BacT/LINK®

Interfacing Software for bioMérieux’s BacT/ALERT® Microbial Detection Systems

External Specifications

April 2003

1. Introduction

BacT/LINK® is the interfacing software for bioMérieux's BacT/ALERT® line of microbial detection systems. BacT/LINK is offered as an option for the data management software that comes with the BacT/ALERT microbial detection system and for the BacT/ALERT® 3D Controller Module (hereafter referred to as the Controller Module) in the stand-alone SelectLink configuration. bioMérieux currently supports three different data management software products: the original BacT/ALERT text-based software; BacT/VIEW® which uses Microsoft Windows®; and OBSERVA® which uses Microsoft Windows 2000.

BacT/LINK allows the BacT/ALERT system to receive patient, specimen, and blood culture test data from a laboratory information system (LIS), and to transmit blood culture test results back - either manually or automatically. Once installed, BacT/LINK's features are fully integrated into the system software.

These specifications describe the special BacT/LINK functions that control interface activity, as well as the communications protocol employed between systems.

While the four products that use BacT/LINK have different user interfaces and the BacT/ALERT 3D SelectLink system only uses a subset of the available data, there are few significant differences in how they implement this protocol. The protocol and the implementation differences are documented herein. For information regarding the user-interface for accessing the BacT/LINK features of a specific product, please refer to the operator manual for that product.

Section 2, **Overview of the BacT/ALERT microbial detection system**, gives an overview of the BacT/ALERT Classic and BacT/ALERT 3D incubation modules and generally describes how an operator should handle bottles.

Section 3, **Overview of the Interface**, briefly describes the concepts behind BacT/LINK's implementation of the interface, its use of the ASTM standards, and when data is transmitted.

Section 4, **Communications interface**, describes in detail the data format and communications protocol used in the exchange of information with a LIS.

Appendix A, **Bar code formats**, describes how BacT/ALERT uses bottle IDs to identify bottles, and lists the various bar code formats accepted for encoding bottle IDs.

Appendix B, **Sample communications sessions**, lists several examples of data transmissions between systems.

2. The BacT/ALERT system

2.1 Overview of the BacT/ALERT microbial detection system

The BacT/ALERT system is a totally closed, automated system for incubating, rocking, and monitoring culture bottles for microbial growth. There are two models of BacT/ALERT instruments: the upright "Classic" cabinet model and the drawer-style "3D" model.

The Classic system is comprised of one or more cabinets connected to a single IBM compatible PC running either BacT/ALERT text (BTA) or BacT/VIEW (BTV) software. The primary function of BTA or BTV software is to interpret raw data transmitted from the instruments on a continuing basis in order to determine positive and negative samples. This is called the system's "monitoring" mode. In addition, either BTA or BTV software is essential for performing all basic instrument related operations with a Classic instrument, including loading and unloading bottles, performing QC and calibration, and maintaining problem logs. BTA and BTV software additionally perform the data management functions for the Classic system – entering and editing data (including user-defined fields), querying for and viewing data, reporting data (including statistical reports), and LIS interfacing. OBSERVA software may not be used for this system.

The 3D system is comprised of one or more Incubation Modules connected to a Controller Module. The Controller Module performs all of the monitoring and basic instrument related operations for this system regardless of configuration. Data management functions may be performed in either of two ways, however. This first option, the BacT/ALERT 3D Signature configuration, implements a BTV or OBSERVA (but not a BTA) computer for data management functions and the LIS interface. The other option, BacT/ALERT 3D SelectLink configuration, uses the Controller Module for limited data management and implementation of a subset of the BacT/LINK specifications.

2.2 System operation

A single specimen or accession is inoculated into BacT/ALERT culture bottles consistent with the type of organism expected to be recovered. Different bottle types encourage the growth of different types of organisms. The system tracks each bottle individually by way of a mandatory unique bottle ID, which is encoded in a bar code label on the bottle. The bar codes must follow a specific format defined by bioMérieux. In addition to tracking the culture, the ID also indicates the type of bottle, which must be known to insure proper testing of bottles and the correct assignment of an algorithm to process the bottle data. Each specimen may be associated with more than one different bottle ID depending on how many different types of bottles each specimen is inoculated into.

An operator loads bottles into the instrument one at a time with the assistance of the system software. For BacT/ALERT Classic instruments, after each bar code label is scanned, the system indicates a position or cell in the instrument where the operator should load the bottle. The system then watches to verify that the bottle is properly loaded into its cell, after which the operator moves on to the next bottle, etc. For BacT/ALERT 3D instruments, an operator scans a bottle at the Controller Module then sticks it into an Incubation Module cell. A flag within the cell detects where the bottle was loaded and transmits that information to the Controller Module. The operator then moves to the next bottle, etc.

After loading, the system monitors the bottles continuously and without further operator assistance. The BTA, BTV, or Controller Module software will notify the lab when growth in a bottle (a positive) is detected or when a lab-specified number of days have passed without growth being detected (a negative). The lab then uses special functions to identify and unload the positive or negative bottles and to insure that only the right bottles are removed. For Classic instruments, these functions are contained within the BTA or BTV software; for 3D instruments, these function are part of Controller Module software.

The data management software gives the lab considerable flexibility in determining how much associated patient and specimen data are entered for each sample. The minimum is none; that is, the lab can load and test bottles without the system knowing any more than the bottle's ID. In such cases, locally printed results can only reference the bottle ID; the lab must rely on some other patient identification it has applied to the bottle.

Optionally, the lab may enter an accession number that ties together the results from the two bottles used to test a sample. Other information about the accession may also be entered into the BTA, BTV, or OBSERVA software (not the Controller Module), such as date collected, location of collection, etc.

Unlike bottle IDs, labs are allowed to re-use accession numbers; that is, multiple accessions may be given the same accession number if the accession number is more than 3 days old. BTA software and BTV keeps the accessions separate by appending a hidden suffix to the accession number when needed. In cases where an operator makes an ambiguous reference to an accession number, the system presents a list of all accessions having the same number and forces the operator to choose one. The Controller Module does not allow for accession reuse, however accession records remain in memory a limited amount of time. After a count of 1920 bottle records is reached, the oldest bottle records (with associated accession and patient records) begin to be removed from the system and its accession number can be reused.

Each accession may optionally be associated with a patient via that patient's hospital/patient ID. Patient information (name, birthdate, etc.) associated with that hospital ID is maintained in a separate record of the database, but can be entered at the same time as the accession data. Multiple accessions for the same patient need only reference the patient's hospital ID; the patient data itself is entered only once. (NOTE: Patient name is the only other patient information that can be entered into a Controller Module in the SelectLink configuration.

This three-tiered hierarchical record structure is enforced, but each higher level is optional. A bottle cannot be associated directly with a patient -- it must first be associated with an accession and the accession must be associated with the patient. These associations may be made or changed at any time, before or after testing has begun on the bottles themselves. For instance, upon receipt of a set of barcoded bottles, the lab can load them immediately without entering any other data. Later, at the lab's leisure, the other information can be entered. An additional copy of each bar code label can be saved and used during the data entry if bottles have already been loaded.

3. Overview of the interface

Many labs are expected to have a computer system that brings together all test results for a patient and provides uniform test reporting. In such labs, it would be advantageous for the lab computer system to download test orders that include patient and specimen information to the data management software, and for these systems to upload test results to the lab system. This would free lab personnel from having to manually enter completed test results into the lab system, and would allow the systems to perform their own intelligent reporting and tracking of results without lab personnel having to enter any additional information. Thus the need for this interface.

The BacT/LINK interfacing software provides automated and manual methods for transferring patient and accession information from a lab information system (LIS) to the BacT/Alert microbial detection system's data management software (either BTA software, BTV or OBSERVA) or directly to the Controller Module , and for transferring the results of bottle tests from the data management software or Controller Module to an LIS. This is sometimes called a *bi-directional* interface since data can be sent in both directions. The intent of the interface is to eliminate the need for an operator to re-enter specimen data that has been entered at the LIS level, and to reduce or eliminate having an operator enter test results into the LIS.

The communications portion of the BacT/LINK interface complies with two standards issued by the American Society for Testing and Materials (E1381 and E1394) regarding the interfacing of laboratory instrumentation to lab information systems. The standards dictate the format of the data sent between systems and the protocol used by both systems to transfer the data.

To be interfaced, each of bioMerieux's data management products and the Controller Module must include the ability to understand how and when data should be sent and what to do with it when it is received. bioMérieux provides the necessary software, the BacT/LINK option, for the BacT/ALERT system's side of the interface. The lab's LIS vendor provides the proper software for its side of the interface.

Not necessarily all LIS's support all of the capabilities described here. LIS's vary in the degree to which they can automatically transfer data to or receive data through the BacT/LINK interface. They also vary in exactly what data can be passed back and forth. Therefore, the configuration and use of the BacT/LINK interface software is quite flexible. The lab should consult with its LIS vendor to determine which options can be used with BacT/LINK.

BacT/LINK supports the bi-directional transfer of information without operator assistance. With the LIS's cooperation, patient and accession data can be received from the LIS automatically, and bottle test results can be sent to the LIS automatically.

If the LIS is unable to support BacT/LINK’s automated features, the lab can take advantage of several BacT/LINK functions used to "manually" transfer data between systems. These functions are available when using the automated features as well.

BacT/LINK provides no functions for sending modified patient or accession data to the LIS. The only data that BacT/LINK sends to the LIS are bottle test results and their patient and sample identifications.

Once loaded and enabled in the data management software, BacT/LINK becomes part of the BacT/ALERT system. Thus, for the remainder of this document, the term "BacT/ALERT" will mean the BacT/ALERT system's data management software (either BTA software, BTV, OBSERVA, or Controller Module) with the BacT/LINK interface option installed.

3.1 Test orders

Test orders, sent by the LIS to the BacT/ALERT system, describe the characteristics of specimens to be tested and the patients they came from. The transfer of test orders to BacT/ALERT eliminates the need for an operator to perform order entry using BacT/ALERT’s data entry functions.

Each test order consists of numerous fields of data, many of which are native to BacT/ALERT databases, such as sex, birthdate, date and time the specimen was collected, etc. The system stores these data into the appropriate places in its databases when the test order is processed. Even though BacT/ALERT does not directly support many other fields in the test order, such as the patient's room number or ordering physician, it can still accept and store these data in its databases through the use of user-defined fields. The exception is the Controller Module which can only store the Hospital ID, Patient Name, and Accession Number.

Ideally, the LIS also includes with each test order the IDs of the BacT/ALERT culture bottles containing the specimen. The bottle IDs are important for tracking and properly testing individual bottles. Providing them with the test order ties them to an accession and patient automatically. If the LIS does not support this feature, then the lab must perform some minimal data entry in BacT/ALERT to associate the bottles with the proper accessions. (Appendix A covers bottle ID and bar code issues at length.)

New test orders are those which have been created or changed by the LIS without BacT/ALERT yet being informed. Once the LIS sends new test orders and BacT/ALERT acknowledges receipt, they are no longer considered new.

BacT/ALERT distinguishes between receiving test orders and processing them. Despite what type of activity it may be engaged in, it is able to receive test orders from the LIS at any time. However, it must also process the test orders before the data they contain are integrated into the database.

The frequency of LIS message processing depends on the type of BacT/ALERT system. OBSERVA and the Controller Module check frequently for having received test orders (or any other type of data sent by the LIS) which need processing. Due to this constant attention, there is generally little delay in processing test orders with these systems. This is also true for BTA software when in "monitoring" mode (e.g. no one is logged on). BTV checks on a less frequent basis, and there may occasionally be some delays in processing orders.

Outside of monitoring mode, BTA software only processes test orders when the operator chooses one of the "Send" or "Request" functions in the "Interfacing functions" menu. If the operator chooses none of these functions, then the system is delayed processing test orders until the operator logs off and returns to monitoring mode. BTV, OBSERVA, and the Controller Module do not have this restriction, and will process orders in the background during times when the system in not otherwise occupied regardless of whether any user is logged on or off.

Note that the lab is free to load the bottles themselves into the incubation cabinets and begin testing before or after the system processes the test orders.

Both the LIS and BacT/ALERT can initiate the transmission of test orders, as described below.

3.1.1 Lab-initiated transmission of test orders

If possible, it is best for the LIS to send test orders to BacT/ALERT automatically, either when the original test order is issued to the LIS, or when lab personnel log received specimens into the LIS. Alternatively, the LIS may require an operator to initiate transfer of test orders via a function of its own software. In any case, BacT/ALERT is always capable of receiving the test orders at any time.

3.1.2 BacT/ALERT initiated transmission of test orders

If necessary, the lab can set up the BacT/ALERT to periodically request new test orders from the LIS. The time period can be set to whatever interval is desired, typically between one and several hours. Exactly when these automatic requests occur depends on the type of BacT/ALERT software. BTA software issues these automatic requests during monitoring mode, and so they can be delayed during periods when the lab must log on to perform other functions. The lab controls this feature using the "Edit interface configuration" function.   In BTV, the lab controls this feature using the "Schedule macro" function; like any BacT/VIEW macro, it will run only when the operator is logged off. In OBSERVA, the lab controls this feature from the LIS configuration tab. OBSERVA's auto request feature can be enabled/disabled from the LIS configuration tab. The default period of 15 minutes can be modified by bioMérieux customer service. The Controller Module’s auto request feature can be enabled/disabled and the frequency can be configured by bioMérieux customer service.

A BacT/ALERT operator can also manually request test orders by performing any of several special interface functions provided. One such function requests all new test orders. In BTA software and in BTV, such "request" functions make a specific request of the LIS, and then wait for the LIS to respond with the appropriate order information. OBSERVA and the Controller Module are different in that they do not force the user to wait for the response; instead, they allow the user to move on to other things, and receive and process the LIS response in the background. Both BTA software and BTV have other "request" functions that OBSERVA and the Controller Module do not, such as requesting all test orders for one or more patients, and requesting all test orders for one or more accessions.

3.2 Test results

Test results, sent by BacT/ALERT to the LIS, describe the results of testing specimens consisting of one or more bottles. The transfer of test results to the LIS eliminates the need for an operator to enter results manually into the LIS. BacT/ALERT only transmits test results for bottles associated with an accession. Test results are not reported to the LIS for bottles loaded without any accession identification.

A specimen having multiple bottles has separate results for each bottle. Whenever BacT/ALERT reports a result for a specimen, the results of all the bottles involved in the test are reported regardless of whether testing has been completed on any of them. One type of result consists of a simple positive/negative determination. An additional result gives the time to detection: OBSERVA transmits time to detection for loaded bottles regardless of their status, while BTA, BTV, and the Controller Module transmit time to detection only for positive bottles. The test results are sent along with the patient's ID, specimen ID, and bottle ID, which is sufficient for the LIS to identify where the results belong. The system does not include other patient or accession data in the results.

Because BacT/ALERT systems are strictly for screening, they always report positive results as being "preliminary" to the LIS. Positives typically require lab personnel to perform Gram-stains and subcultures to confirm the presence of microorganisms. It is up to the lab system to make intelligent use of BacT/ALERT’s preliminary positive results. They should never be reported as "final" by the lab system until after confirmation by the lab. BacT/ALERT systems do report unloaded negative bottles as "final", however, since they require no further work-up by the lab.

For an accession having multiple bottles, BacT/ALERT does not consider the test to have a new result until there is a significant change *in the accession's status*. This occurs when a) any of the accession's bottles becomes positive, b) all of the accession's bottles complete testing and have positive or negative status, c) a positive bottle is reloaded into an instrument for further testing (i.e., it was false-positive), or, when using OBSERVA the accession's status changes to or from positive or negative as a result of a bottle being added to or removed from it. The rationale is that it is important to inform the LIS as soon as possible when there are changes in the positive status of a bottle, but negatives can wait until all of the involved bottles have completed testing and have been unloaded. The Controller Module can be configured by customer service to consider any combination of four events as a significant change in the accession’s status. The four events are defined as when any bottle in the accession (1) is loaded (2) goes negative (3) goes positive (4) is unloaded.

Therefore, a single specimen's results can possibly be reported more than once by the time its testing is completed. For instance, new results are reported when BacT/ALERT determines one of a specimen's bottles is positive. At that time, one bottle is reported as positive and the other as still under test. New results are again reported when the specimen's other bottle is determined negative a few days later and is unloaded. At that time, one bottle is reported as positive and the other as negative.

BacT/ALERT keeps track of which new test results it has transmitted to the LIS successfully. Once the LIS acknowledges receipt of new test results, BacT/ALERT no longer considers the results new. Also, after 3 days (in OBSERVA this limit is configurable and in the Controller Module this limit is determined by the laboratory workload), BacT/ALERT no longer considers results new. In this case, the only way to subsequently send these results to the LIS is to select and send them manually using the other built-in operator functions.

Both the LIS and BacT/ALERT can initiate the transmission of test results, as described below.

3.2.1 Lab-initiated transmission of test results

For BTA software, BTV, and the Controller Module (but not OBSERVA), one way of having test results transmitted to the LIS is for the LIS to send a message to the BacT/ALERT system requesting these results from BacT/ALERT. The LIS can either issue these requests automatically at convenient times, or may require an LIS operator to select special functions for this purpose in the LIS. In any case, BacT/ALERT is always capable of receiving these requests at any time. However, as with test orders, the processing of these requests can be delayed.

3.2.2 BacT/ALERT initiated transmission of test results

If possible, it is best for BacT/ALERT to send new test results to the LIS automatically, as those results are determined. This requires the LIS to be attentive at all times. If the LIS does not acknowledge receipt of the test results, BacT/ALERT tries to send them again later, along with any other new results that were determined in the interim. BTA software tries again after one hour; BTV, OBSERVA, and the Controller

Module tries again at the next regularly scheduled time for uploading new results. So, as long as the LIS is attentive for at least some significant periods throughout the day, BacT/ALERT will eventually be able to get through and effect the transfer.

If the LIS cannot receive test results without help from an operator, then the lab can disable the automatic transmission feature using BTA’s "Edit interface configuration" function, BTV’s "Schedule macro" function, OBSERVA's "LIS Settings" tab, or customer service can disable the transmission feature in the Controller Module.

An operator can also "manually" have BacT/ALERT send test results to the LIS by using the special functions provided for that purpose. One such function sends all new test results. Another sends all test results for one or more accessions, except in the Controller Module. Another function (available in BTA and BTV only) sends all test results for one or more patients. A last function, available only in the Controller Module sends bottles and all associated accessions and patients as bottles are loaded.

4. Communications interface

This section describes the communications protocol employed by BacT/ALERT in receiving data from and transmitting data to a LIS. This protocol is logically broken into two sections, one dealing with the high-level content and structure of the messages sent between systems, and another dealing with the low-level communications methods used to send the messages.

4.1 High-level message content and structure protocol

BacT/ALERT’s high-level protocol is based upon the ASTM's standard E1394-91, "Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems", published June 1991. This standard provides for transmission of test requests (including patient demographics) from the host to the instrument, for transmission of test results back to the host, and for inquiry of data by either system. Almost all of the features and data are left as optional by the standard. The standard also provides for "manufacturer-defined" fields that can be used to fulfill exceptional requirements.

BacT/ALERT implements much of the standard as described, although several features and many fields are not applicable. The following table lists the clarifications or additional details which augment various sections of the ASTM documentation. Sample sessions can be found in Appendix B.

Notes:

Except where noted, "BacT/ALERT" refers to a BacT/ALERT microbial detection system running either BacT/ALERT text (BTA), BacT/VIEW (BTV), OBSERVA, or BacT/ALERT 3D Controller Module (Controller Module) data management software with the BacT/LINK interface option installed.

Except where noted, all functions are implemented and behave as described by the ASTM standard.

Except where noted, all fields are optional and have the meanings described by the ASTM standard.

Where examples involving delimiters are shown, the example delimiters from the standard are shown.

All references to "specimen" in the ASTM document correspond to BacT/ALERT’s use of "accession". All references to "test" in the ASTM document correspond to the BacT/ALERT’s 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 BacT/ALERT’s behavior when uploading this data to the lab system. "D:" refers to BacT/ALERT’s behavior when downloading this data from the lab system.

Many ASTM fields are not directly supported by BacT/ALERT's databases, such as physician, diagnosis, etc.. BacT/ALERT includes features for mapping such data to user defined fields.

BacT/ALERT generally stores and displays the data in the same form as it was received in with a few exceptions, as follows:

- BacT/ALERT converts Dates and times into the appropriate format for storage.
- Text conversions:

  BTA or BTV:
  All data is converted to upper case.

  OBSERVA:
  Data is used as is.

  Controller Module:
  Data is used as is, except certain fields - Patient Name, Hospital ID, and Accession Number - can be configured by customer service to be converted to upper case.
- Support for "coded" fields (e.g. fields that support abbreviations):

  BTA or BTV:
  If BacT/ALERT's field has user-defined codes and the first component of the LIS field matches one of the codes, then only the code is stored, and other components are ignored. As with other coded fields, the expanded form of the field's value is shown on-screen and in reports.

  If BacT/ALERT's field has user-defined codes and the first component of the LIS' field does not match one of the codes, then all components are combined, separated by spaces, and stored with a leading "!" to force storage in BacT/ALERT's database.

  If BacT/ALERT's field does not have user-defined codes, then all components are combined and separated by spaces.

  OBSERVA or the Controller Module:
  There is no support for coded fields. Except where noted, if the LIS sends multiple components for a field, OBSERVA and the Controller Module treat the entire LIS field contents as a single value.

- Support for multi-valued fields:

  BTA or BTV:
  If BacT/ALERT's field is designed to hold a single value, but the LIS' field has multiple values, then all values are combined and separated by commas before being stored.

  If BacT/ALERT's field is designed for multiple values (as are patient field 5 and accession field 5), then multiple values in the LIS' field are stored separately.

  OBSERVA or Controller Module:
  There are no multi-valued fields in OBSERVA and the Controller Module . Except where noted, if the LIS sends multiple components for a field, OBSERVA and the Controller Module treat the entire LIS field contents as a single value.

ASTM Section	Description
5.2.1	BacT/ALERT stores every complete record received. It does not wait for a decremental change in the hierarchical level to trigger storage.
5.2.2	BacT/ALERT's actions vary upon encountering transmission line failure. If the LIS initiated the transfer, it is up to the LIS to try again later. If BacT/ALERT automatically initiated the transfer without operator assistance, then it automatically tries again later. For BTA software and BTV only, if an operator initiated the transfer, then BacT/ALERT asks the operator whether or not to retry. When the BacT/ALERT retries, it sends the entire message again. No attempt is made to exclude records that it could have presumed saved by the LIS, according to the ASTM.
6.1.1 6.1.2	Characters 0 through 31 are prohibited and are stripped from received messages. 32-127 are treated as standard ASCII characters. 128-249 are treated as extended characters, and are typically only significant in foreign language (e.g., non-US) sites. Their exact meaning is character set and software dependent. *BTA*: 128-249 represent characters specified in the IBM-PC extended character set, 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 lower case characters are converted to upper case. *BTV*: By default, 128-249 represent characters specified in the IBM-PC extended character set, especially foreign characters. This can be reconfigured to use the Windows Western character set by setting the SP*IF_CONFIG<49> record to "WINDOWS". Characters 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 lower case characters are converted to upper case. *OBSERVA:* 128-249 represent characters specified in the Windows Western character set, 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. *Controller Module:* 128-249 represent characters specified in the Codepage 850 (IBM-PC: European) character set. 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.
6.2 6.3	BTA, BTV, and the Controller Module can handle records of up to 32768 bytes. OBSERVA's maximum record length is bound only by available memory. Fields within each record can be of any length that does not cause the record to exceed its maximum length.

ASTM Section	Description
6.4	U: *BTA, BTV, or Controller Module*: BacT/ALERT uses the delimiters specified by the lab system in its most recent transmission. That is, BacT/ALERT makes every attempt to respond to the lab system using the same delimiters the lab system prefers. By default, the example delimiters shown in the ASTM standard are used. *OBSERVA*: BacT/ALERT always uses the example delimiters shown in the ASTM standard for uploads.
6.4.1	If any delimiters are missing, repeated, or alphanumeric, then the entire message is ignored.
6.4.6.1	U: The following escape sequences are never sent: &H& &N& &Xhhhh& &Zcccc& D: The following escape sequences are stripped from received messages and ignored: &H& &N& &Zcccc& *BTA or BTV* ASCII characters 0 through 31 and 250 through 255 which result from use of the &Xcccc& escape sequence are prohibited and stripped from received messages. *OBSERVA*: ASCII characters which result from use of the &Xcccc& escape sequences are allowed. *Controller Module:* Escape delimiter supports the following special escape sequences - &S& (imbedded field delimiter), &R& (imbedded repeat field delimiter), &E& (imbedded escape delimiter), &Xhhhh& (hexadecimal data).
6.6.2.1	U: No time zones are included. D: Time zones are ignored.
6.6.6	*BTA or BTV*: BacT/ALERT accepts codes for many fields besides provider and user, as suggested by the ASTM. Fields that accept codes are stated as such below. For all such fields, if a code is specified it must be the first component. If the first component matches a code in BacT/ALERT's list of accepted codes for that field (many of which are user-defined), then the code is stored and any subsequent components are ignored. If the first component does not match any of BacT/ALERT's codes for the field, then the BacT/ALERT combines all components, separates them by spaces, and stores them with a leading "!" to force storage in its database. *OBSERVA or Controller Module*: There is no support for coded fields. Except where noted, if the LIS sends multiple components for a field , OBSERVA and the Controller Module treat them as a single value.
7.1	U: Many message header fields are null. Only non-null fields are described further below. D: Many message header fields are ignored. Only the fields with further description below are not ignored.
7.1.1 7.1.2	As described by ASTM.

ASTM Section	Description
7.1.5	U: "BACT/ALERT^V.##" V.## will vary according to the current version number of the BacT/LINK system software. It is presently A.00 for BTA, BTV, OBSERVA, and the Controller Module.
7.1.10	D: Must be "BACT/ALERT" or else the entire message is ignored.
7.1.12	U: Always "P". D: "P" or null - message is processed normally. Other codes - this entire message is ignored.
7.1.13	U: Always "1".
7.1.14	As described by ASTM.
8.1	U: Most patient fields are null. Only the fields with further mention below are non-null. BacT/LINK does not send patient information back to the lab system. D: Only a few of the patient fields are understood and accepted by BacT/ALERT as "native" data. They are described individually in subsequent sections. Additionally, a lab can associate other "non-native" fields with user-defined fields for patients. In BTA and BTV only, data may be expressed in coded form as described in 6.6.6, except for fields expressing dates, times, telephone numbers, or addresses. The ASTM patient fields which can be used for this purpose are: 8.1.4 LAB ASSIGNED PATIENT ID 8.1.5 PATIENT ID NO. 3 8.1.7 MOTHER'S MAIDEN NAME 8.1.10 PATIENT RACE-ETHNIC ORIGIN 8.1.11 PATIENT ADDRESS 8.1.13 PATIENT TELEPHONE NUMBER 8.1.14 ATTENDING PHYSICIAN ID 8.1.15 SPECIAL FIELD 1 8.1.16 SPECIAL FIELD 2 8.1.17 PATIENT HEIGHT 8.1.18 PATIENT WEIGHT 8.1.19 PATIENT'S DIAGNOSIS 8.1.20 PATIENT ACTIVE MEDICATIONS 8.1.21 PATIENT'S DIET 8.1.22 PRACTICE FIELD NO. 1 8.1.23 PRACTICE FIELD NO. 2 8.1.24 ADMISSION DATE 8.1.24 DISCHARGE DATE 8.1.25 ADMISSION STATUS 8.1.26 LOCATION 8.1.27 NATURE OF ALT DIAG CODE 8.1.28 ALT DIAG CODE AND CLASS 8.1.29 PATIENT RELIGION 8.1.30 MARITAL STATUS 8.1.31 ISOLATION STATUS 8.1.32 LANGUAGE 8.1.33 HOSPITAL SERVICE 8.1.34 HOSPITAL INSTITUTION 8.1.35 DOSAGE CATEGORY
8.1.1 8.1.2	As described by ASTM.

ASTM Section	Description
8.1.3	U: Hospital ID. D: Hospital ID. Optional. If absent, then none of the patient data in the patient record is stored. However, any test orders included in this patient's hierarchy are accepted and stored, albeit without any identifying patient info. In BTA, BTV, and Controller Module, the following special characters are prohibited and stripped from the ID: @ * " \ '
8.1.6	D: *BTA or BTV*: Accepted as described by ASTM, but only the last name is kept separate. The additional components are combined in the order given and separated by spaces. BacT/ALERT maintains the patient name in only two parts: the last name and everything else. *OBSERVA*: Accepted as described by ASTM, but by default only the first and last name components are processed. The additional components can be assigned to user-defined fields. *Controller Module:* First component goes in the last name field and the combination of the remaining components, as space allows, goes into the other name field. Customer service may configure these fields to be translated to upper-case.
8.1.8	D: *BTA, BTV, or OBSERVA:* Birthdate. *Controller Module:* Unused
8.1.9	D: *BTA, BTV, or OBSERVA:* Sex. *Controller Module:* Unused
8.1.26	D: *BTA or BTV*: Used as the default specimen location, if no location is explicitly given by 9.4.28. Data can be expressed in coded form as described in 6.6.6. *OBSERVA*: Unused. Can be assigned to any user-defined field. If assigned, field contents are used as is -- OBSERVA does not support coded fields. *Controller Module:* Unused
9.4	U: Most test order fields are null. Only the fields with further mention below are non-null. BacT/ALERT does not send test order information back to the lab system. D: Only a few of the test order fields are understood and accepted by BacT/ALERT as "native" data. They are described individually in subsequent sections. Additionally, a lab can associate other "non-native" fields with user-defined fields for accessions (up to 5 user-defined fields for BTA and BTV; any number of fields in OBSERVA and no user-defined fields in the Controller Module). In BTA and BTV, data may be expressed in coded form as described in 6.6.6, except for fields expressing dates, times, telephone numbers, or addresses.

ASTM Section	Description
9.4 (cont'd)	The ASTM test order fields which can be used for this purpose are: 9.4.6 PRIORITY 9.4.7 ORDERED DATE AND TIME 9.4.9 COLLECTION END TIME 9.4.10 COLLECTION VOLUME 9.4.13 DANGER CODE 9.4.14 RELEVANT CLINICAL INFO 9.4.16.2 SPECIMEN SOURCE 9.4.17 ORDERING PHYSICIAN 9.4.18 PHYSICIAN'S TELEPHONE # 9.4.19 USER FIELD NO. 1 9.4.20 USER FIELD NO. 2 9.4.21 LABORATORY FIELD NO. 1 9.4.22 LABORATORY FIELD NO. 2 9.4.29 NOSOCOMIAL INFECTION FLAG 9.4.30 SPECIMEN SERVICE 9.4.31 SPECIMEN INSTITUTION
9.4.1 9.4.2	As described by ASTM.
9.4.3	U: *BTA, BTV, or Controller Module*: Lab-assigned accession number. *OBSERVA*: Accession number. By default accession number is mapped to this field, but can be remapped to 9.4.4; in that case, accession number will be sent in 9.4.4 instead. D: *BTA, or BTV*: Lab-assigned accession number. Only the first component is significant. Other components are ignored. When the action code (9.4.12) specifies creation of a new test order but an accession less than 3 days old having this number is already in BacT/ALERT's database, BacT/ALERT appends a hidden unique suffix (beginning with *) to this number to insure uniqueness. This is done since re-use of these accession numbers is allowed. When test results are sent back to the lab system, this alternative accession number is specified in 9.4.4. When the action code implies an action to be taken on an existing test order, then the most recent accession having this number is used; if no accession exists with this number, a new accession is created. If the lab system never repeats accession numbers, then 9.4.4 should be used to specify the accession number instead of this field since it results in faster access. If 9.4.4 is present, this field is ignored. Either this field or 9.4.4 is required. If both are absent, then the entire hierarchy of records which follows for this test order is ignored. The following special characters are prohibited and stripped from the number: @ " \ '

ASTM Section	Description
9.4.3 (cont'd)	*OBSERVA*: Accession number. By default, accession number is mapped to this field, but can be remapped to 9.4.4; in that case, OBSERVA looks for accession number in that field instead. Components are not recognized; field contents are used as is. The rule for reusing accession numbers (the "reuse" rule) is configurable. By default, an accession number is unique (e.g. cannot be reused for a new accession) for up to three days. When the action code (9.4.12) specifies the creation of a new test order but an accession having this number is already in OBSERVA's database, the reuse rule determines whether the existing accession is used or a new accession with that number is created. When the action code implies an action to be taken on an existing test order, then the most recent accession having this number is used; if no accession exists with this number, a new accession is created. Whether mapped to 9.4.3 or 9.4.4, accession number is required. If absent, then the entire hierarchy of records which follows for this test order is ignored. *Controller Module:* Lab-assigned accession number. Only the first component is significant. Other components are ignored. If this field is null, the Controller Module uses the next field (9.4.4) as the accession number and it is assumed to be unique. Internal to the Controller Module, a suffix is appended to the lab-assigned accession number to ensure it is a unique accession number. When the action code is "add", the most recent version of the accession/suffix is used. For other action codes, a new accession/suffix is created if the specified lifetime of the newest version of that number has expired. Otherwise the most recent accession/suffix is used. The lifetime for an accession number can be configured by customer service.
9.4.4	U: *BTA, BTV, or Controller Module*: Alternative accession number. This is the same as the lab-assigned accession number (9.4.3), but may be appended with an asterisk (*) and a qualifying suffix (e.g. ABC3859*1234) if it is not unique in the BacT/ALERT database. *OBSERVA*: Not sent by default, but can be remapped so that accession number is sent in this field rather than 9.4.3. D: *BTA or BTV*: Alternative accession number. BacT/ALERT assumes that this accession number will never be used again, and therefore is unambiguous. This field is preferred over 9.4.3 for specifying the accession number. Either this field or 9.4.3 is required. If both are absent, then the entire hierarchy of records which follows for this test order is ignored. The following special characters are prohibited and are stripped from the accession number: @ " \ ' *OBSERVA*: See 9.4.3.

ASTM Section	Description
9.4.4 (cont'd)	*Controller Module:* Alternative accession number. The Controller Module assumes that this accession number will never be used again (for a different accession), and therefore is unambiguous. This field is preferred over 9.4.3 for specifying the accession number for systems generating unique accession numbers. Field 9.4.3 must be null. Either this field or 9.4.3 is required. If both are absent, then the entire hierarchy of records which follows for this test order is ignored.
9.4.5	Universal test ID. U: Always null. Uploaded results are always sent in result records. D: As described in 10.1.3 below. Providing the universal test ID in this record obviates the need to send result records with the order. This field may be multi-valued to specify the test IDs for more than 1 bottle at a time.
9.4.8	D: Date and time collected. *BTA or BTV*: If absent and the action code (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 the action code (9.4.12) specifies a new test order, the value used depends on how the data field is configured; by default, OBSERVA uses the current date and time. *Controller Module:* Unused
9.4.11	D: *BTA, BTV, or OBSERVA:* Collector ID. *Controller Module:* Unused
9.4.12	D: "P","Q","N", or null - Creates a new accession having the number specified by 9.4.3 or 9.4.4., or updates an existing accession, depending on the rule for reusing accession numbers (see 9.4.3). "A","X" - Adds these tests or other data to the accession specified, or creates a new accession if it doesn't already exist. "C" - Deletes the accession and its bottles. Other codes - Test order is ignored.
9.4.15	D: *BTA, BTV, or OBSERVA:* Date and time received. *Controller Module:* Unused

ASTM Section	Description
9.4.16.1	BacT/ALERT may refer to specimen type as the source, but has the same meaning (blood, etc.) D: Source. *BTA or BTV* Data can be expressed in coded form as described in 6.6.6, although there cannot be a second component giving the code's description. *OBSERVA*: Field contents are used as is. OBSERVA does not support coded fields. *Controller Module:* Unused
9.4.23	U: *BTA, BTV, or OBSERVA:* The most recent date and time when BacT/ALERT has considered this accession's tests to have a "new" result. *Controller Module:* Unused
9.4.26	U: "F" - All bottles are negative and have been unloaded. "P" - At least one bottle is positive. All positive results are regarded as preliminary by BacT/ALERT. "I" - At least one bottle is still in an instrument or is untested. "Y","Z" - As described by ASTM. Not used by the Controller Module. Other codes - Never sent.
9.4.28	D: Location of collection. *BTA or BTV*: If null, then the patient location (8.1.26) is used. Only the first component is stored. Data can be expressed in coded form as described in 6.6.6. *OBSERVA*: Field contents are used as is. OBSERVA does not support coded fields. *Controller Module:* Unused
10.1	U: Most result fields are null. Only the fields with further mention below are non-null. D: Only a few result fields are understood and accepted by BacT/ALERT as "native" data. They are described individually in subsequent sections. In OBSERVA, a lab can associate other "non-native" fields with user-defined fields for bottles. The ASTM test result fields which can be used for this purpose are: 10.1.1 OPERATOR OF INSTRUMENT 10.1.2 OPERATOR VERIFIER 10.1.5 DATA OR MEASUREMENT UNITS 10.1.6 REFERENCE RANGE 10.1.7 ABNORMAL FLAGS 10.1.8 NATURE OF ABNORMALITY 10.1.10 DATE OF NORMATIVE CHANGE 10.1.11 OPERATOR Result records downloaded with a test order indicate BacT/ALERT bottle IDs that are part of that order.

ASTM Section	Description
10.1.1 10.1.2	*BTA, BTV, or the Controller Module:* As described by ASTM. *OBSERVA:* Can be mapped to a user-defined bottle field.
10.1.3	Universal test ID. U: This test ID indicates the type of result provided in 10.1.4 and identifies which bottle had this result. Components 1-3 - Null. Component 4 - Test ID. This indicates the type of result supplied in 10.1.4. "BC" - This result record gives a standard pos/neg blood culture result. "TTD" - This result record gives the time to detection. BacT/ALERT text and BacT/VIEW transmit time to detection records for positives only; OBSERVA transmits time to detection records for any bottle as long as it has a date loaded and a date determined. Component 5 - Bottle type, as follows: "U" - Unknown "BSV" - BTA SV "BSA" - BTA SA "BSN" - BTA SN "BPF" - BTA PF "BFA" - BTA FA "BFN" - BTA FN "BLYM" - BTA LYM "BMP" - BTA MP "BMB" - BTA MB" "BIA" - BTA iAST "BIN" - BTA iNST "BIL" - BTA iLYM Other new types will appear in the future. Component 6 - Bottle ID. See Appendix A for a complete list of the bottle ID formats possible. D: This field provides additional test details regarding individual bottles. It also indicates the type of result provided in 10.1.4, if any, and identifies which bottle had this result. Components 1-3 - Ignored. Component 4 - Test ID. This indicates the type of result supplied in 10.1.4. *Controller Module:* Test ID component is ignored. All tests are assumed to be "BC." "BC" or null - Specifies a standard blood culture test. If a result is given in 10.1.4, it is assumed to be a blood culture result. "ID" - *BTA or BTV* Specifies an organism identification test. BacT/ALERT does not perform this test, but the results of a test performed elsewhere may be specified in 10.1.4 for storage in its database. *OBSERVA*: This result record is ignored.

ASTM Section	Description
10.1.3 cont'd	"SM" - *BTA or BTV* Specifies an organism smear test. BacT/ALERT does not perform this test, but the results of a test performed elsewhere may be specified in 10.1.4 for storage in its database. *OBSERVA*: This result record is ignored. Other values - This result record is ignored. Component 5 - Bottle type, as listed above. If null, then the type defaults according to special characters found in the bottle ID. See Appendix A for a list of the default bottle types. Component 6 - Bottle ID. See Appendix A for a complete list of the bottle ID formats accepted. *BTA or BTV*: If null and the "BC" test ID was given, then this result record is ignored. If this field is null and either the "ID" or "SM" test ID was given, then the first positive blood culture bottle, if any, associated with this test order is assigned the results in 10.1.4. *OBSERVA or Controller Module*: If null, then this result record is ignored. Component 7 - Maximum number of days to test. May be fractional. If null, then the BacT/ALERT system default is used. Components 8-10 - Optional lab-defined bottle data fields. *BTA or BTV*: Stored in the bottle's first, second and third user-defined fields respectively *OBSERVA*: Can be stored in any user-defined bottle fields. *Controller Module:* Fields ignored.
10.1.4	Bottle's result. The nature of the result depends on the test ID provided in 10.1.3, as follows: For test ID = "BC", the result is the blood culture bottle status, as follows: "+" - positive. The bottle may or may not still be loaded in the instrument. "–" - negative. The bottle has reached its maximum test time without going positive. It may or may not still be loaded in the instrument. "*" - negative to date. The bottle is still under test. Null - The bottle has not yet been loaded for testing. U: Tested status of the bottle. D: *BTA, BTV, or OBSERVA:* Ignored. Controller Module: “+” – positive “–” – Negative “*” – negative to date

ASTM Section	Description
10.1.4 (cont’d)	For test ID = "TTD", the result is the time to detection, in hours and tenths, e.g., "18.3". U: Time to detection. D: Not applicable. The result record is ignored. For test ID = "ID", the result is an organism identification. U: Not applicable. ID result is never sent. D: Organism ID. *BTA or BTV*: Data can be expressed in coded form as described in 6.6.6. Multiple results may be specified through the use of repeat delimiters. *OBSERVA or Controller Module*: Not applicable. OBSERVA and the Controller Module do not support ID result records. For test ID = "SM", the result is an organism smear. U: Not applicable. SM result is never sent. D: Organism smear. *BacT/Alert text or BacT/VIEW*: Data can be expressed in coded form as described in 6.6.6. Multiple results may be specified through the use of repeat delimiters. *OBSERVA or Controller Module*: Not applicable. OBSERVA and the Controller Module do not support smear result records.
10.1.9	U: "F" - This is a final status. BacT/ALERT only indicates a final status for negatives which have been unloaded and therefore will not change status further. "P" - This is a preliminary status. This can occur when the bottle is negative (has completed its test period without becoming positive), but is still loaded and therefore could still become positive. This also occurs when the bottle is positive. Positive results are always regarded as "preliminary" since they require verification through other procedures not monitored by the BacT/ALERT systems. "I" - Bottle is negative to date, i.e., still under test. Null - Bottle has not been tested yet. Other codes - Never sent. D: *BacT/Alert text, BacT/VIEW, or OBSERVA*: "N","C","P","F","S","R","V", or null – Bottle is modified or a new bottle is set up, if necessary. Other codes - This result record is ignored. *Controller Module*: "F","P", or "I" – Bottle is modified or a new bottle is set up, if necessary. Other codes - This result record is ignored.
10.1.12	U: The date and time the bottle was first loaded into an instrument. Null if the bottle has never been loaded.
10.1.13	U: The date and time status determined of the bottle positive or negative. Null if the bottle has never been loaded.
10.1.14	U: The instrument cell ID where the bottle was tested. A cell ID consists of an instrument number (up to two digits), a block letter (A-K, excluding I), and a two-digit cell number (01-24), e.g., 1A01, 23J22. Null if the bottle has never been loaded.

ASTM Section	Description
11.1	U: Comment records are never sent. D: *BTA, BTV, or OBSERVA:* Comments are accepted for all record types. *Controller Module:* Comment records are not supported.
11.1.1 11.1.2	As described by ASTM.
11.1.3	U: N/A D: Comment source: *BTA or BTV*: Ignored. *OBSERVA*: Unused; can be mapped to a user-defined field. *Controller Module:* *Comment records are not supported.*
11.1.4	U: N/A D: Comment text. *BTA or BTV*: Can be expressed in coded form as described in 6.6.6. *OBSERVA*: Field contents are used as is. OBSERVA does not support coded fields. *Controller Module:* Unused
11.1.5	U: N/A D: Comment type: *BTA or BTV:* Ignored. *OBSERVA:* Unused; can be mapped to a user-defined field. *Controller Module:* Unused
12.1	*BTA, BTV, or Controller Module:* As described by ASTM. *OBSERVA:* OBSERVA ignores query records sent by the LIS.
12.1.1 12.1.2	As described by ASTM.

ASTM Section	Description
12.1.3.1	*BTA or BTV* 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. (See 9.4.3 and 9.4.4 for a description of the distinctions between lab-assigned and alternative accession numbers.) U: BacT/ALERT never specifies the hospital ID and accession number, both components 2 and 3 are given, if known. D: 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. *Controller Module:* If both components are specified, the only results returned are those belonging to both specifications. If only the Hospital ID is specified, all results associated with the patient are returned. If only the Accession is specified, only results belonging to the accession are returned. *OBSERVA:* Not applicable.
12.1.3.2	U: "ALL" is used to request new test orders from the lab system. D: *BTA, BTV, or Controller Module:* "ALL" is assumed to request just new results. *OBSERVA:* Not applicable.
12.1.4	U: Always null. BacT/ALERT never requests a range of IDs. D: *BTA or BTV:* As described by ASTM. BacT/ALERT's search for a range of IDs only works when the IDs are either strictly numeric, or have the same number of characters. *OBSERVA:* Not applicable. *Controller Module:* Ignores field, requests for a range of ID's is not supported.
12.1.5	U: Null. D: *BTA, BTV, or Controller Module:* Ignored. BacT/ALERT treats all requests as though "ALL" was specified in this field. *OBSERVA:* Not applicable.
12.1.6	U: BacT/ALERT never requests data based on these dates/times. D: Ignored.
12.1.7 12.1.8	U: BacT/ALERT never requests data based on these dates/times. D: Ignored.
12.1.9 through 12.1.12	U: Null. D: Ignored.

ASTM Section	Description
12.1.13	<u>*BTA or BTV:*</u> U: "A" - Aborts the request. "O","D" - As described by ASTM. Other codes - Never sent. D: "N" - Requests all results which meet the selection criteria and which have changed since the last transmission of the results. "A" - As described by ASTM. Null or other codes - Requests 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 lab system returns the current status for all selected tests, whether or not those tests have been completed. <u>*OBSERVA:*</u> Not applicable <u>*Controller Module:*</u> U: "O" – Requests all new test orders. Other codes - Never sent. D: "N" - Requests all results which meet the selection criteria and which have changed since the last transmission of the results. "A" - As described by ASTM. Null or other codes - Requests all results that meet the selection criteria.
13.	All fields are as described by ASTM. <u>*Controller Module:*</u> Not used.
14.	U: Scientific records are never sent. D: Ignored.
15.	U: Manufacturer records are never sent. D: Ignored.

Low-level communications protocol

BacT/ALERT’s low-level communications protocol is based upon the ASTM's standard E1381-91, "Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems", published May 1991. This standard includes provisions for the electrical connections, framing of messages, contention, detection of errors, and retransmission. Few aspects of the protocol are optional or variable.

This standard, while at first appearing to be quite rigorous, does have some ambiguity in its terminology, especially in what constitutes a message and how it relates to the high-level protocol's use of the terms message and record. BacT/ALERT attempts to implement every feature of the standard as described, but must make certain assumptions about this terminology. BacT/ALERT does build-in some flexibility to accommodate host systems that make different assumptions. The following table lists the clarifications or additional details which augment various sections of the ASTM documentation. Sample sessions can be found in Appendix B.

Notes:

Except where noted, the protocol is implemented as described by the ASTM standard.

ASTM Section	**Description**
3.3.2	A message, as defined here, seems to agree with the usage of message in the high-level standard, ASTM E1394. That is, a single message consists of all of the high-level records sent at one time, starting with the header record and ending with the message termination record. Later in this standard, however, the use of message appears to relate to individual high-level records. This ambiguity requires some additional explanation in the sections that follow.
5.2.2.5	BacT/ALERT supports user-selectable communications parameters. The number of data bits may be 7 or 8. Parity may be even, odd, mark, space, or none. The number of stop bits may be 1 or 2. Defaults are as specified by ASTM. For messaging, BTA and BTV use the 8-bit international character set standard in IBM-compatible PCs. BacT/VIEW can be reconfigured to use the Windows Western character set. OBSERVA and the Controller Module uses the Windows Western character set exclusively.
5.2.3	BTA supports user-selectable baud rates of 300, 1200, and 2400. BTV and OBSERVA support baud rates up to 9600.
6.2.6	Upon receiving NAK, BacT/ALERT waits the minimum 10 seconds before trying again.
6.2.7	BacT/ALERT sends <NAK> when its hard disk is too full to accept more data.
6.2.7.1(b)	BacT/ALERT waits the minimum 1 second.
6.3	The use of messages here is interpreted as corresponding to high-level records. The alternative, that multiple entire messages can be sent during one session, is not necessary. BacT/ALERT never transmits more than one message during a session. It does, however, accept multiple messages input during an input session.
6.3.1	Assuming the interpretation of messages in 6.3, this section prescribes that each high-level record begins in a new frame, and that each has its own end frame. This is how BacT/ALERT breaks up and transmits records. For input of a message, however, BacT/ALERT does accept the alternative interpretation, i.e., a single large message may be broken into a series of frames, ending with a single end frame. In such a case, most records begin in the same frame as the previous record.
6.3.5.2	Upon receipt of EOT, BacT/ALERT halts transmission of further frames. The last record sent may be incomplete.
6.5.1	BacT/ALERT also sends <NAK> if its hard disk becomes too full to accept more data. This effectively ends the session since the host will retransmit the maximum number of times and then terminate.
6.5.2.4	BacT/ALERT discards only the last incomplete record. This is in conformance with E1394's minimum requirement to store data at certain intervals. To interpret the use of message here as meaning the entire set of records would be to violate that E1394 requirement.

Appendix A: Bar code formats

This section contains specifications for the bar code labels used with the BacT/ALERT bottles. It provides the information necessary for a LIS to accept entry of bottle IDs, or to print its own bar code 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 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 be significant to the methods used by BacT/ALERT to test the bottle. These unique bottle IDs are encoded in bar codes on the bottles and are read into the BacT/ALERT Classic systems using a hand-held reader. Note that systems that use the "Classic" cabinets scan bottles using a scanner attached to the computer running BacT/ALERT software; systems that use the BTA 3D cabinets scan the bottles at the controller module.

Somewhere, an operator must identify which BacT/ALERT bottles belong with a specimen by associating the bottles' IDs with the specimen's accession number. 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 must use special functions of the BacT/ALERT system software to make these associations. The remainder of this section describes methods for a LIS to deal with BacT/ALERT's bottle IDs so that an operator does not have to perform these additional duties.

The most convenient way for the LIS to know what bottle IDs belong to a specimen is to generate them itself. The primary requirement is that the generated bottle IDs be unique, preferably for all time, but practically for at least a year. 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 bar code that encodes the bottle's unique ID generated by the LIS. This could, conceivably, be the only label ever applied to the bottle since it includes all 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, e.g. 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 themselves be unique. If not, then some form of date code must be included in the bottle ID to guarantee its uniqueness.

IDs generated by the LIS must conform to one of the formats listed in the tables below. The preferred ID formats start 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 indicate separately the types of bottles since they are implied by the bottle IDs. However, BacT/ALERT accepts other "generic" ID formats, meaning they are assumed to contain no information that indicates the type of bottle. If the LIS generates these types of bottle IDs, then the Universal Test IDs must include the bottles' types. Generic bottle IDs can, however, pose an inconvenience to 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 BacT/ALERT before the operator attempts to load them into the instrument, then the system software insists that the operator manually enter the bottle types before loading.

Another way the LIS could know and relay bottle IDs to BacT/ALERT is for it to provide the operator some way of entering bottle IDs into the LIS manually using a bar code reader. In this case, the operator would use bar code labels provided by bioMérieux especially for use with BacT/ALERT bottles. These bar codes are provided either on separately applied labels, or directly in the labels already on the bottles. While not quite as convenient as having the LIS generate bottle IDs, this method does, at least, concentrate all data entry activities on one system and at one time.

Bar code labels printed by the LIS must be compatible with BacT/ALERT's bar code wand and scanner as well as the scanner located in the 3D controller module, whose specifications are:

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

The following tables list the various bottle ID and bar code formats accepted by BacT/ALERT:

Type code is a sequence of up to five characters which appears at the beginning of the bottle ID and provides the key information that determines the bottle type and the rest of the bar code format.

Length is 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 4 distinct pairs of digits, and is only 12 characters long (2 greater than 10). However, ZA922B0C2C1F is not acceptable since it has only 1 distinct pair of digits, but is 12 characters long.

Symbology indicates the type of encoding used in the bar codes. For bottle bar codes 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.

The following table lists the bar code and bottle ID 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 IDs into the LIS system for relay down to BacT/ALERT.

Bar code prefix	Length	Symbology	Example	Bottle type
G	8-10	Code 128	G00231185	Unknown (generic)
U	7-10	N/A	U88637J	Unknown
!V	8	Code 128	!V379857	BTA SV
!A	8	Code 128	!A549860	BTA SA
!N	8	Code 128	!N398763	BTA SN
!P	8	Code 128	!P287365	BTA PF
!F	8	Code 128	!F928374	BTA FA
!G	8	Code 128	!G269388	BTA FN
!M	8	Code 128	!M299938	BTA MP
!B	8	Code 128	!B792875	BTA MB
IA	8	Code 128	IA654832	BTA i AST
IN	8	Code 128	IN654832	BTA i NST
IL	8	Code 128	IL654832	BTA i LYM
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

Bar code prefix	Length	Symbology	Example	Bottle type
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

The following table lists the other bar code and bottle ID formats acceptable for use with BacT/ALERT systems. This information is intended for those LIS systems that print their own bar code labels for use with BacT/ALERT bottles. No check digits are used in these barcodes.

Bar code prefix	Length	Symbology	Example	Bottle type
0 through 9	5-15	Code 128 or 39	922192352A	Unknown (generic)
ZBSV	5-15	Code 128 or 39	ZBSV379857098	BTA SV
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
ZBFA	5-15	Code 128 or 39	ZBFA9283744	BTA FA
ZBFN	5-15	Code 128 or 39	ZBFN269388764	BTA FN
ZBMP	5-15	Code 128 or 39	ZBMP2999383	BTA MP
ZBMB	5-15	Code 128 or 39	ZBMB7928	BTA MB

Appendix B: Sample Communications Sessions

This section contains examples of communications between a LIS and BacT/ALERT system. The first 5 examples demonstrate use of ASTM standard E1394. They show typical high-level records sent to accomplish a particular function, e.g., sending new test results from BacT/ALERT to the LIS. Example 6 demonstrates use of ASTM standard E1381. It shows the complete low-level data stream necessary to transfer all of the test orders shown in Example 1.

Sample data that is too long to fit on one line is continued on additional indented lines. Special characters are represented as follows:

<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

Example 1: BacT/ALERT sends a request to the LIS for new test orders. Note that it is preferred that the LIS send test orders whenever necessary, without waiting for or requiring BacT/ALERT to send such a request.

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

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.

```
H|\^&|||BIGBROTHER|||||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^SA^SA023023^5\^^^BC^SN^SN021883^5|S^STAT|19
      921119100000|19921119104700|||MDB|N|A^AIDS||19921119111500
      |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^SN^SN021884^5\^^^BC^SA^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>
```

Example 2: The LIS sends to BacT/ALERT the same two test orders as in Example 1, but specifies the universal test IDs in separate result records following the order records.

```
H|\^&|||BIGBROTHER|||||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|||MDB|N|
      A^AIDS||19921119111500|B^LA|0228^C. MYERS|||||||||O||
      ER^EMERGENCY ROOM<cr>
R|1|^^^BC^SA^SA023023^5<cr>
R|2|^^^BC^SN^SN021883^5<cr>
```

```
P|2|P32767|||CHARLES^BABY BOY||19921111|M|||||0722^R. FRANK
      (PEDS)||||||||||19921118<cr>
O|1||923240190||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>
R|1|^^^BC^SN^SN021884^5<cr>
R|2|^^^BC^SA^SA003398^5<cr>
L|1|F<cr>
```

Example 3: BacT/ALERT sends to 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 BacT/ALERT with the requested patient data.

```
H|\^&|||BIGBROTHER|||||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>
```

Example 4: The LIS sends to BacT/ALERT a request for new test results. Note that it is preferred that BacT/ALERT send test results whenever necessary, without waiting for or requiring the LIS to send such a request.

```
H|\^&|||BIGBROTHER|||||BACT/ALERT||P|1|19921120171003<cr>
Q|1|ALL||||||||||N<cr>
L|1<cr>
```

BacT/ALERT sends to 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^SN^SN021884|*|||||I|||19921119112749||1B11<cr>
R|2|^^^BC^SA^SA003398|+|||||P|||19921119112740|19921120170323|
      1B08<cr>
R|3|^^^TTD^SA^SA003398|29.6|||||P|||19921119112740|
      19921120170323|1B08<cr>
L|1|F<cr>
```

Example 5: BacT/ALERT sends the LIS all pending new test results. The following shows an additional later result for the sample sent in Example 4, and 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^SA^SA023023|-|||||F|||19921119112715|
      19921124112715|1B15<cr>
R|2|^^^BC^SN^SN021883|-|||||F|||19921119112726|
      19921124112726|1B18<cr>
P|2|P32767<cr>
O|1|923240190|923240190||||||||||||||||||||||P<cr>
R|1|^^^BC^SN^SN021884|-|||||F|||19921119112749|
      19921124112749|1B11<cr>
```

```
R|2|^^^BC^SA^SA003398|+|||||P|||19921119112740|19921120170323|
      1B08<cr>
R|3|^^^TTD^SA^SA003398|29.6|||||P|||19921119112740|
      19921120170323|1B08<cr>
L|1<cr>
```

Example 6: This example shows all low-level handshaking and protocols necessary for the LIS to transmit the test orders shown in Example 1, according to ASTM standard E1381. Normal lines show data sent by the LIS, as it was received by BacT/ALERT. Underlined lines show responses transmitted by BacT/ALERT. Note that the "SUSPECTED INFECTION" comment is received with errors three times, and is rejected each time, before finally being received successfully.

```
<enq>
<ack>
<stx>1H|\^&|||BIGBROTHER|||||BACT/ALERT||P|1|19921119112519<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||USPECTED INFECTION FOLLOWING GUNSHOT<cr><etx>B3<cr>
      <lf>
<nak>
<stx>3C|1||SUSPECTED a!~CTION FOLLOWING GUNSHOT<cr><etx>B3<cr>
      <lf>
<nak>
<stx>3C|1||SUSPECTED INFECTION FULLOWING 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^SA^SA023023^5\^^^BC^SN^SN021883^5|
      S^STAT|19921119100000|19921119104700|||MDB|N|A^AIDS||
      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^SN^SN021884^5\^^^BC^SA^SA003398^5|
      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||PRIORITY TEST - DO NOT HOLD
      RESULTS<cr><etx>BB<cr><lf>
<ack>
<stx>0C|2||CONTACT DR. WEIER X2667 IMMEDIATELY IF POSITIVE<cr>
      <etx>98<cr><lf>
<ack>
<stx>1L|1|F<cr><etx>FC<cr><lf>
<ack>
<eot>
```