Bioneer ExiStation™

LIS Interface Specification

Document Number: BIS-JG-103-1-1.0.0.1

BIONEER
Innovation • Value • Discovery

Contents

Chapter 1. Using this guide

In this chapter	Using this guide How this Guide is Organized

Using this guide

The Bioneer LIS Interface Specification is written primarily for information technology specialists and support personnel who are familiar with laboratory information system (LIS) communication protocols.

This guideline introduces and provides necessary information to integrate between Bioneer's Instruments and your laboratory information system (LIS) interface.

How this guide is organized

The following table provides an overview of the guide and explains the contents of each section:

Chapter 2, OVERVIEW
- Describes LIS interface specifications and its descriptions.

Chapter 3, INTERFACING WITH THE LIS
- Explains on the communication types of information through LIS interface.

Chapter 4, THEORY OF OPERATION
- Explains theory on ASTM Protocol and its provision that how this interface provides work flow. Information regarding ASTM message, frame, record etc is provided with specific details.

Chapter 5, RECORD FORMATS
- Explains about the interface that provides record types and what it stands for such as Patient information, Test order, Result record, etc.

APPENDIX, ASTM EXAMPLES
- Provides ASTM example messages.

Chapter 2. Overview

In this chapter	Overview Operational overview Modes of operation Configuring the LIS Interface LIS Communication Protocols Mechanical and Electrical Interface Data Link Layer Presentation Layer

Overview

Bioneer Instrument System can transmit data to a computer or laboratory information system (LIS) by TCP/IP interface. LIS Interface operates on the PC where the ExiStation software is run.

Operational Overview

Bioneer LIS Interface provides the following function:

- Receives test orders from an LIS host.
- Transmits Test order from LIS host through LIS Interface to the instrument software.
- Automatically transmits quantitative and qualitative test results to the LIS host. Also supports functions to request test results and transmit test result manually.
- Manages test requests, test results, log information, and configuration settings for the purpose of exchanging information with an LIS host.

Modes of Operation

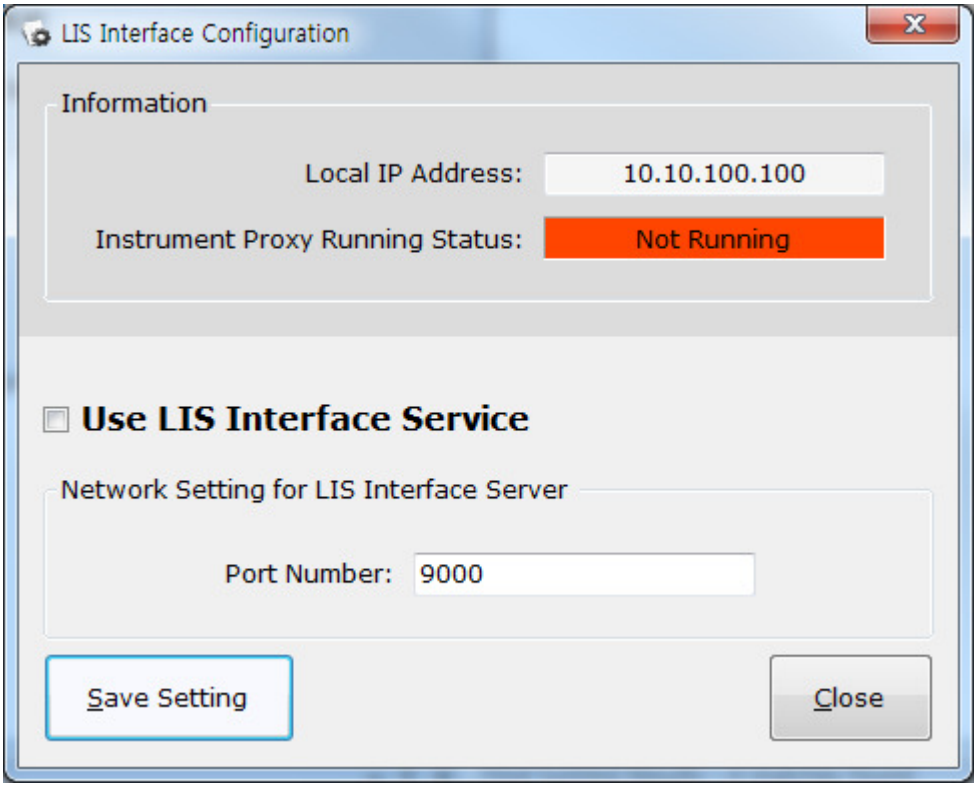
The LIS interface supports the following modes of operation:

- Receiving test orders from an LIS (single direction)
- Sending test results to an LIS (single direction)

The instrument acts as a receiver when the LIS host downloads test requests and as a sender when results are uploaded to the LIS host.

Configuring the LIS Interface

Run "C:₩ExiStation₩InstProxy₩InstProxyConfig.exe".
Once you run the program, the following screen, "LIS Interface Configuration" setting will come up.



Enabling LIS interface service.

1. Mark the check box on the 'Use LIS Interface Service'.
2. Set the LIS interface server port number section:
   Default 'Port Number' is 9000.
3. Press 'Save Setting' button.

Disabling LIS Interface service.

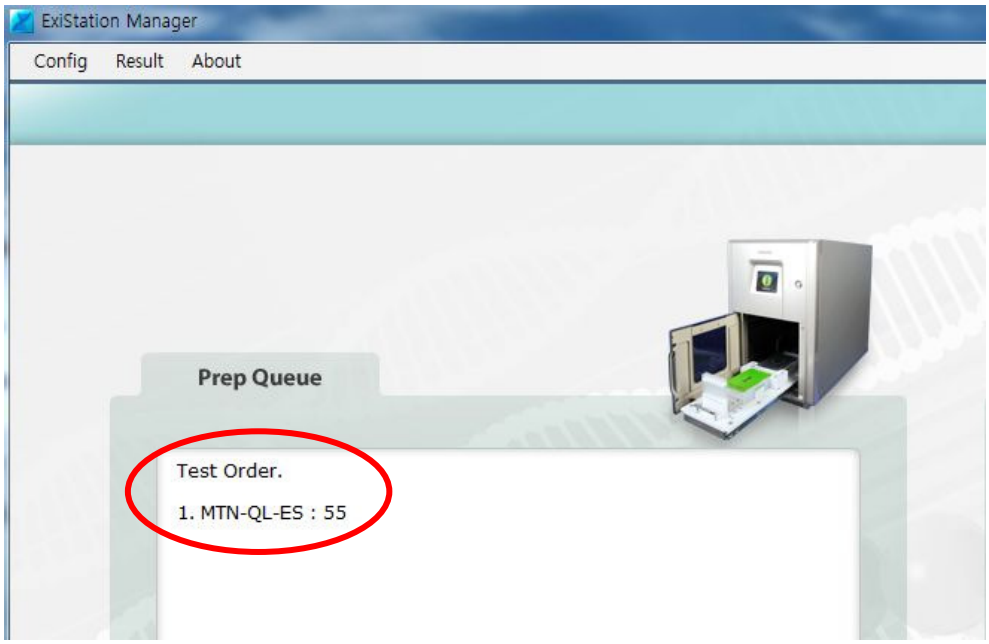
1. Uncheck 'Use LIS Interface Service'.
2. Press 'Save Setting' button.

[Notice]
The Information section on top of the window is a display purpose only. It is not editable by the user.

Using the LIS Interface

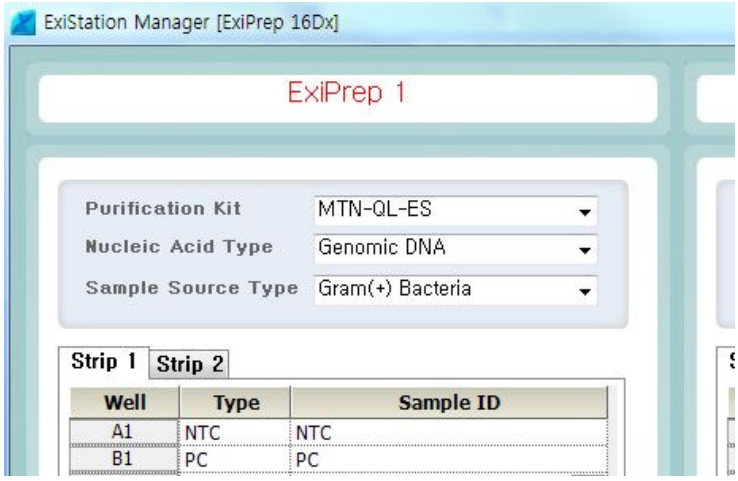
Displaying List of Test Order

When the test order is received from the LIS host, the order list is displayed in the 'Prep Queue' section by the diagnostic kit.



Test Order Assign to Prep Well

From the Existation Manager window, click the 'ExiPrep' image to go to the Prep process; 'ExiStation Manager [ExiPrep 16 Dx]' window will be displayed.

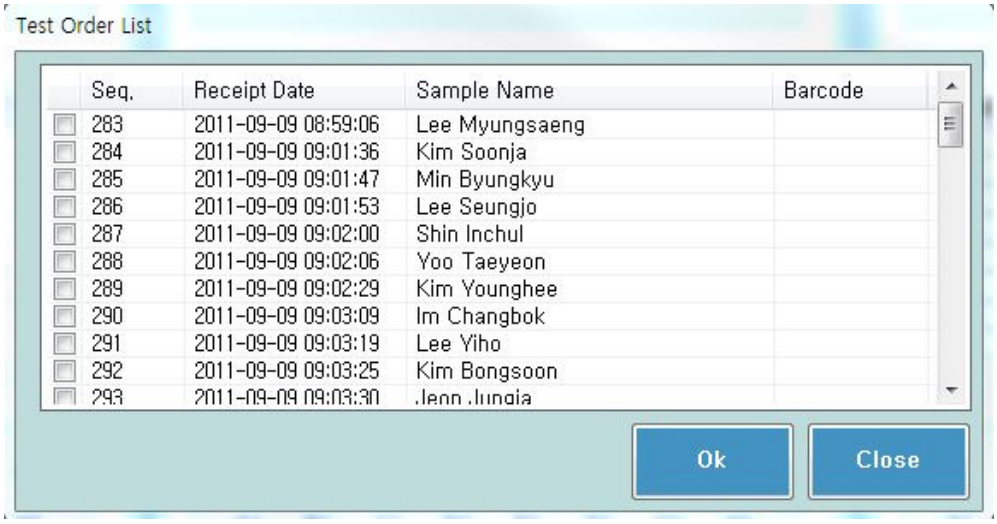


Set-up Sample Kit Information.

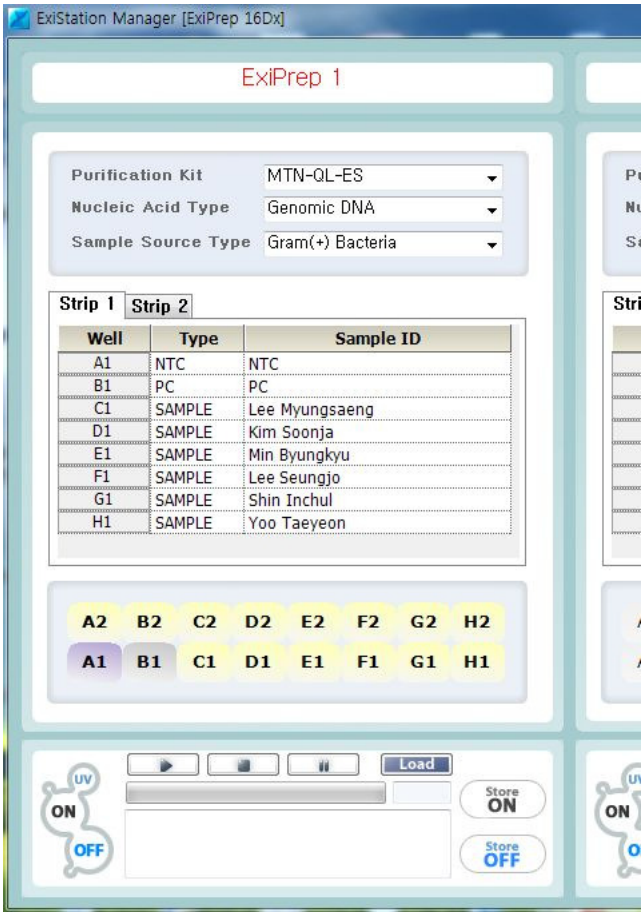
1. Select 'Purification Kit' from the list.
2. Select 'Nucleic Acid Type' from the list.
3. Select 'Sample Source Type' from the list.
4. Once Step 1 to Step 3 is completed, the dialog box appears and displays the Test Order list according to the 'Purification Kit'.

Assigning the Test Order to Prep Well.

1. Mark the check box(s) of the 'Sample Name' to assign.
2. Click 'OK' button.

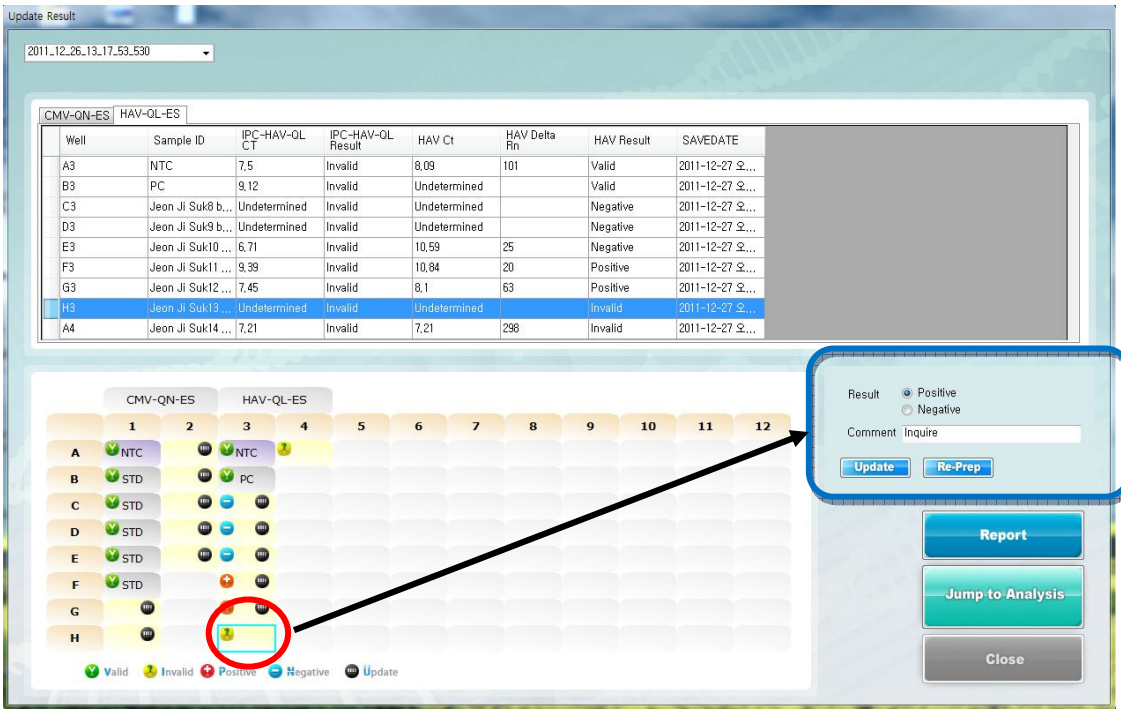


Once 'OK' button is clicked, the sample is automatically assigned to the Prep Well. (See the figure below)



Reporting Test Results

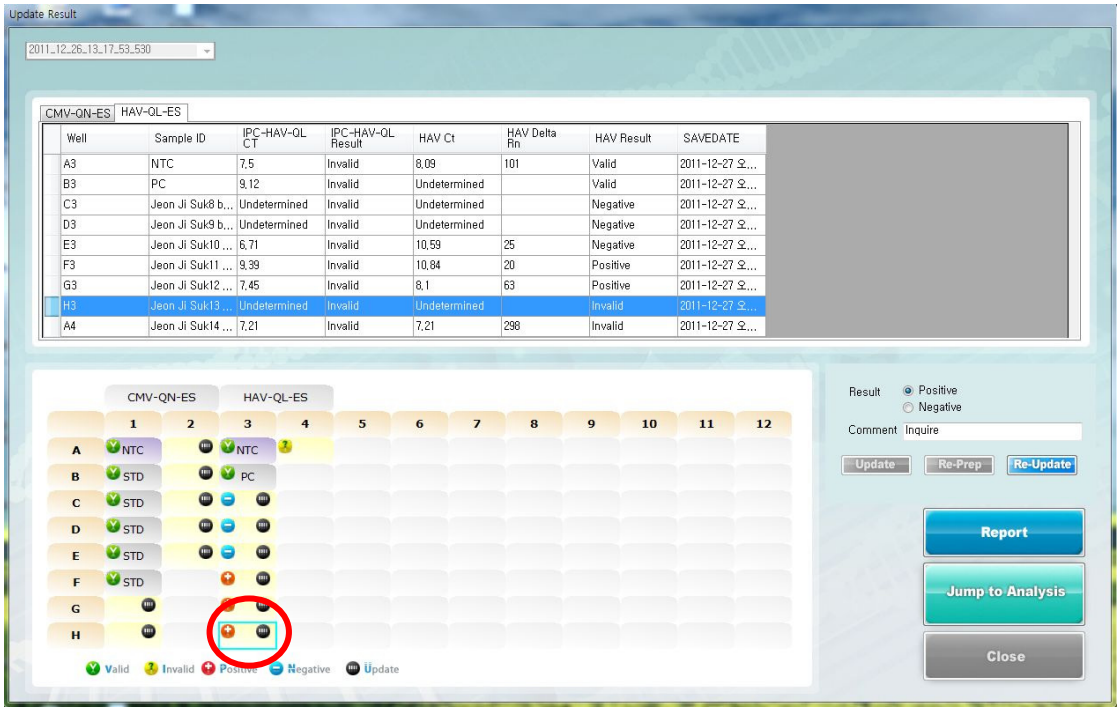
In order to transmit the test result, each sample test result must be confirmed by the user. If the user tries to transmit the sample test result with unconfirmed test results, a dialog will display unconfirmed sample list. These samples test decision must be confirmed in order to report to the LIS host.



Confirmation on Unconfirmed Test Results.

1. From the 96 Plate Well section, select the Well with Invalid icon.
2. From the Top-Right Result section, the user can choose either option.
   Update: The user selects either Positive or Negative test result with a comment.
   Re-Prep: The sample will restart the Prep process.

Either 'Update' or 'Re-Prep' is proceeded, the Invalid icon will become Update icon as the figure below.



Reporting Result Data to the LIS host

1. Confirm the test result on all samples, and press 'Report' button.

If the user pressed the 'Report' button with unconfirmed test results, a dialog will display unconfirmed sample list. These samples test decision must be confirmed in order to report to the LIS host.

[Notice]

If a certain sample(s) is ordered to 'Re-Prep', the sample will NOT be transmitted to the LIS host. The sample has to restart the prep process again.

LIS Communications Protocols

The physical layer and data link layer protocols are defined in ASTM document E 1381-95, *Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems*. The application layer protocol is defined in ASTM document E 1394-97, *Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems.*

Mechanical and Electrical Interface

The LIS interface supports one physical connection:

- TCP/IP Network Connection

Data Link Layer

The data link layer contains the procedures for link connection and release, delimiting and synchronism, sequential control, error detection, and error recovery as specified in ASTM document E 1381-95.

Presentation Layer

The LIS interface uses the ASTM E 1394-97 message transfer specification for exchanging test order information with an LIS host. For detailed information about record format, refer to *Record Formats*.

The LIS interface supports the following record types when communicating with the LIS host:

- Message Header
- Message Terminator
- Patient Information
- Request Information
- Patient Comment
- Test Order
- Test Result
- Test Comment

Unless otherwise specified, the LIS interface ignores unexpected records and fields.

Chapter 3. Interfacing with the LIS

In this chapter	Receiving Test Orders Batched Test Requests Requests for Multiple Tests Sending Test Results Results Contents

This section describes the LIS interface processes for exchanging:

- Receiving Test Requests
- Sending Test Results

Receiving Test Orders

The LIS interface transmits the test request to the instrument from the LIS host.
LIS interface supports the following record types:

- Header
- Patient (as a container for Order records)
- Order
- Message Terminator

LIS interface supports other types of records (such as the Scientific Record or the Manufacturer Information record), but the content will be ignored.

The following properties must be satisfied in order for the test order to transmit to the LIS interface.

- Be properly structured as specified in the ASTM E 1394-97 protocol.
- Contain a sample identifier that unambiguously identifies the physical sample to be measured.
- Contain one or more test names (assay names) that specify the test(s) to be performed on the sample.

NOTES:
The LIS interface manages a single test request with multiple test names as multiple test request data structures.

Batched Test Requests

The LIS interface accepts work orders for multiple test requests in the following formats:

- A batched set of test orders where the test orders appear in the same message.

For examples of downloaded batched test requests, refer to Appendix, *ASTM Examples*

Requests for Multiple Tests

The LIS interface accepts requests for multiple tests on a single physical sample in the following formats:

- Requests that have multiple order records associated with a single patient record.
- Requests that have multiple tests listed in a single order record.
- Combinations of the formats listed above.

Sending Test Results

LIS interface receives the test result from instrument software, and retransmits to the LIS host. The interface handles qualitative and quantitative result formats.

Results Contents

The following information is contained in the test result:

- Instrument identifier
- Operator name
- Run date
- Reference ranges
- Well location
- Sample identifier
- Result value
- Result value units

Chapter 4. Theory of Operation

In this chapter	Description of Transmission Control Application Layer Presentation Layer Data Link Layer

Overview of the Interface

The physical connection between the LIS interface and the host is TCP/IP. Logically LIS interface uses *ASTM Standard Protocol*.
ASTM applies functions to exchange messages according to hierarchical layers that are similarly structured as an OSI model type. Unlike Open Systems Interconnections (OSI) model that has seven layers, ASTM simplified to the data transmission model into four layer structures.

Description of Transmission Control

ASTM

The ASTM protocol uses four hierarchical layers for communications and data processing:

- **Application layers:** It represents the message layer. (i.e., Test Order, Test Result, etc).
- **Presentation layers:** It represents the record layer. A single message structured by a single or multiple records.
- **Data link layers**: It provides the functional and procedural means to transfer data between network entities and to detect and possibly correct errors that may occur in the Physical Layer.
- **Physical layers**: It is defines the standard TCP/IP interface and provides the link between devices or/and instruments. A single frame can have 240 characters maximum, and 7-byte identifier and check-sum.

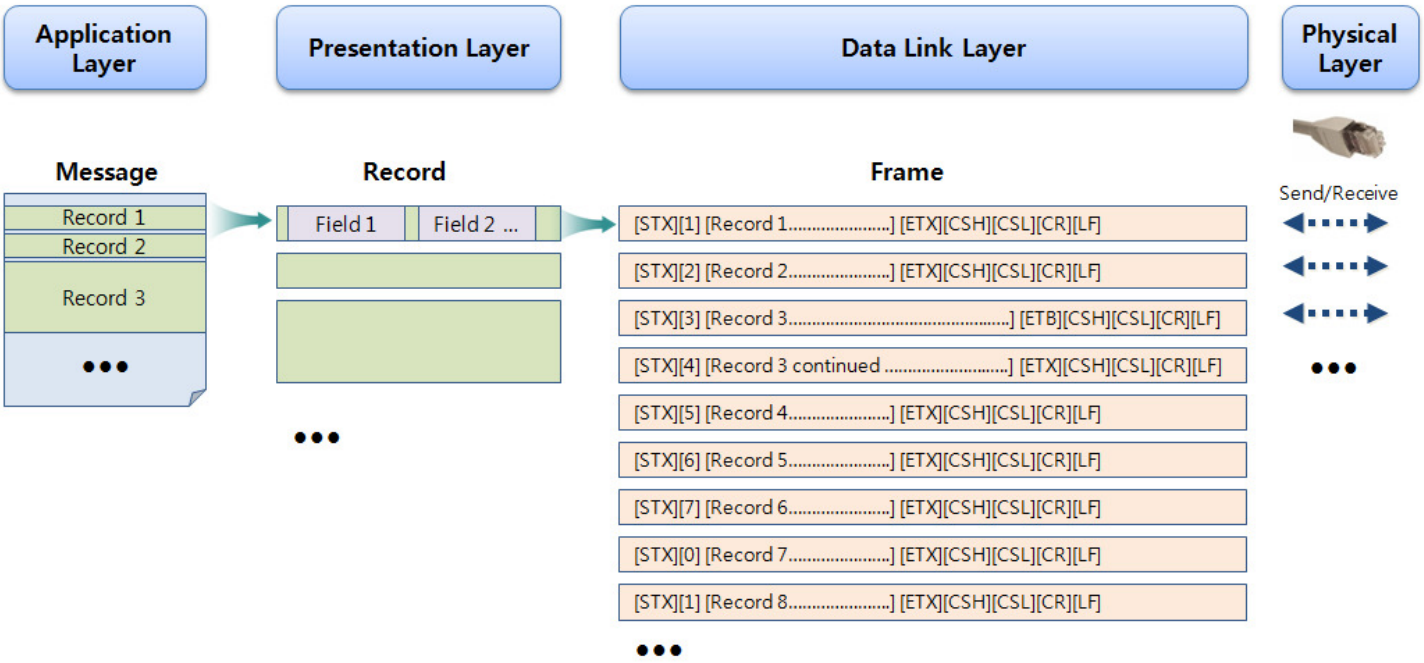


Figure: Layers of the ASTM Protocol

There are two different levels of the ASTM protocol definition: low and high. The lower level protocol is defined in which the data transmission through the data frame, where as the upper level protocol is defined as the message structure, retransmission processes, and record structures and its types of usage.

More information on ASTM Protocol can be found in the following reference:

- ASTM E 1381-95 Low Level Protocol [1]:

Standard Specification for Low Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems.

- ASTM E 1394-97 High Level Protocol [2]:

Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems.

Description of Terms Specific to ASTM

To clarify some terms this chapter defines some specific wording according to the ASTM specifications.

- **Message** - a textual body of information. Example: The test results of all orders for group of patients and the related data.
- **Battery** - a group of tests ordered together, for example, an admitting battery. The term battery is used in the document synonymously with the term profile or panel. The test elements within a battery may be characteristic of a single physiologic system, for example, liver function tests, or many different physiologic systems.
  The battery is simply a convention by which a user can order multiple tests by specifying a single name.
- **Test** - a determination of a single analysis or a combination of values from other determinations or observations which constitute a measure of a single system attribute. Example: Determination of TSH in serum.
- **Record** - an aggregate of fields describing one aspect of the complete message.
  Example: The Patient Information Record in a "Measured Data Message" contains information related to the patient whose test results are reported.
- **Field** - one specific attribute of a record which may contain aggregates of data elements further referring the basic attribute. Example: The Patient Name Field in the Patient Information Record.
- **Repeat field** - a single data element which expresses a duplication of the field definition it is repeating. Used for demographics, requests, orders and the like, where each element of a repeat field is to be treated as having equal priority or standing to associated repeat fields. Example: The Test ID Field of an Order Record may contain the IDs of more than one test. The IDs of the multiple tests are all listed in the Test ID Field separated by the Repeat Delimiter.
- **Component field** - a single data element or data elements which express a finer aggregate or extension of data elements which precede it. For example, parts of a field or repeat field entry. As an example, the patient's name is recorded as last name, first name, and middle initial, each of which is separated by a component delimiter. Components cannot contain repeat fields.
- **Upload** - data transmitted from a clinical instrument to a computer system.

- **Download** - data transmitted from a computer system to a clinical instrument.

Application Layer

It defines a layer that processes messages exchange between LIS/HIS host and the instrument. The message is defined as a set of records (i.e., Test Order, Test Results, etc)

Supported Work Flows

LIS interface interacts the LIS host and instrument each other by the following method:

- LIS host initiates the data communication to the instrument.
- The instrument initiates the data communication to the LIS host.

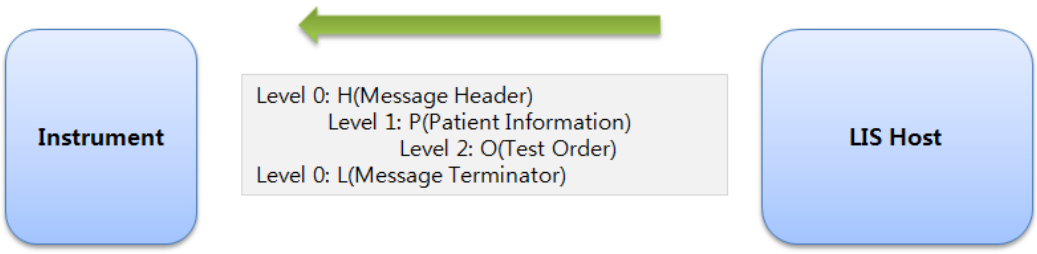
The above interactions can be classified as below:

- Order Download: The LIS host sends a new test order to the instrument.
- Result Upload: The instrument sends the test result to the LIS host.
- Request Orders: The instrument requests a test order.
- Request Results: The LIS host requests the test result from the instrument.

Work Flow(1) Order Download

The test order is sent from the LIS host to the instrument.

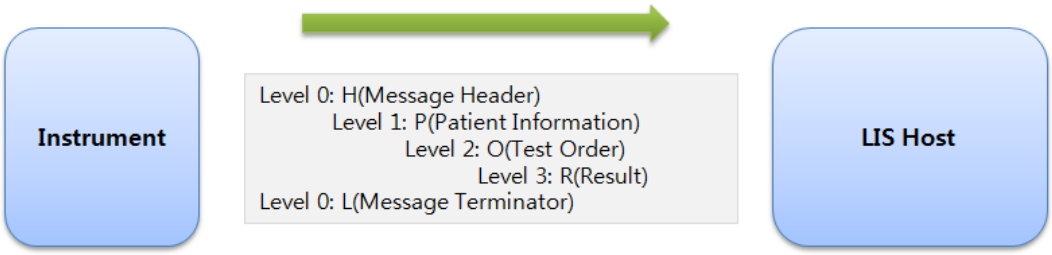
Example: LIS host sends a work-list (list of test orders) the instrument.



Work Flow(2) Result Upload

The test result is sent from the instrument to the LIS host.

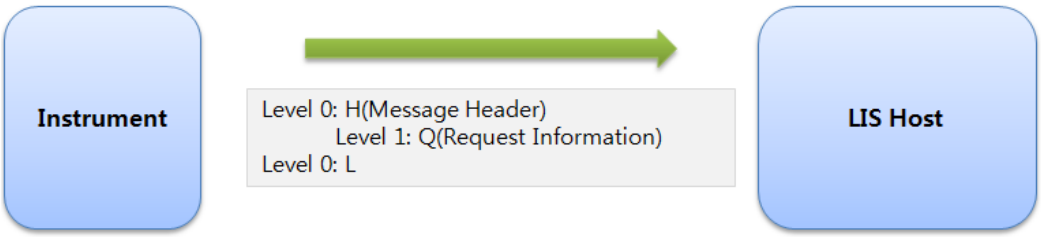
Example: Instrument finished the requested test order from the LIS host and sends the result back to the LIS host.



Work Flow(3) **Request Orders**

The instrument requests a test order to the LIS host.

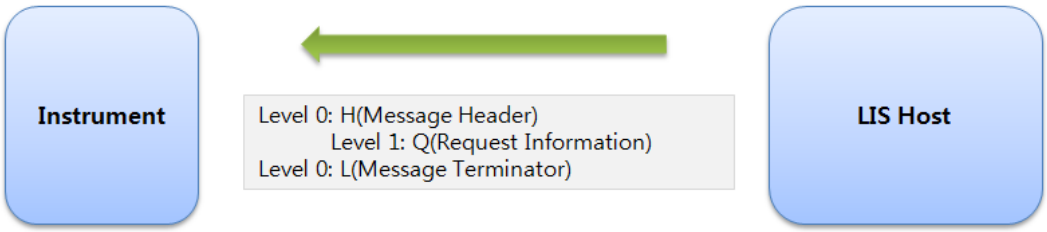
Example: When the instrument scans sample bar-codes, the instrument requests the LIS host what test needs to be done with each sample.



Work Flow(4) **Request Result**

LIS host requests the test result from the instrument.

Example: The LIS host requests a specific result of test order from the instrument.



Presentation Layer

The LIS interface uses the protocol which is defined in ASTM E 1394-97 standard. The protocol is a basis for the message content layer of instrument and LIS host to communicate. The layer specifies structures and types of the message sharing infrastructure between instruments and external host systems.

Message Structure: Records

Typical message types are defined in four different levels as following:
(i.e., The message related to the test result in four levels)

- Level 1: Specific Patient Information related the Test Result
- Level 2: Test Order related to the Test Result
- Level 3: Test Result related to the Test Order and the patient
- Level 4: Comments regarding the Test Result

A single test can have multiple comments, a single order can carry multiple test results, and a single message can include multiple patients' information.

Comment record can be inserted within any layer. However, comment MUST be inserted immediately after each patient's information, order, or the test result. If the comment record comes after the patient's record (level one), the comment is presumably assigned level 2. The comment record CANNOT come after the message terminator.

Manufacturer's information records can be placed in any level, except level 0 (message header). Besides this exception, the rest of regulations of the Manufacturer's information is the same as the comment record.

Additional record types are the request-information record and the terminator record.
The request-information record provides for the request of demographics or test results to or from the clinical instrument for specified patients, specimens, tests, dates, and so on.
The message terminator record must be the very last record of the message.

```
(Level 0) HEADER
(Level 1)     MANUFACTURER INFORMATION 1
(Level 1)     PATIENT 1 (general information about patient)
(Level 2)     |     COMMENT 1 Record (relates to previous patient PATIENT 1)
(Level 2)     |     ORDER 1 (information about the first battery requested)
(Level 3)     |     |     COMMENT 1 Record (relates to previous order ORDER 1 )
(Level 3)     |     |     RESULT 1 (information about the first result of battery 1)
(Level 3)     |     |     RESULT 2 (information about the second result of battery 1)
(Level 4)     |     |     |     COMMENT 1 Record (Relates to RESULT 2)
(Level 4)     |     |     |     COMMENT 2 Record (Relates to RESULT 2)
(Level 4)     |     |     |     ...
(Level 3)     |     |     RESULT n (information about the last result of battery 1)
(Level 2)     |     ORDER 2 (information about battery 2)
(Level 3)     |     |     RESULT 1 (information about the first result of battery 2)
(Level 3)     |     |     RESULT 2 (information about the second result of battery 2)
(Level 3)     |     |     ...
(Level 3)     |     |     RESULT n (information about the last result of battery 2)
(Level 2)     |     ORDER n (information about the last battery for the first patient)
(Level 3)     |     |     RESULT 1 (first result of the last order)
(Level 3)     |     |     ...
(Level 3)     |     |     RESULT n (information about the last result of battery n)
(Level 4)     |     |     |     COMMENT 1 Record (Relates to RESULT n)
(Level 1)     PATIENT 2 (all of the structure repeats)
(Level 1)     ...
(Level 1)     PATIENT n
(Level 0) MESSAGE TERMINATOR
```

Figure: Hierarchical Structure of Message

ASTM defines the following record types. The record types are related to each other in a definite hierarchy:

- Level 0: Message header and terminator.
- Level 1: Patient record, request-information record, and scientific record.
- Level 2: Test order record.
- Level 3: Test result record.

  Comment record can be inserted anywhere before the terminator.

Level	Record Name	Identifier
0	Message Header Record	H
1	Patient Information Record	P
2	Test Order Record	O
3	Result Record	R
0..3	Comment Record	C
0..3	Manufacturer Information Record	M
0	Message Terminator Record	L

1	Request Information Record	Q
1	Scientific Record (This record is not used by the Bioneer instruments.)	S

Table: Standard Record Types and Levels

- Message Header Record (H) - This record contains information about the sender and the receiver, that is, it identifies the instrument(s) and the computer systems whose records are being exchanged. It also defines the field, repeat field, and component field delimiter characters.
- Patient Information Record (P) -This record type contains information about an individual patient.
- Test Order Record (O) - When sent from the computer system to the instrument, this record represents a test order and may be followed by one or more result records which would contain information pertinent to the test being ordered. When sent by the instrument to the computer system, it provides information about the specimen/test request, and may be followed by result records (at least one record for each test within the ordered batteries).
- Result Record (R) - Each result record contains the results of a single analytic determination.
- Comment Record (C) - Comment records can apply to any other record except the message trailer record. They may be free standing messages sent to or from the instrument, unrelated to a particular patient or test procedure.
- Request Information Record (Q) - This record is used to request information for new tests, for tests previously ordered, and possibly for tests previously reported. A single request information record may request demographic information, or results for an individual test, multiple tests, or all tests for a single date, a series of dates, or a range of dates, or both, and for an individual patient, group of patients, individual specimens, groups of specimens, etc.
- Manufacturer Information Record (M) - This record, which is similar to the comment record, may be used to send complex structures where use of the existing record types would not be appropriate. The fields within this record type are defined by the manufacturer.

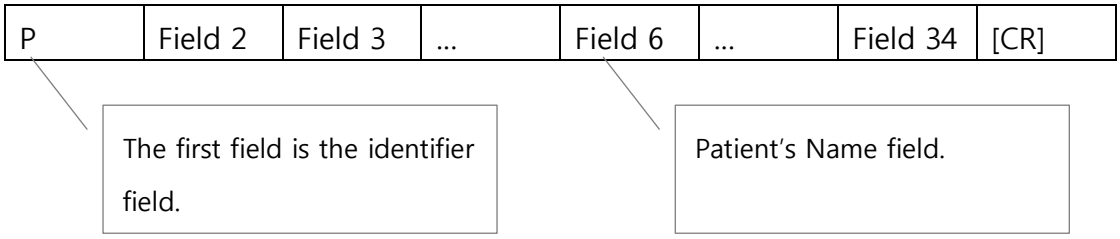
A sequence of Patient records, Test Order records and the Result records placed at

a single level are terminated when the higher level of record type appears. Therefore, a sequence of Test Result for single battery of tests is terminated by the next Test Order, Patient Information, Manufacturer's Information, Request Information, or a message terminator record.

To maintain the hierarchical structure, Patient Information, Test Order and Test result MUST be preceded accordingly.

Message Structure: Field

Fields are a set of characters that defines a specific group of information creating a record.



Each field is position dependent that is identified by their positions in the record. (i.e., field, "P" is the identifier, and the field, "6" is the patient's name)

Delimiters Message records and fields use Standard delimiter characters defined by ASTM.

Message Delimiter Characters

Delimiter	Character Representation	Definition
Field Delimiter	Vertical Bar (|) (ASCII 124)	The field delimiter is used to separate adjacent fields.
Repeat Delimiter	Backslash (\) (ASCII 92)	The repeat delimiter is used to separate variable numbers of descriptors for fields containing parts of equal members of the same set.
Component Delimiter	Caret (^) (ASCII 94)	The component delimiter is used to separate data elements within a field.

Escape Delimiter	Ampersand (&) (ASCII 38)	The escape delimiter is used within text fields to signify special case operations.

Field Delimiters (|)

The record is read one character at a time. When the first field delimiter is read, the instrument knows that it has come to the end of the first field. All characters read after that delimiter is considered to be part of the second field until the second field delimiter is read.
When a second field delimiter is read, all characters past that delimiter are considered to be part of the next field until another field delimiter is read. This process continues until the entire record has been read.

Example:
Record ID field | field 2| field 3 | ... | field n | [CR]

Delimiters and Empty Fields

A record can have empty fields. The fields that do not contain information are indicated by two delimiters in a row, as shown below.

Example:
R|1||0295|||||||198327132247[CR]

If Carriage Return (CR) appears, the next following fields are empty. CR is an indication of the last field of the record.

Repeat Delimiters (\)

To partition the same element being repeated, repeat delimiter can be used. When used, the repeat elements of a field relate to the rest of the record in the same way as if the whole record were replicated, with the only difference being the repeat field.
When only one field is repeating within a record, then the repeat information relates to the rest of the record in a similar fashion as the first.

0|1|Sample#1|^^^Test1₩^^^Test2₩^^^Test3...[CR]
is equivalent to:
0|1|Sample#1|^^^Test1 . . .
0|2|Sample#1|^^^Test2 . . .
0|3|Sample#1|^^^Test3 . . .

Patient ID fields may never repeat since this would violate the hierarchy of records. Sample ID fields may utilize repeat delimiters to indicate the use of multiple samples required for a test.

Component Delimiters (^)

Some fields may be combined with more than a single string. In this case, caret (^) is used as the delimiter.
For instance, a patient's name uses the component delimiter to distinguish the first name, last name, middle name, suffix, title, etc

Example: |**BLAKE^LINDSEY^ANN^MISS**|

Escape Delimiters (&)

The ASTM E 1394-97 protocol allows the use of escape delimiters to provide a method for communicating control characters (*i.e.*, nonprintable ASCII characters, or protocol control characters) that would otherwise create abnormal conditions to occur on the receiving end. The Interface recognizes the need for using the escape delimiters, and identifies specific conditions that may be supported by Bioneer instruments. The use of escape delimiters is limited to communication data characters that are in direct conflict with the delimiters used by the communicating system.

- Field delimiter imbedded within data is communicated as **&F&**
- Component delimiter imbedded within data is communicated as **&S&**
- Repeat delimiter imbedded within data is communicated as **&R&**
- Escape delimiter imbedded within data is communicated as **&E&**

where **&** is the escape delimiter used by the communicating system.
These four conditions may be checked at input and converted to their equivalent characters for viewing. On output, the data are parsed and any delimiters

imbedded within data are converted to their escape strings. All other uses of the escape delimiters are not recommended.

Common Field Types

- Universal Test ID - This field is defined as a four part field with provisions to further define the test identification via use of component fields. The test ID field is used to identify a test or battery name. The four parts which are defined below are the universal test identifier, the test name, the test identifier type and the manufacturer defined test code. All test ID parts must be separated by a component delimiter and are position dependent. As an example, additional information which may be included in this field type are instrument ID, organism ID (for sensitivity tests), well number, cup number, location number, tray number, bar code number, etc. It is the responsibility of the instrument manufacturer to define the data content of the test ID field. When the test ID is used in the result record, there must be sufficient information within the test ID field to determine the relationship of the test result to the test battery or batteries ordered.
- Universal Test ID (Part 1) - This is the first component of the test ID field. This field is currently unused but reserved for the application of a universal test identifier code, should one system become available for use at a future time.
- Universal Test ID Name (Part 2) - This would be the test or battery name associated with the universal test ID.
- Universal Test ID Type (Part 3) - In the case where multiple national or international coding schemes exist, this field may be used to determine what coding scheme is employed in the test ID and test ID name fields.
- Manufacturer's or Local Code (Part 4) - This is the code defined by the manufacturer. This code may be a number, characters, or multiple test designator based on manufacturer defined delimiters. Extensions or qualifiers to this code may be followed by subsequent component fields which must be defined and documented by the manufacturer.
- Dates and Times - In all cases, dates are recorded in the YYYYMMDD format as required by ANSI X3.30.
  December 1, 1989 would be represented as 19891201.
  When times are transmitted, they are represented as HHMMSS, and are linked to dates as specified by ANSI X3.43. Date and time together are specified as

up to a fourteen-character string: YYYYMMDDHHMMSS.

- Time Zone - The time zone may be optionally appended to the date/time field in the format +HHMM or -HHMM as appropriate. The default time zone is that of the sender.
- Telephone Numbers - Phone numbers are recorded as free text, which may contain extensions such as area code, country code, beeper number, hours to mail, etc.
- Multiple Phone Numbers - When multiple telephone numbers apply, they may be included in one field and separated from each other by repeat delimiters. The first such entry is considered the primary or the daytime number.
- Fixed Measurements and Units - When a field contains a specific observation, for example, patient's weight, patient's height, or collection volume, the default units of measurement for that observation are specified in the field definition. When the observation is measured in the default units, the units need not be transmitted. If the measure is recorded in units different from the default, for example, if the weight is measured in pounds rather than kilograms, the measurement units must be transmitted. In this case the units are transmitted in the same field as the measurement. The units follow the measure and are separated from it by a component delimiter, for example, 100^lb. Units should be expressed in ISO standard abbreviations in accordance with ISO 2955.
- Addresses - An address occupies a single field in a record. The address may be comprised of five components (street address, city, state, zip or postal code, and country code) separated by component delimiters so that the receiving party can break them into separate fields as needed.
  An example would be 52 Hilton Street #B42^Chicago^IL^60305^USA.
  The country need only be transmitted when it cannot be assumed from the context. The components of this field are position dependent.
- Provider and User IDs - Physician's and other health staff codes may be transmitted as internal code numbers, as full names, or both, as mutually agreed upon between the sender and the receiver. When both the name and ID number are sent, ID numbers should come first and be separated from the name by a component delimiter. Each component of the name is also separated by a component delimiter. The order of the components of the name are (1) last name, (2) first name, (3) middle initial or name, (4) suffix, for example, Jr., Sr., etc., and (5) title, for example, Dr., Mr., etc.

Thus, if Dr. John G. Jones, Jr. had an identifier of 401-0, his number and name would be transmitted as

401-0^JONES^JOHN^G^JR^DR.

When necessary, more than one ID may be sent within one field. Multiple IDs in one field are separated by repeat delimiters.

- Record Sequence Number - This is a required field used in record types that may occur multiple times within a single message. The number used defines the n^{th} occurrence of the associated record type at a particular hierarchical level and is reset to one whenever a record of a greater hierarchical significance (lower number) is transmitted or if the same record is used at a different hierarchical level (for example, comment records).

Data Link Layer

General Description

Data link layer provides the following services.

- Connect and/or disconnect:
  Determines and prepares the task in which a system will transmit or receive data.
- Partitions messages into frame segments:
  Provides functions to recognize frames.
- Assign frame number to classify and transmit/receive in the sequential manner.
- Error identification:
  Identifies transmission and/or receiving errors from the frame.
- Error recovery:
  Once errors are detected, it attempts to recover by re-transmitting defective frames or returning the link to a neutral state if the errors are not recoverable.

ASTM low level Protocol is one-way: stop and wait.
Information cannot be transmitted in both directions at the same time.
After the Information is transmitted, the receiver must send the response to the sender.
Information transfer is accomplished in three steps as follows.

1. Establishment Phase (Link Connection)
   - To establish which system is the sender or the receiver.
2. Transfer Phase
   - To transfer step taken into an action.
3. Termination Phase (Link Release)
   - To Close the transport steps.

Establishment Phase(Link Connection)

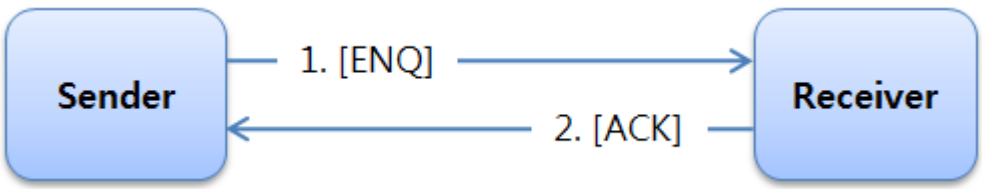
The established phase determines the direction of the information flow, and the receiving side is to prepare to accept the transmitted information. The system to send available data will initiate the Establishment Phase.

LIS host or the instrument has the data to transmit, transmit [ENQ] characters to go into the Establishment Phase.
As ASTME 1381-95 Standard specifies, if there is no incoming response within 15 seconds [ACK], [NAK], or [ENQ], the termination phase will be taken into the place. After instruments wait at a specified time (i.e., 30 seconds, 60 seconds, etc.), it re-enters the establishment phase again.
If more than a certain number of times to enter the establishment phase, but if fails, the error log will be generated.

Sending an [ENQ] and Receiving an [ACK]

After Data link layer is in the neutral state, a system that has available data to send will transmit [ENQ] control character to the receiving side.

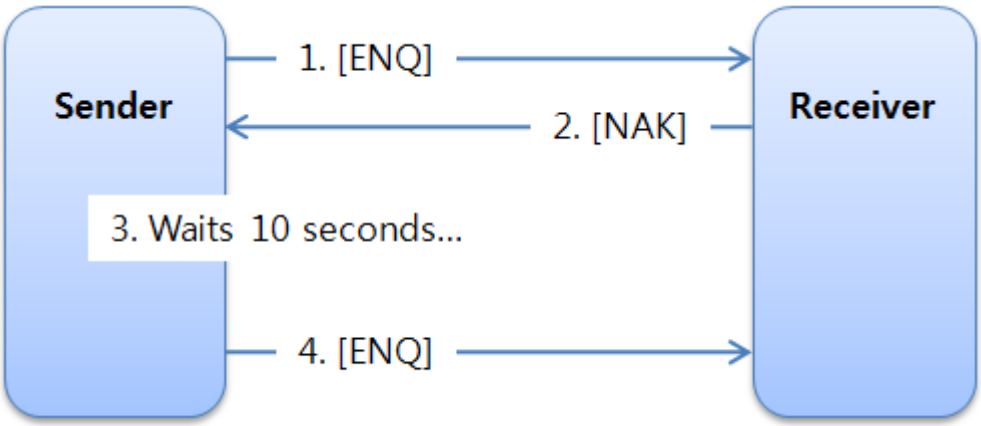
The receiver must send Message Acknowledged [ACK] transmission character back to the sender. If the receiver is not ready to receive the data, Message Not Acknowledged [NAK] transmission character will be sent.
From the Establishment phase point of view, only [ENQ], [ACK], and [NAK] are accepted.



Sending an [ENQ] and Receiving an any character than [ACK]

If the receiver is NOT ready to receive the data, [NAK] will be sent in response to

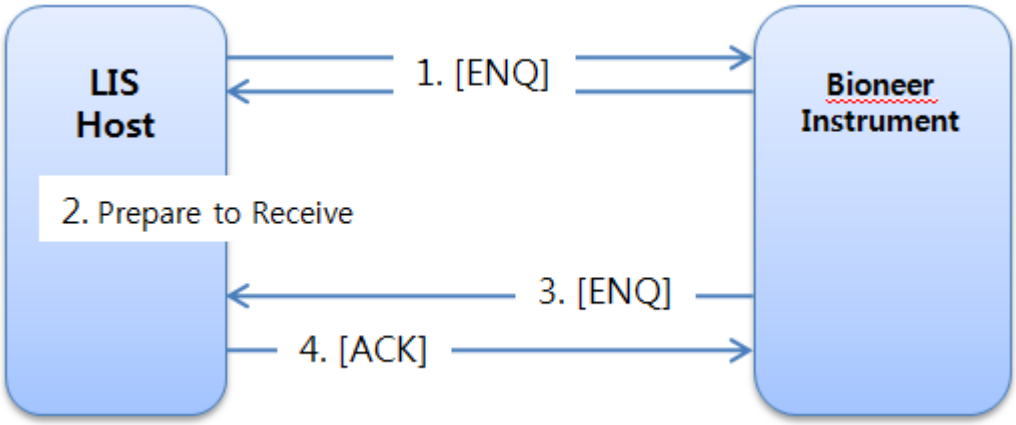
send [ENQ]. If the sender receives [NAK] response, the sender will send [ENQ] after waits 10 seconds again before sending [ENQ] to Receiver.



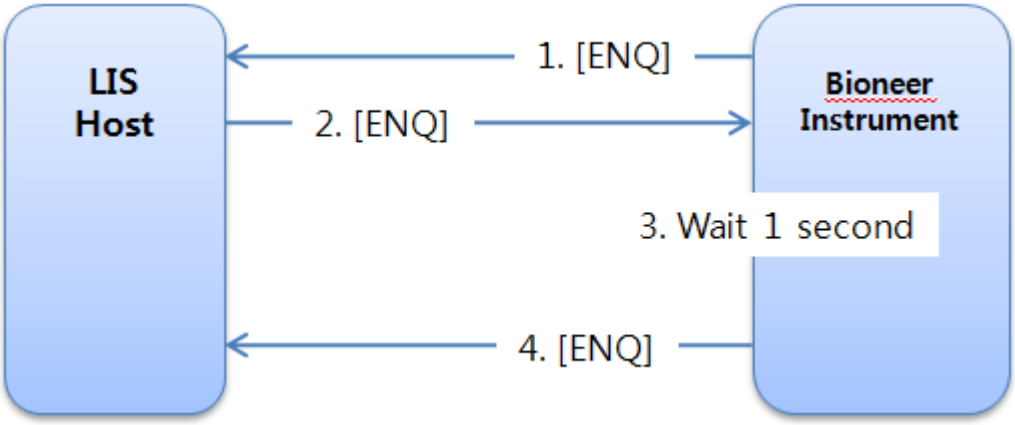
Sending an [ENQ] and Receiving an [ENQ]

If LIS host and Bioneer Instrument both sends [ENQ] at the same time, Bioneer Instrument will have priority to transmit the data than the LIS host.

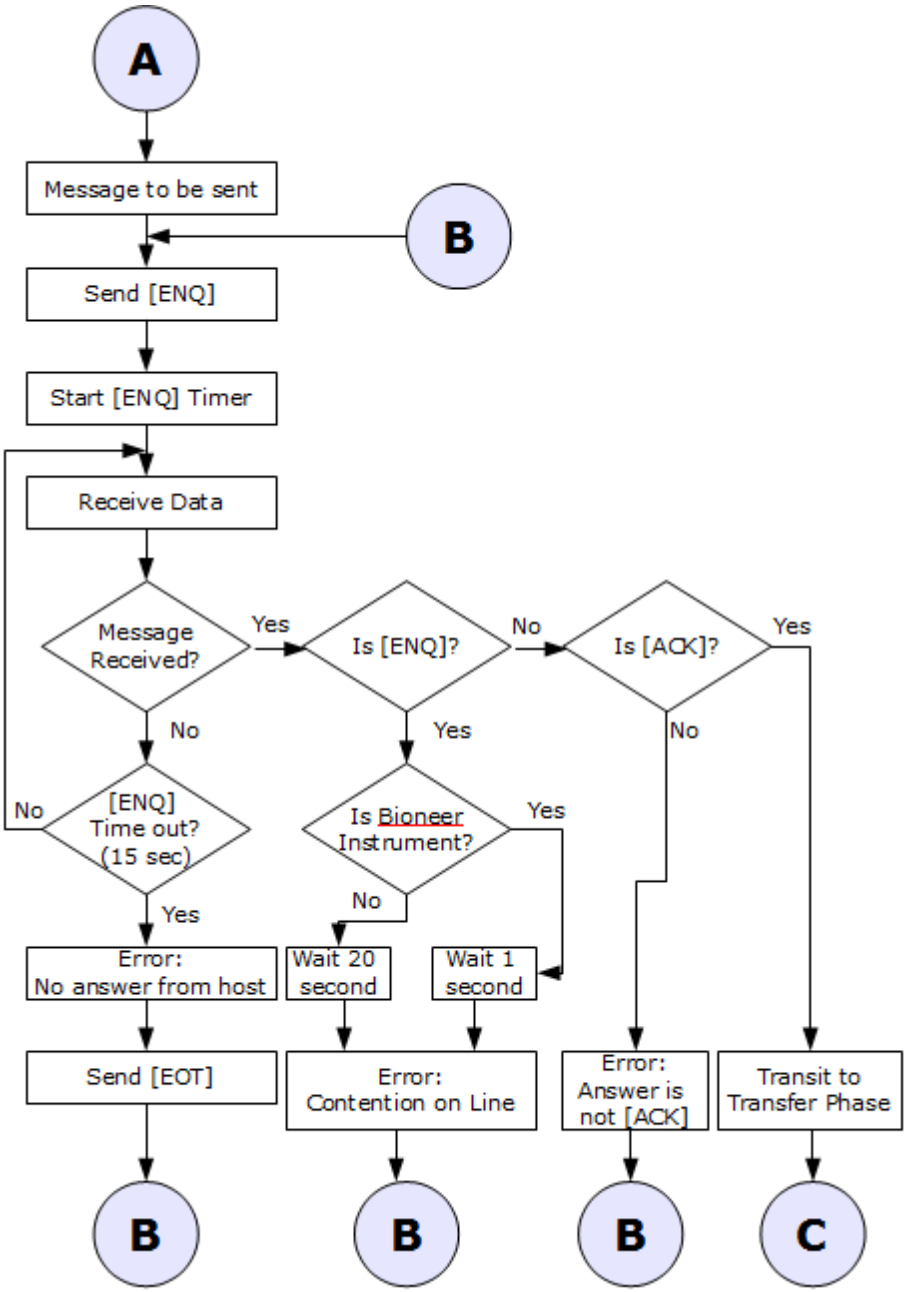
The following diagram is an example of the LIS host and the Bioneer instrument sending [ENQ] at same time.
The LIS host computer immediately stops trying to transmit data, and becomes ready to receive data. When the LIS host computer receives [ENQ] from the instrument, the LIS Host computer sends the [ACK] or [NAK] based-on the receiving availability.



Like the situation above, Bioneer instrument waits for at least 1 second before sending out [ENQ] character.
The LIS host computer sends another [ENQ] in order to attempts to send a certain data, it has to wait at least 20 seconds.



Establishment Phase Flow Chart



Transfer Phase

The message is transmitted in frames to the receiver. Each frame can contain up to 247 characters. In order to finish a single message transmission, complete frames contained in a message must be transmitted.

The following table is used for the frame describing special control characters.

Table: Special Control Characters

Symbol	Character	Description
[STX]	Start of Text transmission control character	First character transmitted at the beginning of a frame.
F#	Frame Number	The frame number is an ASCII digit from 0 to 7. Its purpose is to permit the receiver to distinguish between new and re-transmitted frames. This single digit is sent immediately after the STX character. The frame number begins with 1 when the transfer phase is initialized and increments by 1 each time a new frame is transmitted and acknowledged. After 7, the frame number returns to 0 and repeats the above sequence.
[ETB]	End of Transmission Block transmission control character	Character used to indicate end of an intermediate frame.
[ETX]	End of Text transmission control character	Character used to indicate the end of an end frame.
CSH	Most significant character of checksum 0 – 9 and A – F	The checksum determines if a frame is defective. The checksum is encoded as two characters and is sent after the ETB or ETX character. The checksum is computed by adding the binary values of the characters (modulo 256), keeping the least significant 8 bits of the result. The 8 bits can be considered as two groups of 4 bits which are converted to ASCII and represented in hexadecimal format. The two ASCII characters are transmitted as the checksum with the most significant character first. The STX character initializes the checksum to zero. The first character used in computing the checksum is the frame number. The last character used is the ETB or ETX. The STX, CR, or LF are not included. Using the following Frame as an example, the checksum for
CSL	Least significant character of checksum 0 – 9 and A – F	

<table>
<tr>
<td></td>
<td></td>
<td>this frame is calculated.

<STX> 1 ABCDEFGHI <ETX> A1 [CR] <LF>
<table>
<tr><th>Character</th><th>Decimal Value</th><th>Description</th></tr>
<tr><td><STX></td><td>2</td><td>Not included in calculation</td></tr>
<tr><td>1</td><td>49</td><td>1st character for calculation</td></tr>
<tr><td>A</td><td>65</td><td>2nd</td></tr>
<tr><td>B</td><td>66</td><td>…</td></tr>
<tr><td>C</td><td>67</td><td>…</td></tr>
<tr><td>D</td><td>68</td><td>…</td></tr>
<tr><td>E</td><td>69</td><td>…</td></tr>
<tr><td>F</td><td>70</td><td>…</td></tr>
<tr><td>G</td><td>71</td><td>…</td></tr>
<tr><td>H</td><td>72</td><td>…</td></tr>
<tr><td>I</td><td>73</td><td>…</td></tr>
<tr><td><ETX></td><td>3</td><td>Last character for calculation</td></tr>
<tr><td>Total=</td><td>673</td><td>Total sum value</td></tr>
</table>

Then 673 (decimal) = 2A1 (HEX)
The most significant byte (2) is discarded and the remainder is then transmitted as two characters, “A” (ASCII 65) and “1” (ASCII 49) to form the checksum.</td>
</tr>
<tr><td>[CR]</td><td>ASCII character for carriage return</td><td>Character used to end an LIS2-A2 record and the second to last character transmitted in a frame.</td></tr>
<tr><td>[LF]</td><td>ASCII character for line feed</td><td>The LF character is used as the last character of a frame. The LF character may not display in the message text.</td></tr>
</table>

Frame Format Bioneer instrument supports ASTM E 1394-97 record type. If the record is longer than 240 characters, the message must be partitioned and placed in multiple

frames.
In this case, the last frame MUST specify 'end-frame'; the previous frames MUST specify as 'intermediate-frames'.
If the record length is less than 240, the record specifies the 'end-frame', and transmitted as a single frame.

Each message has to start with a new frame. A frame cannot contain more than one message information.
There are two types of frame.

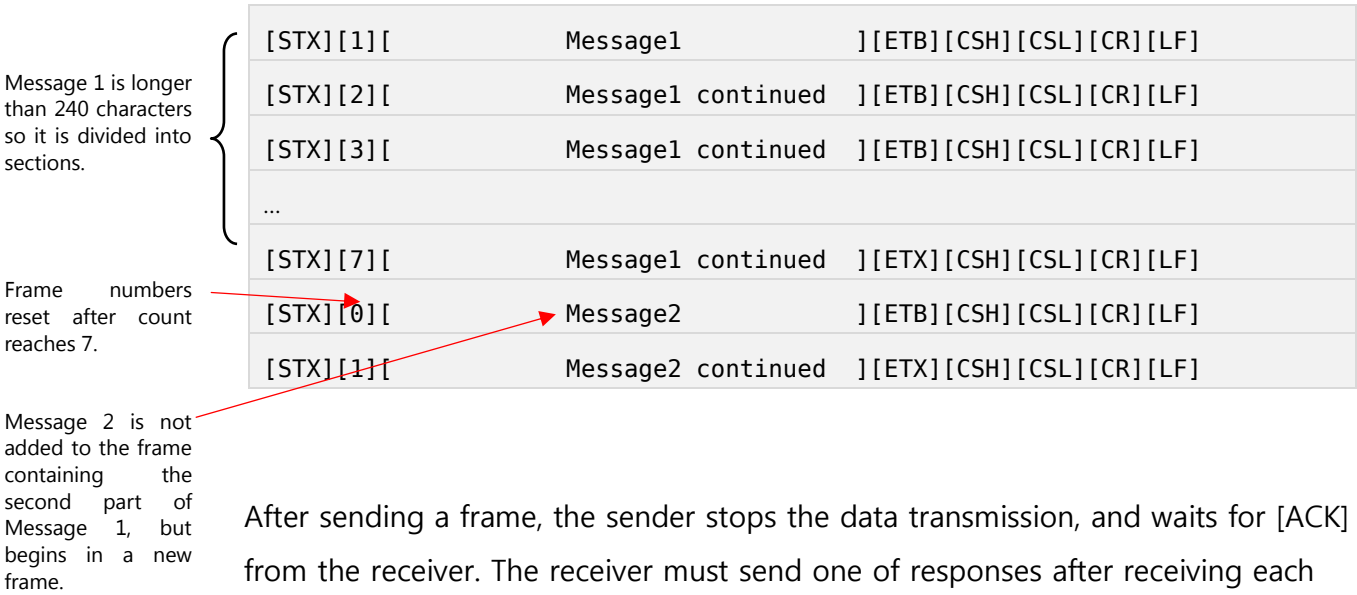
- End frames. A message with 240 characters or less is sent in a single end frame.

```
[STX][F#][          Message        ][ETX][CSH][CSL][CR][LF]
```

- Intermediate frames. Messages that are longer than 240 characters are broken into pieces that are 240 characters or less in length and sent in multiple or intermediate frames with the last part of the message sent in an end frame

```
[STX][F#][          Message        ][ETB][CSH][CSL][CR][LF]
```

The following figure shows how a message with more than 240 characters is sent.



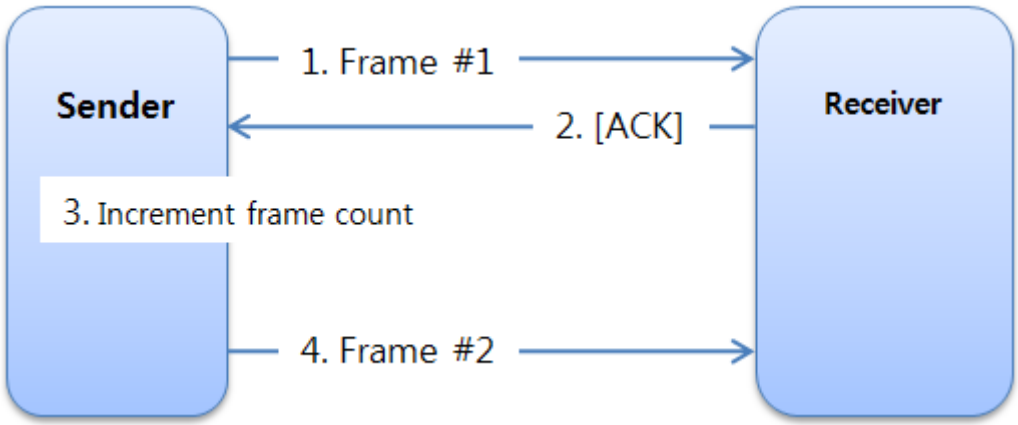
After sending a frame, the sender stops the data transmission, and waits for [ACK] from the receiver. The receiver must send one of responses after receiving each frame:

- Message Acknowledged [ACK]
- Message Not Acknowledged [NAK]
- End of Transmission [EOT]

Each of the replies is discussed below.

A reply of [ACK]

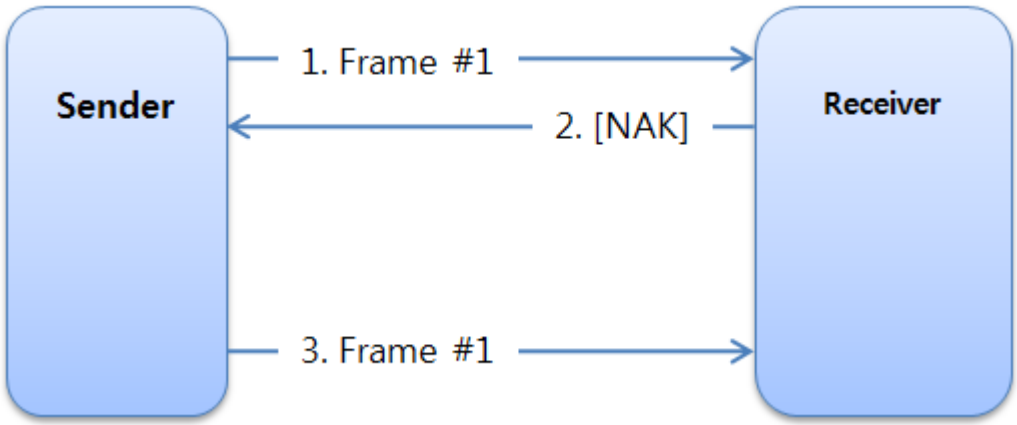
- [ACK] response means that the receiver received the data frame successfully, and is ready to receive a new frame. The sender increases the frame number and sends a new frame. If there is no frame or message to transmit, the data transmission can be terminated.



A reply of [NAK]

[NAK] response means that the receiver did not receive the data frame that was sent from the sender. It also means that the receiver is ready to receive the frame again.

The sender can re-transmit the frame or becomes the Termination phase.



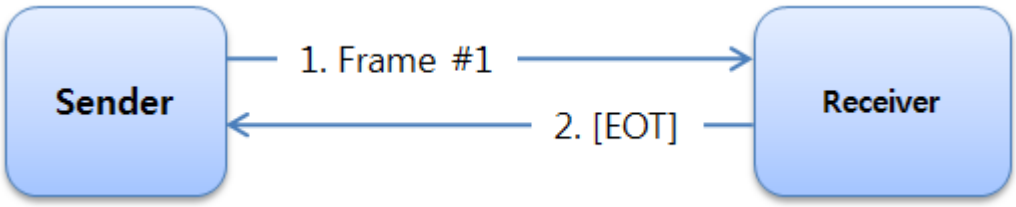
Instruments and systems [NAK] a frame for the following reasons:

- Invalid frame number or frame number out of sequence.
- Restricted character received in message text.
- Invalid checksum received.

Characters received before [STX] are ignored. Once [STX] is received, the Bioneer instrument expects a complete frame.

A reply of [EOT]

[EOT] response means that the receiver successfully received the frame, but request the data transmitted to stop transmitting further data.
The sender must send the response to the received before the time-out.

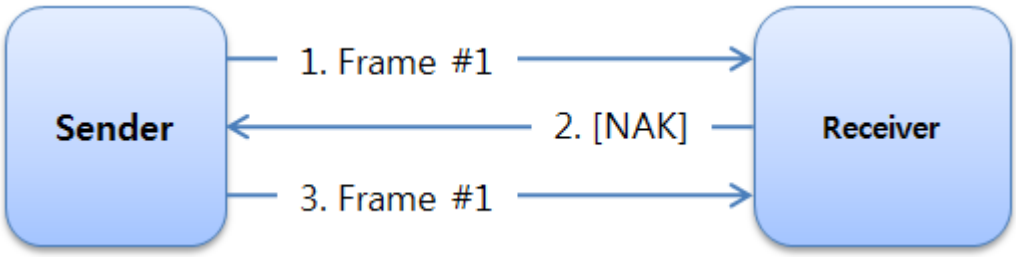


The sender can ignore the transmission-stop request and keep sending data to the receiver. In this case, the receiver requests to stop transmitting again. When Bioneer instrument is the sender, the receiver's transmission-stop request will be ignored.

Receiving [EOT] character in place of [ACK] character, it will be treated both [ACK] and [EOT] as the [ACK] character.
If Bioneer instrument is the sender, and when data transfer is completed, [EOT] will be sent to the receiver and it will become a Termination Phase.

Error Handling

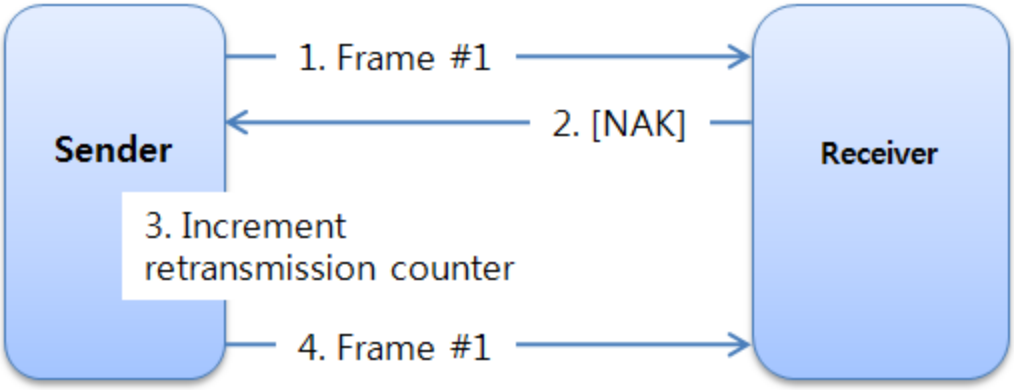
If an error occurs during data transmission, the sender and receiver must perform error correction procedures.
The receiver checks errors from each and every frame. If the receiver sends a [NAK] response, it means the frame contains error(s) or defective. When the sender receives a [NAK] response, the frame will be re-transmitted to the receiver. The frame number and re-transmitted frame number must be identical.



A frame is rejected by the receiver for several reasons, including:

- The frame checksum from the sender does not match the checksum on the receiving end.
- The frame number is incorrect. The number must be the same as the last one rejected or one number higher than the last one accepted by the receiver.

If the sender receives other than [ACK] or [EOT], it increases a re-transmit count and re-transmits the frame. The frame can be re-transmitted up to 6 times. Even though the re-transmitted 6 times, the sender receives other than [ACK] or [EOT], the sender will stop transmitting the frame and becomes the Termination phase.
If Bioneer instrument is set to be the receiver and received [EOT] during the operation, it will assume that the sender has completed transmitting data and becomes the Termination phase.
If there is/are further data to transmit, the data communication process begins from the Establishment Phase again.



Time out There are several timers on both the sender and receiver to control and recover if there is any communication line problem occurs.

During the Establishment Phase

The sender sets a timer when sending an [ENQ].

If a response is not received within 15 seconds, a time-out occurs and the sender becomes to the Termination Phase.

If the host computer, operating as the receiver, detects conflict with the receiver, it sets a timer.

If an [ENQ] is not received from the instrument within 20 seconds, a time-out occurs and the receiver regards the link as being in a neutral state.

During the Transfer Phase

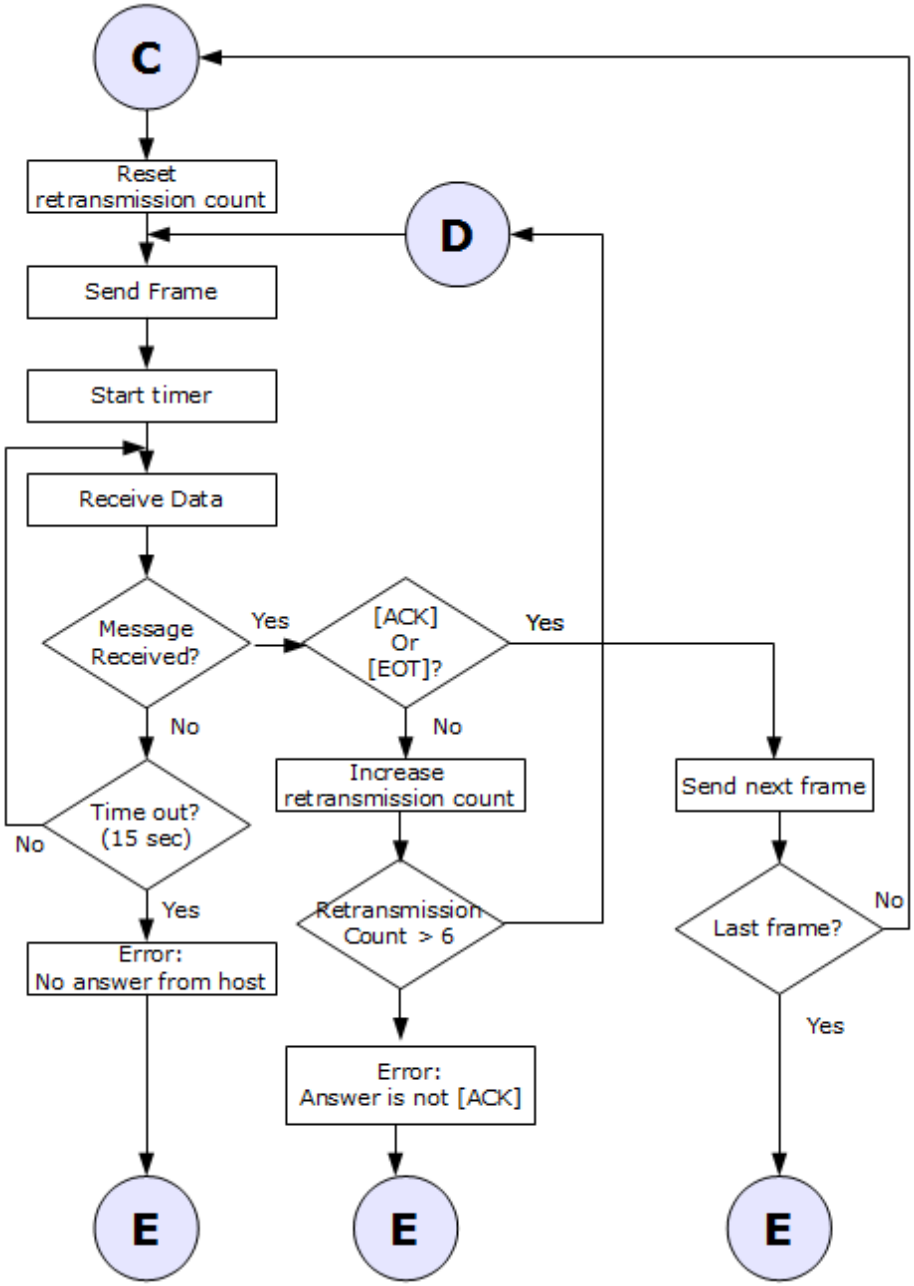
The sender sets a timer when transmitting the last character of a frame.

If a reply is not received within 15 seconds, a time-out occurs and the sender proceeds to the Termination Phase.

The receiver sets a timer when first entering the Transfer Phase or when replying to a frame. If no reply is received within 30 seconds, a time-out occurs and the receiver regards the link as being in a neutral state.

A time out also occurs if an incomplete frame is received and the timer expires. For example, if instruments do not receive the [CR] [LF] characters at the end of a frame, a time-out may occur while the instrument is waiting for the last characters, before processing the frame.

Transfer Phase Flow Chart



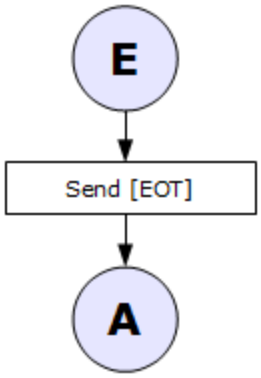
Termination Phase

During the Termination Phase, the sender transmits the [EOT] transmission control character, notifying the receiver that all of the information has been sent.

The sender regards the link to be in a neutral state.

After receiving the [EOT], the receiver regards the link to be in a neutral state.

Termination Phase Flow Chart



Restricted Characters

Certain characters cannot be used in messages. The following table lists characters not allowed in message text.

Character Symbol	Definition
[SOH]	Start of header
[STX]	Start of Text Transmission
[ETX]	End of Text Transmission
[EOT]	End of Transmission
[ENQ]	Enquiry
[ACK]	Acknowledge
[DLE]	Data Link Escape
[NAK]	No Acknowledge
[SYN]	Synchronous Idle
[ETB]	End of Intermediate frame block
[LF]	Line Feed
[DC1]	Device Control Character 1
[DC2]	Device Control Character 2
[DC3]	Device Control Character 3
[DC4]	Device Control Character 4

Chapter 5. Record Formats

In this chapter	ASTM Records for Test Order (Download) ASTM Records for Request Result (Download) ASTM Records for Test Results (Upload) ASTM Records for Request Order (Upload)

The LIS interface supports the following types of records:

- Message Header Record
- Message Terminator Record
- Patient Information Record
- Patient Comment Record
- Test Order Record
- Result Record
- Result Comment Record
- Request Information Record

ASTM Records for Test Order (Download)

The LIS interface accepts the following records from the LIS host:

- Message Header
- Patient Information
- Request Information
- Test Order
- Message Terminator

Message Header Record - Download

Field	Field Name	Value
H1	Record Type	H
H2	Delimiters	|\^&
H10	Receiver ID	This field is optional. However, if the Receiver ID is specified in the header record, it must match the Instrument Identifier value that is entered in the Connection View.

Example: H|\^& [CR]

NOTE: The H2 Delimiters field should always be included in the message header for downloaded test orders.

Patient Information Record - Download

Field	Field Name	Value
P1	Record Type	P
P2	Sequence Number	The nth occurrence of a patient information record.
P4	Laboratory Assigned Patient ID	This identifier shall be the unique processing number assigned to the patient by the laboratory.
P6	Patient name	*Name*—The patient's name shall be presented in the following format: last name, first name, middle name or initial, suffix, and title, and each of these components shall be separated by a component delimiter.

Example: P|1|PID3003678|Jacson^Michael^^^[CR]

Test Order Record – Download

Field	Field Name	Value
O1	Record Type	O
O2	Sequence Number	The nth occurrence of a test order record following the patient information record.
O3	Specimen ID	The sample identifier for the sample to be tested. Valid characters for the sample identifier are those single-byte characters that have values in the following ranges: 32-126, 128-254. The following is the format: Sample Id^Sample Kit^Sample Name^Well Row^Well Column^Barcode

		<table><tr><td>Sample ID</td><td>Distinct ID assigned to each Sample</td></tr><tr><td>Sample Kit</td><td>Name of the Bioneer Sample Kit</td></tr><tr><td>Sample Name [Optional]</td><td>Different than Sample ID that the user can identify or classify the sample by his/her needs.</td></tr><tr><td>Well Row</td><td>Loaded sample well row number. A,B,C,D,E,F,G,H…</td></tr><tr><td>Well Column</td><td>Loaded sample well coloum number. 1,2,3,4,5,6,7,8,9,10,11,12…</td></tr><tr><td>Barcode</td><td>Barcodes of samples</td></tr></table>
O5	Universal Test ID	The universal test identifier is formatted as: ^^^Test Code^Test Name or ^^^Test Code^Test Name\^^^Test Code^Test Name\... Valid characters for the test name are those single-byte characters that have values in the range: 32-126. Leading and trailing spaces are not allowed. If multiple tests (multiple assays) should be performed, then the test identifiers are concatenated with the repeat delimiter (\). <table><tr><td>Test Code</td><td>A unique identifier that LIS has given to the test order</td></tr><tr><td>Test Name</td><td>Test Code to classify the type of diagnostic test. (i.e., HIV, HCV, HBV, etc.)</td></tr></table>
O12	Action Code	**Action code is set to N (new)** Send a new test order, and only N-code is accepted.

		Other action code Do not send other action codes to the LIS interface.
O26	Report Type	The Report Type field value should be blank or O (order record). In the case of the test order field that LIS host transfer to the instrument, the message sends empty field. When the instrument sends the test result to the LIS host, it uses “F” value to classify that it is final test result.

Example:

O|1|SID0001^HBV Sample Kit^Blood sample^B^1^11082100555||^^^TID00_HBV^HBV|||||||N|[CR]

Example:

O|1|SID0001^HBV Sample Kit^Blood sample^B^1^11082100555||^^^TID00_HBV^HBV\^^^TID89_HIV^HIV|||||||N|[CR]

NOTES:

• The Test Order record for incoming messages must contain field delimiters (|) for all fields. The Record Type, Sequence Number, Specimen ID, and Universal Test ID fields must be specified. Other fields may be left empty.

• The action code should be set to N only.

Message Terminator Record - Download

Field	Field Name	Value
L1	Record Type	L
L2	Sequence Number	1
L3	Termination Code [Optional]	N

Example: L|1[CR]

Example: L|1|N[CR]

NOTE: Incoming messages should always be terminated with a Message Terminator Record. The Message Terminator Record must be sent exactly as shown in the above example. Message Terminator Records that contain additional field delimiter characters (|) will not be processed by the LIS Interface.

ASTM Records for Request Result (Download)

The LIS interface accepts the following records from the LIS host:

- Message Header
- Request Information
- Message Terminator

Message Header Record - Download

Field	Field Name	Value
H1	Record Type	H
H2	Delimiters	|\^&
H10	Receiver ID	This field is optional. However, if the Receiver ID is specified in the header record, it must match the Instrument Identifier value that is entered in the Connection View.

Example: H|\^& [CR]

NOTE: The H2 Delimiters field should always be included in the message header for downloaded test orders.

Request Information Record - Download

Field	Field Name	Value
Q1	Record Type	Q
Q2	Sequence Number	The nth occurrence of a patient information record.
Q5	Universal test ID	Query always for ALL tests.
Q13	Status code	The following codes shall be used: F—Final results

Example: P|1|||^^^ALL|||||||F[CR]

Message Terminator Record – Download

Field	Field Name	Value
L1	Record Type	L
L2	Sequence Number	1
L3	Termination Code [Optional]	N

Example: L|1[CR]

Example: L|1|N[CR]

NOTE: Incoming messages should always be terminated with a Message Terminator Record. The Message Terminator Record must be sent exactly as shown in the above example. Message Terminator Records that contain additional field delimiter characters (|) will not be processed by the LIS Interface.

ASTM Records for Test Results (Upload)

The LIS interface sends the following records to the LIS host:

- Message Header Record
- Patient Information Record
- Test Order Record
- Result Record
- Result Comment Record
- Message Terminator Record

Message Header Record – Upload

Field	Field Name	Value
H1	Record Type	H
H2	Delimiters	|\^&

Example:
H|\^&| [CR]

Patient Information Record – Upload

Field	Field Name	Value
P1	Record Type	P
P2	Sequence Number	The n*th* occurrence of a patient information record following the message header record.
P4	Laboratory Assigned Patient ID	This identifier shall be the unique processing number assigned to the patient by the laboratory.
P6	Patient name	*Name*—The patient's name shall be presented in the following format: last name, first name, middle name or initial, suffix, and title, and each of these components shall be separated by a component delimiter.

Request Information Record - Upload

Field	Field Name	Value
Q1	Record Type	Q
Q2	Sequence Number	The nth occurrence of a patient information record.
Q5	Universal test ID	Query always for ALL tests.
Q13	Status code	The following codes shall be used: O — Requesting test orders

Example: P|1|||^^^ALL||||||||O[CR]

Test Order Record – Upload

Field	Field Name	Value
O1	Record Type	O
O2	Sequence Number	The nth occurrence of a test order record following the patient information record.
O3	Specimen ID	The sample identifier for the sample to be tested. Valid characters for the sample identifier are those single-byte characters that have values in the following ranges: 32-126, 128-254. The following is the format: Sample Id^Sample Kit^Sample Name^Well Row^Well Column^Barcode

Sample ID	Identifies uniqueness of each sample
Sample Kit	Bioneer Sample kit name(s)
Sample Name [Optional]	Different than Sample ID that the user can identify or classify the sample by his/her needs.
Well Row	Loaded sample well row number A,B,C,D,E,F,G,H…

		<table><tr><td>Well Column</td><td>Loaded sample well column number 1,2,3,4,5,6,7,8,9,10,11,12…</td></tr><tr><td>Barcode</td><td>Barcodes of samples</td></tr></table>
O5	Universal Test ID	The universal test identifier is formatted as: ^^^Test Code^Test Name or ^^^Test Code^Test Name\^^^Test Code^Test Name\... Valid characters for the test name are those single-byte characters that have values in the range: 32-126. Leading and trailing spaces are not allowed. If multiple tests (multiple assays) should be performed, then the test identifiers are concatenated with the repeat delimiter (\). <table><tr><td>Test Code</td><td>A unique identifier that LIS has given to the test order.</td></tr><tr><td>Test Name</td><td>Test Code to classify the type of diagnostic test such as HIV, HCV,</td></tr></table>
O26	Report Type	The instrument uses ‘F’ code to transfer the test result to the LIS host.

Result Record – Upload

Field	Field Name	Value
R1	Record Type	R
R2	Sequence Number	The n*th* occurrence of a result record following a test order record.
R3	Universal Test ID	The Test Result of each sample has IPC CT, IPC Result, CT, Delta Rn, Result and etc. ExiStation™ transmits such results above; each These result items are transmitted individually in Test Result Records. Due to the item that will be transmitted is dependent on a Sample Kit(s), more information is on "*The List of Test Result Transmission Regarding to The Sample Kit*" document. Universal Test ID is a name of a result item. Simply, it is a name of the result in the *R4 Data Value* field. The format is as following: ^^^Test Code^Test Name^Result Name Universal Test ID of the Test Order Record and the measured Result Name is concatenated as a string by Component Delimiter.
R4	Data Value	A result value of an item. * More information is on "*The List of Test Result Transmission Regarding to The Sample Kit*" document.

R5	Unit	The unit of measure in which the result is reported. For quantitative reports, the units field is one of: • The primary units (e.g., copies/mL) if results are reported in the primary units. • The secondary units (e.g., IU/mL) if results are reported in the secondary units. • The primary units with a "log" indicator (e.g., log copies/mL) if results are reported as logarithmic values in the primary units. • The secondary units with a "log" indicator (e.g., log IU/mL) if results are reported as logarithmic values in the secondary units. For qualitative reports, the units field is empty. Units are not associated with either internal control (IC) results or with cycle threshold (Ct) values.
R6	Reference Range	For Low Positive Controls, High Positive Controls, Positive Controls, and Negative Controls, this field contains Control Range values. Reference range values are provided only for results where the Well Type is Low Positive Control, High Positive Control, Positive Control, or Negative Control. Reference range values are not given in secondary units and are not reported as logarithmic values, even when the reporting unit (see the description for R5 above) applies to secondary units and/or logarithmic values. Reference range values are included only for assay test results (i.e., when the Channel value is HIV, CT, GC, etc.). Reference range values are not included for internal control (IC) results or cycle threshold (Ct) results. In fields where there are two reference range values, the values are separated by a semicolon (;).

R7	Result Abnormal Flag	N(Normal)
R9	Results Status	F(Final)
R11	Operator Identification	The Operator value that appears in the instrument results report.
R13	Date/Time Test Completed	The Run date value that appears in the instrument results report. Format = YYYYMMDDHHMMSS.
R14	Instrument Identification	The Instrument ID value that appears in the instrument results report.

Example:
R|1|^^^TID00_HBV^HBV|1.00e+007|copies/mL|2.00e+003;1.00e+007|N||F||RSmith||20051104122116|RD320001[CR]

Result Comment Record – Upload

Field	Field Name	Value
C1	Record Type	C
C2	Sequence Number	The nth occurrence of a comment record following a test order record.
C3	Comment Source	I (Clinical instrument)
C4	Comment Text	The value that appears in the Notes column of the instrument results report.
C5	Comment Type	G (Generic, free text comment)

Example: C|1|I|Notes=2.00e+001|G[CR]

Message Terminator Record – Upload

Field	Field Name	Value
L1	Record Type	L
L2	Sequence Number	1
L3	Termination Code	Indicates why the session ended. N: Normal termination(default) E: Unknown Error

Example: L|1|N[CR]

ASTM Records for Request Order (Upload)

The LIS interface sends the following records to the LIS host:

- Message Header Record
- Request Information Record
- Message Terminator Record

Message Header Record – Upload

Field	Field Name	Value
H1	Record Type	H
H2	Delimiters	|\^&

Example:
H|\^&| [CR]

Request Information Record - Upload

Field	Field Name	Value
Q1	Record Type	Q
Q2	Sequence Number	The nth occurrence of a patient information record.
Q5	Universal test ID	Query always for ALL tests.
Q13	Status code	The following codes shall be used: O — Requesting test orders

Example: P|1|||^^^ALL|||||||O[CR]

Message Terminator Record – Upload

Field	Field Name	Value
L1	Record Type	L
L2	Sequence Number	1
L3	Termination Code	Indicates why the session ended. N: Normal termination(default) E: Unknown Error

Example: L|1|N[CR]

Appendix. ASTM Examples

In this chapter	Download Examples Upload Examples

Download Examples

Batched Test Orders

The following example shows an ASTM message with several (batched) test orders.

```
H|\^&[CR]
P|1||PID0001||Lee^Chang Yeop^^^^|[CR]
O|1|SID0001^HBV Sample Kit^Lee Chang Yeop blood
sample^B^1^11082100555||^^^TID00_HBV^HBV|||||||N|[CR]
P|2||PID0002||Moore^Gary^^^^|[CR]
O|1|SID0002^HBV Sample Kit^Gary Moore blood
sample^B^2^11081801033||^^^TID00_HBV^HBV|||||||N|[CR]
P|3||PID0003||Waters^Roger^^^^|[CR]
O|1|SID0003^HBV Sample Kit^Roger Waters blood
sample^B^3^11081900758||^^^TID00_HBV^HBV|||||||N|[CR]
P|4||PID0004||Mason^Nick^^^^|[CR]
O|1|SID0004^HBV Sample Kit^Nick Mason blood
sample^B^4^11082301062||^^^TID00_HBV^HBV|||||||N|[CR]
P|5||PID0005||Gilmour^David^^^^|[CR]
O|1|SID0005^HBV Sample Kit^David Gilmour blood
sample^B^5^11082301275||^^^TID00_HBV^HBV|||||||N|[CR]
P|6||PID0006||Wright^Richard^^^^|[CR]
O|1|SID0006^HBV Sample Kit^Richard Wright blood
sample^B^6^11082301623||^^^TID00_HBV^HBV|||||||N|[CR]
P|7||PID0007||Choi^Sunny^^^^|[CR]
O|1|SID0007^HBV Sample Kit^Choi Sunny blood
sample^B^7^11082301435||^^^TID00_HBV^HBV|||||||N|[CR]
L|1[CR]
```

Requests for Multiple Tests

The following examples show supported request formats for multiple tests on a single physical sample.

A Request with Multiple Order Records

```
H|\^& [CR]
P|1||PID00100[CR]
O|1|S001||^^^HIV|||||||||||||||||||[CR]
O|2|S001||^^^HCV|||||||||||||||||||[CR]
L|1[CR]
```

A Request for Multiple Tests in a Single Order Record

```
H|\^& [CR]
P|1||PID00100[CR]
O|1|S001||^^^HIV\^^^HCV||||||||||||||||||||[CR]
L|1[CR]
```

A Request with a Combination of Multiple Test Requests

```
H|\^& [CR]
P|1||PID00100[CR]
O|1|S001||^^^HIV\^^^HCV||||||||||||||||||||[CR]
O|2|S001||^^^CT+GC||||||||||||||||||||[CR]
L|1[CR]
```

Upload Examples

```
H|\^&[CR]
P|1||PID00100|[CR]
C|1|I|Run=HIV modified test 07 Feb 2007 11:52:24;WellType=Calibrator|G[CR]
O|1|SID0002^HIV Sample Kit^William Lee blood sample^B^2^11082401031||^^^TID00_HIV^HIV|||||||N|[CR]
R|1|^^^TID00_HIV^HIV|0.016|uIU/ml|0.230^3.80|L||F|||19970425120351|19970425122213|[CR]
L|1|N[CR]
```

```
H|\^&[CR]
P|1||PID0002||Hong Gil dong1^^^|[CR]
O|1|SID0002^HBV Sample Kit^Hong gil dong1 blood sample^B^2^11082401031||^^^TID00_HBV^HBV|||||||||||||||||||||F||||||[CR]
R|1|^^^TID00_HBV^HBV^IPC CT|29.72|||N||F||||||[CR]
R|2|^^^TID00_HBV^HBV^IPC Result|Valid|||N||F||||||[CR]
R|3|^^^TID00_HBV^HBV^HBV Ct|36.45|||N||F||||||[CR]
R|4|^^^TID00_HBV^HBV^HBV (copy/rxn)|2.88E+02|||N||F||||||[CR]
R|5|^^^TID00_HBV^HBV^HBV (copy/ml)|1.44E+04|||N||F||||||[CR]
R|6|^^^TID00_HBV^HBV^HBV (IU/ml)|1.44E+03|||N||F||||||[CR]
R|7|^^^TID00_HBV^HBV^Result|1.44E+03|||N||F||||||[CR]
P|2||PID0003||Hong Gil dong2^^^|[CR]
O|1|SID0003^HBV Sample Kit^Hong gil dong2 blood sample^B^3^11082401343||^^^TID00_HBV^HBV|||||||||||||||||||||F||||||[CR]
R|1|^^^TID00_HBV^HBV^IPC CT|28.49|||N||F||||||[CR]
R|2|^^^TID00_HBV^HBV^IPC Result|Valid|||N||F||||||[CR]
R|3|^^^TID00_HBV^HBV^HBV Ct|Undetermined|||N||F||||||[CR]
R|4|^^^TID00_HBV^HBV^HBV (copy/rxn)|-|||N||F||||||[CR]
R|5|^^^TID00_HBV^HBV^HBV (copy/ml)|-|||N||F||||||[CR]
R|6|^^^TID00_HBV^HBV^HBV (IU/ml)|-|||N||F||||||[CR]
R|7|^^^TID00_HBV^HBV^Result|< 5.00E+01|||N||F||||||[CR]
P|3||PID0004||Hong Gil dong3^^^|[CR]
O|1|SID0004^HBV Sample Kit^Hong gil dong3 blood sample^B^4^11082501033||^^^TID00_HBV^HBV|||||||||||||||||||||F||||||[CR]
R|1|^^^TID00_HBV^HBV^IPC CT|28.3|||N||F||||||[CR]
R|2|^^^TID00_HBV^HBV^IPC Result|Valid|||N||F||||||[CR]
R|3|^^^TID00_HBV^HBV^HBV Ct|38.87|||N||F||||||[CR]
R|4|^^^TID00_HBV^HBV^HBV (copy/rxn)|5.72E+01|||N||F||||||[CR]
R|5|^^^TID00_HBV^HBV^HBV (copy/ml)|2.86E+03|||N||F||||||[CR]
R|6|^^^TID00_HBV^HBV^HBV (IU/ml)|2.86E+02|||N||F||||||[CR]
```

```
R|7|^^^TID00_HBV^HBV^Result|2.86E+02|||N||F||||||[CR]

L|1|[CR]
```

Reference

[1] ASTM Standard E 1381-95, Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems

[2] ASTM Standard E 1394-97, Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems