligrams per deciliter or millimoles per liter.
6	Reference Ranges	Not used.
7	Result Abnormal Flags	Not used.
8	Nature of Abnormality Testing	Not used.
9	Status	F (Stands for Final)
10	Date of Change in Instrument Normative Values field	Not used.
11	Operator Identification field	Not used.
12	Date/Time Test Started field	Not used.
13	Date/Time Test Completed	Date and time in the format: YYYYMMDDHHMMSS
14	Instrument Identification	Not used.

The fields are separated with a defined Field Delimiter, “|”; empty or Not used fields will only contain the Field Delimiter. The final field may or may not end with the Field Delimiter. The end of the Results Record will be indicated with a Carriage Return character (ASCII 13). Any ASTM E1394-97 prescribed fields following the Carriage Return character will not be used and therefore not sent.

The Result Record 4 fields are explained below:

#	Field	Value or Use
1	Record type ID	R (Stands for Results type record)
2	Sequence number	4 (Test result 4 of 4.)
3	Universal Test ID and Manufacturer's Code	^^^mMA1c Part 3 of the Universal Test ID is blank and thus a Component Delimiter is given for that place. Components of this field is mM A1c , which is the Manufacturer's Code.
4	Data Value	Value of 0.0 through 999.9 , with one fixed decimal place.
5	Units of data	mM HbA1c / Mol Hb
6	Reference Ranges	Not used.
7	Result Abnormal Flags	Not used.
8	Nature of Abnormality Testing	Not used.
9	Status	F (Stands for Final)
10	Date of Change in Instrument Normative Values field	Not used.
11	Operator Identification field	Not used.
12	Date/Time Test Started field	Not used.
13	Date/Time Test Completed	Date and time in the format: YYYYMMDDHHMMSS
14	Instrument Identification	Not used.

The fields are separated with the Primus defined Field Delimiter, “I”; empty or Not used fields will only contain the Field Delimiter. The end of the Results Record will be indicated with a Carriage Return character (ASCII 13). Any ASTM E1394-97 prescribed fields following the Carriage Return character will not be used and therefore not sent.

10.2.5 Message Terminator

The Message Terminator is sent once all the results have been sent to the LIS. The Message Terminator fields are explained below:

#	Field	Value or Use
1	Record type ID	L (Stands for Message Terminator record)
2	Sequence number	1

The fields are separated with a defined Field Delimiter, “|”. The final field may or may not end with the Field Delimiter. The end of the Message Terminator Record will be indicated with a Carriage Return character (ASCII 13). Any ASTM E1394-97 prescribed fields following the Carriage Return character will not be used and therefore not sent.

10.2.6 Communication to LIS Example

The following is an example of communication to a Laboratory Information System (LIS) and the computer on the Premier Hb9210™ analyzing hemoglobin A1c samples using the software.

10.2.7 Bi-directional Communication between the Premier Hb9210™ and the LIS

The following is an example of communication to a Laboratory Information System (LIS) and the computer on the Premier Hb9210™ analyzing glycated hemoglobin samples using the software from system 100051.

```
RX: H|^&||||PREMIER^100051||||ASTM RECVR||||P|
  E 1394-97/20090519153949<OD>
RX: P|1<OD>
RX: O|1||Sam Smith|^^^PREMIER GHBI||||||||||||WX6I:01|F<OD>
RX: R|1|^GHI|---|I%||||F||||20090519153950||<OD>
RX: R|2|^HbA1c|9.0I%||||F||||20090519153950||<OD>
RX: R|3|^AGI|---|mg/dl||||F||||20090519153950||<OD>
RX: R|4|^mMA1c|73.2|mMolHbA1c/MolHb||||F||||20090519153950||<OD>

RX: P|2<OD>
.....
.....
RX: L|1<OD>
```

10.3 Premier Hb9210™ Data Transmission using Data Dump

10.3.1 Introduction

Trinity Biotech's glycohaemoglobin analyzer, the Premier Hb9210™, has the ability to transmit data to a Laboratory Information System, (LIS). There are two modes of transmitting data to a LIS, ASCII data dump out of a "dumb" communication port and one that uses the ASTM E1394-97 and ASTM E1381-95 protocols.

10.3.2 General

Trinity Biotech's Premier Hb9210™ Glycohaemoglobin (GHb/HbA1c) software is written specifically for HbA1c analysis on Trinity Biotech's analyzer, the Premier Hb9210™.

The laboratory runs any number of whole blood and haemolysate samples in a **batch** mode. After analysis of the samples in the batch, the sample identifications and results are sent to a host computer or a LIS in a **batch** mode, immediately after each sample, or both. During analysis of the batch of samples, each sample will yield a chromatogram, or graph, of the separated glycated and non-glycated hemoglobin proteins. The percentage area of the glycated hemoglobin protein peak is calculated and results of %HbA1c and millimoles HbA1c/mol Hb (mM A1c) are given. Please note that analysis is transmitted to a LIS, each chromatogram should have a trained user quickly look at each chromatogram for acceptability. The results are then transmitted to the LIS.

Communication between the HbA1c software and the LIS is uni-directional. This option of data transfer does not use any acknowledgment of data sent; that is to say it is a "dumb" data dump.

10.3.3 Physical Connection & Communication

On the front panel of the CPU Module on the Premier Hb9210™ is an RS-232-C, male, 9-pin pin connector for interfacing the analyzer with a LIS; generally com port 2. A null modem cable is used to connect to this port to a LIS. Communication is user selectable baud rate, number of data bits, parity, and stop bits. The default is 9600 baud rate, 8 data bits, no parity, 1 stop bit.

10.3.4 Data Field Usage

A record will start with "/TRINITY BIOTECH PREMIER". Then identified by what type of result record, "(Individual)" or "(Batch)" and followed with the Field Delimiter, "I" (ASCII 124). Following is the name of the system, batch number, rack position, and sample ID. Then the results are given with the proper units. Each of the fields are separated by the Field Delimiter, "I" (ASCII 124). The record ends with a carriage return and a line feed (ASCII 13 and ASCII 10).

Each record will be treated as having a varying number of fields with the following conditions...

- ✓ Each field is delimited with a "I" character.
- ✓ The first field will start with a "/TRINITY BIOTECH PREMIER". Then identified by what type of result record, "(Individual)" or "(Batch)". The first field will be consistent with each version of software.

- ✓ Subsequent fields may be in *any* order. These fields will have the general form: “Fieldname=Value&Units”

10.3.5 Premier Hb9210™ Communication to LIS Example

The following is an example of communication to a Laboratory Information System (LIS) and the computer on the Premier Hb9210™ analyzing glycohaemoglobin samples using the software from system 100051, batch 3129.

10.3.6 Uni-directional Communication Between Premier Hb9210™ and the LIS

```
RX: /TRINITY BIOTECH PREMIER (Batch)|System Serial#=100051 |Batch=3129|  
Position=WX6I:01|ID=Sam Smith|GHb=---%|HbA1c=8.9%|  
AG=---mg/dl|mMA1c=72.5 mMolHbA1c/MolHb|<0D><0A>
```