BacT/LINK®

External Specification for BacT/ALERT® Systems

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Intellectual Property

Warranty

STANDARD WARRANTY

Unless otherwise set forth in the purchase documentation, bioMérieux SA (“bioMérieux”) warrants the Instrument(s) to the original purchaser for a period of one (1) year after date of installation (the “Warranty Period”) against defects in material and workmanship and failures to conform to bioMérieux’s specifications applicable on the date of installation. bioMérieux agrees to correct, either by repair or, at its election, by replacement, any such defect found on examination to have occurred, under normal use and service, during the Warranty Period provided bioMérieux is promptly notified in writing upon discovery of such defect.

Upon said notification, bioMérieux will provide the following: (i) make commercially reasonable efforts to provide onsite engineering support within forty eight (48) hours of determination by bioMérieux that an on-site visit is necessary, Monday-Friday, 8:00am-5:00pm local time in the Continental U.S., excluding locally observed holidays; and (ii) remote applications and engineering support Monday-Friday, 8:00am-5:00pm local time in the Continental U.S., excluding locally observed holidays (hereinafter the “Warranty Period Services”). In no event shall these Warranty Period Services include Preventive Maintenance service. Disposables and replacement items with a normal life expectancy of less than one (1) year such as batteries, lamps, bulbs, and card trays are excluded from this warranty. bioMérieux shall not be liable under this warranty for any defect arising from abuse of the Instrument; failure to operate and maintain the Instrument in accordance with the User Manual; operation of the

Instrument by a technologist who has not been trained in its operations at bioMérieux's training school; or repair service, alteration, or modification of the Instrument by any person other than the authorized service representative of bioMérieux. bioMérieux SA warranties either implied or expressed are valid to consignee's premises only. Any transshipment VOIDS these warranties and bioMérieux assumes no liability or obligation. The Instrument is warranted to be new, except if otherwise specified.

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ENHANCED WARRANTY

The Enhanced Warranty is available for purchase during the Warranty Period as a supplement to Standard Warranty to increase the level of coverage and add additional features, as set forth below:

The Enhanced Warranty provides the following additional Warranty Period Services: (i) commercially reasonable efforts to provide on-site engineering support within twenty four (24) hours of hours of determination by bioMérieux that an onsite visit is necessary, seven (7) days a week, 7:00am-7:00pm local time in the Continental U.S., excluding locally observed holidays; and (ii) remote applications and engineering support twenty four (24) hours a day, seven (7) days a week (hereinafter the "Enhanced Warranty Period Services"). These Enhanced Warranty Period Services include one (1) Preventive Maintenance service. Except as specifically set forth in this Enhanced Warranty Section, this Enhanced Warranty is subject to the same Base Warranty terms and conditions as set forth above.

Standard Symbols

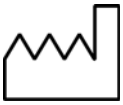
The following table defines symbols that may appear in the instructions for use or on the instrument, package inserts, or packaging.


CE-Marking of Conformity


Consult Instructions for Use


Use by


Manufacturer


Date of manufacture


Contains sufficient for <*n*> tests


Keep dry


Fragile, handle with care


Caution, consult accompanying documents


Biological risk


Electric shock warning


Radiation warning


Potential pinch-point warning


Laser


Shearing hazard


High temperature


Hazardous magnetic field


Potential tip over/crush hazard


Temperature limitations


Upper limit of temperature


Lower limit of temperature


Keep away from magnetic field

In Vitro Diagnostic Medical Device

Batch code

Authorized Representative in the European Community

Catalog number

Serial number

Sterile

Do not reuse

Recyclable

Separate collection for waste electrical and electronic equipment

Very toxic

Corrosive

Sodium azide

Irritant

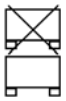
Positive control

Negative control

Keep away from sunlight

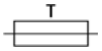
Protect from light

This way up



Do not stack

Humidity limitation



Fuse

Direct current

Alternating current

Both direct and alternating current

Three-phase alternating current

Earth (ground) terminal

Protective conductor terminal

Frame or chassis terminal

Equipotentiality

ON (supply)

OFF (supply)

ON (only for a component of the system equipment)

OFF (only for a component of the system equipment)

Equipment protected throughout by double insulation or reinforced insulation (Equivalent to Class II of IEC 536)

Environmentally friendly use period. Actual number of years may vary by product. This symbol is typically orange in color.

Table of Contents

1 Introduction

This manual provides information about the BacT/LINK® software interface and how it is used to transfer patient, accession, and bottle information from the Laboratory Information System (LIS) to the BacT/ALERT® instrument, and transfer bottle test results to the LIS.

Intended Audience

The BacT/ALERT® system (with or without data management software) and BacT/LINK® interface software are intended for laboratory use by trained, professional, Clinical and Industry users.

This manual is not intended for laboratory use and should be presented to trained LIS personnel to assist with the correct configuration of the LIS, if required.

Note: *For customers that use Myla® data management software, contact your bioMérieux representative for Myla® interfacing specifications.*

Contact your local bioMérieux service representative if you require assistance with the use of the BacT/LINK® software interface.

Chapter Contents

Chapters in this manual provide the following information:

Overview of BacT/LINK® — This chapter describes the various BacT/ALERT® systems, associated data management software, and the BacT/LINK® software interface.

Communications Protocol — This chapter contains information describing the use of the Low-Level and High-Level Protocols for BacT/ALERT® systems.

Bottle ID and Barcode Formats — This appendix contains specifications for the barcode labels used with the BacT/ALERT® bottles.

Sample Communications Sessions — This appendix contains examples of communications between an LIS and a BacT/ALERT® system.

Important Information

This manual uses two different methods to alert you to important information. Information is labeled in text where they occur and set off from surrounding paragraphs, as shown in the following examples.

IMPORTANT: ***Important relates to content presented in this manual. It is used to reinforce the importance of your understanding or remembering something.***

Note: *Note supplies additional information about a topic.*

Technical Support

For technical support in the United States, contact bioMérieux Customer Service at (800) 682-2666. Outside of the USA, contact your local bioMérieux representative.

2 Overview of BacT/LINK®

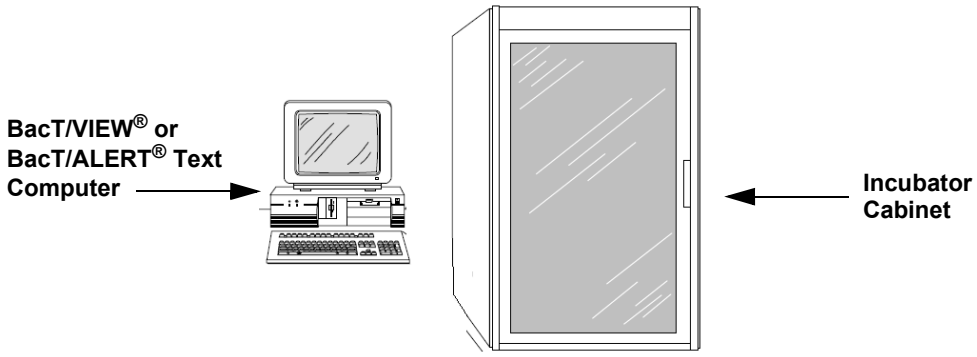
This chapter describes the various BacT/ALERT® systems, associated data management software, and the BacT/LINK® software interface.

BacT/ALERT® System Description

There are two main types of BacT/ALERT® systems: the upright "Classic" system, and the BacT/ALERT® 3D microbial detection system (Controller Module, Combination Module, and 3D 60).

The BacT/ALERT® "Classic" system is comprised of one or more incubator cabinets connected to a single PC that runs either BacT/ALERT® Text or BacT/VIEW® software (see Figure 2-1). The primary function of BacT/ALERT® Text and BacT/VIEW® software used with the "Classic" system is to interpret raw data transmitted from the incubator cabinets on a continuous basis to determine the presence (a positive status) or absence (a negative status) of bacteria, fungi, or mycobacteria. In addition, the BacT/ALERT® Text or BacT/VIEW® software is essential to performing all basic instrument-related operations; such as loading and unloading bottles, performing instrument Quality Control (QC) and calibrations, and maintaining problem logs. The BacT/ALERT® Text and BacT/VIEW® software perform data management functions for the system, and they interface with a Laboratory Information Systems (LIS) to receive test orders from the LIS and to send test results to the LIS.

Figure 2-1: BacT/ALERT® "Classic" System



There are three BacT/ALERT® 3D hardware configurations (see Figure 2-2):

- **Controller Module** — The Controller Module is capable of directing one to six incubation modules.
- **Combination Module** — The Combination Module either stands alone (two drawers with 60 cells each), or it may direct three additional incubation modules.
- **BacT/ALERT® 3D 60** — The 3D 60 is a stand-alone instrument with 60 cells for bottle monitoring.

Figure 2-2: BacT/ALERT® 3D Hardware Configurations

Controller Module with one Incubation Module

Combination Module

BacT/ALERT® 3D 60

The BacT/ALERT® 3D Controller Module, Combination Module, and 3D 60 supervise the reading of the bottle sensors and interpret the readings on a continuous basis to determine the presence or absence of bacteria, fungi, or mycobacteria. They also perform all instrument-related operations.

The BacT/ALERT® 3D Controller Module and Combination Module have three software configurations:

- **BacT/ALERT® 3D Select Configuration** — The BacT/ALERT® 3D system is not connected to an external bioMérieux data management system, or to an LIS. Limited data management is available through the system.
- **BacT/ALERT® 3D SelectLink Configuration** — The BacT/ALERT® 3D system is connected to an LIS but is not connected to an external bioMérieux data management system. Limited data management is available through the system.
- **BacT/ALERT® 3D Signature Configuration** — The Controller Module or the Combination Module is connected directly to an external bioMérieux data management system, either BacT/VIEW® or OBSERVA®.

IMPORTANT: The BacT/ALERT® 3D 60 is available only in the BacT/ALERT® 3D Select and SelectLink software configurations.

System Operation

A specimen is inoculated into one or more BacT/ALERT® culture bottles. Each bottle has a unique Bottle ID, which is encoded into the barcode label on the bottle. The bottle type is also encoded in the bottle barcode. The barcode ID must follow a specific format defined by bioMérieux to ensure proper testing of the bottle. Refer to Appendix A of this document for detailed information regarding barcode formats.

When a bottle is loaded into a BacT/ALERT® system, the system tracks each specimen using the unique Bottle ID. Once the bottle is loaded, the system continuously monitors the bottle until growth in the bottle is detected (a positive test result), or until the maximum test time has passed without growth being detected (a negative test result). The maximum test time is the maximum time a bottle is to be tested before the bottle is determined to be negative (for example, five days is the recommended maximum test time). The BacT/ALERT® system notifies the user when a bottle has a positive test result, or when a

bottle has reached the maximum test time and has a negative test result. When the BacT/ALERT® system notifies the user of a bottle result, the bottle should be unloaded from the system.

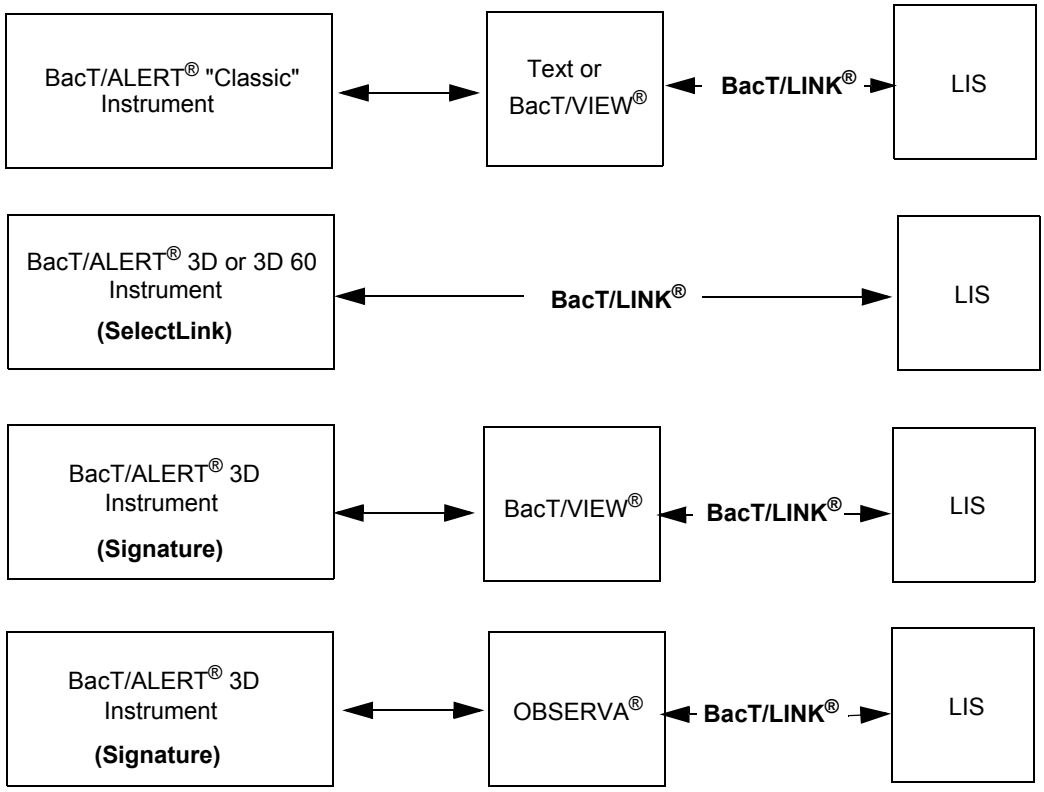
If a specimen is assigned an Accession Number, the system links all bottles for that specimen to the assigned Accession Number. Accession Numbers may be associated with a patient via the Hospital/Patient ID. The result is a three-tiered hierarchical record structure. The first level (base) is the Bottle ID, the second level is the Accession Number, and the third level is the Hospital/Patient ID. Levels higher than the Bottle ID are optional, but if they are used, the three-tiered structure is strictly enforced. A Bottle ID cannot be directly associated to a Hospital/Patient ID, and must first be associated with an Accession Number. Accession Numbers can be unique or they may be used again. With the BacT/ALERT® Text and BacT/VIEW® software, an Accession Number is considered to be unique for a minimum of three days. For OBSERVA® software, the default setting for the reuse of an Accession Number is 30 days. For BacT/ALERT® 3D systems, the default re-use setting is always set to **unique**; however, Accession Numbers remain in the database for a limited amount of time. After a count of 1,920 bottle records is reached, the oldest bottle record (along with the associated Accession Number and patient records) is removed from the system, and the Accession Number can be reused on another sample.

IMPORTANT: The BacT/ALERT® 3D re-use setting for Accession Numbers can only be changed by bioMérieux personnel.

BacT/ALERT® 3D Data Management Systems

BacT/ALERT® "Classic" systems require an external bioMérieux data management system. (either BacT/ALERT® Text or BacT/VIEW® software). The BacT/ALERT® 3D Signature system utilizes either the BacT/VIEW® or the OBSERVA® data management software programs. The bioMérieux data management software provides a high level of flexibility in data storage, query, sorting, and reporting. A detailed description of the data management software is included in your appropriate *BacT/VIEW®* or *OBSERVA® User Manual*. For systems with an external data management system, the LIS interface is established between the data management system and the LIS. The BacT/ALERT® 3D Select and SelectLink software configurations have limited internal data management capabilities. For the BacT/ALERT® SelectLink configuration, the LIS interface is established between the Controller Module, Combination Module or BacT/ALERT® 3D 60 and the LIS. Figure 2-3 illustrates the BacT/LINK® interfaces with the various BacT/ALERT® software configurations and data management systems.

Figure 2-3: BacT/LINK® Interfaces



Overview of the BacT/LINK® Interface

The BacT/LINK® interfacing software provides both automated and manual methods for transferring patient, accession and bottle information from the LIS to the BacT/ALERT®, and for transferring the bottle test results to the LIS. This is referred to as a bidirectional interface since the data can be sent in both directions. Once loaded and enabled in the software, BacT/LINK® becomes part of the BacT/ALERT® system. For the remainder of this document, the term BacT/ALERT® includes the BacT/ALERT® system software with the BacT/LINK® interface option installed.

Transmission of Test Orders

The LIS sends test orders to the BacT/ALERT® automatically when the original order is issued to the LIS, or when the laboratory personnel log received specimens into the LIS. Some LIS's may require an operator to initiate the transfer of test orders through a function of its own software. In either case, the BacT/ALERT® is capable of receiving orders at any time.

The BacT/ALERT® can also be configured to periodically request new test orders from the LIS. The interval depends upon the type of BacT/ALERT® software used with your system. BacT/ALERT® Text software issues requests for new data during the Monitor mode. BacT/VIEW® software allows the user to control the interval by scheduling a macro function to automatically run at user-defined intervals when the operator is logged off the software (refer to your *BacT/VIEW® User Manual* for instructions on how to set the interval). For OBSERVA® software, a user with Administrator access can enable/disable

the automatic request for test orders from the Configuration dialog box (refer to your *OBSERVA® User Manual*); however, the time interval can only be changed by bioMérieux customer service. For BacT/ALERT® 3D SelectLink software, the automatic request for test orders, and how often this automatic request occurs, can only be changed by bioMérieux customer service.

Transmission of Test Results

The test results sent by the BacT/ALERT® to the LIS describe the results of testing accessions consisting of one or more bottles. The BacT/ALERT® only transmits test results for bottles associated with an Accession Number.

IMPORTANT: Test results are not reported to the LIS for bottles loaded without an association to an Accession Number.

When multiple bottles are associated with an Accession Number, each bottle has a separate result. Whenever the BacT/ALERT® reports a result for an Accession Number, the results of all the associated bottles are reported regardless of whether testing has been completed on the bottles. The BacT/ALERT® sends two types of result reports: a positive/negative determination report and a Time-to-Detection (TTD) report. The BacT/ALERT® and BacT/VIEW® only send a TTD result for positive bottles. The BacT/ALERT® 3D sends a TTD result for all negative-to-date and positive bottles. OBSERVA® sends a TTD result for all bottles, regardless of the status.

Because the BacT/ALERT® systems are strictly for screening, positive results are always reported as preliminary results to the LIS. Positive results require laboratory personnel to perform gram stains (or other smear examination) and subcultures to confirm the presence of microorganisms. Positive results should never be reported as final by the LIS until after confirmation has been performed. BacT/ALERT® systems report unloaded negative results as final results.

BacT/ALERT® Text, BacT/VIEW®, and OBSERVA® automatically send results to the LIS whenever the Accession Number is considered to have a significant change. A significant change is defined as:

- Any bottle associated with an Accession Number becomes positive.
- All bottles associated with an Accession Number that complete testing and have either a positive or negative status.
- A positive bottle associated with an Accession Number is reloaded into the instrument for further testing (for example, it was a false positive).
- For OBSERVA® only — If the status of an Accession Number changes from positive to negative, or from negative to positive, as a result of a bottle being added to, or removed from, association with the Accession Number.

BacT/ALERT® 3D SelectLink systems can be configured by bioMérieux to consider any combination of the following four events to be seen as a significant change:

- Any bottle associated with an Accession Number is loaded.
- Any bottle associated with an Accession Number becomes positive.
- Any bottle associated with an Accession Number becomes negative.
- Any bottle associated with an Accession Number is unloaded.

Results for a single Accession Number can be sent to the LIS more than once by the time testing of all associated bottles is completed. For example, new results are reported when the BacT/ALERT® determines one of an Accession Number's associated bottles becomes positive. At that time, the positive bottle results are sent to the LIS as positive, and the other associated bottle result is sent to the LIS as negative-to-date. A few days later, when the other bottle is determined to be negative, the BacT/ALERT® sends results for the Accession Number again and sends the results for both the positive bottle and the negative bottle.

The BacT/ALERT® monitors all results transmitted to the LIS. Once the LIS acknowledges receipt of the new test results, the BacT/ALERT® no longer considers the results as new. With BacT/ALERT® Text and BacT/VIEW® systems, a result that has not been acknowledged by the LIS after three days is no longer considered to be new. If there is no communication between the BacT/VIEW® or BacT/ALERT® Text system and the LIS for more than three days, the results are not automatically sent to the LIS when communication is restored. With OBSERVA®, the default time for a result to be considered new is three days; however, bioMérieux personnel can change this default time at the customer’s request. The BacT/ALERT® 3D retains the record as new until the record is successfully transmitted to the LIS, or until it has aged off the system due to the addition of 1,920 new bottle records. For the timely transmission of results, it is recommended that the BacT/ALERT® automatically sends results to the LIS. Automatically sending the results requires the LIS to be attentive to the BacT/ALERT® at all times. If the LIS does not acknowledge receipt of the results, the BacT/ALERT® resends the results later, along with any new results that were determined during this period of time. The interval for resending unacknowledged results to the LIS varies with the system. BacT/ALERT® Text software attempts to resend them after one hour. BacT/VIEW®, OBSERVA®, and BacT/ALERT® 3D SelectLink resends unacknowledged results at the next regularly scheduled time for uploading new results.

3 Communications Protocol

Overview of Communications Interface

The transfer of data between the BacT/ALERT® and the LIS follows a format divided into two protocols: the Low-Level Protocol and the High-Level Protocol.

The Low-Level Protocol describes the hardware and cable connections needed to establish connection, the methods for establishing communication between the instrument and the LIS, the methods for error detection and recovery, and the methods for sending and receiving messages. The BacT/ALERT® low-level communications protocol is based upon the *American Society for Testing and Materials (ASTM) Designation E1381*. In 2002, ASTM transferred responsibility for ASTM E1381 to the Clinical and Laboratory Standards Institute (CLSI®) and is now available from CLSI® as *LIS1-A Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems; Approved Standard—Vol. 23 No. 7*.

Note: *LIS1-A is a copyrighted publication and is not available from bioMérieux.*

The High-Level Protocol defines the conventions for the structure of messages exchanged between the instrument and the LIS. The BacT/ALERT® high-level communications protocol is based upon *ASTM Designation E1394*. Responsibility for this document was also transferred to CLSI® in 2002 and is now available from CLSI® as *LIS2-A Specification for Transferring Information Between Clinical Instruments and Computer Systems; Approved Standard—Vol. 23 No. 8*.

Note: *LIS2-A is a copyrighted publication and is not available from bioMérieux.*

This BacT/LINK® External Specification is intended to be used in conjunction with CLSI® *Standards LIS1-A and LIS2-A*. These documents are required when interfacing an LIS with a BacT/ALERT® system.

Low-Level Protocols for BacT/ALERT® Systems

BacT/ALERT® implements the protocols described in *LIS1-A*. This section provides an overview of the implementation of the Low-Level protocols as interpreted by the BacT/LINK® interface software.

Physical Layer

This sets the agreement for the physical and electrical connections between the BacT/ALERT® and the LIS computer. BacT/ALERT® supports user-selectable communication parameters. The available settings are listed in Table 3-1.

Table 3-1: Electrical Settings

Setting	Acceptable Settings
Data Bits	**7** or **8**
Parity	**Odd**, **Even**, or **None**

Table 3-1: Electrical Settings (Continued)

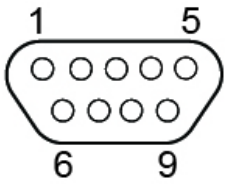
Setting	Acceptable Settings
Stop Bits	**1** or **2**
BAUD Rate	BacT/ALERT® Text: **300**, **1200**, **2400** BacT/VIEW®: **300**, **1200**, **2400**, **9600** OBSERVA®: **300**, **1200**, **2400**, **9600** BacT/ALERT® 3D: **19200**, **1200**, **2400**, **4800**, **9600**

The conforming connector on the BacT/ALERT® instrument is a male style 9-pin sub D RS-232 connector. The pin assignments are listed in Table 3-2.

Table 3-2: Connector Pin Settings

Pin No.	Description	Instrument	Computer
1	Shield	Connects to Frame	No Connection
2	Received Data	Input	Output
3	Transmitted Date	Output	Input
5	Signal Ground		

Figure 3-1: RS232 Male Connector Pin Numbering



The cable to connect the BacT/ALERT® to the LIS computer requires a female connector on one end to connect to the instrument and a male connector on the other end to connect to the LIS computer. If the connecting cable uses a DB-25P (subminiature D Female) style connector to connect to the BacT/ALERT®, an RS-232 25-pin to 9-pin adapter must be used.

Note: *bioMérieux does not supply the cable or the adapter.*

Data Link Layer

The BacT/LINK® interface adheres to the protocols listed in *LIS1-A*, Section 6. Information travels in one direction at a time, and a reply is required for each data transfer. The link is considered to be in the neutral state when neither system (for example, BacT/ALERT® or LIS) is actively sending a message. There are three distinct phases to the Data Link Layer: the Establishment Phase, the Transfer Phase, and the Termination Phase. *LIS1-A,* Section 6 defines the protocol followed by the Data Link Layer.

Establishment Phase

The Establishment Phase determines the direction of the flow of data. Initially, the link is in the neutral state. Both systems monitor the link to detect the beginning of the Establishment Phase. The system with information to send initiates the Establishment Phase by sending an **<ENQ>**; this system is the sender, and the other system becomes the receiver. The receiver must respond to the sender's **<ENQ>** with an **<ACK>**. When

sending an **<ENQ>** during the Establishment phase, if the BacT/ALERT® receives an **<NAK>** from the receiver (LIS), the BacT/ALERT® waits 10 seconds before sending another **<ENQ>**. If the BacT/ALERT® sends an **<ENQ>** and the LIS responds with an **<ENQ>**, the BacT/ALERT® waits one second before sending another **<ENQ>**.

Transfer Phase

The Transfer Phase is the period of time when the sender sends data to the receiver. The data sent is referred to as a "message." In *LIS1-A*, the use of the term "message" is not clear between Sections 3.3.2 and 6.3.1.

In *LIS1-A*, Section 3.3.2, the term "message" is consistent with how "message" is used in the high-level CLSI® Standard *LIS2-A*, Section 3.1.5. 9. In *LIS2-A*, the term "message" refers to the hierarchy of records starting with the Header Record and ending with the Terminator Record.

In *LIS1-A*, Section 6.3.1, the term "message" is consistent with an interpretation as corresponding to individual high-level records. That is, each high-level record begins in a new frame and has its own end frame.

In accordance with *LIS1-A*, Section 3.3.1, the BacT/ALERT® never transmits more than one message during a session. The BacT/ALERT® begins each session with a Header Record, sends each of the hierarchy of records as defined in *LIS2-A*, and ends with the Terminator Record. The BacT/ALERT® can, however, accept multiple messages during an input session from the LIS. Since *LIS1-A*, Section 6.3.1 prescribes that each high-level record begins in a new frame and that each has its own end frame, BacT/ALERT® divides a message so that each high-level record has its own frame and end frame. However, when a message is input from an LIS, the BacT/ALERT® does accept the alternative interpretation. For example, a single large message may be broken into a series of frames, ending with a single end frame. In this case, most records begin in the same frame as the previous record.

The frame structure is as follows:

<STX>^FN^TEXT^<ETX>or<ETB> ^Checksum^<CR>^<LF>

Table 3-3: Low-Level Protocol Frame Characters or Components

Character	Description
STX>	**S**tart of **T**e**x**t transmission control
FN	**F**rame **N**umber (0–7)
TEXT	data content of message
<ETB>	**E**nd of **T**ransmission **B**lock (intermediate frames)
<ETX>	**E**nd of **T**e**X**t transmission (end frames)
Checksum	two digit hexadecimal number to check for message integrity
<CR>	**C**arriage **R**eturn
<LF>	**L**ine **F**eed

The frame number allows the receiver to distinguish between a new frame and a re-transmitted frame. The first frame of a transmission has a frame number of **1**. The

frame number increments by one with each successive frame until reaching frame number **7**. The frame number rolls to **0** for the first frame after **7** and once again increments by one until **7** is reached. The frame number sequence continues in this manner until all frames are sent.

The checksum allows the receiver to detect a defective frame. It is determined by adding the binary values of all characters starting with the frame number through **<ETB>** or **<ETX>**. The checksum does not include the **<STX>**, **<CR>**, or **<LF>**. The Checksum uses the least significant 8 bits of the resulting sum. The 8 bits are considered as two groups of 4 bits, which are then converted to ASCII characters based on the hexadecimal representation.

After sending a frame, the sender stops transmitting until a reply is received. The receiver must acknowledge every frame with one of the following:

- **<ACK>** — The last frame was successfully received and receiver is ready to receive a new frame.
- **<NAK>** — The last frame was not successfully received and the receiver is prepared to receive the frame again.
- **<EOT>** — The last frame was successfully received, the receiver is ready to receive another frame, and requests the sender to stop transmitting as soon as possible.

When the BacT/ALERT® receives an **<EOT>** reply to a frame, it immediately halts the transmission of further frames. This may result in an incomplete high-level record.

Termination Phase

The sender transmits an **<EOT>** to signify that all messages have been sent. The sender considers the link to be in the neutral state. The receiver considers the link to be in the neutral state when it receives an **<EOT>** from the sender.

Error Recovery and Timeouts

The receiver checks every frame for errors, and if any errors are detected, it sends a **<NAK>**. When the sender receives a **<NAK>**, it retransmits the frame using the same frame number. If the frame is sent and not accepted six times, the sender aborts the message and moves to the termination phase.

Both the sender and the receiver use timers to detect possible loss of communication during the Establishment Phase and the Transfer Phase.

- **Establishment Phase** — If the sender does not receive an **<ACK>**, **<NAK>**, or **<EOT>** from the receiver within 20 seconds of sending the **<ENQ>**, a timeout occurs and the sender considers the link to be in the neutral state.
- **Transfer Phase** — If the sender does not receive a reply within 15 seconds of sending the last character, a timeout occurs, the message is aborted, and the sender moves to the Termination Phase of communication.
- **Transfer Phase** — If the receiver does not receive another frame or an **<EOT>** within 30 seconds of a response to the last frame received, a timeout occurs, the last incomplete message is discarded, and the receiver considers the line to be in the neutral state.

High-Level Protocol

This section details the communication protocol used in defining the content, structure and elements of the messages sent between the BacT/ALERT® system and the LIS. BacT/ALERT® high-level communication is based upon *ASTM Standard E1394-91*, published June 1991. In 2002, the *ASTM E1394* standard was transferred to CLSI® (formerly NCCLS), and was revised and republished as *LIS2-A*, April 2003 (ISBN 1-56238-490-2).

The significant difference between ASTM E1394-91 and *LIS2-A* is that ASCII characters greater than 127 are undefined in ASTM E1391-91 (versus being defined by ISO-8859-1, as in *LIS2-A*). BacT/ALERT® implements much of the standard as described, although several features and many fields are not applicable.

Definitions

Definitions for commonly used terms are included in Table 3-4.

Table 3-4: Definitions

Message	A body of text communication.
Test	A specific examination or determination to be performed by an analytical system.
Record	A group of fields which make up one aspect of a complete message.
Field	A division of a record containing information for one specific record attribute.
Repeat Field	A convention that allows for the duplication of a field within the field's position within a record. This creates two or more elements within the field that have equal standing within the message. Repeat fields are separated by a repeat delimiter within the field.
Component Field	A single data element that expresses a singular quality of the field. An example could be found in the **Patient Name** field, which consists of last name, first name separated by a component delimiter within the field.
Upload	The transmission of data from the instrument to the computer system.
Download	The transmission of data from the computer system to the instrument.

Message Hierarchy

High-level messages may contain requests or results for one or more patients. The message consists of a hierarchy of records, and the record types are related to each other in a hierarchical sequence. Records which are higher in the hierarchy contain information that is common for all lower records within that hierarchy. Each of the records lower in the hierarchy is directly related to the immediate preceding higher record in the sequence.

Record Level 0 is considered to be the highest record. Records at Level 0 contain information regarding the sender, the receiver, the date and time of transmission, or the termination of a message. This record is referred to as the Header Record (H). A message

should only have one Header Record. This record also defines the characters used to designate field, repeat field and component delimiters.

Level 1 is the next level in the hierarchy. Level 1 records contain information regarding the individual patient. This record is referred to as the Patient Record (P). The first Patient Record in a message must be preceded by a Header Record and may be followed by either a Comment Record or a Level 2 record. Multiple Patient Records may follow a Header Record. With each appearance of a Patient Record, a new hierarchical sequence is created.

Level 2 is the next hierarchy level. Level 2 records contain information regarding test orders and specimens. This record is referred to as the Order Record (O). The Order Record must be preceded by a Patient Record and is directly related to this Patient Record. Multiple Order Records may be related to a single Patient Record. Order Records may be followed by either Comment Record or by a Level 3 record. In this case, the lower records are related directly to the Order Record.

Level 3 records follow in the hierarchy. Level 3 records contain information regarding test results and are referred to as Result Records (R). Result Records must be preceded by an Order Record and are directly related to this record. Multiple Result Records can be related to a single Order Record. When sent by the instrument, the Result Record contains the result of a single determination. When sent by the LIS, the Result Record contains information regarding the test that is requested.

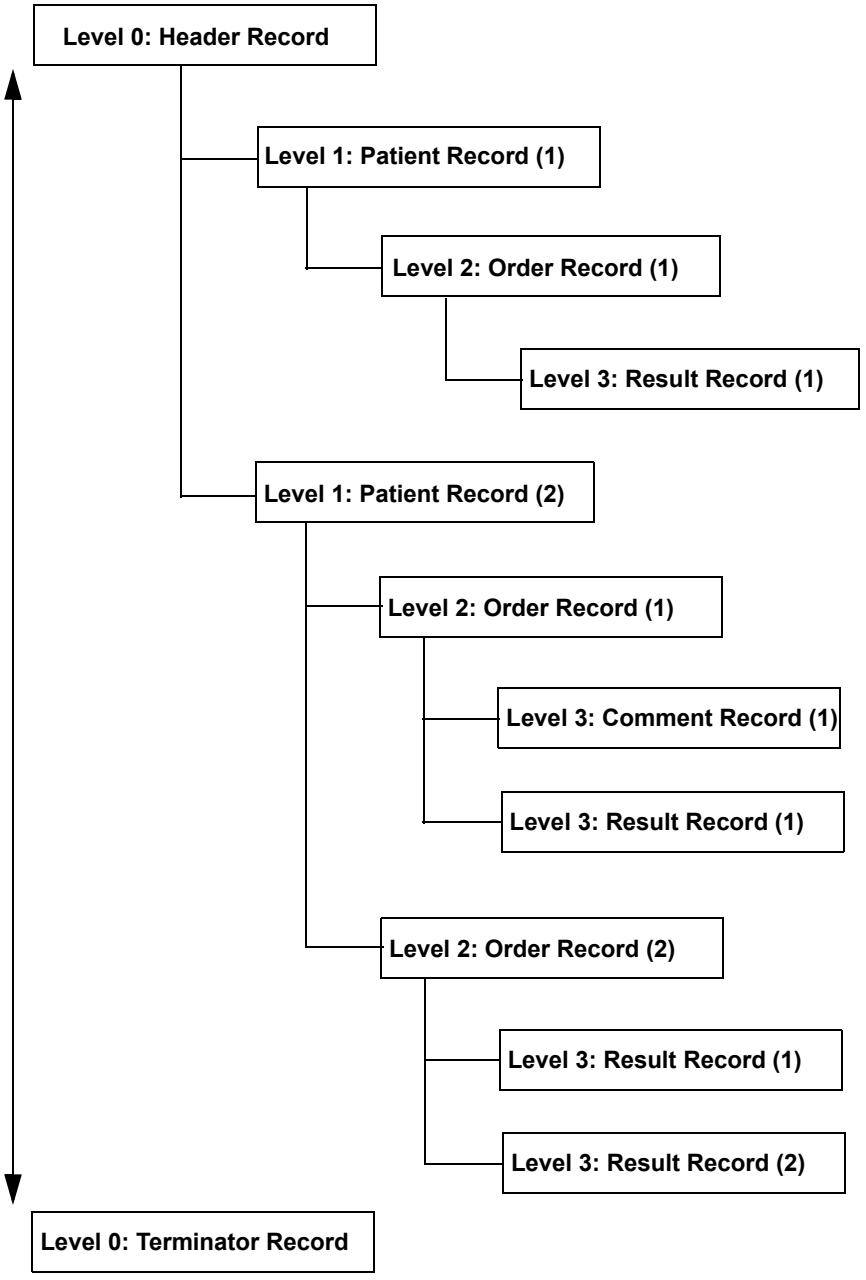
A Comment Record (C) can be created at any level of the hierarchy and relates to the hierarchy record that immediately precedes the Comment Record. For example, if a Comment Record came immediately after an Order Record, it would relate to that particular Order Record.

In addition to these record types, there are request-information records (I), which allow for the request of demographics, orders, or test results.

The last record type is the Terminator Record (L). The Terminator Record ends the message and must be the last record of a message. There should only be one Terminator Record within a message.

Figure 3-2 is an example of the message hierarchy. In this example, there are two Patient Records. The Patient Record for Patient (1) has one Order Record, and the Order Record has one Result Record. The appearance of a Level 1 record begins a new hierarchical sequence for Patient (2). Patient (2) has two distinct Order Records: The first Order Record has a Comment Record and a Result Record. The second Order Record for Patient (2) has two distinct Result Records.

Figure 3-2: Message Hierarchy



Character Codes

Values 0 through 31 are prohibited and are stripped from received messages. Values 127 and 255 are not allowed. Values 32 through 126 are treated as standard ASCII characters. Values 128 through 249 are treated as extended characters and are typically only significant in foreign language sites (non-US sites). The exact meaning of values 128 through 249 is character set and software dependent.

- **BacT/ALERT® Text** — Values 128 through 249 represent characters specified in the IBM® PC extended character set (Code page 437), especially foreign characters. Characters 250 through 255 are prohibited. These characters are stripped from received messages and are never sent. Leading and trailing spaces are trimmed from all fields in all records. All lowercase characters are converted to uppercase.

- **BacT/VIEW®** — By default, values 128 through 249 represent characters specified in the IBM® PC extended character set (Code page 437), especially foreign characters. This can be reconfigured to use the Windows® Western character set (Code page 1252) by setting the SP*IF_CONFIG<49> record to **WINDOWS**. Values 250 through 255 are prohibited.These characters are remapped when they appear in received messages and are never sent. Leading and trailing spaces are trimmed from all fields in all records. All lowercase characters are converted to uppercase.
- **OBSERVA®** — Values 128 through 249 represent characters specified in the IBM® PC extended character set (Code page 437), especially foreign characters. Leading and trailing spaces are trimmed from all fields in all records. Patient, Accession and Bottle IDs are case-insensitive. All other fields are case-sensitive and are used as is.
- **BacT/ALERT® 3D SelectLink** — Values 128 through 249 represent characters specified in the IBM® PC European character set (Code page 850). No characters are stripped or prohibited except where noted in the field definitions. Leading and trailing spaces are trimmed from all fields in all records. Bottle IDs are case-insensitive. Patient IDs and Accession Numbers can be configured to be case-insensitive.

IMPORTANT: The use of other character sets may result in failed LIS transmissions and can delay the transmission of results.

Maximum Record Length

The BacT/ALERT® Text, BacT/VIEW®, and BacT/ALERT® 3D SelectLink can support records of up to 32768 bytes. The maximum record length for OBSERVA® is limited by the available memory. Fields within each record can be any length as long as this does not cause the record to exceed its maximum length.

Delimiters

Within each record, high-level protocol uses a positional convention to define the field elements of records and the structure of messages. Positions within a record are determined by the use of delimiters. Definitions of the delimiters are provided in *LIS2-A*, Section 6.4. Table 3-5 lists the characters that are used as delimiters.

Table 3-5: High-Level Protocol Use of Delimiters

Delimiter	Character
Field Delimiter	Vertical bar **|** [Latin-1 (124)]
Repeat Delimiter	Backslash **** [Latin-1 (96)]
Component Delimiter	Caret **^** [Latin-1 (94)]
Escape Delimiter	Ampersand **&** [Latin-1 (38)]

The delimiters used in a given transmission are specified in field 2 of the Message Header Record. When uploading to the host computer, the BacT/ALERT® Text, BacT/VIEW ®, and BacT/ALERT® 3D SelectLink make every attempt to use the delimiters specified in the Header Record most recently received from the host computer. OBSERVA® always uses the example delimiters shown in *LIS2-A* when uploading to the host computer.

BacT/ALERT® High-Level Protocol General Considerations

BacT/ALERT® implements much of the High-Level Protocol standard as described, although several features and many fields are not applicable.

- Except where noted, all functions are implemented and behave as described by *LIS2-A*, all fields are optional, and the meanings are described by the CLSI® standard.
- All references to "specimen" in *LIS2-A* correspond to the BacT/ALERT® use of "accession." All references to "test" in *LIS2-A* correspond to the BacT/ALERT® use of "bottle."
- Where quoted material appears, only the quoted contents are significant. The quotes themselves are not transmitted.
- Under the description column, **U:** refers to the BacT/ALERT® behavior when uploading this data to the lab system, and **D:** refers to the BacT/ALERT® behavior when downloading this data from the lab system.
- BacT/ALERT® generally stores and displays the data in the same form as it was received with the following exceptions:
    - BacT/ALERT® sends and receives the date and time in the prescribed YYYYMMDDHHMMSS format (*LIS2-A*, Section 6.6.2). However, dates and times received from the host computer are converted into the software-determined format for storage.
    - All text fields received by BacT/ALERT® Text and BacT/VIEW® are converted to uppercase. BacT/ALERT® 3D SelectLink incorporates text information as it is transmitted with the exception of **Patient Name**, **Hospital ID,** and **Accession Number** fields. The user may configure these fields to be converted to uppercase. OBSERVA® stores and displays data as it is received from the LIS.

Support for Coded Fields

For BacT/ALERT® Text and BacT/VIEW® systems, if the field has a user-defined code and the first component of the LIS field matches a code in the BacT/ALERT® list of accepted codes for that field, then the full term is stored. Any other information sent in this field is ignored. Within the software application, the expanded form of the code displays the following:

- **Example 1** — The Source field in BacT/VIEW® has a user-defined code for URINE of "UR." The LIS sends "UR." This will be stored and displayed as URINE.
- **Example 2** — The Source field in BacT/VIEW® has a user-defined code for URINE of "UR." The LIS sends "UR CATH." Since the first component of the LIS field, "UR," matches the user-defined code, this will be stored and displayed as URINE; the CATH component is ignored.

For BacT/ALERT® Text and BacT/VIEW®systems, if the field has user-defined codes and the first component of the LIS field does not match one of the codes in BacT/ALERT® list of accepted codes for that field, then all information in the field is stored with a leading "!" to force storage in the database. Within the software application, the field displays the character "!" followed by the information sent by the LIS.

- **Example** — The Source field in BacT/VIEW® has a user-defined code for SPINAL FLUID of "CSF." However, the LIS sends "Sp Fl" in this field. This is stored and displayed as "!SP FL."

Note: *In BacT/ALERT® Text and BacT/VIEW®, the following fields cannot accept data in coded form: 8.1.7, 8.1.11, 8.1.13, 8.1.14, 8.1.17, 8.1.18, 8.1.24, 9.4.7, 9.4.9, 9.4.18.*

For OBSERVA®, if the field has a user-defined LIS code and the LIS field matches a code in the BacT/ALERT® list of accepted codes for that field, then the text for that code is stored.

Support for Multi-Value Fields

In BacT/VIEW®, if a field is designed for multiple values (as are Patient field 5, Accession field 5, and Comment fields) then multiple values separated with a repeat delimiter and sent by the LIS are stored separately. If a field is designed to hold a single value, but the LIS field has multiple values, then all values are ignored.

IMPORTANT: ***OBSERVA® does not accept multi-value field data from the LIS.***

IMPORTANT: ***BacT/ALERT® 3D does not have multi-value fields.***

Many ASTM fields are not directly supported by BacT/ALERT® databases (such as physician, diagnosis, etc.). BacT/ALERT® Text, BacT/VIEW® and OBSERVA® include features for mapping this type of data to user-defined fields.

The Universal Test ID is a unique field used in either the Order Record or the Result Record to define the test. See Record Specifics for more detailed information regarding this field.

Date/Time Format

The format for transmitting dates and times is described in *LIS2-A*, Section 6.6.2.

Date only:	YYYYMMDD
Time only:	HHMMSS
Date and Time:	YYYYMMDDHHMMSS

Record Specifics

Table 3-6 through Table 3-15 list the clarifications and/or additional details which describe the use of the various sections of the high-level protocol documentation as applied by the BacT/ALERT®.

D: — Refers to messages sent from the LIS to the BacT/ALERT®.

U: — Refers to messages sent from the BacT/ALERT® to the LIS.

Table 3-6: *LIS2-A* Section 6.6.1 — Universal Test ID

6.6	This multi-component field is used to define the test identification through the use of component fields. On download, the Universal Test ID is used by the LIS to request a blood culture test. On upload, it is used by BacT/ALERT® to identify the type of test results being sent to the LIS. The Universal Test ID can be used in an Order Record or in a Results Record to identify the test.
6.6.1.1	Component field not used by BacT/ALERT®.
6.6.1.2	Component field not used by BacT/ALERT®.
6.6.1.3	Component field not used by BacT/ALERT®.
6.6.1.4	**Manufacturer's Test ID** **D:** "BC" indicates a test request for a BacT/ALERT® culture. If the LIS is sending test results, it indicates that the results are for a culture. "ID" (BacT/ALERT® Text or BacT/VIEW® only) in component 4 of the Universal Test ID specifies results of an organism identification test, which were not performed by the BacT/ALERT® system. "SM" (BacT/ALERT® Text or BacT/VIEW® only) in component 4 of the Universal Test ID specifies results of a smear examination. **U:** "BC" indicates the result transmitted in field 10.1.4 is a positive/negative culture result. "TTD" indicates the result transmitted in field 10.1.4 is the time to detection for the culture.

Table 3-6: *LIS2-A* Section 6.6.1 — Universal Test ID (Continued)

6.6.1.5	**Bottle Type** **D:** The Bottle Type is expressed in coded form in component 5. The list below provides the code and the associated bottle type. "U" – Unknown "BSA" – BacT/ALERT SA "BSN" – BacT/ALERT SN "BFA" – BacT/ALERT FA "BFN" – BacT/ALERT FN "BPF" – BacT/ALERT PF "BMP" – BacT/ALERT MP "BMB" – BacT/ALERT MB "BIA" – BacT/ALERT *i*AST "BIN" – BacT/ALERT *i*NST "BIL" – BacT/ALERT *i*LYM "BIFA" – BacT/ALERT *i*FA "BIFN" – BacT/ALERT *i*FN "BIPF" – BacT/ALERT *i* PF "BPA" – BacT/ALERT BPA "BPN" – BacT/ALERT BPN "BFA+" – BacT/ALERT FA Plus "BFN+" – BacT/ALERT FN Plus "BPF+" – BacT/ALERT PF Plus "BIFA+" – BacT/ALERT *i*FA Plus "BIFN+" – BacT/ALERT *i*FN Plus If component 5 is null, the bottle type defaults according to special characters found in the Bottle ID provided by bioMérieux on the bottle. If the bioMérieux Bottle ID is not used, then the bottle type must be specified in component 5. **U:** Bottle type as listed above.
WARNING	
⚠	**Sending incorrect bottle type abbreviation codes to the instrument may result in false positive or false negative test results. The bottle type directs the instrument to select the proper algorithm of determination for results. Algorithms are optimized for each bottle type. The bottle type is printed on the BacT/ALERT® bottle label.**

Table 3-6: *LIS2-A* Section 6.6.1 — Universal Test ID (Continued)

6.6.1.6	**Bottle ID** Each BacT/ALERT® bottle label has a unique Bottle ID in human-readable format and in barcode format. See Appendix A for detailed information regarding acceptable Bottle ID formats. **D:** When the Universal Test ID is used for ordering a culture, and component 6 is null, the Bottle ID associated with the test order is assigned by the BacT/ALERT® when the bottle is loaded into the instrument. When the Universal Test ID is used in a Result Record with Test ID of "BC," and component 6 is null, the Result Record is ignored. In BacT/ALERT® Text or BacT/VIEW® only, when the Universal Test ID is used in a Result Record with Test ID equal to ID or SM, and component 6 is null, the first positive blood culture bottle, if any, associated with this test order is assigned the results sent in field 10.1.4. **U:** Always sent by BacT/ALERT® in a Result Record to identify the bottle which has the results sent in field 10.1.4.
6.6.1.7	**Maximum Test Time** **D:** This indicates the maximum number of days to test a bottle until determining a status of negative. This may be expressed in tenths of a day. If this field is null, the BacT/ALERT® system default value is used. **U:** BacT/ALERT® does not upload this component to the LIS.

Table 3-7: *LIS2-A* Section 7 — Message Header Record

7.1	**D:** Many Message Header fields are ignored. Only the fields with further description listed in this table are not ignored. **U:** Many Message Header fields are null. Only non-null fields are described in this table.
7.1.1	**Record Type ID** This field uses the character "H" to designate this as a Header Record.
7.1.2	**Delimiter definition:** as described in LIS 2-A2.
7.1.5	**Sender Name** **U:** "BacT/ALERT ^V.##. V,## varies according to the current version number of BacT/LINK® software. It is presently version A.0.
7.1.10	**Receiver ID** **D:** LIS must send "BACT/ALERT" or the entire message is ignored.
7.1.12	**Processing ID** **D:** If "P" or null is sent, the message is processed normally. If any other code is sent, the entire message is ignored. **U:** Always "P".
7.1.14	**Date and Time of Message** As described in *LIS2-A*, Section 6.6.2.

Table 3-8: *LIS2-A* Section 8 — Patient Information Record

8.1	**D:** Only a few of the fields in the Patient Record are mapped by default to receive data from the LIS. These fields are described in the subsequent rows of this table. A laboratory can use fields not described in this table to transmit information to user-defined fields for patients. These fields must be mapped within the software to receive data from the appropriate transmission field. **U:** Most patient fields are null. With the exception of the Patient ID, BacT/LINK® does not send patient information back to the LIS.
8.1.1	**Record Type** This field uses the character "P" to designate this as a Patient Record.
8.1.2	**Sequence Number** This is an incremental number for this hierarchy level as described in *LIS2-A*, Section 6.6.7. The number starts at 1 for the first Patient Record and is incremented to the next number with each additional Patient Record.
8.1.3	**Patient ID** **D:** The sending of a Patient ID is optional. If absent, none of the data sent in the Patient Record is stored. Any test orders included in this patient's hierarchy are accepted and stored; however, there will be no identifying patient information. **U:** Patient ID.
8.1.6	**Patient Name** **D**: BacT/ALERT® Text and BacT/VIEW® maintain the name in two parts; the last name and then all other components sent in this field. Each component is separated by spaces. OBSERVA® accepts the first two components of this field (last name and first name). User-defined fields can be created within the software and mapped to accept additional components of this field. BacT/ALERT® 3D SelectLink places the information of the first component into the Last Name field. Information sent in the remaining components is combined and stored in the First Name field, as space allows. **U:** Not uploaded by BacT/LINK®.
8.1.8	**Birth Date** **D:** BacT/ALERT® Text, BacT/VIEW®, and OBSERVA® accept this field. BacT/ALERT® SelectLink ignores this field. **U:** Not uploaded by BacT/LINK®.
8.1.9	**Patient Sex** **D:** BacT/ALERT® Text, BacT/VIEW®, and OBSERVA ® accept this field. BacT/ALERT®3D SelectLink ignores this field. **U:** Not uploaded by BacT/LINK®.
8.1.26	**Location** **D:** BacT/ALERT® Text and BacT/VIEW® use this field as the default specimen location is no location is given in field 9.4.28. Data can be expressed in coded form. OBSERVA® does not use this field, but it can be assigned to any user-defined field. BacT/ALERT®3D SelectLink ignores this field. **U:** Not uploaded by BacT/LINK®.

Table 3-9: *LIS2-A* Section 9 — Test Order Record

9.4	**D:** Only a few of the fields in the Order Record are mapped by default to receive data from the LIS. These fields are described in the subsequent rows of this table. A laboratory can use fields not described in this table to transmit information to user-defined fields for patients. These fields must be mapped within the software to receive data from the appropriate transmission field. **U:** Most Order Record fields are null. With the exception of the Accession Number, BacT/LINK® does not send order information back to the LIS.
9.4.1	**Record Type** This field uses the character "O" to designate this as an Order Record.
9.4.2	**Sequence Number** This is an incremental number for this hierarchy level as described in *LIS2-A*, Section 6.6.7. The number starts at 1 for the first Order Record and is incremented to the next number with each additional Order Record associated with this hierarchy sequence. When another Patient Record appears, a new hierarchy sequence begins and the Order Record sequence number is reset to 1.
9.4.3	**Specimen ID (Accession Number)** **D:** Laboratory assigned Accession Number. Only the first component is significant and other components are ignored. If Accession Numbers are always unique (for example, never repeated), then field 9.4.4 should be used to specify the Accession Number since it results in faster access. If an Accession Number is present in field 9.4.4, this field is ignored. The following characters are prohibited for use in Accession Numbers: @ " \ '. BacT/ALERT® Text and BacT/VIEW® strip these characters from the Accession Number. BacT/ALERT® 3D SelectLink: The BacT/ALERT® 3D systems can receive the Accession Number in either fields 9.4.3 or 9.4.4. By default the BacT/ALERT® 3D assumes Accession Numbers are never reused, but it can be set to allow the reuse of Accession Numbers. If Accession Numbers are reused (not unique), the Accession Number must be sent in field 9.4.3 and the BacT/ALERT® 3D must be configured to allow for the reuse of Accession Numbers. If Accession Numbers are not reused, the BacT/ALERT® 3D can accept the Accession Number from either fields 9.4.3 or 9.4.4 and uploads the Accession Number in both fields without adding a suffix to either field. **U:** BacT/ALERT® Text, BacT/VIEW®: BacT/ALERT® Text and BacT/VIEW® allow for an Accession Number to be reused after 3 days. If the accession sent by the LIS already exists in the database and field 9.4.12 specifies the creation of a new test order, these systems append a hidden suffix to this Accession Number to assure uniqueness. When test results are sent back to the LIS, the un-appended number is sent in field 9.4.3 and the appended Accession Number is sent in field 9.4.4. OBSERVA®: OBSERVA® is mapped to receive the Accession Number in this field and upload the accession to the LIS in this field when sending results. OBSERVA® can be mapped to receive the Accession Number in field 9.4.4. If OBSERVA® receives the Accession Number in field 9.4.4, it uploads the Accession Number in 9.4.4 when sending results to the LIS. BacT/ALERT® 3D SelectLink: For BacT/ALERT® 3D systems, the Accession Number is sent in fields 9.4.3 and 9.4.4; however, if an accession is reused (not unique), it is appended with an * and a unique suffix.

Table 3-9: *LIS2-A* Section 9 — Test Order Record (Continued)

9.4.4	**Specimen ID (Accession Number)** This is the alternative Accession Number. **D:** If the Accession Number is always unique (not reused) this is the preferred field for sending the Accession Number. **U:** Refer to 9.4.3 for information regarding the upload of the Accession Number.

Table 3-9: *LIS2-A* Section 9 — Test Order Record (Continued)

9.4.5	**Universal Test ID** **D:** This field is comprised of component fields and specifies the test to be performed and may be multi-valued to specify Accession Numbers with more than one bottle. Components 1 to 3 are ignored. Component 4 – Test ID: the download to this component field must always be "BC." Component 5 – Bottle Type, as follows: "BSA" – BacT/ALERT SA "BSN" – BacT/ALERT SN "BPF" – BacT/ALERT PF "BFA" – BacT/ALERT FA "BFN" – BacT/ALERT FN "BMP" – BacT/ALERT MP "BMB" – BacT/ALERT MB "BIA" – BacT/ALERT *i*AST "BIN" – BacT/ALERT *i*NST "BIL" – BacT/ALERT *i*LYM "BIFA" – BacT/ALERT *i*FA "BIFN" – BacT/ALERT *i*FN "BIPF" – BacT/ALERT *i*PF "BPA" – BacT/ALERT BPA "BPN" – BacT/ALERT BPN "BFA+" – BacT/ALERT FA Plus "BFN+" – BacT/ALERT FN Plus "BPF+" – BacT/ALERT PF Plus "BIFA+" – BacT/ALERT *i*FA Plus "BIFN+" – BacT/ALERT *i*FN Plus This field can be null if bioMérieux Bottle ID barcodes are used. If the laboratory or LIS assigns Bottle IDs, this field must have the correct bottle type code. Component 6 – Bottle ID: See Appendix A for a complete list of the Bottle ID formats possible. This field can be null. Component 7 – Maximum Test Time: The maximum number of days to incubate the bottle before a negative status is assigned. If null, then the BacT/ALERT® system default is used. Components 8 to 10 – Optional lab-defined bottle data fields. BacT/ALERT® Text and BacT/VIEW®: This information is stored in the bottle's first, second, and third user-defined bottle fields. OBSERVA®: This data, any user-defined bottle field can be mapped to these components. BacT/ALERT® 3D SelectLink ignores these components. **D:** BacT/ALERT® does not send the Universal Test ID to the LIS in field 9.4.5. The Universal Test ID is sent to the LIS in a Result Record. Refer to field 10.1.3.

Table 3-9: *LIS2-A* Section 9 — Test Order Record (Continued)

WARNING	
⚠	**Sending incorrect bottle type abbreviation codes to the instrument may result in false positive or false negative test results. The bottle type directs the instrument to select the proper algorithm of determination for results. Algorithms are optimized for each bottle type. The bottle type is printed on the BacT/ALERT® bottle label.**
9.4.8	**Specimen Collection Date and Time** **D:** For BacT/ALERT® Text and BacT/VIEW®, if absent and field 9.4.12 specifies a new test order, then today is assumed for the date and the time is left unspecified. OBSERVA®: If absent and field 9.4.14 specifies a new test order, then the current date and time is used. BacT/ALERT® 3D SelectLink ignores this field.
9.4.11	**Collector ID** **D:** BacT/ALERT® Text, BacT/VIEW®, and OBSERVA® can accept this field. BacT/ALERT® 3D SelectLink ignores this field.
9.4.12	**Action Code** **D:** "P", "Q", "N', or null creates a new accession using the number specified by 9.4.3 or 9.4.4. "A" or "X" add these test or other data to the accession specified or creates a new accession if it does not already exist. "C" deletes the accession and its bottles. ***Note:*** *If there is a physical bottle in the system, it will remain under test with no accession.* The use of any other codes in this field will cause the Test order to be ignored.
9.4.15	**Date/Time Specimen Received** **U:** BacT/ALERT® Text, BacT/VIEW®, and OBSERVA® can accept data from this field. BacT/ALERT® 3D SelectLink ignores this field.
9.4.16.1	**Specimen Type** BacT/ALERT® systems refer to "specimen type" as "source." Information sent in the first component of this field is used to populate the Source field in BacT/ALERT® software. **D:** BacT/ALERT® Text, BacT/VIEW®, and OBSERVA® can accept data expressed in coded form. BacT/ALERT® 3D SelectLink ignores this field.
9.4.17	**Ordering Physician** **D:** BacT/ALERT® Text, BacT/VIEW®, and OBSERVA® can accept data in coded form. BacT/ALERT®3D SelectLink ignores this field.

Table 3-9: *LIS2-A* Section 9 — Test Order Record (Continued)

9.4.23	**Date/Time Results Reported or Last Modified** **U:** For BacT/ALERT® Text, BacT/VIEW®, and OBSERVA®, this is the most recent time when the BacT/ALERT® considered this accession's tests to have a "new" result. BacT/ALERT®3D SelectLink does not send information in this field.
9.4.26	**Report Types** **U:** "F": All bottles are negative and have been unloaded. "P": At least one bottle is positive. BacT/ALERT® regards all positive results as preliminary. "I": At least one bottle associated with the Accession Number is still under test (has negative-to-date status) or has not yet been loaded into the BacT/ALERT® system. "Y", "Z": Not used by BacT/ALERT® 3D SelectLink. BacT/ALERT® never sends other codes.
9.4.28	**Location or ward of specimen collection** **D:** BacT/ALERT® Text or BacT/VIEW®: If this field is null, then the patient location (8.1.26) is used. Only the first component is stored. Data can be expressed in coded form. OBSERVA® uses this field for the **Specimen Location** field. BacT/ALERT® 3D SelectLink ignores this field.

Table 3-10: *LIS2-A* Section 10 — Result Record

10.1	**D:** Only a few of the fields in the Result Record are mapped by default to receive data from the LIS. These fields are described in the subsequent rows of this table. A laboratory can use fields not described in this table to transmit information to user-defined fields for patients. These fields must be mapped within the software to receive data from the appropriate transmission field. Result Records downloaded with a test order indicate BacT/ALERT® Bottle IDs that are part of that order. **U:** Most result fields are null. Only fields with further mention below are non-null.
10.1.1	**Record Type** This field uses the character "R" to designate this as a Result Record.
10.1.2	**Sequence Number** As described in *LIS2-A* Section 6.6.7.
10.1.3	**Universal Test ID** Refer to *LIS2-A*, Section 6.6.1, Universal Test ID, of this table.

Table 3-10: *LIS2-A* Section 10 — Result Record (Continued)

10.1.4	**Bottle Result** **For Test ID =** "BC", the result is the blood culture bottle status, as follows: "+" = Positive. The bottle may or may not be currently loaded in the instrument. "-" = Negative. The bottle has reached its maximum test time without becoming positive. It may or may not be currently loaded in the instrument. "*" = Negative to date. The bottle is still under test. "Null" = The bottle has not yet been loaded into the instrument for testing. **D:** BacT/ALERT® Text, BacT/VIEW®, and OBSERVA® ignore this field. BacT/ALERT® 3D accepts values listed above and reassigns the bottle status based on the information sent in this field. **U:** Tested status of the bottle.
	For Test ID = "TTD", the result is the time to detection in hours and tenths (for example, "18.3"). **D:** The Result Record is ignored. **U:** Time to detection is sent.
	For Test ID = "ID" (BacT/ALERT® Text and BacT/VIEW® only). **D:** The organism ID. **U:** ID result is never sent by the BacT/ALERT® to the LIS.
	For Test ID = "SM" (BacT/ALERT® Text and BacT/VIEW® only). **D:** The organism smear observations. **U:** Smear result is never sent by the BacT/ALERT® to the LIS.
10.1.9	**Result Status** The following codes are used: "P" - Preliminary results. "F" - Final results. "I" - In Instrument, results pending. "Null" - Bottle has not yet been loaded into the BacT/ALERT® for testing. **D:** BacT/ALERT® Text, BacT/VIEW®, and OBSERVA®: "N","C", "P","F","S","R","V", or "Null" causes the bottle result to be modified or a new bottle to be set up, if necessary. Use of any other codes will cause the Result Record to be ignored. BacT/ALERT® 3D only accepts "F","P", or "I". Use of other codes will cause the Result Record to be ignored. **U:** BacT/ALERT® 3D only sends "F","P","I", or "Null" in this field.
10.1.12	**Date/Time Test started** **U:** This is the date and time the bottle was first loaded into the instrument expressed in the format detailed in *LIS2-A*, Section 6.6.2. This field is null if the bottle has never been loaded.
10.1.13	**Date/Time Test completed** **U:** This is the date and time the bottle was determine to have a positive or negative status expressed in the format detailed in *LIS2-A*, Section 6.6.2. This field also contains the time of the last reading for negative-to-date results. This field is null if the bottle has never been loaded.

Table 3-10: *LIS2-A* Section 10 — Result Record (Continued)

10.1.14	**Instrument Identification** **U:** This is the instrument cell ID where the bottle was tested. A cell ID consists of an instrument number (up to two digits), a block or drawer letter, and a two-digit cell number (for example, 1A01). This field is null if the bottle has never been loaded**.**

Table 3-11: *LIS2-A* Section 11.1 — Comment Record

11.1	**D:** BacT/ALERT® Text, BacT/VIEW®, and OBSERVA® accept comment for all record types. BacT/ALERT® 3D does not accept comment records. **U:** Comment Records are never sent by BacT/ALERT®.
11.1.1	**Record Type** This field uses the character "R" to designate this as a Comment Record.
11.1.2	**Sequence Number**: As described in *LIS2-A*, Section 6.6.7.
11.1.3	**Comment Source** **D:** BacT/ALERT® Text and BacT/VIEW® ignore this field. OBSERVA® does not use this field.
11.1.4	**Comment Text** **D:** For BacT/ALERT® Text BacT/VIEW®, and OBSERVA®, the field contents are used as is. The use of codes is not supported for Comments.
11.5.1	**Comment Type** **D:** This field is not used.

Table 3-12: *LIS2-A* Section 12.1 — Request Information Record

12.1.1	**Record Type** This field uses the character "Q" to designate this as a Query Record.
12.1.2	**Sequence Number**: As described in *LIS2-A*, Section 6.6.7. The Request Information or Query Record is used by either the clinical instrument or the LIS to request information from the reciprocal instrument.

Table 3-12: *LIS2-A* Section 12.1 — Request Information Record (Continued)

12.1.3	**Starting Range ID Number** This field may contain three component fields to define the selection criteria. For BacT/ALERT® Text and BacT/VIEW®, the first component is the patient's Hospital ID. The second component is the lab-assigned Accession Number. The third component is the alternative Accession Number (refer to 9.4.3 and 9.4.4 for a description of the distinctions between lab-assigned and alternative Accession Numbers). **D:** For BacT/ALERT® Text and BacT/VIEW®, if both the Hospital ID and Accession Number are given, then the Hospital ID is ignored and the search is based on the Accession Number. If the alternative Accession Number is given, it takes precedent over the lab-assigned Accession Number. For BacT/ALERT® 3D, if both components are specified, the only results returned are those that meet both specifications. If only the Hospital ID is specified, all results associated with the patient are returned. If only the Accession Number is specified, only results belonging to the Accession Number are returned. For BacT/ALERT® Text, BacT/VIEW®, and BacT/ALERT® 3D, if the second component is "ALL," only the new test results are sent. OBSERVA® does not respond to a query for results. **U:** Both components 2 and 3 are sent, if known. For BacT/ALERT® Text and BacT/VIEW®, just the first component is sent to request patient demographics. "ALL" is sent in the second component to request new test orders from the LIS.
12.1.4	**D:** As described by *LIS2-A*. For BacT/ALERT® Text and BacT/VIEW®, a search for a range of IDs only works when the Ids are either strictly numeric, or have the same number of characters. BacT/ALERT® 3D and OBSERVA® do not support the field.
Fields 12.1.5 through 12.1.12 are ignored by BacT/ALERT®.	
12.1.13	**Request Information Status Codes** BacT/ALERT® Text and BacT/VIEW®: **D**: "N" = request all results which meet the selection criteria and which have changed since the last transmission of results. "A" = Abort/cancel last request criteria (allows a new request to follow) "Null" or other codes = request all results that meet the selection criteria. BacT/ALERT® does not interpret the codes that distinguish between "final", "partial", or "preliminary" results. Any request from the LIS returns the current status for all selected tests, whether or not those tests have been completed. **U:** "A" = Abort request. "O" = Request test orders and demographics only. "D" = Request demographics only (for example, patient record).
	BacT/ALERT® 3D: **D:** "N" = Request all results which meet the selection criteria and which have changed since the last transmission. "A" = Abort/cancel last request criteria. "Null" or other codes = request all results that meet the selection criteria. **U:** "O" = Request all new test orders. Other codes are never sent.
	OBSERVA® does not support this field.

Table 3-13: *LIS2-A* Section 13 — Message Terminator Record

13.	All fields are as described in *LIS2-A*. BacT/ALERT® 3D: Not used.

Table 3-14: *LIS2-A* Section 14 — Scientific Record

14.	**D:** Ignored. **U:** Scientific records are never sent.

Table 3-15: *LIS2-A* Section 15 — Manufacturer Information Record

15.	**D:** Ignored. **U:** Manufacturer records are never sent.

A Bottle ID and Barcode Formats

Introduction

This section contains specifications for the barcode labels used with the BacT/ALERT® bottles. This section also provides the information necessary for an LIS to accept entry of Bottle IDs, or to print its own barcode labels that are appropriate for use with BacT/ALERT® bottles. BacT/ALERT® bottle barcodes are used with the BacT/ALERT® system, which may include data management software (BacT/ALERT® Text, BacT/VIEW®, or OBSERVA®), and one or more BacT/ALERT® Classic or BacT/ALERT® 3D instruments.

Each BacT/ALERT® bottle must have its own unique ID, separate from any Accession Number. Uniqueness is required, in part, because BacT/ALERT® provides long-term storage of bottle test results. Also, since a single specimen is often inoculated into more than one bottle or bottle type, these Bottle IDs provide the critical tracking information needed to handle bottles individually. In addition to guaranteeing uniqueness, the Bottle ID can also encode the type of bottle, which is significant to the methods used by the BacT/ALERT® to test the bottle. These unique Bottle IDs are encoded in barcodes on the bottles and are read into the BacT/ALERT® Classic systems using a hand-held reader, or they may be entered by manually typing the Bottle ID using a keyboard. Systems that use the Classic cabinets scan bottles using a scanner attached to the computer running BacT/ALERT® software. Systems that use the BacT/ALERT® 3D cabinets scan the bottles at the Controller Module.

An operator must identify which BacT/ALERT® bottles belong with a specimen by associating the Bottle IDs with the Accession Number of the specimen. Ideally, the LIS serves this function, and is able to include the constituent Bottle IDs in the Universal Test ID when it sends a test order to BacT/LINK®. If the LIS cannot know or send the Bottle IDs in the test order, then an operator can make these associations at the time of loading the bottle(s). The remainder of this section describes methods for an LIS to process BacT/ALERT® Bottle IDs so that an operator does not have to perform these additional duties.

The best method for the LIS to know what Bottle IDs belong to a specimen is for the LIS to generate the Bottle IDs. The primary requirement is that the generated Bottle IDs are unique for at least a year; however, it is preferred that the Bottle IDs remain unique indefinitely. The LIS must also be able to print a label for each bottle. In addition to human-readable identification information, the label must include the barcode that encodes the bottle's unique ID generated by the LIS. This could be the only label ever applied to the bottle since it includes all of the necessary information.

One way to generate IDs guaranteed to be unique is to maintain a counter that is simply bumped by one for each Bottle ID generated (for example, ZA003457, ZN003458, etc.). Another way is to derive the Bottle ID from the Accession Number by adding a prefix or suffix. For example, Accession Number 922190134 could generate Bottle IDs ZA922190134 and ZN922190134, or 922190134A and 922190134B. This method requires that the Accession Numbers are unique. If they are not unique, then some form of date code must be included in the Bottle ID to guarantee its uniqueness.

Bottle ID and Barcode Label Specifications

Bottle IDs generated by the LIS must conform to one of the formats listed in Table A-1 and Table A-2. The preferred Bottle ID formats begin with special character codes that directly indicate the types of bottles. With these types of Bottle IDs, the Universal Test IDs included with the test orders do not need to separately indicate the types of bottles since the Bottle IDs indicate the bottle types. However, the BacT/ALERT® does accept other "generic" ID formats that do not contain information that indicates the type of bottle. If the LIS generates these types of generic Bottle IDs, then the Universal Test IDs must include the bottle types. However, generic Bottle IDs can inconvenience the operator when loading. If the test order for a set of bottles having generic IDs is not sent by the LIS or processed by the BacT/ALERT® before the operator attempts to load them into the instrument, the system software forces the operator to manually enter the bottle types before loading.

Another method the LIS can recognize and relay Bottle IDs to the BacT/ALERT® is through the use of a barcode reader. The operator uses a barcode reader to manually enter Bottle IDs into the LIS. In this case, the operator uses barcode labels provided by bioMérieux especially for use with BacT/ALERT® bottles. These barcodes are provided either on separately applied labels, or directly in the labels already on the bottles. While not as convenient as having the LIS generate the Bottle IDs, this method does concentrate all data entry activities on one system and at one time.

Barcode labels printed by the LIS must be compatible with the BacT/ALERT® barcode wand and scanner as well as the scanner located in the BacT/ALERT® 3D Controller Module. The barcode specifications are:

- Nominal narrow element width: 0.19 mm (0.0075 in.)
- Wavelength: 655 nm (visible light)
- Minimum contrast: 45%

The various Bottle ID and barcode formats accepted by the BacT/ALERT® are listed below:

- **Type Code —** A sequence of up to five characters that appears at the beginning of the Bottle ID and provides the key information that determines the bottle type and the rest of the barcode format.
- **Length** — The total number of characters in the Bottle ID, including the type code. Alphanumeric characters are generally allowed everywhere, although the following limitation applies when using very long Bottle IDs with Classic systems: for formats supporting Bottle IDs longer than 10 characters, there must be at least one pair of digits for each character in excess of 10. For example, ZA9200A21982 is acceptable since it has four distinct pairs of digits, and is only 12 characters long (2 greater than 10). However, ZA922B0C2C1F is not acceptable since it has only one distinct pair of digits, but is 12 characters long.
- **Symbology** — Indicates the type of encoding used in the barcodes. For bottle barcodes printed by the LIS, Code 128 or Code 39 are preferred, although any symbology may be used which can directly encode the necessary characters.
- **Bottle Type —** Indicates the specific type of BacT/ALERT® bottle implied by the type code.

Table A-1 lists the Bottle ID and barcode formats found in labels supplied by bioMérieux for use with BacT/ALERT® systems. This information is intended for those LIS systems that accept entry of these Bottle IDs into the LIS system for relay down to BacT/ALERT®.

Table A-1: Bottle ID and Barcode Label Formats Supplied by bioMérieux

Barcode Prefix	Length	Symbology	Example	Bottle Type
!B	8	Code 128	!B792875	BTA MB
SA	8	Code 128	SA645954	BTA SA
SN	8	Code 128	SN354945	BTA SN
SF	8	Code 128	SF346157	BTA FA
SG	8	Code 128	SG643528	BTA FN
SP	8	Code 128	SP356497	BTA PF
SM	8	Code 128	SM356497	BTA MP
SI	8	Code 128	SI356497	BTA *i* AST
ST	8	Code 128	ST253464	BTA *i* NST
SL	8	Code 128	SL356194	BTA *i* LYM
PA	8	Code 128	PA356546	BTA BPA
PN	8	Code 128	PN348675	BTA BPN
AA	8	Code 128	AA354367	BTA *i* FA
AN	8	Code 128	AN353275	BTA *i* FN
AP	8	Code 128	AP346743	BTA *i* PF
AR	8	Code 128	AR748395	BTA FA+
NR	8	Code 128	NR647623	BTA FN+
PR	8	Code 128	PR689473	BTA PF+
AI	8	Code 128	AI384756	BTA *i* FA+
NI	8	Code 128	NI547263	BTA *i* FN+

Table A-2 lists the other Bottle ID and barcode formats acceptable for use with BacT/ALERT® systems. This information is intended for those LIS systems that print their own barcode labels for use with BacT/ALERT® bottles. No check digits are used in these barcodes.

Table A-2: Bottle ID and Barcode Label Formats Acceptable for Use

Barcode Prefix	Length	Symbology	Example	Bottle Type
0 –9	5–15	Code 128 or 39	922192352A	Unknown (generic)
ZBSA	5–15	Code 128 or 39	ZBSA5498	BTA SA
ZBSN	5–15	Code 128 or 39	ZBSN398763345	BTA SN
ZBPF	5–15	Code 128 or 39	ZBPF28736576	BTA PF

Table A-2: Bottle ID and Barcode Label Formats Acceptable for Use (Continued)

Barcode Prefix	Length	Symbology	Example	Bottle Type
ZBFA	5–15	Code 128 or 39	ZBFA9283744	BTA FA
ZBFN	5–15	Code 128 or 39	ZBFN269388764	BTA FN
ZBIA	5–15	Code 128 or 39	ZBIA12345	BTA i AST
ZBIN	5–15	Code 128 or 39	ZBIN12345	BTA i NST
ZBIL	5–15	Code 128 or 39	ZBIL12345	BTA i LYM
ZBIFA	6-15	Code 128 or 39	ZBIFA12345	BTA i FA
ZBIFN	6-15	Code 128 or 39	ZBIFN12345	BTA i FN
ZBIPF	6-15	Code 128 or 39	ZBIPF12345	BTA i PF
ZBMP	5–15	Code 128 or 39	ZBMP2999383	BTA MP
ZBMB	5–15	Code 128 or 39	ZBMB7928	BTA MB
ZBPA	5–15	Code 128 or 39	ZBPA760476	BTA BPA
ZBPN	5–15	Code 128 or 39	ZBPN487904	BTA BPN
ZBAR	5–15	Code 128 or 39	ZBAR534786	BTA FA+
ZBNR	5–15	Code 128 or 39	ZBNR8674569	BTA FN+
ZBPR	5–15	Code 128 or 39	ZBPR7477834	BTA PF+
ZBAI	5-15	Code 128 or 39	ZBAI7564878	BTA i FA+
ZBNI	5-15	Code 128 or 39	ZBNI8339837	BTA i FN+

B Sample Communications Sessions

Introduction

This section contains examples of communications between an LIS and a BacT/ALERT® system. The communications examples shown in Figure B-1 through Figure B-6 demonstrate the use of CLSI® *LIS2-A Specification for Transferring Information Between Clinical Instruments and Computer Systems; Approved Standard—Vol. 23 No. 8*. These examples show high-level records sent to accomplish a specific function (for example, sending new test results from the BacT/ALERT® to the LIS. Figure B-7 demonstrates the use of CLSI® *LIS1-A Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems; Approved Standard—Vol. 23 No. 7*. This example shows the complete low-level data stream necessary to transfer all of the test orders shown in Figure B-1.

Sample data that is too long to fit on one line is continued on additional indented lines. Special characters are represented as shown in Table B-1.

Table B-1: Special Characters

<stx>	ASCII decimal 2
<etx>	ASCII decimal 3
<eot>	ASCII decimal 4
<enq>	ASCII decimal 5
<ack>	ASCII decimal 6
<lf>	ASCII decimal 10
<cr>	ASCII decimal 13
<nak>	ASCII decimal 21

Figure B-1: Example 1

In this example, the BacT/ALERT® sends a request to the LIS for new test orders. It is preferred that the LIS send test orders whenever necessary, without waiting for, or requiring, the BacT/ALERT® to send a request for new test orders.

```
H|\^&|||BACT/ALERT^A.00|||||||P|1|19921119112423<cr>
Q|1|ALL||||||||||O<cr>
L|1<cr>
```

The LIS responds to the BacT/ALERT® with test orders for two patients.The LIS specifies the Universal Test ID as part of the Order Record. The LIS does not know the Bottle IDs that will be used for this test. The Universal Test ID only sends component 1 through 4.

```
H|\^&|||LIS|||||BACT/ALERT||P|1|19921119112519<cr>

P|1|245-13-3672|||MCELROY^CYNTHIA^ROBERTA||19420713|F
|||||0138^B.DAVIS|||||||||19921118<cr>

C|1||SUSPECTED INFECTION FOLLOWING GUNSHOT<cr>

O|1||923240189|^^^BC|S^STAT|19921119100000|1992111910470
0|||MDB|N|A^AIDS||19921119111500|B^LA|0228^C.MYERS|
||||||||O||ER^EMERGENCY ROOM<cr>
```

Figure B-2: Example 2

The BacT/ALERT® sends a request to the LIS for new test orders. It is preferred that the LIS send test orders whenever necessary, without waiting for, or requiring the BacT/ALERT® to send such a request.

The LIS responds to BacT/ALERT® with test orders for two patients, each having one sample. This example specifies the Universal Test IDs as part of the order record, and uses the repeat delimiter to include the second bottle test request. In this example, the LIS sends the Bottle IDs with the order.

```
H|\^&|||LIS|||||BACT/ALERT||P|1|19921119112519<cr>

P|1|245-13-3672|||MCELROY^CYNTHIA^ROBERTA||19420713|F
|||||0138^B.DAVIS|||||||||19921118<cr>

C|1||SUSPECTED INFECTION FOLLOWING GUNSHOT<cr>

O|1||923240189|^^^BC^BSA^SA023023^5\^^^BC^BSN^SN021883^5|S
^STAT|19921119100000|19921119104700|||MDB|N|A^AIDS||1992
1119111500|B^LA|0228^C. MYERS| ||||||||O||ER^EMERGENCY
ROOM<cr>

P|2|P32767|||CHARLES^BABY BOY||19921111|M|||||0722^R.
FRANK (PEDS)||||||||||19921118<cr>

O|1||923240190|^^^BC^BSN^SN021884^5\^^^BC^BSA^SA003398^5|S
^STAT|
19921119095600|19921119102500|||RRL|N|||19921119110300
|B^RA|1026^M. WEIER|||||||||O||W2^WEST 2ND FLOOR<cr>

C|1||PRIORITY TEST - DO NOT HOLD RESULTS<cr>
C|2||CONTACT DR. WEIER X2667 IMMEDIATELY IF POSITIVE<cr>
L|1|F<cr>
```

Figure B-3: Example 3

The LIS sends to the BacT/ALERT® the same two test orders as in Figure B-2, Example 2, but specifies the Universal Test IDs in separate Result Records following the Order Records.

```
H|\^&|||LIS|||||BACT/ALERT||P|1|19921119112519<cr>

P|1|245-13-
      3672|||MCELROY^CYNTHIA^ROBERTA||19420713|F|||||
      0138^B.DAVIS||||||||||19921118<cr>

C|1||SUSPECTED INFECTION FOLLOWING GUNSHOT<cr>

O|1||923240189||S^STAT|19921119100000|19921119104700|||M
      DB|N|
      A^AIDS||19921119111500|B^LA|0228^C.
      MYERS|||||||||O||
      ER^EMERGENCY ROOM<cr>

R|1|^^^BC^BSA^SA023023^5<cr>

R|2|^^^BC^BSN^SN021883^5<cr>

P|2|P32767|||CHARLES^BABY BOY||19921111|M|||||0722^R.
      FRANK (PEDS)||||||||||19921118<cr>

O|1||923240190||S^STAT|19921119095600|19921119102500|||R
      RL|N|||
      19921119110300|B^RA|1026^M.
      WEIER|||||||||O||W2^WEST 2ND FLOOR<cr>

C|1||PRIORITY TEST - DO NOT HOLD RESULTS<cr>

C|2||CONTACT DR. WEIER X2667 IMMEDIATELY IF POSITIVE<cr>

R|1|^^^BC^BSN^SN021884^5<cr>

R|2|^^^BC^BSA^SA003398^5<cr>

L|1|F<cr>
```

Figure B-4: Example 4

The BacT/ALERT® sends the LIS a request for the demographics of one patient.

```
H|\^&|||BACT/ALERT^A.00|||||||P|1|19921119113405<cr>

Q|1|245-13-3672||||||||||D<cr>

L|1<cr>
```

The LIS responds to the BacT/ALERT® with the requested patient data.

```
H|\^&|||LIS|||||BACT/ALERT||P|1|19921119113448<cr>
P|1|245-13-
      3672|||MCELROY^CYNTHIA^ROBERTA||19420713|F|||||
      0138^B.DAVIS|||||||||19921118<cr>

C|1||SUSPECTED INFECTION FOLLOWING GUNSHOT<cr>

L|1|F<cr>
```

Figure B-5: Example 5

The LIS sends BacT/ALERT® a request for new test results. It is preferred that the BacT/ALERT® send test results whenever necessary, without waiting for, or requiring, the LIS to send such a request.

```
H|\^&|||LIS|||||BACT/ALERT||P|1|19921120171003<cr>

Q|1|ALL||||||||||N<cr>

L|1<cr>
```

The BacT/ALERT® sends the LIS all pending new test results. This example shows that one of the samples ordered earlier has one positive bottle and one still under test.

```
H|\^&|||BACT/ALERT^A.00|||||||P|1|19921120171058<cr>

P|1|P32767<cr>

O|1|923240190|923240190|||||||||||||||||||||I<cr>

R|1|^^^BC^BSN^SN021884|*|||||I|||19921119112749||19921120170323|
      1B11<cr>

R|2|^^^TTD^BSN^ SN021884|29.6|||||P|||19921119112740|
      19921120170323|1B08<cr>

R|3|^^^BC^BSA^SA003398|+|||||P|||19921119112740|19921120170323|
      1B08<cr>

R|4|^^^TTD^BSA^SA003398|29.6|||||P|||19921119112740|
      19921120170323|1B08<cr>

L|1|F<cr>
```

Figure B-6: Example 6

The BacT/ALERT® sends the LIS all pending new test results. The following shows an additional later result for the sample sent in Figure B-4, Example 4, and the final results for the other sample ordered.

```
H|\^&|||BACT/ALERT^A.00|||||||P|1|19921124121344<cr>
P|1|245-13-3672<cr>
O|1|923240189|923240189|||||||||||||||||||||F<cr>
R|1|^^^BC^BSA^SA023023|-|||||F|||19921119112715|
      19921124112715|1B15<cr>
R|2|^^^BC^BSN^SN021883|-|||||F|||19921119112726|
      19921124112726|1B18<cr>
P|2|P32767<cr>
O|1|923240190|923240190|||||||||||||||||||||P<cr>
R|1|^^^BC^BSN^SN021884|-|||||F|||19921119112749|
      19921124112749|1B11<cr>
R|2|^^^BC^BSA^SA003398|+|||||P|||19921119112740|199211201
      70323|
      1B08<cr>
R|3|^^^TTD^BSA^SA003398|29.6|||||P|||19921119112740|
      19921120170323|1B08<cr>
L|1<cr>
```

Figure B-7: Example 7

This example shows all low-level handshaking and protocols necessary for the LIS to transmit the test orders shown in Figure B-1, Example 1, according to *ASTM designation E1381*. Normal lines show data sent by the LIS, as it was received by the BacT/ALERT®. Bolded lines show responses transmitted by BacT/ALERT®. Note that the SUSPECTED INFECTION comment is received with errors, is rejected, and is finally successfully received.

```
<enq>
<ack>
<stx>1H|\^&|||LIS|||||BACT/ALERT||P|1|19921119112
      519<cr>
      <etx>B3<cr><lf>
<ack>
<stx>2P|1|245-13-
      3672|||MCELROY^CYNTHIA^ROBERTA||19420713|F|||||
      0138^B. DAVIS||||||||||19921118<cr><etx>BA<cr><lf>
<ack>
<stx>3C|1||SUSPECTED INFECTION FOLLOWING
      GUNSHOT<cr><etx>B3<cr>
      <lf>
<nak>
<stx>3C|1||SUSPECTED INFECTION FOLLOWING
      GUNSHOT<cr><etx>B3<cr>
      <lf>
<ack>
<stx>4O|1||923240189|^^^BC^BSA^SA023023^5\^^^BC^BSN^SN0218
      83^5|
      S^STAT|19921119100000|19921119104700|||MDB|N|A^AID
      S||
      19921119111500|B^LA|0228^C.
      MYERS|||||||||O||ER^EMERGENCY
      ROOM<cr><etx>8E<cr><lf>
<ack>
<stx>5P|2|P32767|||CHARLES^BABY
      BOY||19921111|M|||||0722^R. FRANK
      (PEDS)||||||||||19921118<cr><etx>2A<cr><lf>
<ack>
<stx>6O|1||923240190|^^^BC^BSN^SN021884^5\^^^BC^BSA^SA0033
      98^5|
      S^STAT|19921119095600|19921119102500|||RRL|N|||
      19921119110300|B^RA|1026^M.
      WEIER|||||||||O||W2^WEST 2ND
      FLOOR<cr><etx>B7<cr><lf>
<ack>
<stx>7C|1||CONTACT DR. WEIER X2667 IMMEDIATELY IF
      POSITIVE<cr>
      <etx>98<cr><lf>
<ack>
<stx>0L|1|F<cr><etx>FC<cr><lf>
<ack>
<eot>
```

Revision History

This section contains a summary of changes made to each released revision of this manual beginning with part number 514777-1EN1.

Release Date	Reference Number	Change Type	Change Summary
2014-03	514777-1EN1	Requirement	Updated the Intended Audience section to make clear that this document is intended for use by trained LIS personnel.
			Added - Added Industry FAN Plus bottles to Table 3-6, LIS2-A Section 6.6.1 — Universal Test ID and added a Warning about sending incorrect bottle type abbreviations.
			Added - Added Industry FAN Plus bottles to Table 3-9, LIS2-A Section 9 — Test Order Record and added a Warning about sending incorrect bottle type abbreviations.
			Added - Added Industry FAN Plus barcode formats to Table A-1, Bottle ID and Barcode Label Formats Supplied by bioMérieux and corrected the example for the BTA PF+ bottle type.
			Added - Added Industry FAN Plus Z barcode formats to Table A-2, Bottle ID and Barcode Label Formats Acceptable for Use.
		Administrative	Corrected - Corrected the title in Table 3-15, LIS2-A Section 15 — Manufacturer Information Record.
			Corrected - Corrected line R|2| in Table B-7, Example 7.