ARCHITECT

SYSTEM

Abbott Standard Interface RS-232 Manual

Part Number (91407-108)

Abbott Laboratories
Abbott Park, IL 60064

Foreword

This manual has been designed to help you familiarize yourself with all aspects of the Abbott Standard Interface for the ARCHITECT System.

Customer Support

If you have any questions regarding your ARCHITECT System, please contact your local representative or find country-specific contact information on www.abbottdiagnostics.com.

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- UL 61010A-1 or UL61010-1 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1 General Requirements
- CAN/CSA-C22.2 No. 1010.1 or CAN/CSA-C22.2 No. 61010.1 Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1 General Requirements
- 21CFR Part 1040.10: Performance Standards for Light Emitting Products
- IEC 60825-1: Safety of Laser Products (Class I Laser Products)
- Directive 2002/96/EC: Waste Electrical and Electronic Equipment
- CE Marking

CE	*In Vitro* Diagnostic Directive	98/79/EC
	Legal Manufacturer	Abbott Laboratories Diagnostic Division Abbott Park, IL 60064 USA
	Authorized Representative in the European Community	Abbott Max-Planck-Ring 2 65205 Wiesbaden Germany +49-6122-580

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4,533,457	4,619,739	4,647,362	4,678,755
4,797,192	5,025,389	5,413,770	

The following U.S. Patents are relevant to the ARCHITECT System or its components.

5,468,646	5,536,049	5,543,524	5,545,739
5,565,570	5,669,819	5,682,662	5,723,795
5,795,784	Des. 397,938	Des. 401,699	Des. 401,697
Des. 401,700	5,783,699	5,856,194	5,859,429
Des. 404,829	Des. 406,901	5,915,282	5,915,583
5,938,120	Des. 413,539	5,965,828	6,022,746
6,063,634	6,150,113	6,153,377	6,162,645
6,413,780	6,562,298	6,588,625	

There are other such patents and patent applications in the United States and worldwide.

System labeling

The symbols in the following table are used on ARCHITECT® System labeling.

Key to symbols used on labeling

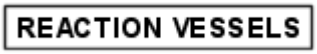
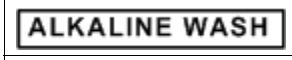
Label	Description
	Authorized Representative in the European Community
	Legal manufacturer Note: A new presentation of the Legal manufacturer label will be phased into the system labeling in a future revision.
	*In vitro* Diagnostic Medical Device
	Manufacturer
	Date of manufacture
	Serial number
	Alternating current
	Laser
	Caution, risk of electrical shock
	Electrical and electronic equipment waste
	Temperature limitation
	Use by/Expiration date
	Consult operating instructions
	Caution, consult accompanying documents
	Batch code/Lot number

Key to symbols used on labeling

Label	Description
QTY	Quantity
UNIT	Unit
	Biological risks
	Biohazard
	Caution, hot surface

ASSAY DISK	Assay disk
VERSION	Version
CONVENTIONAL UNITS	Conventional units
STANDARD INTERNATIONAL UNIT	Standard international unit
SAMPLE CUPS	Sample cups
ICT Cleaning Fluid	ICT Cleaning Fluid
ICT Lyophilized Cleaning Solution	ICT Lyophilized Cleaning Solution
Water Bath Additive	Water Bath Additive

PRE-TRIGGER SOLUTION	Pre-Trigger Solution
TRIGGER SOLUTION	Trigger Solution
CONCENTRATED WASH BUFFER	Concentrated wash buffer
WASH BUFFER	Wash buffer

	Reaction Vessels
	Septum
	Replacement Caps
	Multi-assay Manual Diluent
	Catalog number/List number
	Acid Wash
	Alkaline Wash
	ICT Reference Solution
	Detergent A
	Detergent B

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Introduction

The Abbott Standard Interface RS-232 Manual/ ARCHITECT System Edition provides the necessary information for interfacing the ARCHITECT System to hospital or laboratory information systems across the serial RS-232 communications port.

Topics in this section include:

- Overview of the Manual
- Alternative Reference Materials

NOTES

Overview of the Manual

All Abbott Standard Interface RS-232 Manuals are designed to provide clear and concise information on the communications capabilities of Abbott Diagnostic Instruments and Systems that support the Abbott Standard Interface (ASI). This interface is based on the following industry supported standards:

- CLSI (Clinical and Laboratory Standards Institute, formally NCCLS) LIS1-A "Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems" (ASTM E 1381-91)
- CLSI LIS2-A2 "Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems" (ASTM E 1394-91)

The manuals provide specific information on the communications capabilities of Abbott ASI instruments and systems as well as general information on the Abbott implementation of the CLSI LIS1-A and LIS2-A2 communication protocols.

NOTE: Due to a numbering change at the record level, ASTM field numbers will be called out. Refer to Appendix A to convert the field number to the CLSI LIS2-A2 field number.

Different editions exist for different instruments and systems, however they are all organized in a similar manner. This manual is organized as follows:

- How to Use This Manual: Discusses the purpose of the manual and provides a good overview of the information contained within.
- Section 1: Discusses the Abbott implementation of the CLSI LIS1-A and LIS2-A2 (ASTM E 1381-91 and E 1394-91) standards. This section is common to all Abbott Standard Interface Manuals.
- Section 2 – Section 4: Discusses specific information about the instrument or system covered by that particular edition. They cover topics such as content of communications messages and support of ASI options. These sections are unique for each instrument. Sections 2 – 4 of this edition describe the ARCHITECT System and its specific interface implementation.
- Section 5: Refers to the ARCHITECT Host/Instrument Interface Data Disk, and the ARCHITECT SCC Simulator (for LIS Vendors).
- Section 6: Discusses the differences between the ARCHITECT System and the AxSYM interface.

- Appendix A: Discusses the different numbering format for the records between the ASTM 1394 standard and the CLSI L1S2-A2 standard.

This manual assumes the reader is familiar with programming techniques and is capable of programming using a high level language. This manual also assumes the reader has a good working knowledge of serial communications as they relate to the computer system that interfaces with the Abbott instrument or system.

For readers not familiar with the CLSI LIS1-A and LIS2-A2 (ASTM E 1381-91 and E 1394-91) communications standards, we highly recommend ordering these standards by calling or writing CLSI using the information provided in "Alternative Reference Materials" on page 5: All readers should carefully study the “Overview of the Abbott Standard Interface” section and all subsequent sections to understand how Abbott instruments implement the CLSI standards. The reader should then be able to develop and program the logic required to effectively communicate with the ARCHITECT System as well as setup and diagnose communications.

Refer to the ARCHITECT System Operations Manual for information on communication setup and instrument communication troubleshooting.

Alternative Reference Materials

Bibliography of standards and references.

Further information regarding the Clinical and Laboratory Standards Institute (CLSI), formerly the National committee for Clinical Laboratory Standards (NCCLS), Standards referenced within this document, are available by contacting:

Clinical and Laboratory Standards Institute

940 West Valley Road, Suite 1400

Wayne, PA 19807

USA

1-877-477-1888

www.clsi.org

NOTES

Introduction

This section explains the Abbott implementation of the CLSI LIS1-A and LIS2-A2 (ASTM E 1381-91 and E 1394-91) communications standards.

Topics include:

- Abbott Standard Interface (ASI) – Transmission codepage options
- Layered Protocols
- Physical Layer – Electrical, Mechanical, and Signaling Characteristics
- Data Link Layer – Establishment, Transfer, and Termination
- Presentation Layer – Message Content
- Application Layer

NOTES

Abbott Standard Interface (ASI)

Abbott instruments and data management systems provide communications to external host computers via a serial connection conforming to the specifications and requirements set forth in the CLSI LIS1-A (ASTM E 1381-91) and LIS2-A2 (ASTM E 1394-91) standards. At the most basic level these standards allow host systems to download (*i.e.*, send) worklist messages to the Abbott instruments/ systems. The Abbott instruments can then process the worklist, act on the tests that have been requested, and return the results associated with the worklist. The host computer can then process the results, generate reports, and store the information.

Although these standards form the basis of the type of information exchanged between clinical instruments and the manner that the information is transferred, they allow the instrument and system manufacturers considerable latitude in selecting field use and field substructure.

In order to ensure compatibility between Abbott instruments, systems, and external hosts, Abbott has taken the initiative to define the **Abbott Standard Interface (ASI)**. ASI consists of a series of interpretations and definitions of the CLSI standards that provide a strict but consistent compliance to the standards, while providing the needed flexibility to handle the unique data requirements of Abbott's multiple instruments and systems.

By ensuring compatibility and by defining the fields that are instrument specific, developers benefit by structuring their software to be configurable to the highest possible extent, thus minimizing development time and costs.

All ARCHITECT system transmission codepage options: Abbott Standard Interface, Language default, and Unicode (UTF-8) are collectively referred to as the Abbott Standard Interface (ASI) for the remainder of this manual. The Language default or Unicode (UTF-8) options are available in ARCHITECT System software version 5.00 and higher and are extensions of original Abbott Standard Interface option to allow transmission of multi-byte characters. The Language default and Unicode (UTF-8) options are only explicitly mentioned when explaining how they differ from the Abbott Standard Interface option.

Overview of transmission codepage options

On the ARCHITECT system, the Abbott Standard Interface (ASI) currently supports three transmission codepage options that all conform to the CLSI LIS1-A and LIS2-A2 standards: Abbott Standard Interface, Language default, and Unicode (UTF-8). A brief discussion of character sets, codepages, and default codepages is required to better understand each of these options.

NOTE: The Language default and Unicode (UTF-8) options are available in ARCHITECT System software version 5.00 and higher.

The ASCII character set defines characters in the range 0x00 – 0x7F (where 0x is notation for a hexadecimal number). There are many other character sets, primarily European, that define the characters within the range 0x00 – 0x7F identically to the ASCII character set and also define an extended character set from 0x80 – 0xFF. Thus an 8-bit, single-byte character set (SBCS) is sufficient to represent the ASCII character set as well as the character sets for many European languages. However, some non-European character sets, specifically the CJK languages, include many more characters than can be represented in a single-byte coding scheme, and therefore require multi-byte character set (MBCS) encoding.

A multi-byte character set consists of both single-byte (one byte) and double-byte (two byte) characters. Thus a multi-byte character string may contain a mixture of single-byte and double-byte characters. A double-byte multi-byte character has a lead byte and a trail byte. In a particular multi-byte character set, the lead bytes fall within a certain range, as do the trail bytes. When these ranges overlap, it may be necessary to evaluate the context to determine whether a given byte is functioning as a lead byte or a trail byte.

Codepage is a traditional term used for a specific character encoding table: a mapping in which a sequence of bits, usually a single octet representing integer values 0 through 255 (0x00 – 0xFF), is associated with a specific character. Each of the transmission codepage options for the ARCHITECT system is based upon different codepages.

Selection of the language in the ARCHITECT system software also sets the default codepage of the operating system. For example, choosing the English language, results in setting Windows codepage 1252 (Latin 1) as the default codepage of the system. Choosing the Japanese language results in setting Windows codepage 932 (Japanese Shift-JIS) as the default codepage of the system.

Table 1.1: Terms and Definitions

Term	Definition
ASCII	American Standard Code for Information Interchange
ASCII character set	A character encoding based on the English alphabet that defines characters in the range from 0x00 - 0x7F (where 0x is notation for hexadecimal).
Basic Multilingual Plane (BMP)	The range of code numbers from 0 through 65,535 decimal (0xFFFF) that can be represented by character codes of 16-bits. The Unicode characters can be categorized in many different ways, Unicode code points can be logically divided into 17 planes, each with 65,536 (= 2^{16}) code points, although currently only a few planes are used.
Plane 0 (0x0000 - 0xFFFF)	Basic Multilingual Plane (BMP). This is the plane containing most of the character assignments so far. A primary objective for the BMP is to support the unification of prior character sets as well as characters for writing systems in current use.
CJK	A collective term for Chinese, Japanese, and Korean, which constitute the main East Asian languages.
Codepage	A traditional term used for a specific character encoding table: a mapping in which a sequence of bits, usually a single octet representing integer values 0 through 255 (0x00 - 0xFF), is associated with a specific character.
Extended Character Set	Defines characters in the range from 0x80 - 0xFF.
SBCS	Single-byte character set. A character set that uses one byte for each graphic character.
MBCS	Multi-byte character set.
Shift-JIS	A character encoding for the Japanese language originally developed by a Japanese company called ASCII Corporation in conjunction with Microsoft and standardized as JIS X0208 Appendix 1. It is based on character sets defined within JIS standards JIS X 0201:1997 (for the single-byte characters) and JIS X 0208:1997 (for the double-byte characters).
Unicode Character Input	If this option is enabled, the ARCHTECT system software allows keyboard entry of all characters. If disabled, the ARCHITECT system software will reject characters with values greater than 255 (0xFF).
UTF-8	8-bit USC/Unicode Transformation Format is a variable-length character encoding for Unicode.
UTF-16	16-bit USC/Unicode Transformation Format is a variable-length character encoding for Unicode capable of encoding the entire Unicode repertoire.
Unicode transformation format	(UTF) is an algorithmic mapping from every Unicode code point (except surrogate code points) to a unique byte sequence. The ISO/IEC 10646 standard uses the term "UCS transformation format" for UTF; the two terms are merely synonyms for the same concept. Each UTF is reversible, thus every UTF supports lossless round tripping: mapping from any Unicode coded character sequence S to a sequence of bytes and back will produce S again. To ensure round tripping, a UTF mapping must also map all code points that are not valid Unicode characters to unique byte sequences. These invalid code points are the 66 non-characters (including 0xFFFE - 0xFFFF), as well as unpaired surrogates.

Abbott Standard Interface option

The Abbott Standard Interface option is based upon a subset of OEM codepage 850 (Multilingual Latin 1). It includes the alphanumeric values from the ASCII character set and the European character values from the extended character set. It excludes most ASCII control characters and extended character set values for graphic drawing characters. Characters that cannot be successfully encoded or transmitted are translated to the copyright sign (© = 0xA9).

Table 1.2: Abbott Standard Interface Terms and Definitions

Term	Definition
Alphanumeric	ASCII characters within the following ranges: 48-57 (0-9), 65-90 (A-Z), and 97-122 (a-z).
ASI	Abbott Standard Interface: Abbott's implementation of the Clinical and Laboratory Standards Institute (CLSI) Standard. LIS1-A, Standard Specification for Transferring Messages Between Clinical Instruments and Computer Systems. LIS2-A2, Specification for Low-Level Protocol to Transfer Information Between Clinical Laboratory Instruments and Computer Systems.
Allowed Data Formats	All data is represented in ASCII format within the range 0 – 255. Values 0 – 127 are defined by ANSI X3.4-1986 Standard. Values 128 – 255 are defined as needed by specific instruments. Values 0 – 31 cannot be used, with the exception of 13 (<CR>). The value 13 is reserved as a record terminator. Values 32 – 255 can be used, with the exception of 127 and 255. Within a data text field, only the ASCII characters 32 – 126 and 128 – 254 are permitted as usable characters. Characters used as delimiters in the transmission are excluded from the above permitted range. The sender is responsible for checking that a data text field does not contain any delimiters. The record identifier fields (H,P, O, R, L, C, M, and Q) are always uppercase when output from the Abbott instrument. On input, both upper- and lowercase record identifiers are accepted. Fields and records are variable in length with no restriction placed on the maximum length of a field or record. The high-level protocol depends on the receiver's buffering capability and the low-level communication ability to divide the information into workable lengths for transmission and processing purposes. All Abbott Standard Interface RS-232 manuals provide the maximum allowable length of each field transmitted and received.
LIS2-A2 (ASTM E 1394-91) Message	A block of data that is transmitted in a format consistent with the CLSI LIS2-A2 Standard. Data is transmitted in a series of records starting with a Header Record (H) and ending with a Terminator Record (L). When a transmission is lost, the Abbott instrument retransmits or accepts only complete messages.
LIS2-A2 (ASTM E 1394-91) Record	An LIS2-A2 Record is a string of characters starting with a capital ASCII alphabet character and ending with a carriage return (ASCII 13), as defined by the CLSI LIS2-A2 Standard.
Reserved Characters	The following characters have special uses and should not be used for data: Vertical Bar (|) Backslash (\) Ampersand (&) Carriage Return (<CR>) Caret (^)

Table 1.2: Abbott Standard Interface Terms and Definitions *(continued)*

Term	Definition
LIS1-A (ASTM E 1381-91) Message	A block of data that is transmitted in a format consistent with the CLSI LIS1-A Standard. Abbott ASI instruments use an LIS2-A2 Record as the LIS1-A Message. Thus, an LIS1-A Message may be transmitted using multiple (one or more) frames, based on the length of the message.
LIS1-A (ASTM E 1381-91) Frame	A frame is a subdivision of a message and allows transmission of up to 247 characters (240 data characters and 7 control characters). The Abbott instrument transmits one record per frame. Messages more than 247 characters long can be divided into multiple frames, as long as each frame contains only information from one record at a time.
OEM	Original Equipment Manufacturer

Language Default option

The Language default option is an extension of the Abbott Standard Interface option that allows successful transmission of multi-byte characters. Similar to the Abbott Standard Interface option, it is also compliant to the CLSI (ASTM) standards. However, it differs from the Abbott Standard Interface option as follows:

- Characters are encoded for transmission using the operating system default codepage of the System Control Center computer. The Language default option supports the following codepages: 932 (Japanese Shift-JIS), 936 (Simplified Chinese GBK), 949 (*Korean), and 950 (*Traditional Chinese Big 5).

NOTE: *The Korean and Traditional Chinese Big 5 language encodings are not currently available.

- Characters that cannot be successfully encoded or transmitted are translated to the question mark symbol (0x3F).

The SCC is a Unicode (UTF-16) application, but only allows Unicode character input if Unicode input configuration option is enabled for the SCC. The Language default option is required for the CJK languages if Unicode input is enabled. The Abbott Standard Interface option does not properly encode and transmit Unicode characters. The Unicode (UTF-8) option, described in the next section, does successfully transmit Unicode characters, but performs less efficiently than the Language default option for the CJK languages.

Unicode (UTF-8) option

The Unicode (UTF-8) option is another extension of the Abbott Standard Interface option that allows successful transmission of multi-byte characters. Similar to the Abbott Standard Interface option, it is also compliant to the CLSI (ASTM) standards. However, it differs from the Abbott Standard Interface option as follows:

- Characters are encoded for transmission using codepage 65001 (Unicode UTF-8).
- Characters that cannot be successfully encoded or transmitted are translated to the question mark symbol (0x3F).

UTF-8 (8-bit USC/Unicode Transformation Format) is a variable-length character encoding for Unicode. It can represent any character in the Unicode standard, yet its initial encoding of byte codes and character assignments is backwards compatible with ASCII. It encodes each character in 1-4 bytes:

One byte - required to encode the first 128 US-ASCII characters (0x0000 – 0x007F)

Two bytes - for Latin letters with diacritics and for characters from Greek, Cyrillic, Armenian, Hebrew, Arabic, Syriac, and Thaana alphabets (0x0080 – 0x07FF)

Three bytes - for the rest of the Basic Multilingual Plane (which contains virtually all characters in common use)

Four bytes - for characters in other planes of Unicode, which are rarely used in practice

The encoding rules of UTF-8 allow every Unicode character to be transmitted. Encoded Unicode characters become only characters that are allowed by the CLSI LIS2-A2 standard. If the SCC system software is configured for any language not supported by the previous two options, then the Unicode (UTF-8) option should be used. For CJK languages, this option is less efficient than the Language default option since most character encodings would require 3 instead of 2 bytes.

Layered Protocols

The Abbott Standard Interface (ASI) is based on a four-layer protocol implementation, consistent with the terminology and definitions of the Organization for International Standards (ISO) reference model for Open Systems Interconnection (OSI). The OSI model is concerned with the interconnections between different systems and not with the internal functions that are performed by a given system. The OSI model provides a generalized view of a layered architecture. Using this approach, functions and services required to allow two systems to communicate are grouped in various functional layers. A given layer is responsible for performing a specific set of functions and for providing a specific set of services.

A communications architecture can then be defined in terms of the services provided by each layer and the interface between layers. Protocols define the services offered across a layer interface and the rules that are followed in the processing performed as part of a service. Data formats for the data exchanged across an interface are also defined as part of the architecture.

Two types of interfaces exist in a communications architecture. One set of interfaces exists between the layers in a given system. The second set of interfaces exists between comparable layers of different systems. ASI provides information on the second set of interfaces that allow similar layers of different systems to communicate.

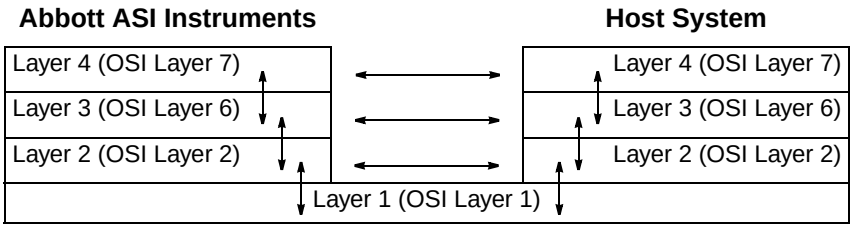


Figure 1.1: Layered Protocol Architecture

The OSI layer designators are used as reference and do not imply compliance with actual ISO/OSI Standards.

Based on this architecture, ASI defines the following layers for implementation of communications software:

- Physical Layer (Layer 1) – Directs transmission of serial binary data bits between the Abbott instruments and systems and external host computers across a mechanical and electrical connection, as defined by this document and CLSI LIS1-A (ASTM E 1381-91) section 4.
- Data Link Layer (Layer 2) – Provides services for establishing a link connection, transferring data, and releasing the connection. Also provides services for delimiting, synchronism, sequence control, error detecting and recovering of the link, as defined by this document and CLSI LIS1-A (ASTM E 1381-91) section 5.
- Presentation Layer (Layer 3) – Provides services for building message content into a standard and interpretable form, as defined by this document and CLSI LIS2-A2 (ASTM E 1394-91).
- Application Layer (Layer 4) – Provides services for processing test requests, running assays, reporting results, etc., as defined by this document and the instrument specific operations manual.

The following figure depicts the general implementation of these layers on new Abbott instruments and systems that support the CLSI Standards.

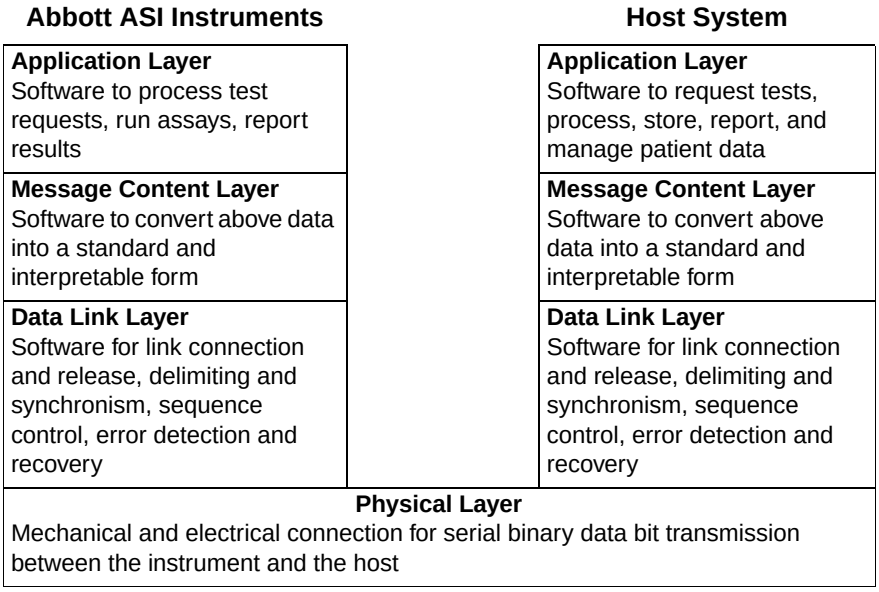


Figure 1.2: ASI Implementations

Physical Layer

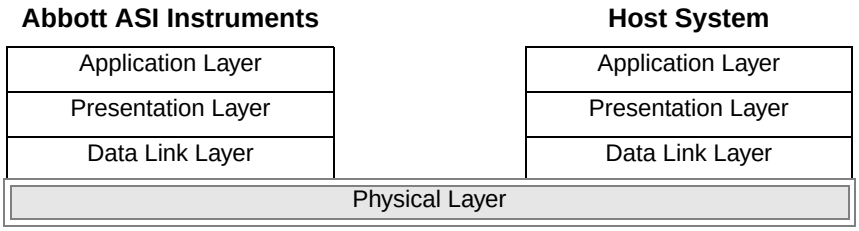


Figure 1.3: Physical Layer

Abbott instruments and systems supporting the Abbott Standard Interface (ASI) implement the physical layer of the interface as specified by the CLSI LIS1-A (ASTM E 1381-91) standard. This interface is based on the EIA RS-232D -1986 standards, for the mechanical and electrical characteristics and the ANSI X3.15-1976 and ANSI X3.16-1976 for the signaling characteristics, such as the structure of the characters being transmitted.

Electrical Characteristics

Abbott instruments use a voltage more negative than minus three volts (with respect to signal ground) to indicate a marking condition (binary one). A voltage more positive than plus three volts (with respect to signal ground) indicates a spacing condition (binary zero). The relevant voltage and impedance levels of the signal generator and the signal receiver circuits of ASI instruments meet the requirements set forth in the RS-232D-1986 standard.

Mechanical Characteristics

ASI instruments use either a 25-pin or a 9-pin connector to facilitate connection to an external computer system. The connection provided conforms to the requirements of the EIA RS-232D Standard. The Communication Setup section of each Abbott Standard Interface RS-232 manual covers the specifics for that instrument.

The cabling and pin-out requirements of Abbott instruments and systems conform to the specifications defined in the CLSI LIS1-A (ASTM E 1381-91) standard. Only pins 1, 2, 3, and 7 are used for the 25-pin connector and only pins 1, 2, 3, and 5 are used for the 9-pin connector. Refer to the following table and figure for pin assignment information. The CLSI LIS1-A (ASTM E 1381-91) standard requires that the external Host computer is configured as a DCE device.

Table 1.3: Pin Assignments for the 25-Pin Connector

Pin No.	EIA Circuit	Description	Direction	
			Abbott Instrument	Computer
1	–	Shield	–	No Connection
2	BA	Transmitted Data	Output	Input
3	BB	Received Data	Input	Output
7	AB	Signal Ground	–	–

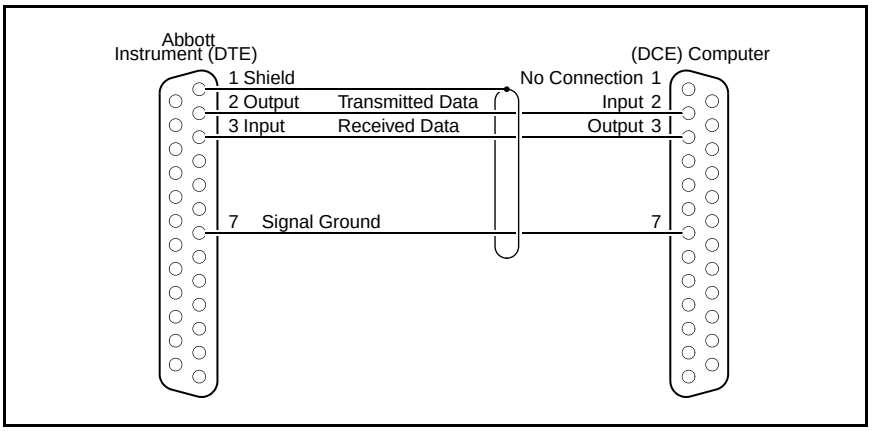


Figure 1.4: Pin-to-Pin Connections (Wiring Diagram)

NOTE: If a computer is configured as a DTE Device (*i.e.*, pin 2 is the output and pin 3 is the input), then the cable connecting the ASI instrument to the computer must have lines 2 and 3 crossed.

Table 1.4: Pin Assignments for the 9-Pin Connector

Pin No.	EIA Circuit	Description	Direction	
			Abbott Instrument	Computer
1	–	Shield	–	No Connection
2	BB	Received Data	Input	Output
3	BA	Transmitted Data	Output	Input
5	AB	Signal Ground	–	–

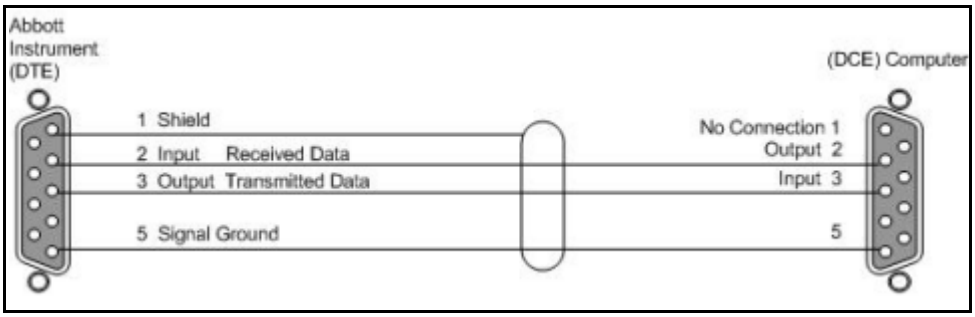


Figure 1.5: Pin-to-Pin Connections (Wiring Diagram)

NOTE: If a computer is configured as a DTE Device (*i.e.*, pin 2 is the output and pin 3 is the input), then the cable connecting the ASI instrument to the computer must have lines 2 and 3 crossed.

For Host computer systems that do not conform to the CLSI standard for the physical connection, other cabling schemes may be required as shown below. Many personal computers may have a 9-pin connector instead of the 25-pin required by the CLSI specifications.

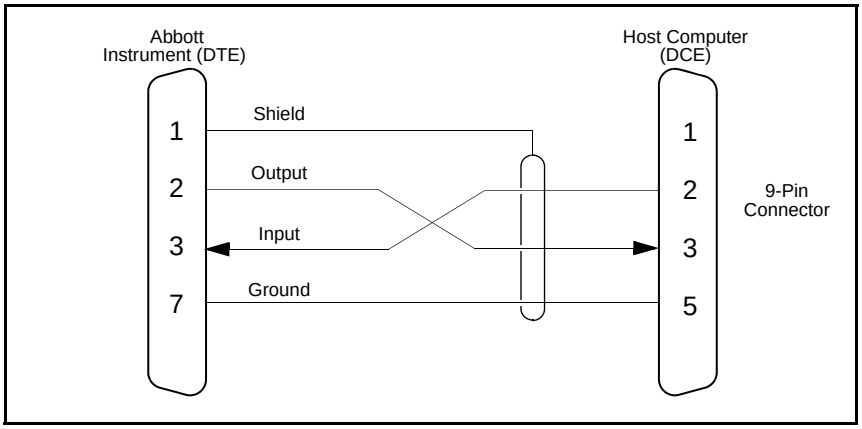


Figure 1.6: Host computer (PC with 9-pin connector) with Non-CLSI compliant connector

NOTE: Pin 1 is the shield connection and connects to the instrument's (DTE) frame. Leave the shield connection open at the computer (DCE) to avoid ground loops.

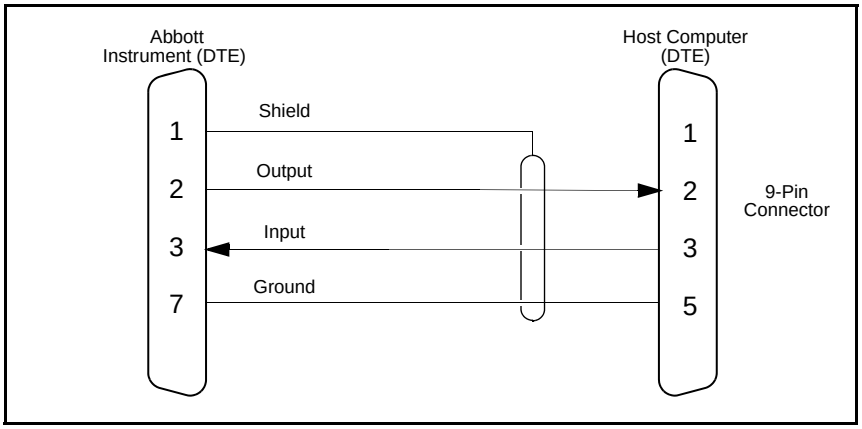


Figure 1.7: Host Computer with 9-Pin PC-AT style connector

If the same computer used a 25-pin connector configured as a DTE, the cabling requirements are as follows:

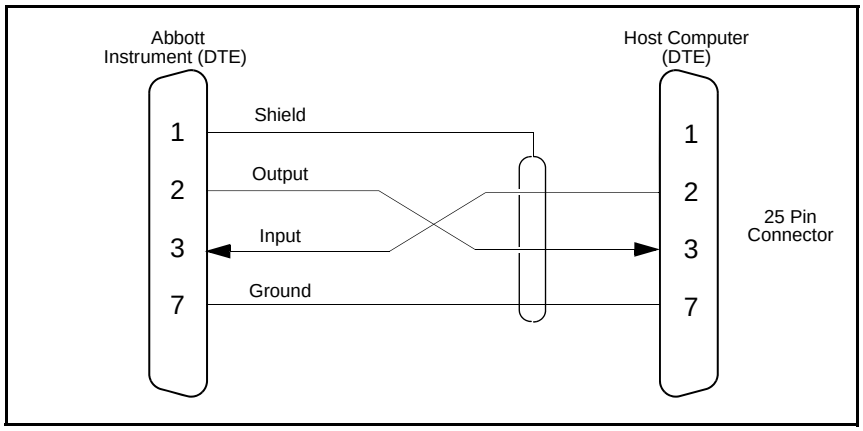


Figure 1.8: Host computer (PC with 25-pin connector) with Non-CLSI compliant connector.

ASI instruments and systems may optionally provide fixed length cables for connecting to external systems. When cable lengths greater than 50 feet are required, then “Low Capacitance” shielded cables are recommended. Local Building Fire Code standards may require the use of “Plenum” rated cables for connecting systems. Please check with your building personnel for specific requirements that apply to wiring and cabling in your specific environment.

The RS-232 signals are assigned to pins in the modular plug and jack as follows:

Table 1.5: RS-232 signal pin assignment

Pin # and Color	Signal name		Remark	Signal source
	DTE (computer or terminal)	DCE (modem)		
1 Blue	DTR, HSKo	CD	Data on pin 3 is valid	Jack
2 Orange	RTS	CTS	I am ready to receive on pin 6	
3 Black	TxD	RxD		
4 Red	Gnd	Gnd		
5 Green	Return, Gnd	Gnd		Plug
6 Yellow	RxD	TxD		
7 Brown	CTS, HSKi	RTS	OK to send on pin 3	
8 Gray	DSR	DTR	Data on pin 6 is valid	

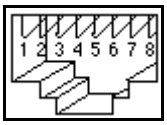


Figure 1.9: Jack

Figure 1.10: Plug

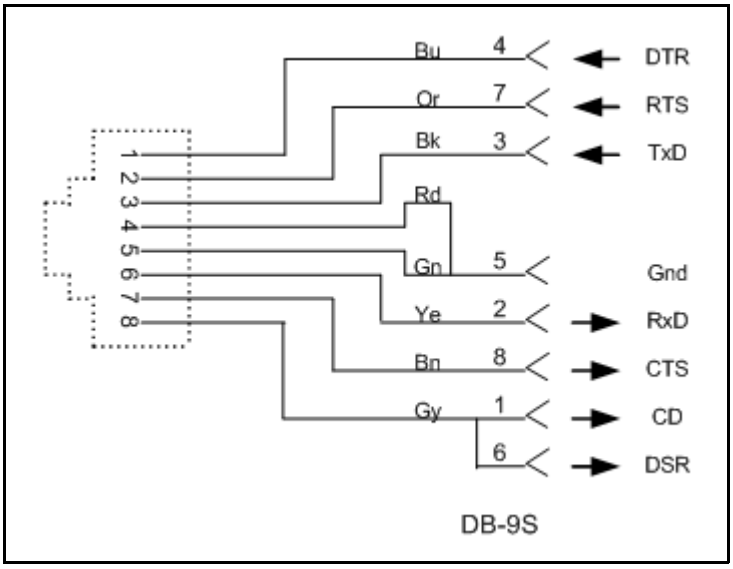


Figure 1.11: 9-pin serial connections

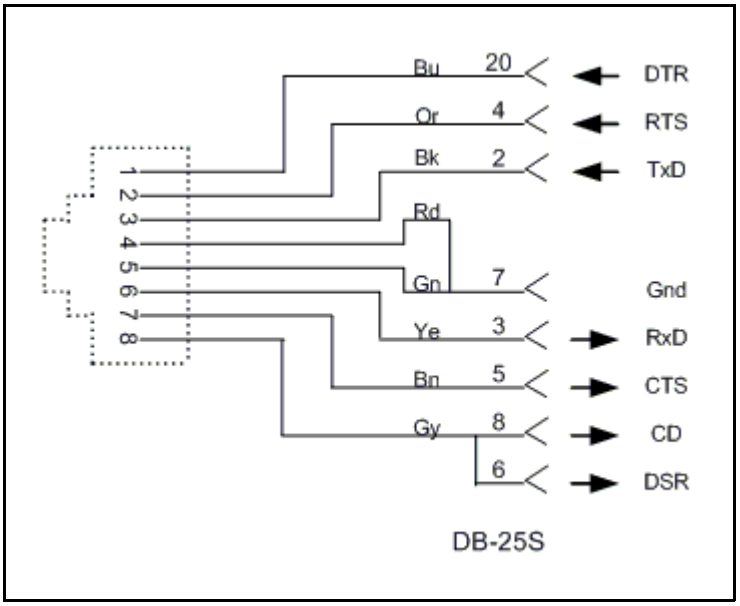


Figure 1.12: 25-pin serial connections

Signaling Characteristics

Character Structure

Character bit patterns and bit rates determine how Abbott instruments communicate with computer systems.

The character bit sequencing, structure, and parity sense definitions conform to ANSI standards X3.15-1976 and X3.16-1976. The default structure for Abbott instruments character bit sequencing is:

1. A start bit with a value of zero.
2. The start bit is followed by eight bits that represent character data.
3. A stop bit with a value of one ends the character structure.

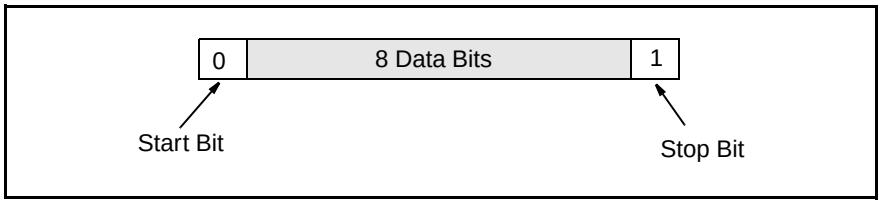


Figure 1.13: Default Abbott Instruments Character Structure. *The start and stop bits separate ASCII characters which are eight bits long.*

All ASI instruments support the CLSI required combinations of:

- Start bits
- Data bits
- Parity bits
- Stop bits

Speed

Abbott instruments that implement ASI provide multiple baud rates for transmitting data to external systems. As a minimum, all ASI instruments support the CLSI preferred communications speed of 9600 baud, and may also support one or more of the following [1200, 2400, 4800, 14400, 19200, 28800, 38400, 57600, 115200]. The default setting of all ASI instruments for host communications is 9600 baud. For information on the exact baud rates supported by the ARCHITECT System, see Configure serial ports window field descriptions in the ARHCITECT System Operations Manual.

Abbott data management systems that are used as hosts support all four of the CLSI LIS1-A (ASTM E 1381-91) required baud rates [1200, 2400, 4800, 9600]. Optionally, they may also support other baud rates [*e.g.*, 19200, etc.] as required.

Data Link Layer

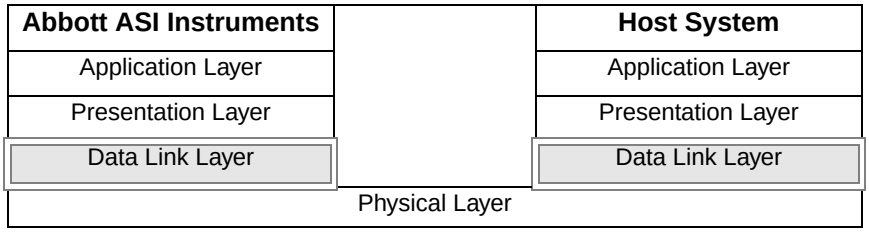


Figure 1.14: Data Link Layer

The data link layer covers methods for the following:

- Establishing communication connections with an external system
- Providing error detection and error recovery of communications
- Delimiting and synchronism
- Controlling sequence
- Sending and receiving messages
- Terminating the communications connections

In addition, the data link layer performs the following inter-layer functions:

- Interacts with higher layers in transferring data
- Handles requests for establishing and terminating connections
- Reports the data link layer status

The data link layer uses a character-oriented protocol to send messages between two systems that are directly connected. One system transmits while the other system monitors the communications link. Thus, information flows in only one direction at a time. Replies occur after information is sent, never at the same time.

Abbott instruments implement the data link layer as specified in the CLSI LIS1-A (ASTM E 1381-91) standard. This standard defines conditions that apply to a device if the device is an instrument, and other conditions if the device is a host computer system. Because Abbott Data Management systems are sometimes used as hosts for other Abbott instruments and other times as a link communicating to Laboratory Information Systems, these systems implement both the CLSI host and the instrument logic of the data link protocol. The configuration of these systems allows them to communicate appropriately based on the role that they are serving.

The data link layer consists of the three following communications phases:

- Establishment phase
- Transfer phase
- Termination phase

Each phase is discussed in detail.

Establishment Phase

The establishment phase determines the direction of information flow and prepares the receiver to accept information. The system with data available for transmission initiates the establishment phase.

When Abbott ASI instruments and systems have data to send, they go into the establishment phase by transmitting the [ENQ] character. If a valid reply ([ACK], [NAK], or [ENQ]) is not received within the 15 second time period specified by CLSI LIS1-A (ASTM E 1381-91), the Abbott instruments and systems enter the termination phase. The instrument returns to the establishment phase after waiting a certain amount of time (*e.g.*, 30 seconds, 60 seconds, etc.) specific to that instrument.

If after a certain number of attempts the instrument is unable to establish communications with the external system, the operator is informed via a dialog box (or error message) and an error message is posted to the error log file.

Sending an [ENQ] and Receiving an [ACK]

After determining that the data link is in a neutral state, the sender transmits an Enquiry [ENQ] transmission control character to the receiver, notifying the receiver that it has information to send. The receiver must send a Message Acknowledged [ACK] transmission character back to the sender before the information is sent. If the receiver is not ready to receive, it sends a Message Not Acknowledged [NAK] transmission character. All other characters are ignored by the sender and receiver. The only valid characters during the Establishment Phase are [ENQ], [ACK], and [NAK].

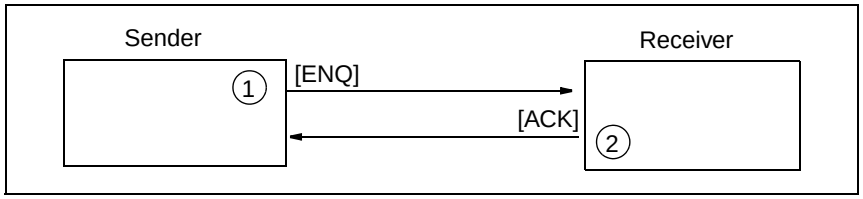


Figure 1.15: Sender Initiating Establishment Phase. *The receiver returns a signal to the sender acknowledging that it is ready to receive.*

Sending an [ENQ] and Receiving a [NAK]

If the receiver is not ready to receive information, it sends a [NAK] in response to an [ENQ]. The sender must wait ten seconds before sending another [ENQ].

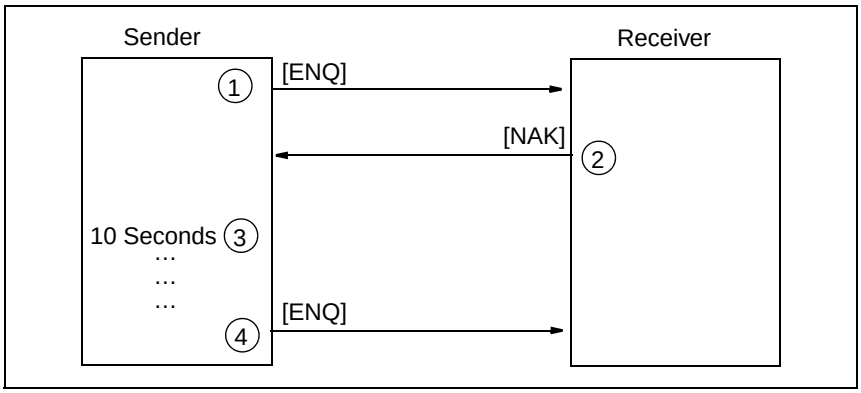


Figure 1.16: Sender Receives a [NAK] Signal. *If the sender receives a [NAK], the sender waits ten seconds before re-initiating the establishment phase.*

Sending an [ENQ] and Receiving an [ENQ]

When both systems simultaneously send an [ENQ], they are in contention. In that case, the Abbott instrument has first priority to transmit information. For example, the following figure shows a computer and an Abbott instrument simultaneously sending an [ENQ]. The computer must immediately stop trying to transmit and prepare to receive. When the next [ENQ] is received by the computer, the computer replies with an [ACK], or a [NAK], depending on its readiness to receive.

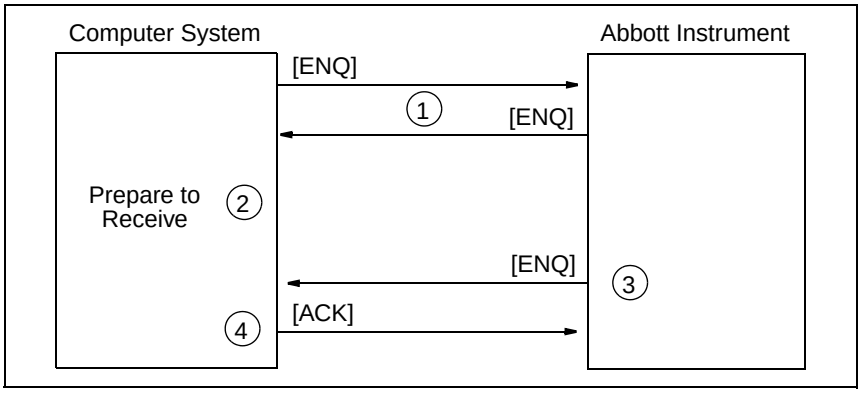


Figure 1.17: Sender Receives an [ENQ] after Sending an [ENQ]. *The sender prepares to receive.*

In the example shown in the following figure, the instrument sends an [ENQ] and receives an [ENQ]. The instrument waits at least one second before re-sending another [ENQ]. The computer system must wait at least twenty seconds before trying to initiate the communications by sending another [ENQ].

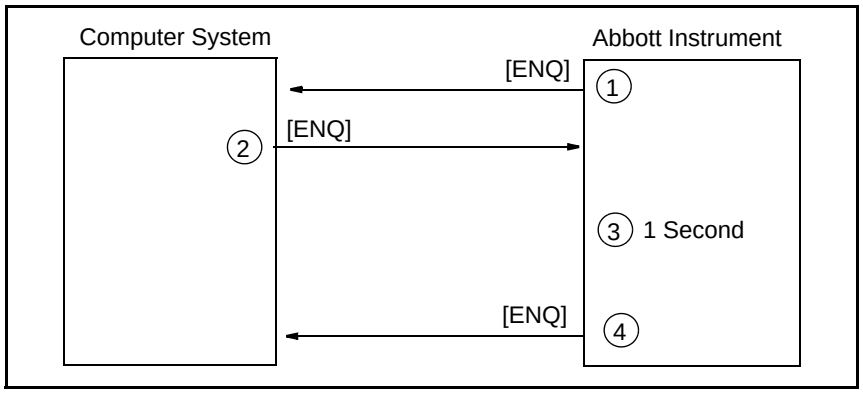


Figure 1.18: Instrument Receives an [ENQ] after Sending an [ENQ]. *The instrument waits one second before re-sending another [ENQ].*

Transfer Phase

During the transfer phase, the sender transmits messages to the receiver until all messages are sent. Messages are sent in frames which contain a maximum of 247 characters.

Special control characters identify the frame type, the beginning and end of a frame, and provide for error detection. The following table lists the special control characters.

Table 1.6: Special Control Characters

Symbol	Character	Description
[STX]	Start of Text transmission control character	First character transmitted at the beginning of a frame.
F#	Frame Number	The frame number is an ASCII digit from 0 to 7. Its purpose is to permit the receiver to distinguish between new and re-transmitted frames. This single digit is sent immediately after the STX character. The frame number begins with 1 when the transfer phase is initialized and increments by 1 each time a new frame is transmitted and acknowledged. After 7, the frame number returns to 0 and repeats the above sequence.
[ETB]	End of Transmission Block transmission control character	Character used to indicate end of an intermediate frame.
[ETX]	End of Text transmission control character	Character used to indicate the end of an end frame.

Table 1.6: Special Control Characters *(continued)*

<table>
<tr><th>Symbol</th><th>Character</th><th>Description</th></tr>
<tr><td>CS1</td><td>Most significant character of checksum 0 – 9 and A – F</td><td rowspan="2">The checksum determines if a frame is defective. The checksum is encoded as two characters and is sent after the ETB or ETX character. The checksum is computed by adding the binary values of the characters (modulo 256), keeping the least significant 8 bits of the result. The 8 bits can be considered as two groups of 4 bits which are converted to ASCII and represented in hexadecimal format. The two ASCII characters are transmitted as the checksum with the most significant character first. The STX character initializes the checksum to zero. The first character used in computing the checksum is the frame number. The last character used is the ETB or ETX. The STX, CR, or LF are not included. Using the following Frame as an example, the checksum for this frame is calculated.

<STX> 1 ABCDEFGHI <ETX> A1 <CR> <LF>
<STX> 002 Not included in calculation
1 049 1st character for calculation
A 065 2nd
B 066 etc.
C 067 etc.
D 068 etc.
E 069 etc.
F 070 etc.
G 071 etc.
H 072 etc.
I 073 etc.
<ETX> 003 Last character for calculation
Total= 673 Total sum value

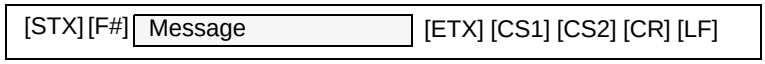
Then 673 (decimal) = 2A1 (HEX)
The most significant byte (2) is discarded and the remainder is then transmitted as two characters, “A” (ASCII 65) and “1” (ASCII 49) to form the checksum.</td></tr>
<tr><td>CS2</td><td>Least significant character of checksum 0 – 9 and A – F</td></tr>
<tr><td>[CR]</td><td>ASCII character for carriage return</td><td>Character used to end an LIS2-A2 record and the second to last character transmitted in a frame.</td></tr>
<tr><td>[LF]</td><td>ASCII character for line feed</td><td>The LF character is used as the last character of a frame. The LF character may not display in the message text.</td></tr>
</table>

Frames

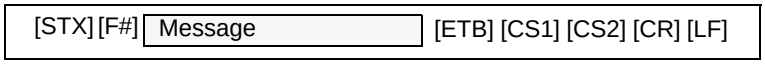
Abbott instruments and systems supporting ASI handle an CLSI LIS2 A2 (ASTM E 1394-91) record as an CLSI LIS1-A (ASTM E 1381-91) message. If the E 1394-91 record is longer than 240 characters, the message is transmitted in multiple frames consisting of end frames and intermediate frames. If the message is less than or equal to 240 characters, the single frame transmitted is an end frame.

Each new message begins in a new frame. A frame never contains more than one message or parts of more than one message. Two types of frames are used:

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



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



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

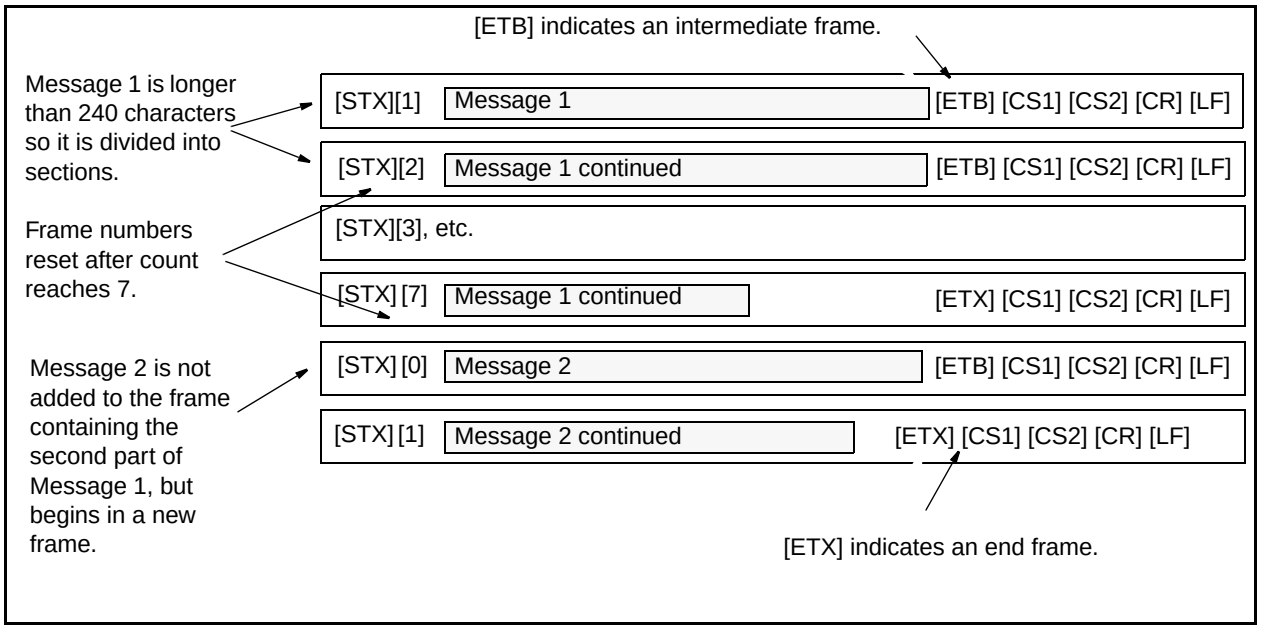


Figure 1.19: Intermediate and End Frames. *Multiple frame messages start with intermediate frames and end with end frames containing only the end of one message.*

After a frame is sent, the sender stops transmitting and waits for an acknowledgment [ACK] from the receiver. The receiver responds to every frame and when it is ready to receive another frame, it sends one of the following replies:

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

Each of the replies is discussed below.

A reply of [ACK] acknowledges that the last frame was received successfully and that the receiver is ready for another frame. The sender must increment the frame number and transmit another frame or terminate the message transfer.

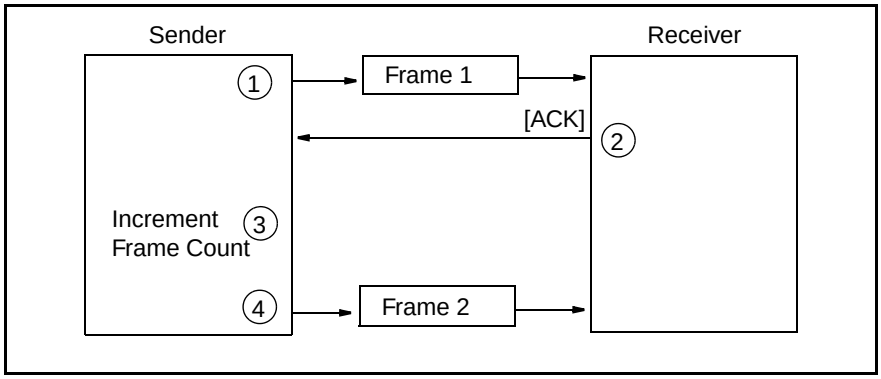


Figure 1.20: Sender Transmitting After Receiving [ACK]. *The sender sends another frame after successfully transferring a frame.*

A reply of [NAK] means that the last frame was not received successfully and that the receiver is ready to receive the frame again. The sender may re-transmit the frame or proceed to the termination phase.

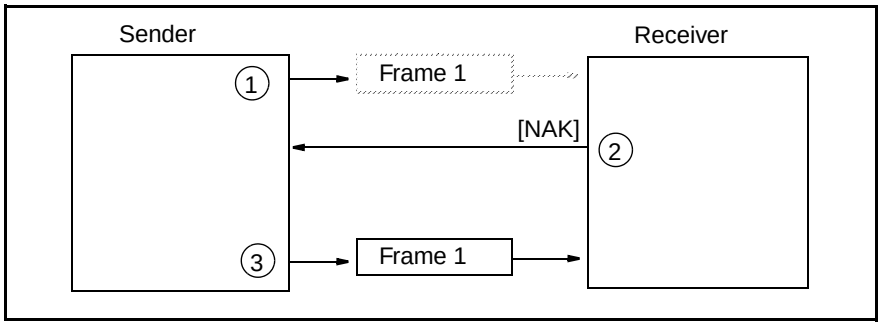


Figure 1.21: Sender Retransmitting a Frame After Transmission Failure. *The receiver indicates transmission failure with [NAK].*

Abbott ASI instruments and systems [NAK] a frame for the following reasons:

- Improperly framed transmission received after [STX]. Certain situations cause a time-out condition to occur if insufficient information is received to properly process the frame. Under these conditions, ASI instruments return to idle state without transmitting a [NAK] or any other characters.
- Invalid frame number or frame number out of sequence.
- Restricted character received in message text.
- Invalid checksum received.

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

A reply of [EOT] acknowledges that the last frame was received successfully and that the receiver is ready for another frame, but the receiver is requesting that the sender stop transmitting. The sender must send a reply within the time-out period.

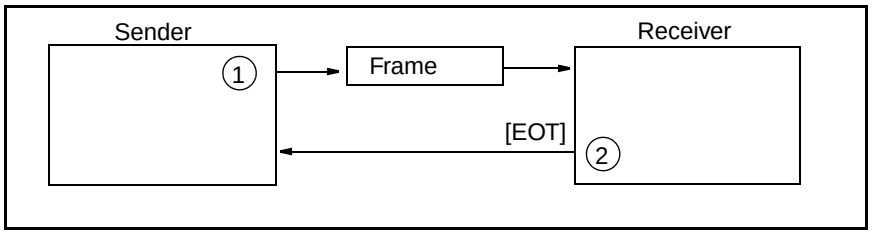


Figure 1.22: End of Transmission. *The receiver indicates successful receipt of the complete message with an [EOT], but requires an interrupt.*

The sender can ignore the request and continue transmitting. In this case, the receiver must re-request the interrupt for the request to remain valid. Abbott ASI instruments and systems (acting as senders) do not honor the interrupt requests originating from the receiver. Receiving the [EOT] character in place of an [ACK] character is treated equivalent to receiving the [ACK] character. Abbott ASI instruments transmit all available data before entering the termination phase and relinquishing control of the data link (return to neutral state).

Error Handling

When errors in the data transmission occur, both the receiver and sender must have orderly recovery procedures.

The receiver checks every frame for defects. The receiver sends a [NAK] reply if it receives a defective frame. When the sender receives a [NAK], it re-transmits the last frame using the same frame number.

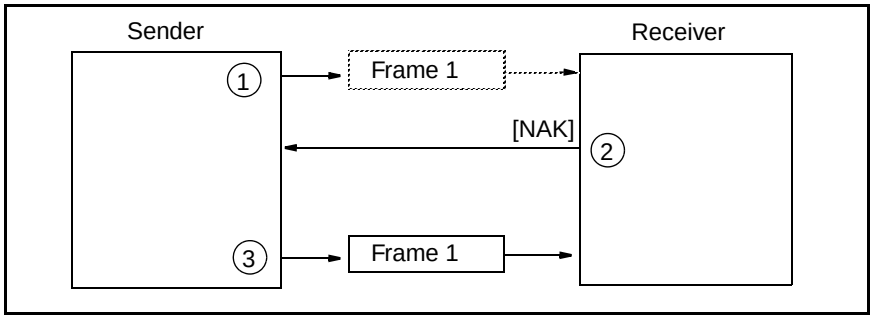


Figure 1.23: Re-sending a Frame After a Transmission Failure. *The receiver indicates a transmission failure with a [NAK].*

ASI instrument communication software depends on properly framed transmissions being received. If an [STX] is received, it is an indication that a frame is being transmitted. If all of the components of a frame are not received in proper relationship to one another, the frame is rejected.

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

- Character structure errors are detected in parity, baud rate, etc., or transmission is improperly framed.
- The frame checksum from the sender does not match the checksum on the receiving end.
- The frame number is incorrect. The number must be the same as the last one rejected or one number higher than the last one accepted by the receiver.

When the sender receives anything other than an [ACK] or an [EOT], it updates a re-transmit counter by one and re-sends the frame. A frame can be re-transmitted a maximum of six times. After that, the sender must abort the message and proceed to the termination phase.

If an [EOT] is encountered by the ASI instruments during the processing of a frame, the instruments return to idle state assuming that the sender terminated transmission prematurely. The sender must re-establish the connection in order to continue.

> **NOTE:** If the [ACK] is corrupted during transmission, the sender of data retransmits the last frame, since any character received other than an [EOT] or [ACK] is treated as a [NAK]. However, since the [ACK] was already transmitted for that frame, the receiver [NAK] duplicates frames to avoid any possibility of infinite loops. This leads to Termination Phase after six attempts.

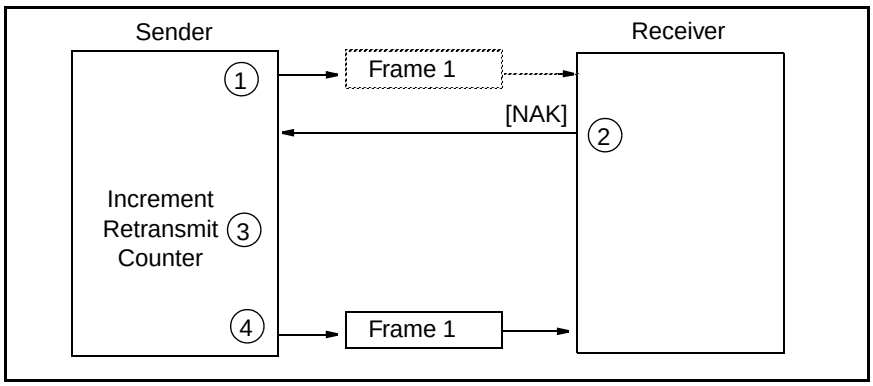


Figure 1.24: Incrementing the Frame Counter. *The sender keeps track of retransmissions with a frame counter.*

Time-outs

The sender and receiver have timers to control the coordination between them and to allow a recovery method in the event a communication line fails to respond.

During the Establishment Phase

The sender sets a timer when sending an [ENQ]. If a reply is not received within 15 seconds, a time-out occurs and the sender proceeds to the termination phase. If the host computer, acting as the receiver, detects contention, it sets a timer. If an [ENQ] is not received from the instrument within 20 seconds, a time-out occurs and the receiver regards the link as being in a neutral state.

During the Transfer Phase

The sender sets a timer when transmitting the last character of a frame. If a reply is not received within 15 seconds, a time-out occurs and the sender proceeds to the termination phase. The receiver sets a timer when first entering the transfer phase or when replying to a frame. If no reply is received within 30 seconds, a time-out occurs and the receiver regards the link as being in a neutral state. A time out also occurs if an incomplete frame is received and the timer expires. For example, if ASI instruments do not receive the [CR] [LF] characters at the end of a frame, a time-out may occur while the instrument is waiting for the last characters, before processing the frame.

Termination Phase

During the termination phase, the sender transmits the [EOT] transmission control character, notifying the receiver that all of the information has been sent. The sender regards the link to be in a neutral state. After receiving the [EOT], the receiver regards the link to be in a neutral state.

Restricted Message Characters

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

Table 1.7: Restricted Message Characters

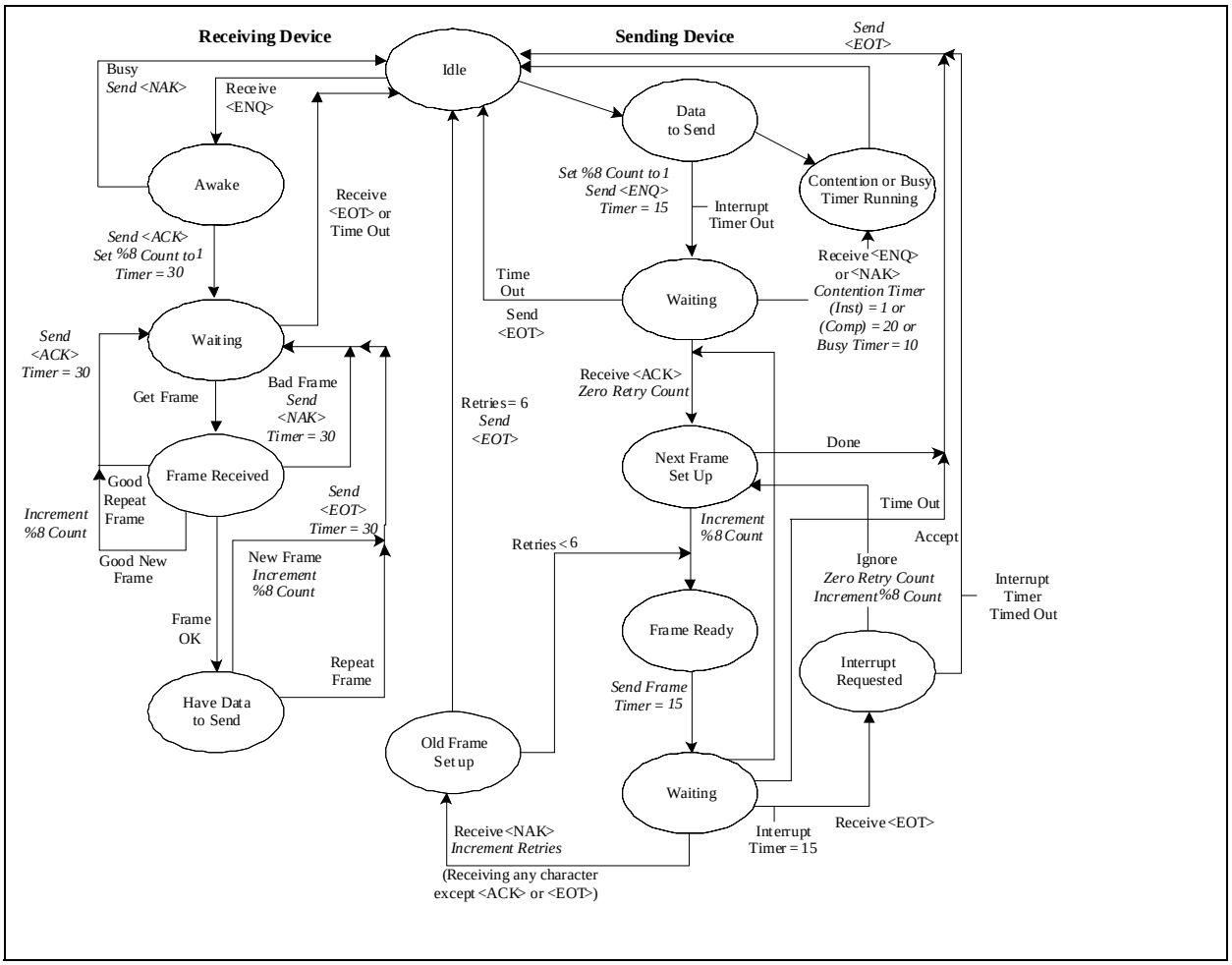
Character Symbol	Definition
[SOH]	Start of Header
[STX]	Start of Text Transmission
[ETX]	End of Text Transmission

Table 1.7: Restricted Message Characters

Character Symbol	Definition
[EOT]	End of Transmission
[ENQ]	Enquiry
[ACK]	Acknowledge
[DLE]	Data Link Escape
[NAK]	No Acknowledge
[SYN]	Synchronous Idle
[ETB]	End of Transmission Block
[LF]	Line Feed
[DC1]	Device Control Character 1
[DC2]	Device Control Character 2
[DC3]	Device Control Character 3
[DC4]	Device Control Character 4

CLSI-LIS1 Sender/ Receiver State Diagram

Figure 1.25: CLSI Document LIS1-A Sender/Receiver State Diagram



NOTE 1 - "%8" represents module 8

NOTE 2 - "=" represents assignment of a value. "Timer: =15" resets the timer to 15 s as used here.

NOTE 3 - Arrow associated normal text denotes a condition; arrow associated italicized text denotes action taken.

Table 1.8: CLSI LIS1-A Communication States (for Instrument)

Initial State	Condition	Action	Final State
idle	Have data to send (periodic check) ContentTimer <=0 BusyTimer <=0	send ENQ transTimer = 15	transENQ
	Received ENQ Have Data to Send ContentTimer <=0 BusyTimer <=0	send NAK	Idle
	Received ENQ ContentTimer <=0 BusyTimer <=0	send ACK	rcvWait
	Received ENQ ContentTimer > 0 or BusyTimer > 0	Protocol error	Idle
transENQ	Received ENQ (from Host)	ContentTimer = 1	Idle
	Received NAK	BusyTimer = 10	Idle
	Received ACK	Send Frame numNAK = 0 transTimer = 15	transWait
	Received other characters	Ignore	transENQ
	Received EOT	Ignore	transENQ
	transTimer <=0	Send EOT	Idle
transWait	Received ACK	Send next Frame numNAK = 0 transTimer = 15	transWait
	Received NAK	Send old frame numNAK = numNAK + 1	transWait
	Received EOT	Send next Frame numNAK = 0 transTimer = 15	transWait
	transTimer <=0	Send EOT	Idle
	numNAK = 6	Send EOT	Idle
rcvWait	Received Good Frame	send ACK rcvTimer = 30 increment frame #	rcvWait
	Received Bad Frame	send NAK rcvTimer = 30	rcvWait
	Received EOT	discard last incomplete message	idle
	rcvTimer <= 0	discard last incomplete message	idle

Presentation Layer – Message Content

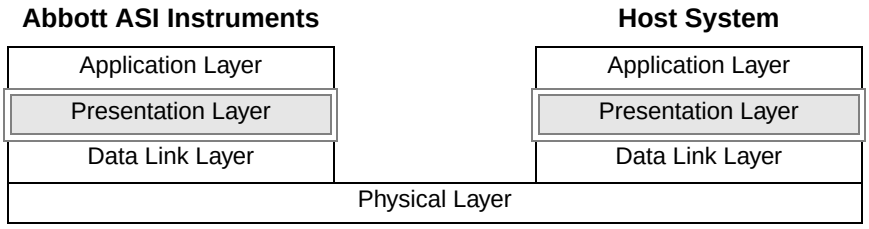


Figure 1.26: Presentation Layer

The Abbott Standard Interface (ASI) uses the protocol defined by CLSI LIS2-A2 (ASTM E 1394-91) standard as the basis for the message content layer of instrument communications software. This layer specifies the conventions used in structuring information (messages) for transmission to external host systems and for receiving information from these host systems.

Messages

The Presentation Layer requires that transmission and reception of all data must be performed using messages. A message consists of complete study files on one or more patients. Each message is a string of records which in turn are made up of fields. The following figure shows the basic structure of a message.

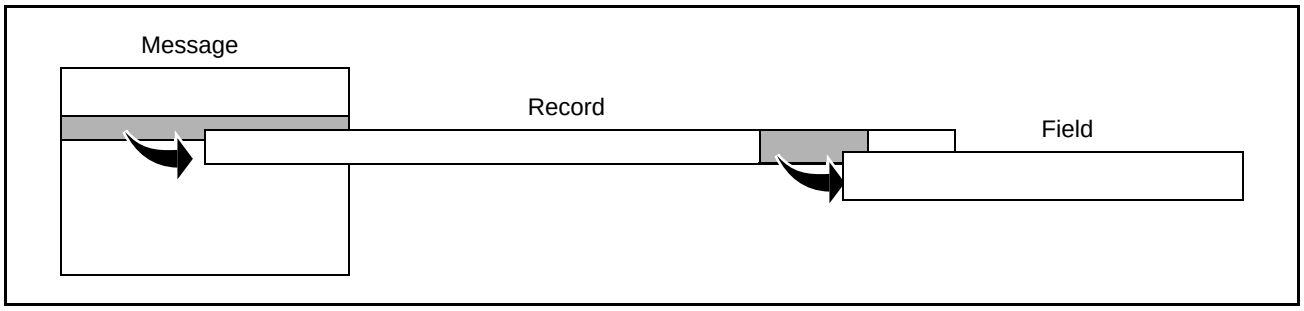


Figure 1.27: Message Logical Structure. *Messages are subdivided into records which are made up of fields.*

The high-level protocol follows two general conventions:

- A hierarchical convention is implemented where records higher in the hierarchy contain information that is common to all records lower in the hierarchy.
- A positional convention is used to define the structure of the records.

These conventions allow the fields, and thus the records, to vary in length. The CLSI LIS2-A2 (ASTM E 1394-91) standard allows manufacturers the flexibility to:

- Create new record types through the use of the Manufacturer Record.
- Define the structure of certain existing fields.
- Define the structure of new manufacturer records.

This manual describes how Abbott instruments use this flexibility.

Records

Records are collections of related information within a message. For example, one record may contain information about the system sending the message and the system receiving the message while another record may contain personal information about a patient who is to undergo tests. Records begin with an ASCII alphabetical character, called a *record identifier*, and end with a carriage return. In the following example, the record identifier is "H", which is used to identify the Header Record.

H [CR]

ASI instruments use uppercase letters for all record identifiers transmitted. ASI instruments can receive upper or lowercase letters for record identifiers. The following table describes the records that Abbott instruments use and their associated record identifier fields.

Table 1.9: Record Types

Record Type	Record ID Field	Level	Description	For Field Contents Refer to Section	
				ASTM E 1394-91	CLSI LIS2-A2
Header	H	0	Identifies the message. Contains information about the sender and receiver of the message, such as location and type of equipment used to send and receive the message.	7	6
Patient Information	P	1	Contains information about a patient.	8	7
Request Information (Query)	Q	1	Used to request information on a range of test results or test orders from another system.	12	11
Test Order	O	2	Contains information defining tests performed or requested.	9	8
Result	R	3	Contains information about test results.	10	9

Table 1.9: Record Types *(continued)*

Record Type	Record ID Field	Level	Description	For Field Contents Refer to Section	
				ASTM E 1394-91	CLSI LIS2-A2
Comment	C	1 – 4	Contains comment text on the preceding record.	11	10
Manufacturer Information	M	1 – 4	Provided for custom use by the instrument or computer system manufacturer.	15	14
Scientific	S	N/A	Not used.	14	13
Message Terminator	L	0	Terminates the message.	13	12

The records within a message are arranged in a hierarchy of levels. The records higher in the hierarchy contain information that is common to all records that are lower in the hierarchy. The lowest number is the highest in the hierarchy. For example a Level 2 record is higher than a Level 3 record.

Manufacturer's Records and Comment Records may be used within any level except Level 0.

Each level, other than Level 0, must be preceded by a higher level. The Manufacturer and Comment Records can be inserted at any level in the hierarchy and are considered to be one level below the preceding record.

For example, a Comment Record below a Patient Record at Level 1 is considered a Level 2 record and contains comments about the patient in the Patient Record. A Comment Record below a Test Order Record (O) is considered a Level 3 record and contains comments about tests described in the Test Order Record.

The following figure shows how the Comment and Manufacturer Records fit into a message hierarchy.

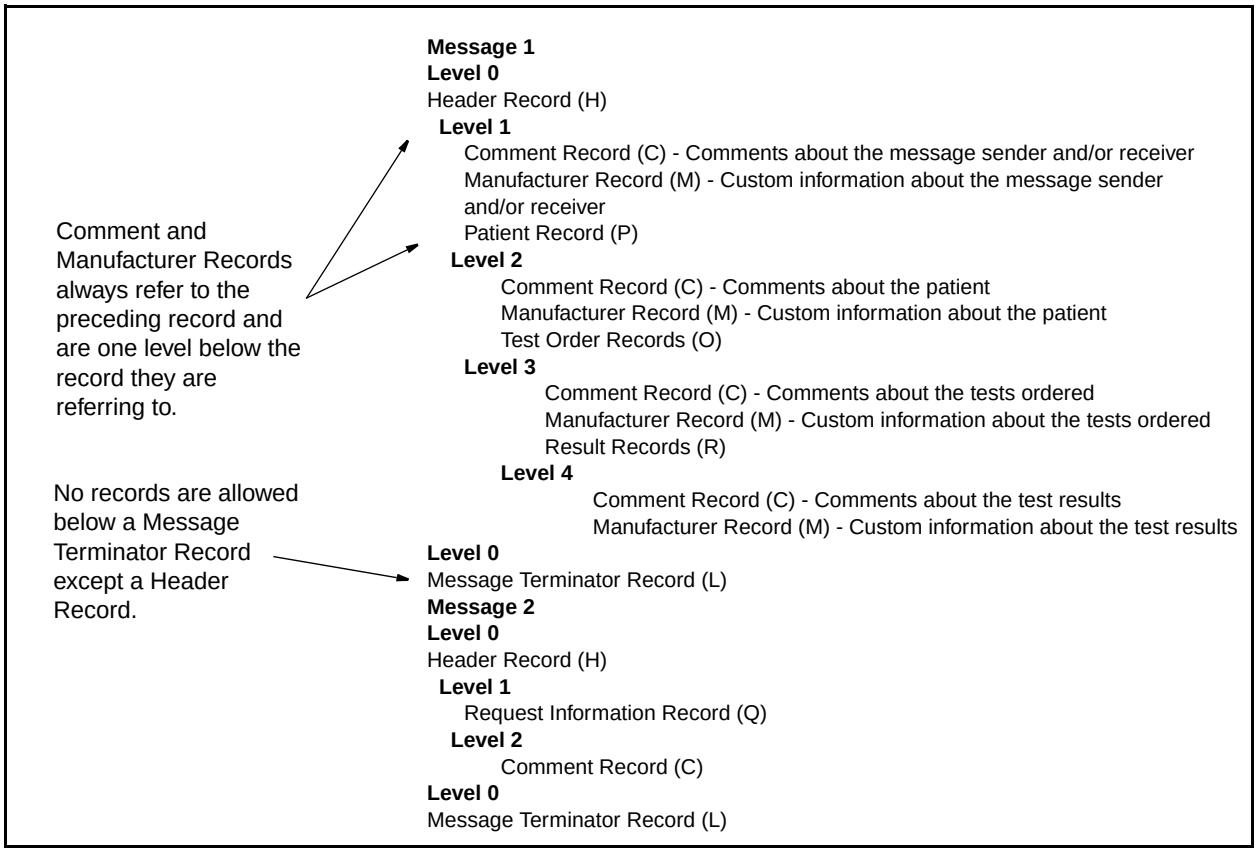


Figure 1.28: Comment and Manufacturer Records. *These records can be placed anywhere in a message between the Header and Message Terminator Records.*

ASI instruments may optionally support the use of the Request Information Record (Q). Refer to the instrument specific section of each Abbott Standard Interface RS-232 manual for details on that instrument's support of the Request Information Record.

ASI instruments do not accept the Request Information Record as part of a message containing Patient (P) and Order (O) Records. Also, ASI instruments do not transmit the Request Information Record as part of a message containing Patient (P), Order (O), and Result (R) Records. When used, the message only includes the following:

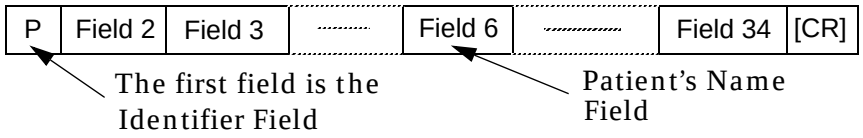
Header Record (H)
Request Information Record (Q)
Terminator Record (L)

Manufacturer and Comment records may be used in conjunction with the Request Information Records, as needed by specific instruments.

ASI instruments and systems may be batch as well as real time. Batch instruments and systems communicate the results of a run all at one time, usually at the end of that run. The results message consists of information on multiple samples. Real time systems, however, communicate the information as it becomes available. These systems normally communicate a shorter results message consisting of information on the results of only one sample test (the one that was just completed).

Fields

Fields are groups of characters that define a specific piece of information within a record, such as a patient's name, telephone number, or street address. For example, the Patient's Name field in the Patient Record is shown below:



Fields are position dependent. That is, fields are identified by their relative position in the record. For example, the field representing a patient's name is always the sixth field in the Patient Record. Fields are all variable length. The Instrument Specific section of the Abbott Standard Interface RS-232 manual provides the maximum allowed length of each field transmitted or received by that instrument.

Delimiters

The CLSI LIS2-A2 (ASTM E 1394-91) standard allows for the use of special characters to be used to separate:

- Adjacent fields
- Repeating information within a field
- Components of a field

Table 1.10: Delimiter Summary

Delimiter Type	Character	Description
Field	|	Separates fields within records.
Repeat	\	Separates multiple occurrences for the same type of information within a field.
Component	^	Separates a field into smaller groups of characters.
Escape	&	Allows imbedding of special characters within the data.

The standard also indicates the use of special characters, such as delimiters, carriage returns, line feeds, etc. imbedded within text fields.

The Abbott Standard Interface defines the delimiters used by Abbott Instruments for transmission to be as follows:

- Field DelimiterVertical Bar (|)
- Repeat DelimiterBackslash (\)
- Component DelimiterCaret (^)
- Escape DelimiterAmpersand (&)

ASI instruments accept any characters defined in the header record and transmitted by the external system as the delimiters for that message.

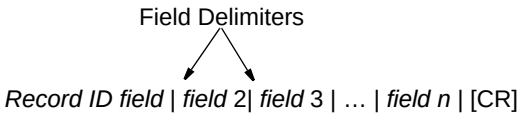
If a received data field contains a character that conflicts with the ASI defined delimiters (| \ ^ &), ASI instruments and systems may optionally use the Escape Delimiter to return the original data (*i.e.*, conflicting character) back to the external system. Refer to the instrument specific sections to determine if this feature is supported by the instrument or the system.

ASI instruments and systems may optionally support the ability to delete contents of specific fields that were previously transmitted by using the ASCII 34 quote character (“) as specified by CLSI LIS2-A2 (ASTM E 1394-91) standard. Refer to the instrument specific sections to determine if this feature is supported by the instrument or the system.

Following is a description of how delimiters work.

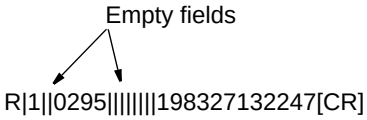
Field Delimiters (|)

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



Delimiters and Empty Fields

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



If a carriage return is introduced, this indicates that all the remaining fields in the record are empty. A carriage return can also indicate the end of the last field in a record.

Repeat Delimiters (\)

Certain fields may be augmented by the use of repeat delimiters to separate equal elements of the same set. When used, the repeat elements of a field relate to the rest of the record in the same way as if the whole record were replicated, with the only difference being the repeat field.

When only one field is repeating within a record, then the repeat information relates to the rest of the record in a similar fashion as the first.

0|1|Sample#1|^^^Test1\^^^Test2\^^^Test3...[CR]

is equivalent to:

0|1|Sample#1|^^^Test1 . . .

0|2|Sample#1|^^^Test2 . . .

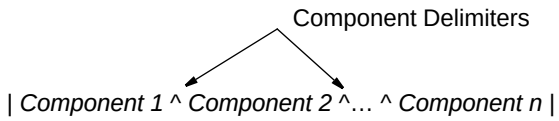
0|3|Sample#1|^^^Test3 . . .

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

ASI instruments do not use repeat delimiters in the primary record fields (*i.e.*, Sample IDs and Universal Test IDs) when returning results. ASI instruments that support repeat delimiters specify the fields that may repeat.

Component Delimiters (^)

Some fields are made of more than one string of characters or components. These strings use carets (^) as delimiters, as shown below:



For example, the Patient Name field uses component delimiters to differentiate between first name, last name, middle name, suffix, and title:

|BLAKE^LINDSEY^ANN^MISS|

Escape Delimiters (&)

The CLSI LIS2-A2 (ASTM E 1394-91) protocol allows the use of escape delimiters to provide a method for communicating control characters (*i.e.*, nonprintable ASCII characters, or protocol control characters) that would otherwise create abnormal conditions to occur on the receiving end. The Abbott Standard Interface recognizes the need for using the escape delimiters, and identifies specific conditions that may be supported by ASI instruments. The use of escape delimiters is limited to communication data characters that are in direct conflict with the delimiters used by the communicating system.

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

where **&** is the escape delimiter used by the communicating system

These four conditions may be checked at input and converted to their equivalent characters for viewing. On output, the data are parsed and any delimiters imbedded within data are converted to their escape strings. All other uses of the escape delimiters are not recommended.

The following figure summarizes the delimiters used by the Abbott instrument.

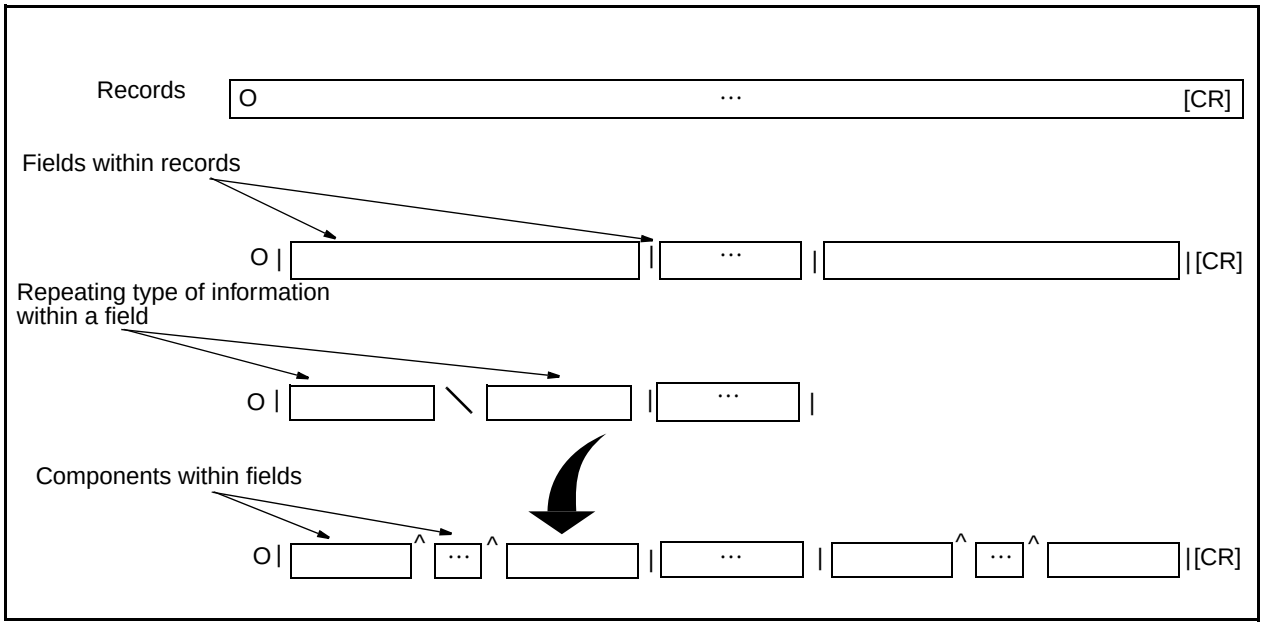


Figure 1.29: Delimiter Summary. *Field delimiters separate fields within records, repeat delimiters separate multiple occurrences of the same type of data within a field, component delimiters separate components within fields.*

ASI Defined Fields

The ASTM E 1394-91 standard allows each manufacturer the ability to define certain fields based on their needs. The following fields are defined by the Abbott Standard Interface:

- Sender Name or ID (ASTM E 1394-91 Field 7.1.5)
- Universal Test ID (ASTM E 1394-91 Field 6.6.1)
- Specimen IDs (ASTM E 1394-91 Field 9.4.3, 9.4.4)
- Patient IDs (ASTM E 1394-91 Fields 8.1.3, 8.1.4, and 8.1.5)
- Action Codes (ASTM E 1394-91 Field 9.4.12)
- Report Type (ASTM E 1394-91 Field 9.4.26)
- Date and Time

Sender Name or ID (ASTM E 1394-91 Field 7.1.5)

This field is used within the Header Record of the Message to provide a unique identification of the instrument communicating, as well as to provide information on the interface version of the instrument. This field consists of the following four components:

- Instrument/System Name
- Instrument/System Software Version Number

- Instrument/System Serial Number
- Interface Version Control

The Interface Version Control is of the form “XnXn...” (without quotes). The “X” is used to indicate the record types the instrument supports. The “n” is used to indicate the implemented version of that record, and “n” can be any number. The valid characters for “X” are (H, P, O, R, L, C, M, and Q). The S (Scientific) record is not supported by ASI instruments.

Thus, the Interface Version Control string “H1P1O1R1L1” indicates an instrument that supports the header, patient, order, result, and terminator records. Any changes to the interface that would affect a particular record, would increment the version number of that record.

An interface version of “H1P1O2R2Q1L1” would indicate that the interface has changes to the order record, the result record, and the instrument/system is now supporting the query record. This allows host systems to compare the interface version control strings and focus their attention on the records that have changed. The component is optional and may not be supported by all instruments. Refer to the instrument specific section for details.

When all components are supported, this field is transmitted as follows:

|Instrument_name^Software_version^Serial_number^Interface_version_control|

This field can be used to assist with field upgrades of interfaced instruments. If host systems support E-mail links to the developers, then this field can be used to inform the interface development team of a potential problem due to a mismatch of interface software between a host and an instrument.

Universal Test ID (ASTM E 1394-91 Field 6.6.1)

The Universal Test ID is used as a unique identifier for requesting test orders and for identifying results associated with those orders. This field is used within the following records:

- Test Order Record
- Results Record
- Request Information Record

The Universal Test ID is composed of four major parts. The first three parts are reserved for future ASTM usage and are not used by ASI instruments and systems. As specified by the ASTM Standard E 1394-91 (section 6.6.1.4), the fourth part of the Universal Test ID is defined by each manufacturer. ASI instruments use the following components for the manufacturer's code:

- Test or Assay Code
- Test or Assay Name
- Dilution or Neutralization Protocol
- Test Qualifier
- Result Qualifier

When all components of the manufacturer's code are used, the Universal Test ID is transmitted as follows:

|^^^Test_Code^Test_Name^Dilution^Test_Qualifier^ Result_Qualifier|

For downloading orders to instruments or systems, the Test_Code is the only required component of the Universal Test ID. Other components are optional and may be used as needed. The Result_Qualifier component is never downloaded from Host (LIS) systems.

The first three parts are reserved for future use and are not currently used by the Abbott instrument. The valid "Test_Code" and "Test_Name" components for each instrument and system may be obtained by reviewing the Test or Assay Parameter screens on each instrument. Valid assay protocols such as Dilutions or neutralization protocols are also defined per test or assay code.

Two continuous component delimiters indicate default dilution for that assay. When the Universal Test ID is used in a Result Record, the last component contains a result type code.

Test_Qualifier

This component may be optionally used to provide a modifier for the test_code. Hematology instruments may use this component to allow an LIS vendor to selectively request only results associated with predefined parameter sets to be returned.

Result_Qualifier

The result qualifier is used as the last component of the Universal Test ID field when transmitting results. ASI instruments and systems use the Result_Qualifier to identify the nature of the result data being communicated. Several codes are defined for use to describe the most common result types returned by Abbott instruments and systems. They are:

Final (F) – Used to identify the calculated values for primary results such as concentrations. The data field contains the actual value of the result. The Units field identifies the units (*i.e.*, type) of the result.

Preliminary (P) – Used to identify the raw instrument readings such as RATES, or POLARIZATIONS, etc. The data field contains the actual value of the result. The units field contains the type of preliminary result.

Interpreted (I) – Used to identify an interpretation such as POSITIVE or NEGATIVE that is based on the ranges defined on the instrument for those interpretations. The data field contains the actual interpretation.

Final Avg. (Favg) – Identifies the average of a set of final results. Returned in cases where multiple repetitions of a test are run for a specific specimen. The data field contains the actual calculated average of the result. The Units field identifies the units of the final result average (*e.g.*, µg/ml, etc.).

Preliminary Avg (Pavg) – Identifies the average of a set of preliminary results. Returned in cases where multiple repetitions of a test are run for a specific specimen. The data field contains the actual calculated average of the preliminary result. The Units field identifies the type of preliminary result average (*e.g.*, RATES, Net Polarization, etc.).

Interpreted Average (Iavg) – Identifies the interpretation associated with the average final result (Favg). The data field contains the actual interpretation such as POSITIVE, NEGATIVE, REACTIVE, etc.

Abbott instruments and systems also communicate other calculated information based on the above result types. For example, it is common for instruments and systems to calculate coefficient of variances, standard deviations, root mean square errors, or curve fit information on final and preliminary results when tests are performed in replicates. In these cases, the result type flag identifies the group of

data used (*i.e.*, Final or Preliminary results), the data field contains the actual calculated data, and the units field identifies the type of calculation (*i.e.*, %CV, RMSE, STD, etc.). Refer to instrument specific sections for the complete set of results (*i.e.*, result types) handled by that particular system.

Specimen IDs (ASTM E 1394-91 Field 9.4.3, 9.4.4)

ASI instruments and systems use the following definition for specimen ID fields in the Order Record:

- Specimen ID
- Location_ID or Group Number
- Position

The only required component is the Specimen ID. The Location_ID and position are optional components that may be used to:

1. Uniquely identify replicate tests of a sample
2. Match orders and results to previously pipetted samples (specimens)
3. Provide a way to identify specimens processed as a group or batch

When all components are transmitted, the field is as follows:

|specimen ID^location_ID^position|

Patient IDs (ASTM E 1394-91 Fields 8.1.3, 8.1.4, and 8.1.5)

The ASTM specification allows for the use of multiple patient IDs that uniquely identify the patient.

The following Patient ID fields are specified for use:

- Practice Patient ID (ASTM E 1394-91 Field 8.1.3)
- Laboratory Patient ID (ASTM E 1394-91 Field 8.1.4)
- Instrument Patient ID (ASTM E 1394-91 Field 8.1.5)

Due to the nature of laboratory instrumentation, it is not possible for all instruments to utilize all three Patient IDs. Therefore, ASI instruments follow these rules for interfacing purposes:

1. ASI recommends that an external host computer provide the Patient ID in the Laboratory Patient ID field (8.1.4). This field is displayed on the instrument screen as the Patient ID. This ID is returned unchanged in the same field to the external host computer when the instrument returns results.
2. If the Patient ID is entered at the instrument or changed at the instrument, the new information is returned to the external host computer in the Instrument Patient ID field (8.1.5). Changes or edits done by an instrument operator to the Patient ID field do not overwrite the previously downloaded Laboratory Patient ID.
3. Other Patient IDs such as Admission IDs may be communicated in the Practice Patient ID field (8.1.3). These fields may be optionally supported by ASI instruments. Also instruments may optionally allow this ID to be mapped to the Patient ID if no Laboratory Patient ID (8.1.4) is defined.

For example, if an institution uses the social security numbers as patient IDs, but also uses unique admission IDs that are specific to each time the patient receives medical services, then the following would need to be communicated.

```
H|.....<CR>
    P|1|ADMIT1111|SSN123456789||Doe^John|...<CR>
        O|1|SID101||^^^Test1|.....<CR>
        O|2|SID102||^^^Test2|.....<CR>
L|1|N<CR>
```

Figure 1.30: Institution Using Laboratory and Practice Patient IDs.

If the instrument supports patient IDs as well as admission IDs then it assigns the following:

Patient ID = SSN123456789 {admission id = ADMIT1111}

Patient name = John Doe

Specimen 1 ID = SID101 Tests Ordered = Test1

Specimen 2 ID = SID102 Tests Ordered = Test2

The admission ID is only captured if supported by the instrument. If the institution wanted to track laboratory results by the admission ID, the host computer would need to communicate the patient IDs as follows:

```
H|.....<CR>
    P|1||ADMIT1111||Doe^John|...<CR>
        O|1|SID101||^^^Test1|.....<CR>
        O|2|SID102||^^^Test2|.....<CR>
L|1|N<CR>
```

Figure 1.31: Institution Using Laboratory Patient ID only.

ASI instruments then use the following:

Patient ID = ADMIT1111

Patient name = John Doe

Specimen 1 ID = SID101 Tests Ordered = Test1

Specimen 2 ID = SID102 Tests Ordered = Test2

These rules are followed by ASI instruments in order to simplify the interfacing concerns associated with patient IDs.

Action Codes (ASTM E 1394-91 Field 9.4.12)

A test order, for a particular patient, is always identified by the combination of sample ID and test code provided in the order record. The Action Code provides ASI instruments additional information on how to process that test order.

Currently the following codes are defined for use:

Cancel (C) – This code is used to cancel a previously transmitted test request (test order). The instrument searches its queue of scheduled test orders and deletes the order matching the specimen ID and test code in this order record. The instrument may optionally return a Test Order Canceled message to the external system with the comment record indicating the reason the order was canceled (*i.e.*, Canceled by Host!) If a match is not found, the instrument ignores this record. If the order is being processed, the instrument ignores this cancel request and returns results upon completion. The instrument may indicate the status by returning the Order record with the flag (I) indicating Instrument Pending.

New (N) – This code is used to indicate a new test order to an instrument. ASI instruments check their queue of scheduled test orders for matching specimen IDs and test codes. If no match is found, this order is scheduled for processing. If a match is found, this order is assumed to be a duplicate request and is flagged as an error.

Additional (A) – This code is used to indicate that an additional test of a previously transmitted test order is being requested. ASI instruments check the scheduled test orders for a matching specimen ID and test codes. If a match is found, this order is added to the previous order. If a match is not found, this order is created and scheduled for processing.

Quality Control (Q) – This code is used to indicate that this specimen should be treated as a control for the specified test code. The instrument checks the predefined controls of that test code for a matching ID. If a match is found, the order is scheduled for processing. If a match is not found, the order is canceled. A Test Order Canceled message may optionally be returned to the Host with the comment record containing the reason for cancellation.

Report Type (ASTM E 1394-91 Field 9.4.26)

The report type flag identifies the purpose of the patient/order or patient/order/result transmission. Refer to the instrument specific section to identify what each instrument supports. The allowed flags and usage of these flags are as follows:

Order (O) – Used to indicate a normal Patient/Order request from a host.

Final Report (F) – Used to indicate a normal report of results (Patient/Order/Results) to a host system.

Query (Q) – Used to indicate that the Patient/Order or Patient/Order/Result transmission is in response to a request for information or Query record. This is the case where an instrument or system had made a request for patient orders or final results.

Canceled (X) – Used to indicate that no results are forthcoming for this order or that no orders are sent in response to a Request Information record. This code may be used to indicate that an instrument error occurred while processing that order and no results are expected from the instrument. An ASI instrument or system may return a comment record containing the reason for this condition.

Instrument Pending (I) – Used to indicate that results are not available for the order (specimen/test) identified in this order record. This flag is used to respond to a query for results when the results are not yet available. This flag also indicates that the order (specimen and test) are valid and known to the responding system. It may also be used in response to a test order cancel request.

No Such Test Ordered (Y) – Used in response to a query for results on a specific test for a specimen. If the ASI instrument or system supports the ability to query by specific test for a specimen, that instrument or system uses this flag to indicate that the test has not been ordered.

Date and Time

Dates are represented in the following format, as required by ANSI X3.30:

YYYYMMDD

Where:

- YYYY is the year
- MM is the month
- DD is the day

For example, May 14, 1960, would be represented as 19600514.

Time is represented in the following format, as required by ANSI X3.43.9:

HHMMSS

Where:

- HH is the hour (24 hour clock)
- MM is the minute
- SS is the second

Date and time together are specified as a fourteen character string:

YYYYMMDDHHMMSS

ASI instruments do not support time zone designations in the date and time fields. The sender is responsible for insuring that all dates and times transmitted are of the form specified above.

Record Sequence Number

The second field in all record types, other than the Header, contains a Record Sequence Number field.

The field contains a number that indicates how many times the same record type is used at a particular hierarchical level. The number is reset to one under the following conditions:

- Whenever a record of greater hierarchical significance (lower number) is transmitted.
- If the same record is used at a different hierarchical level.

An example of the numbering scheme follows.

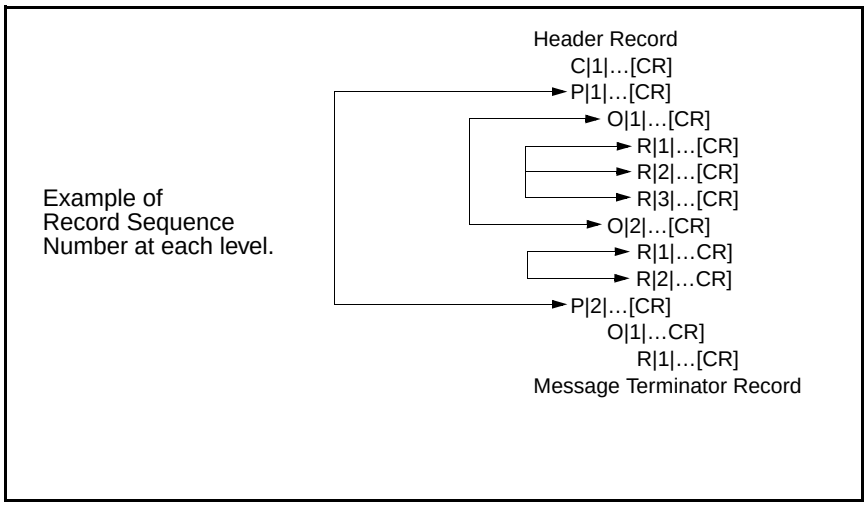


Figure 1.32: Record Sequence Numbers. *Record Sequence Numbers keep track of the number of records of the same type and at the same hierarchical level.*

NOTE: When the high level messages are parsed, ASI instruments check for proper sequencing as defined by the ASTM standards. If a record is encountered with an invalid sequence, an error is logged locally and the remainder of the message is ignored. Records that were parsed prior to the sequencing error are accepted and processed further. An error code is not transmitted to the external system, indicating that the sequencing error occurred.

Records and Fields

The ASI defines the rules of use for fields supported by different instruments and systems. The length of the fields is always assumed to be of variable length. The data type associated with a field is specified by individual instruments and systems. At this time, ASI does not determine the data type for a field (*i.e.*, numeric vs. alphanumeric vs. extended character, etc.). However, as a general rule, fields are assumed to be of variable length and character, unless explicitly defined by a specific instrument.

Instruments and systems may support a subset of the records and fields defined by ASI. If a defined record or field is communicated to an instrument and that instrument does not support that record or field, the instrument ignores it. If, however, records not defined by ASI are received by an instrument, that instrument logs an error and does not process that message.

Certain key fields are identified as required fields if supported by an instrument. These fields are:

- Specimen ID field
- Test Code component of Universal Test ID
- Action Code field

The following tables define the location and contents of each field in a specific type of record. The records and corresponding tables are as follows:

- Table 1.11 Message Header Record
- Table 1.12 Patient record
- Table 1.13 Order Record
- Table 1.14 Result Records
- Table 1.15 Comment Record
- Table 1.16 Request Information Record
- Table 1.17 Terminator Record
- Table 1.18 Manufacturer's Record

Table 1.11: Message Header Record

CLSI (LIS2-A2) Field	ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
6.1	7.1.1	Record Type	H	H	ASI instruments transmit upper case characters, receive upper or lower case.
6.2	7.1.2	Delimiters Field Repeat Component Escape	 | \ ^ &	 * 	ASI instruments accept any valid delimiters specified in the header record.
6.3	7.1.3	Message Control ID			Not supported
6.4	7.1.4	Access Password			Not supported
	* Indicates supported field. Refer to instrument sections for size of supported fields.				

Table 1.11: Message Header Record *(continued)*

CLSI (LIS2-A2) Field	ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
6.5	7.1.5	Sender Name or ID	*	*	This field is made up of the following four (4) components. When transmitting, ASI instruments send their name, software version, and serial number and may also send the interface version control string specified in the fourth component of the field.
		Name	*		Name of instrument.
		^Software version	*		Version of system software.
		^Serial Number	*		Serial number of instrument or system.
		^Interface version	(XnXn.....)		ASI instruments may use this field to implement an interface version control scheme that indicates the record type and version of the record supported by the instrument. “X” is the record type and “n” is the version number. The possible characters for “X” are (H, P, O, R, L, Q, C, M). See the instrument specific section for handling this field.
6.6	7.1.6	Sender Address			Not supported
6.7	7.1.7	Reserved			Not supported
6.8	7.1.8	Sender Telephone			Not supported
6.9	7.1.9	Characteristics of Sender			Not supported
6.10	7.1.10	Receiver ID			Not supported for serial (point-to-point) connections.
		Host_Name ^IP_Address	*	*	Network implementations use this field to contain the name and network address (TCP/IP address) of the Host (LIS) system. The structure of this field is Host_ name^IP_ address.
6.11	7.1.11	Comment			Not supported
	* Indicates supported field. Refer to instrument sections for size of supported fields.				

Table 1.11: Message Header Record *(continued)*

CLSI (LIS2-A2) Field	ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
6.12	7.1.12	Processing ID	P	P	(P)roduction – Treat message as an active message to be completed according to standard processing. If the field is blank, this is the default.
			D	D	(D)ebugging – Message is initiated for the purpose of testing the interface. ASI instruments may use this flag to provide transfer of messages for diagnostic purposes. The diagnostic message consists of at least one record of each type transmitted by the instrument or system. The transmission of this type of message is under operator control and is part of the diagnostics of the instrument/ system. Instruments may optionally receive (D)iagnostic messages consisting of header, patient, and order records.
			Q		(Q)uality Control. Message contains only quality control information. See Instrument specific section for information on how this field is handled.
			T	T	(T) Not supported.
6.13	7.1.13	Version Number	1	1	See the instrument specific section for handling this field.
6.14	7.1.14	Date and Time of Message	YYYYMMDDHHMMSS	YYYYMMDDHHMMSS	See the instrument specific section for handling this field. This field contains the message transmission time and date.
	* Indicates supported field. Refer to instrument sections for size of supported fields.				

Table 1.12: Patient record

CLSI Field	ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
7.1	8.1.1	Record Type	P	P	ASI instruments receive upper or lower case characters.
7.2	8.1.2	Sequence Number	*	*	Sequential number starting with one (1) and continuing until the last patient in the message. (This field follows the sequence number rules set forth by ASTM E 1394-91 Standard Section 6.6.7.)
7.3	8.1.3	Practice Assigned Patient ID	*	*	ASI instruments accept the Practice PID if it is transmitted by the Host and return it, unchanged, to the Host. Otherwise this field is not used.
7.4	8.1.4	Laboratory Assigned Patient ID	*	*	ASI instruments accept the Laboratory PID transmitted by the Host and return it unchanged to the Host. This field is the recommended field for an LIS to communicate Patient IDs to an instrument.
7.5	8.1.5	Patient ID Number 3 (Instrument PID)	*	*	ASI instruments may ignore any PID downloaded in this field. This field is used by the instrument or system to communicate a patient ID entered by the Lab operator or read by the instrument, to a Host (LIS).
7.6	8.1.6	Patient Name	*	*	ASI instruments may optionally handle this field. When used, this field has the following components: Last_name, First_name, Middle_initial, suffix (Jr.,Sr., etc.), and title (Mr., Mrs., Ms., etc.). See the instrument specific section for handling this field.
7.7	8.1.7	Mother's Maiden Name	*	*	ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
7.8	8.1.8	Birthdate	*	*	ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
	* Indicates supported field. Refer to instrument sections for size of supported fields.				

Table 1.12: Patient record *(continued)*

CLSI Field	ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
7.9	8.1.9	Patient Sex	M F U	M F U	ASI instruments may optionally handle this field. When used, this field has the following flags: (M)ale (F)emale (U)nknown See the instrument specific section for handling this field.
7.10	8.1.10	Patient Race – Ethnic Origin	*	*	ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
7.11	8.1.11	Patient Address	*	*	ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
7.12	8.1.12	Reserved			Not supported
7.13	8.1.13	Patient Phone	*	*	ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
7.14	8.1.14	Attending Physician	*	*	ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
7.15	8.1.15	Special Field 1			Not supported
7.16	8.1.16	Special Field 2			Not supported
7.17	8.1.17	Patient Height	*	*	ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
7.18	8.1.18	Patient Weight	*	*	ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
7.19	8.1.19	Patient Diagnosis Code ^Description	 * *	 * *	 Identifies the ICD-9 code for the diagnosis. Text description for the code. Both components are optional and are provided as known. Multiple diagnosis may be communicated via the use of repeat delimiters. Refer to instrument specific section for support of this field and support of repeat delimiters within this field.
	* Indicates supported field. Refer to instrument sections for size of supported fields.				

Table 1.12: Patient record *(continued)*

CLSI Field	ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
7.20	8.1.20	Patient Medications			
		Name	*	*	Identifies the therapy name or generic drug name (*e.g.*, Aspirin).
		^Level	*	*	Identifies the amount or dosage of drug or therapy as well as the frequency (*e.g.*, 2 tablets every 4 hours).
		^Start_Date	*	*	Refers to the beginning date of the therapy or medication.
		^End_Date	*	*	Refers to the stop date of the therapy or medication.
					Multiple Medications may be communicated via the use of repeat delimiters. Refer to instrument specific section for support of this field and support of repeat delimiters within this field.
7.21	8.1.21	Patient Diet	*	*	ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
7.22	8.1.22	Practice Field 1			Not supported
7.23	8.1.23	Practice Field 2			Not supported
7.24	8.1.24	Admission or Discharge Dates	*	*	ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
7.25	8.1.25	Admission Status	*	*	ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
7.26	8.1.26	Location	*	*	ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
7.27	8.1.27	Nature of Diagnostic Codes			Not supported
7.28	8.1.28	Alternative Diagnostic Codes			Not supported
7.29	8.1.29	Patient Religion			Not supported
7.30	8.1.30	Marital Status			Not supported
7.31	8.1.31	Isolation Status	*	*	ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
	* Indicates supported field. Refer to instrument sections for size of supported fields.				

Table 1.12: Patient record *(continued)*

CLSI Field	ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
7.32	8.1.32	Language			Not supported
7.33	8.1.33	Hospital Service			Not supported
7.34	8.1.34	Hospital Institution	*	*	Name of hospital or lab.
7.35	8.1.35	Dosage Category	*	*	Hematology instruments may use this field to communicate Limit Set Information relating to the category the patient/sample should be analyzed against. See instrument specific section for the structure of this field. ASI instruments may optionally handle this field. See the instrument specific section for handling this field.
	* Indicates supported field. Refer to instrument sections for size of supported fields.				

Table 1.13: Order Record

CLSI Field	ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
8.4.1	9.4.1	Record Type	O	O	ASI instruments receive upper- or lowercase characters.
8.4.2	9.4.2	Sequence Number	*	*	Sequential number starting with one (1) and continuing until the last order for a given patient in the message. (This field follows the sequence number rules set forth by ASTM E 1394-91 Standard Section 6.6.7.)
8.4.3	9.4.3	Specimen ID field			ASI Instruments accept the Specimen ID received in this field and return it unchanged to the Host (LIS) when transmitting.
		Specimen ID	*	*	
		^location ID	*	*	The Location Information (location_ID^position) components may be used to uniquely identify replicates of a single sample. This component is optional when downloading orders to ASI instruments and systems.
		^position	*	*	ASI instruments may optionally accept the location ID and position information. (Recommended for batch systems.)
	* Indicates supported field. Refer to instrument sections for size of supported fields.				

Table 1.13: Order Record *(continued)*

CLSI Field	ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
8.4.4	9.4.4	Instrument Specimen ID field			ASI Instruments ignore the contents in this field when receiving information. This field is used by the instrument or system to communicate a specimen ID entered by the lab operator, or read by the instrument to a Host (LIS).
		Specimen_ID	*		
		^location_ID	*		The Location Information (location_ID^position) components may be used to uniquely identify replicates of a single sample.
		^position	*		
8.4.5	9.4.5	Universal Test ID			As defined by ASTM 1394-91 section 6.6.1.4. The manufacturer's local code is made up of five (5) component fields as defined below. ASI instruments handle repeat delimiters in this field.
		^^^Assay_code ^Assay_name	*	*	The Test Information (Assay_code^Assay_name) is used to uniquely identify the test or tests to be done on the specimen.
		^Assay protocol	*	*	Dilution or neutralization protocols defined per assay code. See the instrument specific section for applicable assay protocols.
		^Test Qualifier	*	*	Optional qualifier for test code. See the instrument specific section for handling this field.
		^Result Qualifier	*	*	Not applicable on Order Records.
8.4.6	9.4.6	Priority	S R	S R	(S)tat (R)outine – default value See the instrument specific section for handling this field.
8.4.7	9.4.7	Requested Date and Time	*	*	See the instrument specific section for handling this field.
8.4.8	9.4.8	Collection Date and Time	*	*	Date and time of sample collection. See the instrument specific section for handling this field.
8.4.9	9.4.9	Collection End Time			Not supported
8.4.10	9.4.10	Collection Volume			Not supported
8.4.11	9.4.11	Collector ID	*	*	See the instrument specific section for handling this field.
	* Indicates supported field. Refer to instrument sections for size of supported fields.				

Table 1.13: Order Record *(continued)*

CLSI Field	ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
8.4.12	9.4.12	Action Code		C	(C)ancel – Used to cancel a previously downloaded Test Order.
				A	(A)dd – Used to add a test to a known specimen.
				N	(N)ew – Used to identify new Test Orders for an unknown specimen. If the specimen is known by the instrument/system, this message is ignored as a duplicate transmission.
			Q	Q	(Q)uality Control Specimen See the instrument specific section for handling this field.
8.4.13	9.4.13	Danger Code	*	*	See the instrument specific section for handling this field.
8.4.14	9.4.14	Relevant Clinical Info	*	*	See the instrument specific section for handling this field.
8.4.15	9.4.15	Date/Time Specimen Received	*	*	Date and Time specimen received in the Lab. See the instrument specific section for handling this field.
8.4.16	9.4.16	Specimen Descriptor Specimen Type ^Specimen Source	* *	* *	See the instrument specific section for handling this field.
8.4.17	9.4.17	Ordering Physician	*	*	See the instrument specific section for handling this field.
8.4.18	9.4.18	Physician's Phone	*	*	See the instrument specific section for handling this field.
8.4.19	9.4.19	User Field No. 1	*	*	See the instrument specific section for handling this field.
8.4.20	9.4.20	User Field No. 2	*	*	See the instrument specific section for handling this field.
8.4.21	9.4.21	Lab Field No. 1			Not supported
8.4.22	9.4.22	Lab Field No. 2			Not supported
8.4.23	9.4.23	Date/Time Reported			Not supported
8.4.24	9.4.24	Instrument Charge			Not supported
8.4.25	9.4.25	Instrument Section ID	*	*	Abbott Data Management systems use this field to assign test instruments.
8.4.26	9.4.26	Report Type	*	*	See the instrument specific section for handling this field.
	* Indicates supported field. Refer to instrument sections for size of supported fields.				

Table 1.13: Order Record *(continued)*

CLSI Field	ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
8.4.27	9.4.27	Reserved Field			Not supported
8.4.28	9.4.28	Location or Ward for Collection	*	*	See the instrument specific section for handling this field.
8.4.29	9.4.29	Nosocomial Infection Flag			Not supported
8.4.30	9.4.30	Specimen Service			Not supported
8.4.31	9.4.31	Specimen Institution			Not supported
	* Indicates supported field. Refer to instrument sections for size of supported fields.				

Table 1.14: Result Records

CLSI Field	ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
9.1	10.1.1	Record Type	R		Result records are never accepted from an LIS or Host system. ASI instruments and systems use separate result records for replicates, averages of replicates, intermediate, final, and interpreted results.
9.2	10.1.2	Sequence Number	*		Sequential number starting with one and continuing until the last result record for a given order in the message. (This field follows the sequence number rules set forth by ASTM E 1394-91 Standard Section 6.6.7.)
	* Indicates supported field. Refer to instrument sections for size of supported fields.				

Table 1.14: Result Records *(continued)*

CLSI Field	ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
9.3	10.1.3	Universal Test ID			The manufacturer's local code is made up of five (5) component fields as defined below. ASI instruments do not use repeat delimiters in this field.
		^^^Assay_code ^Assay_name	*		The Test Information (Assay_code^Assay_name) component is used to uniquely identify the test or tests done on the specimen.
		^Assay_protocol	*		Dilution or neutralization protocols defined per assay code. See the instrument specific section for applicable assay protocols.
		^Test Qualifier	*		Further qualification of the test or assay code.
		^Result type	F		(F)inal –Indicates final calculated values of concentrations, etc.
			I		(I)nterpreted –Indicates interpretations of final results based on user-defined criteria.
			P		(P)reliminary – Indicates raw instrument readings such as the RATE.
			Favg		Identifies the average of a set of final results.
			Pavg		Identifies the average of a set of preliminary results.
			Iavg		Identifies the interpretation associated with the average final result. See the instrument specific section for handling this field.
9.4	10.1.4	Data/Measurement	*		See the instrument specific section for handling this field.
9.5	10.1.5	Units	*		See the instrument specific section for handling this field.
	* Indicates supported field. Refer to instrument sections for size of supported fields.				

Table 1.14: Result Records *(continued)*

CLSI Field	ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
9.6	10.1.6	Reference Ranges			This field is used to communicate the laboratory- defined ranges for this assay. It is composed of two components separated by the component delimiter (^).
		Range	*		Multiple ranges may be communicated using repeat delimiters. The range is of the form, value to value. See the instrument specific section for specific ranges communicated.
		^Description	*		Label assigned by the laboratory to the preceding range. See the instrument specific section for handling this field.
9.7	10.1.7	Result Abnormal Flags	L		(L)ess than normal range
			H		(H)igher than normal range
			LL		(LL) – Less than extreme range
			HH		(HH) – Higher than extreme range
			QC		(QC) – Result based on a QC out of range
			>		(>) – Above dynamic range of assay
			<		(<) – Below dynamic range of assay
			EXP		(EXP) - Result based on expired reagent.
			*		*Additional abnormal flags may be defined as needed by instruments.
9.8	10.1.8	Nature of Abnormality	*		See the instrument specific section for handling this field.
9.9	10.1.9	Result Status	F		(F)inal Results – Used to indicate initial transmission of results.
			R		(R)epeat – Used to indicate previously transmitted results.
			X		(X) – Test cannot be completed. Used to indicate error during processing.
9.10	10.1.10	Date of Change in Instrument Values	*		This field may be used to indicate the date of the last calibration of an instrument.
	* Indicates supported field. Refer to instrument sections for size of supported fields.				

Table 1.14: Result Records *(continued)*

CLSI Field	ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
9.11	10.1.11	Operator IDs			
		operator	*		(operator) – When used, this field contains the ID or name of the operator who performed the test.
		^approver	*		(approver) – When used, this field contains the ID or name of the operator who approved the test results. See the instrument specific section for handling this field.
9.12	10.1.12	Date/Time Test Started	*		See the instrument specific section for handling this field.
9.13	10.1.13	Date/Time Test Completed	*		See the instrument specific section for handling this field.
9.14	10.1.14	Instrument ID	*		Used by Abbott Data Management Systems to indicate the source of results. When used, this field contains the serial number or a unique identifier for each instrument returning results.
			MANUALLY ENTERED		If results are manually entered, this field contains the string MANUALLY ENTERED, and the Operator Id (10.1.11) contains the ID or name of the person entering the results.
	* Indicates supported field. Refer to instrument sections for size of supported fields.				

Table 1.15: Comment Record

CLSI Field	ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
10.1	11.1.1	Record Type	C	C	Comment records.
10.2	11.1.2	Sequence Number	*	*	Sequential number starting with one. (This field follows the sequence number rules set forth by ASTM E 1394-91 Standard Section 6.6.7.)
10.3	11.1.3	Comment Source	I		(I)nstrument
				L	(L)IS (Computer System)
			D		(D)ata Management Systems
10.4	11.1.4	Comment Text	*	*	As described by each instrument.
10.5	11.1.5	Comment Type	G	G	(G)eneric free form comments entered by the lab operator.
			I		(I)nstrument generated exception string.
	* Indicates supported field. Refer to instrument sections for size of supported fields.				

Request Information Record

The Request Information Record allows one system to request specific information from another. Each system may request patient demographics and patient/test orders and results. Instruments and systems may request results that were previously transmitted in order to use the information in their analysis of current samples or tests, or to provide time-based comparisons (or tracking) for test results relating to a patient. The request status code (ASTM 12.1.13) identifies the purpose of the request.

Refer to the instrument specific sections to identify which type of request of those defined below are supported by that specific instrument and system. The allowed requests for information may be made based on the following types of data:

Patient IDs – Requests can be made based on single patient IDs or a range of patient IDs. The "ALL" qualifier may be used to request information on all the patient IDs known by this system. This qualifier is not recommended for common use since it returns all of the relevant information stored in the receiving systems database. Ranges of patient IDs may be requested by providing the starting patient ID (12.1.3) and the ending patient ID (12.1.4). Repeat delimiters may not be used to indicate multiple patient IDs or ranges.

Specimen IDs – Requests can be made based on specimen IDs or a range of specimen IDs. The "ALL" qualifier may be used to request information on all the specimen IDs known by this system. This qualifier is not recommended for common use since it returns all the relevant information stored in the receiving systems database. Ranges of specimen IDs may be requested by providing the starting specimen ID (12.1.3) and the ending specimen ID (12.1.4). The specimen ID is the second component in these fields. If the request is made based on the specimen ID only, it would be transmitted as "|^specimen_ID|". If the request is made based on patient ID and Specimen ID, it would be transmitted as "|patient_ID^Specimen_ID|". Repeat delimiters may not be used to indicate multiple specimen IDs or ranges.

Test Code – Requests can be made based on the test code.

Date/Time – Requests can be made based on a specific date and/or time, or a range of date/time. For a single date/time, only field 12.1.7 should be used. If a time is not specified, the entire day is assumed for that date. Field 12.1.6 specifies what type of time and date is being requested.

Ranges – A range may be specified by utilizing the Starting Range (12.1.3) and Ending Range (12.1.4) fields for patient IDs or specimen IDs. The range is interpreted using ASCII byte ordering (numbers before all alphabetic letters and upper case letters before lower case letters) to identify the matched IDs that fall between the starting and ending values. For example, using the following data set:

{Abcd, abcd, ABcd, AB123, aBcd, 12ab, 12bb}

The sort of this data (in ascending order) generates the following order:

{12ab, 12bb, AB123, ABcd, Abcd, aBcd, abcd}

Therefore, if the range had been specified as **12ab** and **abcd** the data associated with all the IDs above would be returned. Some systems may support only upper case letters (or assign equivalent values to upper and lower case letters). A system that treats upper and lower case as equivalent would treat {ABcd, Abcd, aBcd, abcd} as equivalent IDs.

NOTE: Each condition specified in the Request Information Record narrows the request further. The request returns records with information matching all the conditions specified (logical AND operation).

NOTE: ASI instruments and systems may not honor the request that uses only the "ALL" qualifiers for patient and sample IDs together. ASI instruments and systems do not generate queries using the "ALL" qualifier for patient and sample IDs together (*i.e.*, no queries for information on ALL samples of ALL patients).

Nature of Request Time Limits (ASTM/12.1.6)

Since an instrument or system may track the date and time of several events, ASI instruments and systems use this field to identify the date and time an information request is made. Refer to the instrument specific sections to identify which defined flags are supported by each instrument. The currently allowed values for this field are:

- **Specimen Collection Date/Time (S)** – Identifies the date and time a specimen was collected. Relates to field 9.4.9 (Collection End Time) of the Order Record.

- **Order Request Date/Time (O)** – Identifies the date and time the order (specimen/test) was requested for processing. Relates to field 9.4.7 (Request Date/Time) of the Order Record. If no specific information is provided in the Request Date/Time field (field 9.4.7) then the date and time the order message was received is used as the Request Date/Time for this order.
- **Result Date/Time (R)** – Identifies the date and time that a test was completed (*i.e.*, result was generated).

Request Status Codes (ASTM/12.1.3)

The Request Status Code field is used to identify the nature of the request for information. ASI instruments may support all or a subset of the following types of requests. Refer to the instrument specific section in which requests for information are supported by a specific instrument. The allowable request types are as follows:

Final Report (F) – This indicates a request for results. Based on the information provided in the query record and the ability of the instrument or system, this request returns all results (final, preliminary, interpreted, averages, calculations, etc.) associated with that patient, sample and/or test. This query returns previously transmitted results as well as any new results waiting to be transmitted. This request may be made based on single or ranges of patient(s), specimen(s), date(s)/time(s), and/or test code.

New/Edited Results (N) – This indicates a request for results that have not been previously transmitted or that have been edited. ASI instruments and systems supporting this feature do not return previously transmitted results in response to this query. This request may be made based on single or ranges of patient(s), specimen(s), date(s)/time(s), and/or test code.

Orders/Demographics (O) – This indicates a request for patient and order records. This request returns all patient and order records meeting the request criteria. The request may be made based on single or ranges of patient(s), specimen(s), date(s)/time(s), and/or test code.

Patient Demographics (D) – This indicates a request for patient demographics only. This request returns all patient records meeting the request criteria. This request may be made based on single or ranges of patient(s).

Canceled – Cannot be Done (X) – This indicates that the request previously made cannot be performed with the information provided. ASI instruments and systems may return a Comment record following the Request Information Record (Q) with the reason for not completing the request.

Abort Last Request (A) – This indicates that the requesting system would like to cancel the previously transmitted request.

Table 1.16: Request Information Record

CLSI Field	ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
11.1	12.1.1	Record Type	Q	Q	Request Information Records may be used to request information on patients, samples, and tests. These requests may be specific to a date and time or may apply to a time period with a start date and time and an end date and time. Patient IDs, Sample IDs, Test IDs, and Date/Times are AND conditions to make the request more specific.
11.2	12.1.2	Sequence Number	1	1	Sequence number is always one (1). Only one Request Information Record is sent at any one time.
11.3	12.1.3	Starting Range ID Patient ID	 * ALL	 * ALL	From Host: (ALL) indicates return all information associated with all known Patient IDs and/or Specimen IDs. From Instrument: (ALL) indicates return all requested information associated with known Patient IDs and/or Specimen IDs assigned to this instrument.
		^Specimen ID	* ALL	* ALL	
11.4	12.1.4	Ending Range ID Patient ID ^Specimen ID	 * *	 * *	Used when Patient and/or Specimen IDs are sequential. Standard string comparison rules apply to determine if a Patient ID Specimen ID falls within the range provided by ASTM fields 12.1.3 and 12.1.4.
11.5	12.1.5	Universal Test ID	^^^ALL	^^^ALL	Used to request test results for the specified test (assay code) on a specific sample or patient ID. Also used to request test orders on a specific sample ID. This field becomes an AND condition to the previous fields. (ALL) indicates all test codes and result types.
		^^^Assay_code ^Assay_name	*	*	The Test Information (Assay_code ^ Assay_name) component is used to uniquely identify the test or tests to be done on the specimens.
	* Indicates supported field. Refer to instrument sections for size of supported fields.				

Table 1.16: Request Information Record *(continued)*

CLSI Field	ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
11.6	12.1.6	Request Time Limits	S R	S R	(S) Specimen order dates. (R) Result test dates.
11.7	12.1.7	Beginning Request Date and Time	*	*	Instrument's Date and Time. When a time is not specified, the 24-hour range for that date is assumed.
11.8	12.1.8	Ending Request Date and Time	*	*	Instrument's Date and Time. When used, the date and time specified is the end of the time range of interest. When a beginning Date and Time is not specified (field 12.1.7), this field is interpreted as known information up to and including this date and time. If a time is not specified, 12:00 p.m. is used as the default.
11.9	12.1.9	Requesting Physician Name	*	*	See the instrument specific section for handling this field.
11.10	12.1.10	Requesting Physician Phone #			Not supported
11.11	12.1.11	User Field No. 1			Not supported
11.12	12.1.12	User Field No. 2			Not supported
11.13	12.1.13	Request Status Codes	A	A	(A)bort – Cancel last request.
			F	F	(F)inal Report
			N	N	(N)ew or Edited Results
			O	O	(O)rders and Demographics
			D	D	(D)emographics only
			X	X	(X) – Request cannot be done.
	* Indicates supported field. Refer to instrument sections for size of supported fields.				

Table 1.17: Terminator Record

CLSI Field	ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
12.1	13.1.1	Record Type	L	L	Terminator records indicate the end of a message.
12.2	13.1.2	Sequence Number	1	1	Sequential number always equal to one (1).
12.3	13.1.3	Termination Code	N	N	(N)ormal termination. If this field is not transmitted, (N) is assumed.
			I	I	(I)nformation not available on last request.
			F	F	(F)inished processing last request.

Table 1.18: Manufacturer's Record

ASTM Field	Field Name	Transmitted (To Host)	Received (From Host)	Description
15.1.1	Record Type	M		(M)anufacturer Defined Records Refer to instrument specific sections on support and structure of manufacturer – Instrument record types. These records are used to supplement the information provided in the PATIENT/ORDER/ RESULT records. They are used specifically to provide a mechanism for communicating information that does not fit within the PATIENT/ORDER/ RESULT structure.
15.1.2	Sequence Number	*		Any sequential number within a level.
15.1.3	Abbott Record Type			Defines the usage of the Abbott Manufacturer record. It contains two components.
	Record Class	I		Identifies the information content of the record. Valid Classes of manufacturer records are as follows:
	^Instrument_Record_ Type			(I)nstrument Information Records. Examples of instrument information record types are as follows:
		^DM		(DM) – Destination Maps for pipetting information
		^SM		(SM) – Source Maps for pipetting information
		^GR		(GR) – Graphics Record
		^CL		(CL) – Instrument Calibration information
		P		(P)atient class – Contains information relevant to patient demographics.
		O		(O)rder Class – Contains information relevant to order information.
		R		(R)esult Class – Contains information relevant to result information.
LIS2-A2 Refer to Section 14, Manufacturer's Information Record				
* Indicates supported field. Refer to instrument sections for size of supported fields.				

Refer to instrument specific sections for information on supported Manufacturer Records. Additional Abbott Record Types may be created by ASI instruments and systems as needed, to communicate information not covered by the standards and this document.

Example Messages

Below are examples of messages which conform to the requirements defined for instruments implementing the Abbott Standard Interface as described in the preceding section.

Specimen Query from an ASI Instrument

The following example shows a simple request for test information and patient demographics for a range of specimens (SID1000 through SID1008).

```
H|\^&|||ASI^1.0^s/n^H1P1O1R1Q1L1C1|||||My^Host^System||P|1|19930631[CR]
Q|1|^SID1000|^SID1008|^^^ALL|||||||O[CR]
L|1|N[CR]
```

Figure 1.33: Example of Specimen Test Order Query

Test Ordering by an External Host Computer

The following figure shows the partial Test Request message from an external host system to an ASI instrument. It contains patient demographics and test orders associated with each patient. The download of the Test Request message may be initiated by the external system or may be in reply to a query from the ASI instrument as indicated above.

```
H|\^&|||My^Host^Computer|||||ASI^1.0^s/n||P|1|19930631[CR]
P|1||PID1234||Doe^John|Smith|19500522|M|||||Jones^Bob^^^Dr|||||300.0^Anxiety\311.0^Depression|[CR}
O|1|SID1000||^^^10^Test10^protocol1|S|19930631|19930629||||N||||SERUM|Miller^John^^^Dr|||||||||Q|[CR}
O|2|SID1000||^^^22^Test22|S|19930631|19930629||||A||||SERUM|Miller^John^^^Dr|||||||||Q|[CR}
P|2||PID2222||Small^Jane|Smith|19400820|M|||||Jones^John^^^Dr||||||[CR}
O|1|SID1001||^^^20^Test20^protocol4|R|19930631|19930629||||N||||SERUM|Ahmad^Joe^^^Dr|||||||||Q|[CR}
P|3|.....
.........
L|1|F [CR]
```

Figure 1.34: Example of Test Ordering

The Report Type field of the Order record as well as the Terminator record (L|1|F [CR]) indicate that the Test Request message was in response to a query (Report Type = Q, Termination Code = F). Also, the two test orders for patient John Doe (PID1234, SID1000) could be communicated in one order record with the use of the repeat delimiters in the Universal Test ID field. The Test Request message would have been transmitted as follows:

```
H|\^&|||My^Host^Computer|||||ASI^1.0^s/n||P|1|19930631[CR]
P|1||PID1234||Doe^John|Smith|19500522|M|||||Jones^Bob^^^Dr|||||300.0^Anxiety\311.0^Depression|[CR}
O|1|SID1000||^^^10^Test10^protocol1\^^^22^Test22|S|19930631|19930629||||N||||SERUM|Miller^John^^^Dr|||||||||O|[CR}
P|2||PID2222||Small^Jane|Smith|19400820|M|||||Jones^John^^^Dr||||||[CR}
O|1|SID1001||^^^20^Test20^protocol4|R|19930631|19930629||||N||||SERUM|Ahmad^Joe^^^Dr|||||||||O|[CR}
P|3|.....
.........
L|1|N [CR]
```

Figure 1.35: Example of Test Ordering With Repeat Delimiters

The above message was not a response to a query (Report Type = O, Termination Code = N).

Results from an ASI Instrument to a Computer System

The following figure shows a partial Test Results message from an ASI instrument to an external host computer. This message may contain the results for multiple patients and tests if they have been completed and approved. One or more result records associated with a test follows each order record. All result records for that test (per specimen) are communicated together.

```
H|\^&|||ASI^1.0^s/n^H1P1O1R1Q1L1C1|||||My^Host^System||P|1|19930631[CR]
P|1||PID1234||Doe^John|Smith|19500522|M|||||Jones^Bob^^^Dr|||||300.0^Anxiety\311.0^Depression|[CR}
O|1|SID1000||^^^10^Test10^protocol1|S|19930631|19930629|||||||SERUM|Miller^John^^^Dr|||||||||O|[CR}
R|1|^^^10^Test10^protocol1^^P|500.56|RATE|||F||OPERATOR12^SUPER12|| 199306310930|MANUALLY ENTERED[CR}
C|1|I|Accidently deleted result and had to reenter|G [CR]
R|2|^^^10^Test10^protocol1^^F|56.33|ng/ml|25 to 60^normal||F||OPERATOR12 ^SUPER12|| 199306310930|[CR}
O|2|SID1000||^^^22^Test22|S|19930631|19930629|||||||SERUM|Miller^John^^^Dr|||||||||O|[CR}
R|1|^^^22^Test22^^^I|REACTIVE||||F||OPERATOR#5^SUPER12||199306310930|[CR}
P|2|.......
.........
.........
L|1|N [CR]
```

Figure 1.36: Example of Test Results From an ASI Instrument

Query for Final Results

The following example shows a simple request for final results associated with previously run samples and tests for a patient (PID1234). This query may be used to provide a lab operator with a temporary view of patient history to facilitate approval of current results.

```
H|\^&|||ASI^1.0^s/n^H1P1O1R1Q1L1C1|||||My^Host^System||P|1|19930631[CR]
Q|1|PID1234^ALL||^^^ALL|||||||F[CR]
L|1|N[CR]
```

Figure 1.37: Example of ASI Instrument Query for Test Results

Application Layer

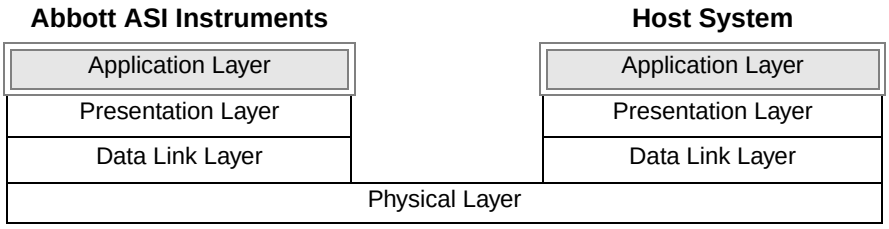


Figure 1.38: Application Layer

Generally, the Application Layer of ASI instruments and systems provides services for user interaction, instrument operation, maintenance, communication, etc. These services vary considerably from instrument to instrument and system to system, based on instrument capability, target market, and other design considerations.

In terms of communications, the Application Layer of each ASI instrument and system defines the type of messages that an instrument or system can support. In order to clarify this point, ASI instruments are grouped in the following four categories.

All ASI instruments and systems, regardless of the category, implement the Data Link layer in a similar fashion. Also, ASI instruments and systems, regardless of category, assay implement Comment and Manufacturer records as part of their supported messages in order to pass back information that does not fit within the CLSI defined records.

Category I

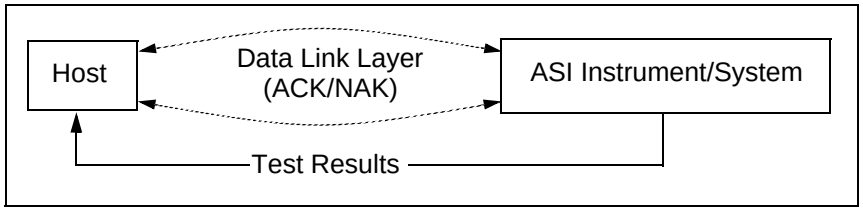


Figure 1.39: Category I Instruments and Systems

Category I instruments and systems have the ability to return test result messages to a host system in accordance with CLSI LIS2-A2 (ASTM E 1394-91) standard and as described in this document. The Test Result messages consist of Header, Patient, Order, Result, and Terminator Records.

Because of the minimal data management capabilities of these instruments and systems, patient demographics is unlikely to be supported (with the possible exception of patient IDs).

Category II

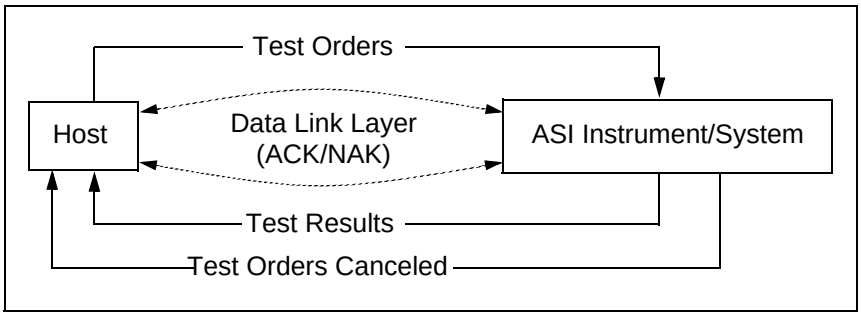


Figure 1.40: Category II Instruments and Systems

Category II instruments and systems have the ability to accept Test Order messages from an external host and return Test Result messages to that host system in accordance with CLSI LIS2-A2 standard and as described in this document. In addition, these instruments and systems also return Test Order Canceled messages if an invalid order is received.

Test Order messages minimally consist of Header, Patient, Order, and Terminator records.

Test Result messages minimally consist of Header, Patient, Order, Result, and Terminator records.

Test Orders Canceled messages consist of Header, Patient, Order, and Terminator records. The Report Type field of the Order record contains an “X” (without quotes). The Test Order Canceled message may also contain a Comment record with the specific reason why the test was canceled.

The extent that patient demographics are supported (with the exception of patient IDs) by these instruments and systems varies based on their data management capabilities.

Category III

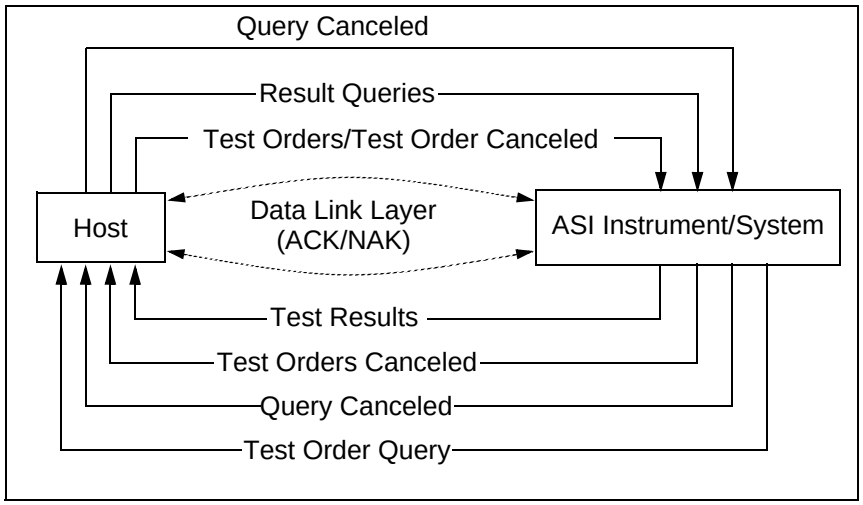


Figure 1.41: Category III Instruments and Systems

In addition to the capabilities described for Category II instruments and systems, Category III instruments accept the Result Query message and return a Query Canceled message whenever they are unable to perform the requested query. Also, they may submit a Test Order Query message requesting test orders assigned to this instrument. Instruments also accept the Query Canceled message if the host is unable to satisfy the request.

Result Query messages consist of Header, Request Information, and Terminator records. The Request Status Code field in the Request Information record contains an F to indicate final results or an N to indicate new or updated results from a certain start date. The Test Order Query message is similar. The Request Status Code field contains an O.

Query Canceled messages consist of Header, Request Information, and Terminator records. The Request Information record contains an X in the Request Status Code field to indicate that the request cannot be done. A variation of the Query Canceled message is used to abort a previously made query.

The extent that patient demographics are supported (with the exception of patient IDs) by these instruments and systems varies based on their data management capabilities. A variation of the Test Order Canceled message is used to abort a previously made test order.

Category IV

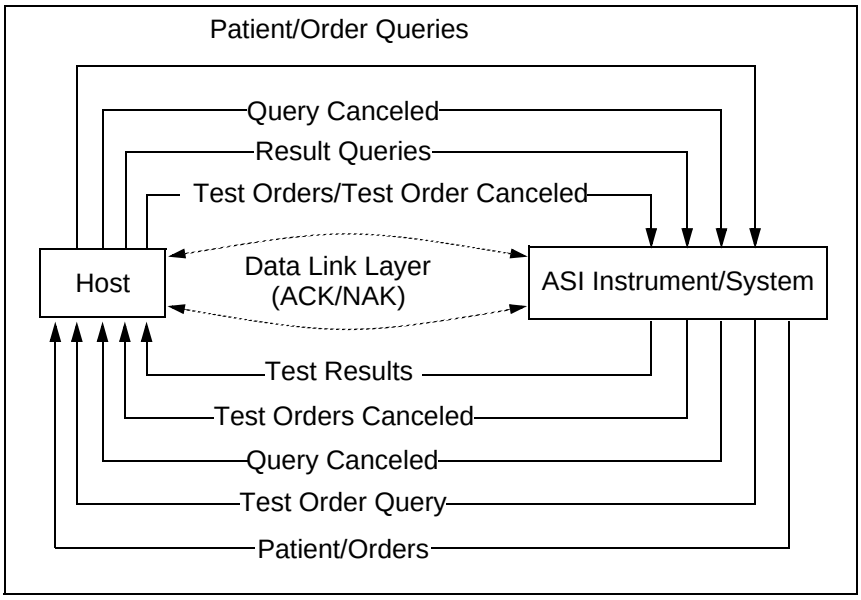


Figure 1.42: Category IV Instruments and Systems

In addition to the abilities described for Category III instruments and systems, Category IV instruments and systems can accept Patient Demographics Query and Test Order Query messages from an external host and return Patient and Order messages to that host system, in accordance with CLSI LIS2-A2 (ASTM E 1394-91) standard and as described in this document. In addition, these systems may generate Patient Demographics Queries and Test Order Queries.

The Patient Demographics Query messages and the Test Order Query messages consist of Header, Request Information, and Terminator records. When requesting patient demographics only, the Request Status Code field in the Request Information record contains a D. When requesting orders also, the field contains an O.

The Patient messages minimally consist of Header, Patient, and Terminator records while the Test Order messages consist of Header, Patient, Order, and Terminator records.

All instruments and systems in Category IV support complete demographic and order information as described in the CLSI LIS2-A2 (ASTM E 1394-91) standard and this document. The instruments and systems provide maximum flexibility for a lab environment. They allow the generation and input of patient demographics and test orders on any interconnected system. Through the use of the Query messages, the systems are able to synchronize the data bases on all relevant patients and orders without requiring redundant manual input of information.

Introduction

This section outlines the CLSI records and field contents needed to establish communication from the ARCHITECT System to a host computer.

For information on communicating from the host to the ARCHITECT System, refer to ARCHITECT System-specific Incoming Messages on page 3-1.

NOTES

Communication: ARCHITECT System to Host

Transmission of Patient test results, Quality control results and Order Query Requests utilize the high-level CLSI records and fields described in this section. Unused fields are not listed.

The generation of System to Host messages involves validation to application level requirements. An application level requirement is defined to be a requirement, which is independent of the particular standard governing the message content layer, in this case, Standard CLSI LIS2-A2.

The data defining the message are validated to application level requirements. If a given application level requirement is violated, the user is notified and the data set which contains the error is considered invalid and is not transmitted to the host.

When generating a System to Host message, the system is only required to transmit the record, up to and including the last populated field of the record and then the trailing carriage return. All empty fields subsequent to the last populated field of the record can be suppressed from transmission to the host.

The system provides the ability to transmit the outcome (result or exception) of Patient and Control test orders to the host. Calibrator results and exceptions are suppressed when transmitting to the host. System ordered constituent results and exceptions are suppressed when transmitting to the host (part of a calculated result).

QC Results Transmission

A Control test result is queued for transmission to the host (and considered pending transmission) if the following conditions are satisfied: (1) it is released, (2) if at the time of its release the QC results Transmit approved results option is Collated or Single, and (3) if at the time of its release the Connection status is Enabled. The record hierarchy is in the same format as Patient results, see Patient Results Transmission.

A Control test exception is queued for transmission to the host (and considered pending transmission) if the following conditions are satisfied: (1) if the control test exception is manually selected for Release or the Release Mode is Automatic with Exceptions, (2) if at the time of its release the QC results Transmit approved results option is Collated or Single, and (3) if at the time of its release the Connection status is Enabled.

Patient Results Transmission

The system is capable of providing Patient results and exceptions to the host in one of three ways: Single, Collated, or Collated by module based upon the selected Patient results transmission option:

Single

When the Patient results transmission option is Single, a Patient test result or exception is queued for transmission to the host (and considered pending transmission), if the result or exception is released (available for transmission), and if, at the time of its release, the Connection status is Enabled.

The record hierarchy of outgoing messages for Patient results is as follows:

Message Header Record
Patient Information Record
Test Order Record
Result Record (Final)
Comment Record (optional)
Result Record (Interpretation- optional)
Result Record (Preliminary- optional)
Message Terminator Record

Collated

When the Patient results transmission option is Collated, the system waits until the outcome (results or exceptions) of all Patient test orders and reruns for a sample are reported, before queuing any outcomes for transmission to the host.

All test results for a given sample are queued for transmission to the host (and be considered pending transmission) if the following conditions are satisfied: (1) all test results for the sample in question are released (available for transmission), (2) all test exceptions for the sample are reported (result or exception), and (3) the Connection status is Enabled.

The system assigns the Pending collation status to any released test outcomes for a sample while it waits for all other patient test orders and reruns to be completed for the sample. The record hierarchy of outgoing messages is as follows:

Message Header Record
Patient Information Record
Test Order Record (Result)
Result Record (Final)
Comment Record (optional)
Result Record (Interpretation - optional)
Result Record (Preliminary - optional)
Test Order Record (Exception)
Comment Record
Test Order Record (Result)
Result Record (Final)
Comment Record (optional)
Result Record (Interpretation - optional)
Result Record (Preliminary - optional)
Message Terminator Record

Collated by Module

When the Patient results transmission option is Collated by module, the system waits until the outcome of all patient test orders and reruns of the same type (*i* System or *c* System) are reported, before queuing any outcomes for transmission to the host.

All test results of the same type (*i* System or *c* System) are queued for transmission to the host (and are considered pending transmission) if the following conditions are satisfied:

1. all test results of the same type (*i* System or *c* System) for the aliquot in question are released (available for transmission)
2. all test exceptions of the same type (*i* System or *c* System) for the aliquot in question are reported

3. the Connection status is Enabled

The system assigns the Pending collation status to any released test outcomes for a aliquot while it waits for all other patient test orders and reruns to be completed for the aliquot. The record hierarchy of the outgoing messages is as follows:

Message Header Record
Patient Information Record (for Module 1)
Test Order Record (Result)
Result Record (Final)
Comment Record (optional)
Result Record (Interpretation - optional)
Result Record (Preliminary - optional)
Test Order Record (Exception)
Comment Record
Test Order Record (Result)
Result Record (Final)
Comment Record (optional)
Result Record (Interpretation - optional)
Result Record (Preliminary - optional)
Test Order Record (Result)
Result Record (Final)
Comment Record (optional)
Result Record (Interpretation - optional)
Result Record (Preliminary - optional)
Patient Information Record (for Module 1)
Test Order Record (Result)
Result Record (Final)
Comment Record (optional)
Result Record (Interpretation - optional)
Result Record (Preliminary - optional)
Test Order Record (Exception)
Comment Record
Test Order Record (Result)
Result Record (Final)
Comment Record (optional)
Result Record (Interpretation - optional)
Result Record (Preliminary - optional)

Test Order Record (Result)
Result Record (Final)
Comment Record (optional)
Result Record (Interpretation - optional)
Result Record (Preliminary - optional)
Message Terminator Record

Order Query Transmission

A Test Order Query Request is transmitted by the system to the host that requests all test orders be run on a given sample, which has been encountered at the bar code reader, when the following conditions exist: (1) no pending test orders exist on the system for that sample, (2) the sample is not a configured control on the system, (3) the sample is a bar coded sample (the system does not query by carrier and position), (4) a batch is not in progress on the system and (5) the Connection status is Enabled. Only one Test Order Query Request is issued by the system to the host at any given time. The system must complete an existing Test Order Query Request prior to initiating a new request. Test Order Query Requests are only made for a single sample.

The system only accepts a Negative Query Response or a Test Order Request(s) from the host in response to a Test Order Query Request.

A Test Order Query Request is considered complete under any of the following conditions:

- The system receives a Negative Query Response for the sample ID in the query
- The system receives a Test Order Request(s) for the sample ID in the query
- The system does not receive a response of a Negative Query Response or a Test Order Request for the sample ID in the query within the configured host query time out period
- A connection has been established with the host, but the system is unable to successfully transmit the Test Order Query Request to the host on its first attempt, due to a communication failure
- A connection cannot be successfully established with the host and the Connection status is Disabled

The system notifies the user if no Test Order Request(s) is received for the Sample ID.

The system does not retry transmission of the Test Order Query Request message in the event of either a communication failure or when a connection can not be successfully established with the host (Connection status is Disabled).

After three consecutive query time out errors, the system disables the query mode, pauses the sample handler and notifies the user.

If the system receives a Negative Query Response for a sample ID other than the sample ID in the issued Test Order Query Request, the system notifies the user and the Negative Query Response is ignored.

If the system receives a Negative Query Response and there are no outstanding Test Order Query Requests, the system notifies the user and the Negative Query Response is ignored.

If the system receives a Test Order Request, which is indicated as a query response for a sample ID other than the sample ID in the issued Test Order Query Request, the system notifies the user and the Test Order Request is handled as an unsolicited Test Order Request.

If the system receives a Test Order Request which is indicated as a query response and there are no outstanding Test Order Query Requests, the system notifies the user and the Test Order Request is handled as a an unsolicited Test Order Request.

The record hierarchy for a Test Order Query Request is as follows:

Message Header Record
Request Information Record
Message Terminator Record

Priority of outgoing Transmissions

The system prioritizes outgoing message transmissions to the host as follows:

1. Queued Test Order Query Request, which has been waiting the predefined maximum amount of time.
2. Released Test Results and Released Exceptions, which have been waiting the predefined maximum amount of time.
3. Queued Test Order Query Request, which has not been waiting the predefined maximum amount of time.
4. Released Test Results and Released Exceptions, which have not been waiting the predefined maximum amount of time.

The system completes the outgoing message transmission that has already started; regardless of the priority of the next message queued for transmission.

When a Test Order Query Request is transmitted to the host, no other outgoing message transmissions are allowed until the Test Order Query Request is complete.

In order to provide the host the opportunity to download Test Order Requests to the system, the system ceases transmission of all outgoing messages to the host, for a predefined amount of time, if a predefined maximum number of consecutive Released Test Results and Released Exception messages have been transmitted to the host.

Logical Transmission Error Recover Requirements

Data is presumed to be saved at the host whenever any decremental change in the hierarchical level is observed.

In the case of transmission line failure of a Test Order Query Message transmission is not retried and the user is notified.

In the case of transmission line failure of a Test Result/Exception Message, the user is notified and transmission is retried based upon the reason for failure and the exact record at which failure occurred, as described below:

If the record fails due to rejection of data content by the Host, the message is re-sequenced based upon the failed record. Transmission of the re-sequenced message is only retried if a complete message with at least one Result can be constructed. The re-sequencing must use the following rules:

- If failure occurs on a record, which is part of a Result, all records comprising the Result are skipped (not included in the re-sequenced message), and the rest of the message is re-sequenced.
- If failure occurs on a record, which is not part of a Result, that record (and all records at a lower level in the hierarchical record structure) is skipped, and the rest of the message is re-sequenced.
- If the record fails due to other communication errors (i.e. timeout waiting for acknowledgement from the Host), then the Test Result/Exception Message is re-sequenced and transmission retried.

The example below illustrates the decremental change in the hierarchical level that defines the point where the data is presumed to be saved at the host. At these level changes, all the data received, not including the record at which the decremental change occurred, is saved. In the example below at the left, storage would occur at points E, G, I, M, O, Q and T.

In order to fulfill hierarchical record level requirements, all logical records necessary to reach the restart record point are sent prior to transmitting the record where the line failure originally occurred. A list of which records would be resent in case of a transmission failure is shown at the right.

Line #	Record Type	(Level)	Increment	Action of Host:
A	Header	(Level 0)	+0	
B	Patient1	(Level 1)	+1	
C	Order1	(Level 2)	+1	
D	Result1	(Level 3)	+1	
E	Order2	(Level 2)	–1	⇐ at this point, saves A thru D
F	Comment1	(Level 3)	+1	
G	Order3	(Level 2)	–1	⇐ at this point, saves E thru F
H	Comment1	(Level 3)	+1	
I	Patient2	(Level 1)	–2	⇐ at this point, saves G thru H
J	Order1	(Level 2)	+1	
K	Result1	(Level 3)	+1	
L	Comment1	(Level 4)	+1	
M	Result2	(Level 3)	–1	⇐ at this point, saves I thru L
N	Result3	(Level 3)	+0	
O	Order2	(Level 2)	–1	⇐ at this point, saves M thru N
P	Comment1	(Level 3)	+1	
Q	Patient3	(Level 1)	–2	⇐ at this point, saves O thru P
R	Order1	(Level 2)	+1	
S	Result1	(Level 3)	+1	
T	Terminator	(Level 0)	–3	⇐ at this point, saves Q thru S

(Terminator record is assumed as saved.)

Line # where failure occurred	ARCHITECT would retransmit:
A	A
B	AB
C	ABC
D	ABCD
E	ABCDE
F	ABEF
G	ABEFG
H	ABGH
I	ABGHI
J	AIJ
K	AIJK
L	AIJKL
M	AIJKLM
N	AIJMN
O	AIJMNO
P	AIOP
Q	AIOPQ
R	AQR
S	AQRS
T	AQRST

Figure 2.1: Example of Logical Transmission Error Recovery (ARCHITECT® to Host)

Format Detail

The following sections detail the exact formats for these CLSI records:

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

NOTE: The field maximum character lengths specified are for single-byte characters. If multi-byte characters are included in the field less characters may be transmitted.

CLSI records that are not used:

- Scientific Record
- Manufacturer Information Record

NOTE: The following definitions apply to the tables:

Alphanumeric 0 to 9, a to z, A to Z

Printable string characters 32-255, excluding 127, 255

(See Section 6, ASI Code Page, Windows Code Page)

Message Header Record

The following table details the exact format of the Message Header Record which shall be sent by the ARCHITECT System to the Host.

Table 2.1: Message Header: ARCHITECT System to Host

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
6.1	Record Type ID	1	H	Header
6.2	Delimiter Definition	4	|	Field delimiter: vertical bar
			\	Repeat delimiter: backslash
			^	Component delimiter: caret
			&	Escape delimiter: ampersand
6.5	Sender Name or ID	9	ARCHITECT	Instrument Name
	Software Version	4	^Version Number (numeric)	Version number in the format 1.23
	Serial Number	25	^Serial Number (alphanumeric)	SCC Serial Number
	Interface Version	16	^Interface Version (alphanumeric)	Record types the system supports
6.12	Processing ID	1	P	Production: Treat message as an active message to be completed according to standard processing
6.13	Version No.	1	1	Mandatory Field
6.14	Date and Time	14	YYYYMMDDHHMMSS	Date and Time of transmission in CLSI format.

```
H|\^&|||ARCHITECT^1.00^123456789^H1P1O1R1C1Q1L1|||||||P|1|19930330133346[CR]
```

Figure 2.2: Example of Message Header Record: ARCHITECT System to Host

Patient Information Record

The following table details the exact format of the Patient Information Record which shall be sent by the ARCHITECT System to the Host.

Table 2.2: Patient Information Record: ARCHITECT System to Host

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
7.1	Record Type	1	P	Patient
7.2	Sequence Number	5	1 to 65535	Must be consistent with sequence number rules, described in CLSI LIS2-A2.
7.3	Practice-Assigned Patient ID	20	Printable string	• Returned unchanged during transmission to the host for patient test orders placed from the host. • Returned empty for test orders placed on the system. • Field returned empty for Control orders.
7.4	Laboratory-Assigned Patient ID	20	Printable string	• Returned unchanged during transmission to the host for patient test orders placed from the host. • Returned empty for test orders placed on the system. • Field returned empty for Control orders.
7.5	Patient ID No. 3	20	Printable string	• Optional for Patient test orders. • Field contains the data displayed in the optional PID attribute on the system for patient test orders • Empty for Control orders
7.6	Patient Name	20	Last (printable string)	• Last, first and middle patient name • Optional for Patient test orders. • Empty for Control orders
		20	^First (printable string)	
		12	^Middle (printable string)	
7.8	Birth Date	8	YYYYMMDD date≥18000101 date≤current system date	• Patient birth date • Optional for Patient test orders. • Empty for Control orders
7.9	Patient Gender	1	M, F, U	• Patient's gender (Male, Female or Unknown) • Optional for Patient test orders. • Empty for Control orders • Field is returned unchanged in transmission to the host for patient test orders placed from the host.

Table 2.2: Patient Information Record: ARCHITECT System to Host *(continued)*

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
7.14	Doctor	20	Printable String	Patient Doctor's name • Field contains the data displayed in the optional Doctor attribute on the UI for Patient Test Orders if "Transmit to host: Doctor, location and draw date/time" configuration option is On. • Field is empty for patient test orders if "Transmit to host: Doctor, location and draw date/time" configuration option is Off. • Field is empty for Control test orders
7.26	Location	20	Printable String	The general clinic location or nursing unit, or ward or bed or both of the patient. • Field contains the data displayed in the optional Location attribute on the UI for Patient Test Orders if "Transmit to host: Doctor, location and draw date/time" configuration option is ON. • Field is empty for patient test orders if "Transmit to host: Doctor, location and draw date/time" configuration option is Off. • Field is empty for Control test orders

```
P|1|||PIDSID13|Patient^Im^A||19320122|F|||||Dr.Amesbury||||||||||||ParkClinic[CR]
```

Figure 2.3: Example of Patient Information Record for Patient order: ARCHITECT System to Host

```
P|1<CR>
```

Figure 2.4: Example of Patient Information Record for Control order: ARCHITECT System to Host

Contents of fields 7.14 and 7.26 are not transmitted to the host if the system configuration of Transmit to host: Doctor, location, draw date and time is configured to Off.

Test Order Record

The following table details the exact format of the Test Order Record which shall be sent by the ARCHITECT System to the Host.

Table 2.3: Test Order Record: ARCHITECT System to Host

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
8.4.1	Record Type	1	O	Order
8.4.2	Sequence Number	5	1 to 65535	Must be consistent with sequence number rules (described in CLSI LIS2-A2).
8.4.3	Specimen ID	20	Printable String	Sample ID downloaded from Host, for Host-originated orders, or entered on the system, for user-originated orders.
8.4.4	Instrument specimen ID	20	Printable String	Instrument Specimen ID, Carrier/Crsl ID and Position are returned for all specimens tested. The position is blank for LAS orders.
	Carrier/Carousel ID	4	^alphanumeric	
	Position	2	^numeric	
8.4.5	Universal Test ID Code	4	^^^Assay Number (numeric)	Specific number that identifies the test
	Name	10	^Assay Name (printable string)	Assay test name
	Assay Protocol	10	^Dilution (printable string)	• Dilution protocol name • Empty for calculated results
	Assay Status	1	^Status (P or C)	Assay status: • P if assay is installed as the primary version • C if the assay is installed as the correlation version
8.4.6	Priority	1	S *or* R	Test specified as STAT. Routine
8.4.8	Collection Date and Time	14	YYYYMMDDHHMMSS ≥ 19700101000000 and ≤ current system date	Date and time of sample collection • Field contains the data displayed in the optional Draw date/time attribute on the UI for Patient Test Orders if “Transmit to host: Doctor, location and draw date/time” configuration option is ON. • Field is empty for Patient Test Orders if “Transmit to host: Doctor, location and draw date/time” configuration option is OFF. • Field is Empty for Control Test Orders
8.4.12	Action Code	1	Q *or* Empty	• Quality Control Result • Empty for Patient result

Table 2.3: Test Order Record: ARCHITECT System to Host *(continued)*

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
8.4.26	Report Types	1	F *or* X	Final Result
				Test could not be performed

```
O|1|SID13|SID3^A123^5|^^^123^Assay1^UNDILUTED^P|R||20010223081223|||||||||||||||||F[CR]
```

Figure 2.5: Example of Test Order Record (Patient): ARCHITECT System to Host

```
O|1|TSHBIORAD 2|TSHBIORAD 2^A123^2|^^^0241^TSH^UNDILUTED^P|R||||||Q|||||||||||||F[CR]
```

Figure 2.6: Example of Test Order Record (Control): ARCHITECT System to Host

The Report Type field (8.4.26) of the Test Order Record contains an X, when the test request cannot be processed. A comment record follows the order record and specifies the reason why the test could not be done.

The content of field 8.4.8 is not transmitted to the host if the system configuration of Transmit to host: Doctor, location, draw date and time is configured to Off.

Result Record

The following table details the exact format of the Result Record which shall be sent by the ARCHITECT System to the Host.

The system shall be capable of transmitting Patient and Control test results to Host systems.

Separate Result Records identifiable by Universal Test ID shall be sent for each of the following (since multiple result records may be sent for a single test result):

- The final result (concentration)
  — *Result type "F" in field 9.3*
- An optional interpretation
  — *Result type "I" in field 9.3*
- The instrument response used to calculate a concentration/result. (This Record is not sent for calculated results.)
  — *Result type "P" in field 9.3*

A Comment record shall follow a Result Record type F if information is entered into the comment section of the Order or Results Review screen, or downloaded from the Host with a Host-originated order.

Table 2.4: Result Record: ARCHITECT System to Host

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
9.1	Record Type	1	R	Result
9.2	Sequence Number	5	1 to 65535	Must be consistent with sequence number rules, described in CLSI LIS2-A2.
9.3	Universal Test ID Code	4	^^^Assay Number (numeric)	Specific number that identified the test
	Name	10	^Assay Name (printable string)	Test name
	Assay Protocol	10	^Dilution (printable string)	Dilution protocol name (empty for calculated test results)
	Assay Status	1	^Status (P or C)	Assay Status: • P if assay is installed as primary version • C if assay is installed as correlation version
	Reagent Lot	15	^alphanumeric	Reagent Master Lot # (empty for calculated results)
	Reagent Serial Number	5	^alphanumeric	Serial number of reagent kit used to process the test result (empty for calculated results)
	Control Lot Number	20	Printable String	Lot number of the control material (empty for patient results and calculated results)
	Result Type	1	^F	Final result concentration patient, or control result
			or	
			P	Preliminary instrument result
			or	
			I	Interpretation of final result for patient test results
9.4	Data Value	20	Printable String	For Result Type F (concentration value if within dynamic range -- may include > or <)
				For Result Type P (numeric instrument response)
				For Result Type I (interpretation)
9.5	Units	7	Result Units (printable string)	Result Type F
			or	
			RLU, Abs, or mV (printable string)	Result Type P (RLU, Abs, or mV)
			or	
			Empty	Result Type I

Table 2.4: Result Record: ARCHITECT System to Host *(continued)*

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
9.6	Reference Ranges	At least 35	Normal/Therapeutic Ranges (printable string formatted as minimum value to maximum value)	For Result Type F for Patient Result
			or	
			Control Range (printable string formatted as minimum value to maximum value)	For Result Type F for Control Result
			or	
			Empty	For Result Type I or P and for Result Type F, if range undefined.
9.7	Result Abnormal Flags	25	IUO EDIT 1-2s 1-3s 2-2s1R1M 2-2s1RxM 2-2sxR1M R-4s 4-1s1M 4-1sxM 10-x1M 10-xxM EXP EXPC A#1 A#2 CNTL < or > INDX FLEX LL or HH PSHH LOW or HIGH CORR	For Result Type F: This field can be blank or contain one of the following flags: LOW, HIGH, LL, HH, <, >, or EDIT, EXP, EXPC, CNTL, Westgard Flags, A#1, A#2, CORR, FLEX, PSHH, IUO, INDX (post launch). For Result Type P and I: This field is blank. **NOTE:** Multiple flags can be sent when the Result Type in field 10.1.3 is F. Multiple flags are sent separated by component delimiters (which are used as a repeat delimiter). The following flags are Westgard analysis flags and only display if the result is a control: 1-2s, 1-3s, 2-2s1R1M, 2-2s1RxM, 2-2sxR1M, R-4s, 4-1s1M, 4-1sxM, 10-x1M, 10-xxM
9.9	Result Status	1	F	Final Results
			or	
			R	Previously Transmitted Results
9.11	Operator Identification	12	Order Operator ID (printable string)	ID of Operator logged into system at time of order
		12	^Release Operator ID (printable string)	ID of Operator logged in at time of result release
9.13	Date/Time Test Complete	14	YYYYMMDDHHMMSS	Date and time the test processing completed.
9.14	Instrument Identification	25	Alphanumeric	Serial # of the module which performed the test. Module serial number for all tests except calculated test results, which returns the system serial number.

```
R|1|^^^0021^B-hCG^UNDILUTED^P^47331M100^00788^^F|< 1.20|mIU/mL|0.35 TO
4.94|EXP^<||F||||19990715081030|I20100[CR]
```

Figure 2.7: Example of Result Record (Result Type F) for a Patient Result: System to Host

```
R|2|^^^0021^B-hCG^UNDILUTED^P^47331M100^00788^^I|NEGATIVE|||||F||||
19990715081030|I20100[CR]
```

Figure 2.8: Example of Result Record (Result Type I) for a Patient Result: System to Host

```
R|3|^^^0021^B-hCG^UNDILUTED^P^47331M100^00788^^P|9245|RLU||||F||||
19990715081030|I20100[CR]
```

Figure 2.9: Example of Result Record (Result Type P) for a Patient Result: System to Host

```
R|1|^^^0241^TSH^UNDILUTED^P^0607M200^01824^40080^F|4.6011|mIU/mL|4.292500 TO
5.397300|||F||ECB^RY||19990715081030|I20100[CR]
```

Figure 2.10: Example of Result Record (result type F) for a Control Result: System to Host

The following list of field contents of 9.7 (Result Abnormal Flags) are not part of the CLSI standard: EXP, CORR, the Westgard Analysis flags (Example: 1-2S, 1-3S, 2-2S, R-4S, 4-1S, 10X), IUO, EXPC, A#1, A#2, PSHH, FLEX, EDIT, CNTL and INDX.

NOTE: The number format for the P value is transmitted as configured by the user. Options are:
Comma
None

Comment Record

The following table details the exact format of the Comment Record which shall be sent by the ARCHITECT System to the Host.

Table 2.5: Comment Record: ARCHITECT System to Host

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
10.1	Record Type	1	C	Comment
10.2	Sequence Number	5	1 to 65535	Must be consistent with sequence number rules, described in CLSI LIS2-A2.
10.3	Comment Source	1	I	Instrument
10.4	Comment Text	At least 260	Printable String	Result Comment or Exception String

Table 2.5: Comment Record: ARCHITECT System to Host *(continued)*

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
10.5	Comment Type	1	G	Result Comment
			or	
			I	Exception String

```
C|1|I|Example Result Comment|G[CR]
```

Figure 2.11: Example of Comment Record: ARCHITECT System to Host

For test results, a comment record follows the final result record if information is entered in the comment field of the patient or QC order or result, or downloaded from the Host.

For test exceptions, a comment record follows the order record and contain the reason for the test exception.

Request Information Record

A Request Information Record is used to request that the host immediately send any outstanding orders for a single specified patient sample.

Only one test order query request is issued by the system to the Host at any given time. The system completes an existing test order request prior to initiating a new request.

The following table details the exact format of the Request Information Record which shall be sent by the ARCHITECT System to the Host.

Table 2.6: Request Information Record: ARCHITECT System to Host

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
11.1	Record Type ID	1	Q	Query
11.2	Sequence Number	1	1	Always contains 1
11.3	ID Number	20	^Specimen ID	Sample ID read from the bar code label on the sample tube
11.5	Universal Test ID	3	^^^ALL	System always requests that ALL outstanding orders are sent
11.13	Status Code	1	O	System only requests Orders

```
Q|1|^SID12345||^^^ALL|||||||O[CR]
```

Figure 2.12: Example of Request Information Record: ARCHITECT System to Host

Message Terminator Record

The following table details the exact format of the Message Terminator Record which shall be sent by the ARCHITECT System to the Host.

Table 2.7: Message Terminator Record

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
12.1	Record Type	1	L	Last
12.2	Sequence Number	1	1	Always set as 1

```
L|1[CR]
```

Figure 2.13: Example of Terminator Record: ARCHITECT System to Host

Introduction

This section outlines the ARCHITECT System records and field contents needed to establish communications from a host computer to the ARCHITECT System.

For information on communicating from the ARCHITECT System to a host computer refer to ARCHITECT System-specific Outgoing Messages on page 2-1.

NOTES

Communication: Host to the ARCHITECT System

Transmission of Patient Demographics, Patient ID, Sample ID, Test Orders, and Query Responses utilize the high level CLSI records and fields described in this section.

Each message is validated to record/message level requirements. The record hierarchy of all Host to System messages adheres to the requirements established in the specific message format (which supplement the CLSI LIS2-A2 Standard requirements). The format (data content) of all records adheres to the requirements established in the specific record format in the following sections.

If a received record is found to violate a given record/message level requirement (hierarchical or format), the user is notified of the error and the rest of the message (including this record) is ignored. The system processes the records of the message received prior to this record.

The format (data content) of a record of a Host to System message is validated against the following criteria in addition to the CLSI LIS2-A2 Standard record format:

- The system only accepts multiple values for a field (through the use of repeat delimiters) in the Universal Test ID field of the Test Order Record.
- If the system receives a record or field of a record, which is not defined by the CLSI LIS2-A2 Standard the user is notified of the error and the rest of the message (including this record) is ignored. The system processes the records of the message received prior to this record.
- The system only validates those fields and components, which it utilizes, as defined in the specific record format. The system ignores the contents of fields and components not defined in these records, but supported by the CLSI LIS2-A2 Standard.
- The system does not support Manufacturer or Scientific Records from the Host. If either of these records is received in a message, it is ignored.
- The system does not accept Negative Query Responses in the same message as the Test Order Requests. The system accepts the first part of the message (Negative Query Response or Test Order Request), and ignores the rest of the message, from violating Negative Query Response or Test Order Request to the end of the message.

- The system accepts Negative Query Responses within the same communication session as Test Order Requests.

Each message is validated to application level requirements. The data extracted from all valid records of a given message adheres to the application level requirement portion of the record that is denoted with an asterisk. If a given application level requirement is violated, the user is notified and the data set which contains the error is considered invalid.

Transmission of patient orders to the ARCHITECT System from the host takes place according to the following logical record hierarchy as a single or multiple request(s).

Message Header Record
Patient Information Record
Test Order Record
Patient Information Record
Test Order Record
Test Order Record
Comment Record (optional)
Patient Information Record
Comment Record (optional)
Test Order Record
Test Order Record
Message Terminator Record

Transmission of a Negative Query Response (those responses that indicate that the Query Request SID is unknown, or has no outstanding orders) utilizes the following logical record hierarchy.

Message Header Record
Request Information Record
Message Terminator Record

NOTE: In the case of a negative Query Response, the Request Information Record is a copy of the original record sent from ARCHITECT System, with the Status Code field set to X.

Logical Transmission Error Recovery Requirements

The ARCHITECT System stores segments of the message as received, according to the following criteria:

- At decremental changes in the hierarchical level. Any unsaved data is saved prior to this record.
- At receipt of a test order. Any unsaved test order record and associated comment record(s) received prior to this record are saved.

According to the hierarchical record level requirements, all logical records necessary to reach the point [record] where transmission failure occurred must be retransmitted.

An example message, showing save points, is provided below at left. A list of which records would need resending in case of transmission failure is shown at right.

Line #	Record Type	(Level)	Increment	Action by ARCHITECT:
A	Header	(Level 0)	+0	
B	Patient1	(Level 1)	+1	
C	Order1	(Level 2)	+1	
D	Order2	(Level 2)	+0	← at this point, saves A thru C
E	Comment1	(Level 3)	+1	
F	Order3	(Level 2)	–1	← at this point, saves D thru E
G	Comment1	(Level 3)	+1	
H	Patient2	(Level 1)	–2	← at this point, saves F thru G
I	Order1	(Level 2)	+1	
J	Order2	(Level 2)	+0	← at this point, saves H thru I
K	Comment1	(Level 3)	+1	
L	Patient3	(Level 1)	–2	← at this point, saves J thru K
M	Comment1	(Level 2)	+1	
N	Order1	(Level 2)	+0	
O	Comment1	(Level 3)	+1	
P	Terminator	(Level 0)	–3	← at this point, saves L thru O

(Terminator record is assumed as saved.)

Line # where failure occurred	ARCHITECT would require retransmission of:
A	A
B	AB
C	ABC
D	ABCD
E	ABDE
F	ABDEF
G	ABFG
H	ABFGH
I	AHI
J	AHIJ
K	AHJK
L	AHJKL
M	ALM
N	ALMN
O	ALMNO
P	ALMNOP

Figure 3.1: Example of Logical Transmission Error Recovery (Host to ARCHITECT®)

Format Detail

The ARCHITECT System recognizes only fields associated with the following records:

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

NOTE: The field maximum character lengths specified are for single-byte characters. If multi-byte characters are included in the field less characters may be transmitted.

The following records are not used by the ARCHITECT System:

- Scientific Record
- Manufacturer Information Record

Message Header Record

Table 3.1: Message Header: Host to ARCHITECT System

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
6.1	Record Type	1	H or h	Header
6.2	Delimiter Definition	4		Bytes 2 and 6 of the record must be the same and bytes 2, 3, 4, and 5 must be different.
6.12	Processing ID	1	P or p	Production: Treat message as an active message to be completed according to standard processing
6.13	Version Number	1	1	Must be 1

```
H|\^&||||||||||P|1[CR]
```

Figure 3.2: Example of Message Header Record: Host to ARCHITECT System

Processing ID must be P and Version Number must be 1 or the message "Message Header Record to Terminator Record" is ignored.

Patient Information Record

The following table details the exact format of the Patient Information Record which shall be sent by the Host to the system.

Table 3.2: Patient Information Record: Host to ARCHITECT System

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
7.1	Record Type	1	P or p	Patient
7.2	Sequence Number	5	1 to 65535	Must be consistent with sequence number rules, described in CLSI LIS2-A2.
*The data extracted from all valid records of a given message adhere to the application level requirement portion of the record that is denoted with an asterisk.				

Table 3.2: Patient Information Record: Host to ARCHITECT System *(continued)*

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
7.3	Practice-Assigned Patient ID	20*	Printable String	• Returned unchanged during transmission to the host • Optional for Patient test orders • Default = empty field • The system does not use contents of this field for Control test orders
7.4	Laboratory-Assigned Patient ID	20*	Printable String	• Returned unchanged during transmission to the host • Optional for Patient test orders • The system does not use contents of this field for Control test orders
7.5	Patient ID No. 3	20*	Printable String	• Optional for Patient test orders • Empty for Control test orders
7.6	Patient Name	20*	Last (printable string)	• Last, first, and middle patient name for Patient test orders • The system does not use contents of this field for Control test orders
		20*	^First (printable string)	
		12*	^Middle (printable string)	
7.8	Birth Date	8	YYYYMMDD date ≥18000101* date ≤ Current System Date*	• Patient birth date • Optional for Patient test orders • The system does not use contents of this field for Control test orders.
7.9	Patient Sex	1	M, F, U	• Patient sex (Male, Female, Unknown) • Optional for Patient test orders • The system does not use contents of this field for Control test orders.
7.14	Doctor	20*	Printable string	Patient Doctor's name • Optional for Patient test orders • The system does not use contents of this field for Control test orders
7.26	Location	20*	Printable string	The general clinic location or nursing unit, or ward or bed or both of the patient • Optional for Patient test orders • The system does not use contents of this field for Control test orders

*The data extracted from all valid records of a given message adhere to the application level requirement portion of the record that is denoted with an asterisk.

Examples:

Patient Test Order

```
P|1|Practice PID|Lab PID||Doe^John^Q||19320122|F|||||Dr. Amesbury||||||||||||ParkClinic[CR]
```

Figure 3.3: Example of Patient Information Record: Host to ARCHITECT System

Control Test Order

```
P|1[CR]
```

Figure 3.4: Example of Patient Information Record for a control: Host to ARCHITECT System

> **NOTE:** If the Date of birth field is left empty, the age on the system (for result flagging purposes) is considered to be 0 (zero) years.

The field contents of Practice Assigned Patient ID (7.3) shall be copied into the Patient ID No. 3 field upon transmission back to the host (7.5) if the field contents of both the Laboratory Assigned Patient ID (7.4) and the Patient ID No. 3 (7.5) are blank. The field contents of Laboratory Assigned Patient ID (7.4) shall be copied into Patient ID No. 3 field upon transmission back to the host (7.5), if the field of the Patient ID No. 3 (7.5) is blank.

Test Order Record

The ARCHITECT System Control Center accepts unsolicited Patient and Control test orders from the LIS regardless of whether the host query option is enabled or not.

The assay name field is ignored when an order record mismatches an assay name with an assay number. An error message is not generated. The correct assay is returned with the result.

Replicates for an assay may be ordered using one of the two methods:

- Use of Repeat Delimiter in Universal Test ID (Field 5) of Test Order Record.
- Multiple Order Records containing Action Code A for Patient test orders.

NOTE: The only field in which the ARCHITECT System supports the repeat delimiters, within Incoming Messages, is the Universal Test ID of the Test Order Record.

The following table details the exact format of the Test Order Record which shall be sent by the Host to the system.

Table 3.3: Test Order Record: Host to ARCHITECT System

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
8.4.1	Record Type	1	O or o	Order
8.4.2	Sequence Number	5	1 to 65535	Must be consistent with sequence number rules, described in CLSI LIS2-A2.
8.4.3	Specimen ID	20*	Printable String	Sample ID downloaded from Host
	Carrier ID	4	^alphanumeric	Carrier ID and position are ignored on input
	Position	2	^numeric	
8.4.4	Instrument specimen ID	N/A	N/A	Field ignored on input
	Carrier ID			
	Position			
8.4.5	Universal Test ID (The only required component of this field is the assay number)	4*	^^^(numeric)*	Specific number that identifies the test
		10*	^(printable string)	Assay test name -- optional for all test orders. The system ignores the assay name sent by the Host and place the test order according to the assay number.
		10*	^(printable string)	Dilution protocol name -- optional for all test orders. If left blank, the system places the test order for the default dilution.
		1	^(P, p, C, or c)	Assay status • P or p if assay is installed as the primary version • C or c if the assay is installed as the correlation version (optional for all test orders. If left blank, the system places the test order for the primary version of the assay)
8.4.6	Priority	1	S or s	STAT (any other printable character or blank for Routine)
*The data extracted from all valid records of a given message adhere to the application level requirement portion of the record that is denoted with an asterisk.				

Table 3.3: Test Order Record: Host to ARCHITECT System *(continued)*

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
8.4.8	Collection Date and Time	14	YYYYMMDDHHMMSS ≥ 19700101000000* and ≤ current system date*	Date and time of sample collection • Optional for Patient test orders • The system does not use contents of this field for Control test orders
8.4.12	Action Code	1	N	New order for a patient sample
			or	
			A	Unconditional Add order for a patient sample
			or	
			C	Cancel or Delete the existing order
			or	
			Q	Control Sample
8.4.13	Danger Code	15	Printable String	Part of the Test Order Comment Field (optional)
8.4.14	Clinical Information	15	Printable String	Part of the Test Order Comment Field (optional)
8.4.16	Specimen Type	5	Printable String	Part of the Test Order Comment Field (optional)
	Specimen Source	15	^(printable string)	
8.4.26	Report Types	1	O or o	Order
			or	
			Q or q	Order in response to a Query Request.

*The data extracted from all valid records of a given message adhere to the application level requirement portion of the record that is denoted with an asterisk.

```
O|1|MCC1||^^^16\^^^606|||20010223081223||||A|Hep|lipemic||serum|||||||||Q[CR]
```

Figure 3.5: Example of Test Order Record: Host to ARCHITECT System

Refer to the ARCHITECT System configuration details for assay parameters to determine assay numbers and dilution protocol names to be used for Universal Test IDs.

Before a test order is created on the system, the system validates the Test Order Request received from the LIS. The system validates the assay information in each Test Order Request as follows:

- If a Test Order Request received from the host specifies an assay (defined by Assay Number and Assay Status) that is not defined (or is disabled) by the system, the system considers this request invalid and notifies the user.
- If a Test Order Request received from the host does not specify the Assay Protocol (Dilution), the system requests the test order for the default dilution of the assay.

- If a Test Order Request received from the host does specify the dilution, the system considers the specified dilution as valid and requests the test order for the specified dilution of the assay if all of the following conditions are met: the dilution protocol exists for that assay (dilution names are case sensitive) and is not a hidden calibration dilution, and the specified sample (SID) does not have a manual (offline) dilution factor specified. If the specified dilution is not valid, the system notifies the user and the Test Order Request is considered invalid.
- If a Test Order Request received from the host does not specify the Assay Status, the system requests the test order for the primary version of the assay.

If the field content of 8.4.12 (Action Code) is **N** for Patient test orders, the test order is considered a new test. However, if the same test order for this sample ID already exists (Pending, Scheduled, or Running), the system considers this an invalid request and error message is generated.

If the field content of 8.4.12 (Action Code) is **A**, the test order shall be processed as a mandatory added test order. It shall be added to the test order list regardless of whether or not the same test order exists (Pending, Scheduled, or Running) in the instrument's database.

If the field content of 8.4.12 (Action Code) is **C**, the test order shall be processed as a request to cancel the specified test order. The instrument shall cancel the first pending test order found, from its pending test order list which has the same SID, Assay Number, Dilution Name, and Assay Status. If no such order is found, the system ignores this request.

If the field content of 8.5.12 (Action Code) is **Q**, the sample is established and verified as a control for the requested analytes. If verified, the QC tests are created.

Comment Record

The following table details the exact format of the Comment Record which shall be sent by the Host to the system following the patient record, or the test order record.

Table 3.4: Comment Record: Host to ARCHITECT System

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
10.1	Record Type	1	C or c	Comment
10.2	Sequence Number	5	1 to 65535	Must be consistent with sequence number rules, described in CLSI LIS2-A2.

Table 3.4: Comment Record: Host to ARCHITECT System

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
10.3	Comment Source	1	L	Computer system
10.4	Comment Text	50	Printable characters	Comment text
10.5	Comment Type	1	G	Generic comment

C|1|L|Example Comment|G[CR]

Figure 3.6: Example of Comment Record: Host to ARCHITECT System

When the Comment Record follows a patient record, the comment in 10.4 refers to that patient sample and is duplicated in the comment field for each test order for that patient sample.

When the Comment Record follows a test order, it refers only to that test order.

The following comment text—limited to a maximum of 50 characters in length—is placed in the comment field of an ARCHITECT System test order in the following sequence:

1. Text in field 10.4 (refer to table 5.4 – Comment Record) of one or more comment records associated with the patient record.

   then

2. Text in fields 8.4.13, 8.4.14 and two components of 8.4.16 (refer to table 5.3 – Test Order Record).

   then

3. Text in field 10.4 of one or more comment records associated with the test order.

Negative Query Response Record

The system shall accept a Negative Query Response from the Host system. The Negative Query Response is used to indicate that an earlier Query Request from the system resulted in no orders being sent, either due to:

- The sample ID specified in the original Query Request was unknown to the Host system

  or

- The sample ID specified had no outstanding orders at the time the Query Request was received.

The following table details the exact format of the Negative Query Response Record which shall be sent by the Host to the system.

Table 3.5: Negative Query Response Record: Host to ARCHITECT System

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
11.1	Record Type ID	1	Q or q	Query
11.2	Sequence Number	1	1	Always contains 1
11.3	ID Number	20*	^Specimen ID (printable string)	Sample ID that was originally sent by the system
11.5	Universal Test ID	3	^^^ALL	Field contents originally sent by the system
11.13	Status Code	1	X	Indicates that either the Sample ID is unknown to the Host, or there are no outstanding orders for the specified Sample ID
*The data extracted from all valid records of a given message adhere to the application level requirement portion of the record that is denoted with an asterisk.				

```
Q|1|^SID1234||^^^ALL|||||||X[CR]
```

Figure 3.7: Example of Negative Query Response: Host to ARCHITECT System

The system shall discontinue waiting for either Test Orders or a Negative Query Response in response to an earlier issued Query Request, as defined in the user-configurable option “Host query timeout”.

After a predefined number of allowed consecutive host time-out errors (currently set to 3), the software shall:

- Log an error
- Disable the query mode

Message Terminator Record

The following table details the exact format of the Message Terminator Record which shall be sent by the Host to the system.

Table 3.6: Message Terminator Record: Host to ARCHITECT System

CLSI Field	Field Name	Maximum Characters	Field Contents	Field Description
12.1	Record Type	1	L or l	Last
12.2	Sequence Number	1	1	Must be 1

```
L|1[CR]
```

Figure 3.8: Example of Message Terminator Record: Host to ARCHITECT System

NOTES

Introduction

This section describes ARCHITECT System Support of ASI Options. The Abbott Standard Interface defines the following items as optional. The ARCHITECT System supports these items as defined in this section.

The following topics are included in this section:

- Establishment Phase
- ASI Code Pages for the ARCHITECT System

NOTES

ARCHITECT System Support of ASI Options

Establishment Phase

The system meets the requirements of the CLSI LIS1-A (ASTM E 1381-91) Standard Specification for Low-Level Protocol to Transfer Messages between Clinical Instruments and Computer Systems, and in addition, meets the following requirements. Where these requirements are in conflict with the CLSI LIS1-A (ASTM E 1381-91) Standard, these requirements take precedence.

The <EOT> character is a restricted message character and may not display in the message text part of a frame (per ASTM E 1381-91 Section 6.6.2). However, when the system is acting as the receiver, during the Transfer Phase of communication with a sender, and an <EOT> character is received, the system interprets this as an attempt by the sender to terminate the current communication session, and proceeds to the Termination Phase of communication with the sender (see ASTM E 1381-91 Section 6.4.1).

When the system is acting as the sender, during the Transfer Phase of communication with a receiver, and an <EOT> character is received in response a sent frame (a request by the receiver to interrupt the current communication session per ASTM E 1381-91 Section 6.3.5), the system ignores the request to interrupt the current communication session, and process the <EOT> character the same as a received <ACK> character (see ASTM E 1381-91 Sections 6.3.4.2 and 6.3.4.4).

When the system is acting as the sender during the Establishment Phase of communication with a prospective receiver (see ASTM E 1381-91 Section 6.2), and is unable to establish a connection after a predefined number of consecutive attempts (10), the system toggles the Connection status to Disabled. The system waits a predefined period of time (15 seconds) between consecutive attempts to establish a connection, when a given attempt fails to establish a connection.

Any of the following conditions is considered one failed attempt at establishing a connection:

- The prospective receiver is busy or does not have the ability to receive information (per ASTM E 1381-91 Sections 6.2.6 and 6.2.7),

- Contention still exists after a predefined number of consecutive attempts (3) to resolve the contention per ASTM E 1381-91 Section 6.2.7.1, or
- The prospective receiver does not respond within the required time period (per ASTM E 1381-91 Section 6.5.2.1).

ASI Code Pages for the ARCHITECT System

Table 4.1 shows the code page (a subset of MS-DOS® code page 850) supported by the ARCHITECT System Abbott Standard Interface option. ASCII characters with values between 0 and 127 are as defined by the CLSI LIS1-A (ASTM E 1381-91) and ANSI X3.4-1986 Standards. Characters with values between 128 and 255 are defined as shown. Certain values are not supported by the ARCHITECT System. These characters are translated to the copyright symbol (©) when received via the host port and again when transmitted to the host system. An incoming record is rejected if character 127 or 255 is present in the field.

The Language default option will transmit characters using the default codepage of the operating system for the selected language. For a list of code page tables for languages on the ARCHITECT System refer to Configure host-release mode window (Options - Communication view) field descriptions in the ARCHITECT System Operations Manual. For the language default option, characters with values of 32 through 255 will be translated by default the current default codepage of the operating system, with the exception of the reserved characters 127 and 255. Characters that cannot be successfully encoded or transmitted are translated to the question mark symbol (0x3F).

The Unicode (UTF-8) option will transmit characters using codepage 65001 (Unicode UTF-8). The encoding rules of UTF-8 allow every Unicode character to be transmitted. Characters that cannot be successfully encoded or transmitted are translated to the question mark symbol (0x3F).

NOTE: The Language default and Unicode (UTF-8) options are available in ARCHITECT System software version 5.00 and higher.

Table 4.1: ASI Code Page for ARCHITECT

Decimal		0	16	32	48	64	80	96	112	128	144	160	176	192	208	224	240
	Hex	0	1	2	3	4	5	6	7	8	9	A	B	C	D	E	F
0	0	NUL	DLE	SP	0	@	P	`	p	Ç	É	á	*	*	*	Ó	*
1	1	SOH	DC1	!	1	A	Q	a	q	ü	æ	Í	*	*	*	ß	*
2	2	STX	DC2	"	2	B	R	b	r	é	Æ	ó	*	*	Ê	Ô	*
3	3	ETX	DC3	#	3	C	S	c	s	â	ô	ú	*	*	Ë	Ò	*
4	4	EOT	DC4	$	4	D	T	d	t	ä	ö	ñ	*	*	È	õ	*
5	5	ENQ	NAK	%	5	E	U	e	u	à	ò	Ñ	Á	*	*	Õ	*
6	6	ACK	SYN	&	6	F	V	f	v	å	û	*	Â	ã	Í	µ	*
7	7	BEL	ETB	'	7	G	W	g	w	ç	ù	*	À	Ã	Ì	p	*
8	8	BS	CAN	(	8	H	X	h	x	ê	ÿ	¿	*	*	Ï	P	*
9	9	HT	EM	)	9	I	Y	i	y	ë	Ö	*	*	*	*	Ú	*
10	A	LF	SUB	*	:	J	Z	j	z	è	Ü	*	*	*	*	Û	*
11	B	UT	ESC	+	;	K	[	k	{	ï	*	*	*	*	*	Ù	*
12	C	FF	FS	,	<	L	\	l	|	î	*	*	*	*	*	y´	*
13	D	CR	GS	-	=	M	]	m	}	ì	*	¡	*	*	*	Y´	*
14	E	SO	RS	.	>	N	^	n	~	Ä	*	*	*	*	Ì	*	*
15	F	SI	US	/	?	O	_	o	*	Å	*	*	*	*	*	*	*

* – Unsupported characters.

NOTES

Introduction

This section provides information about the Abbott ARCHITECT Host/Instrument Interface tools. Tools include:

- Abbott ARCHITECT Host/Instrument Interface Data Disk
- ARCHITECT SCC Simulator (for LIS Vendors)

NOTES

Abbott ARCHITECT Host/Instrument Interface Data File

This data file provides scripts and examples to simulate different scenarios of CLSI interface functioning with the Abbott ARCHITECT System. There are 3 subdirectories:

- **arch** subdirectory contains necessary scripts, and data files to simulate the data sent by the ARCHITECT System.
- **host** subdirectory contains necessary scripts, and data files to simulate the data expected by the ARCHITECT System from a Host system.
- **specs** subdirectory contains common configuration files, that need to be installed, for successful simulations of bi-directional communication from and to the ARCHITECT System.

Contact your Area Customer Support to obtain the data file.

NOTES

ARCHITECT SCC Simulator (for LIS Vendors)

The ARCHITECT SCC (System Control Center) Simulator is intended as a tool for LIS (Laboratory Information System) developers. This tool simulates communication between the LIS and the ARCHITECT System. Using this tool and the Abbott Standard Interface RS-232 Manual, the LIS developers can test the LIS functionality as if the LIS is attached to the ARCHITECT System.

Installation Information

The SCC Simulator can run on a Windows® 2000 System with a COM port connected to an LIS. The connection requires a three wire RS-232 interface with configurable settings for baud rate, data bits, parity, and stop bits. Prior to running the SCC Simulator, you must set up your system or systems with an RS-232 cable and null modem.

Minimum System Requirements for installation:

- Windows 2000
- PENTIUM® 350 MHz processor
- 640 MB RAM

> **NOTE:** Do not load the ARCHITECT SCC Simulator software on the SCC that is part of the ARCHITECT System.

Contact your Area Customer Support to obtain the SCC Simulator tool.

SCC Simulator components

The SCC Simulator is an Abbott-developed software application which includes a database. A log file (SccMessageLog.txt), located in the C:\ directory, contains all low-level messages sent to or from the LIS. The SCC Simulator simulates the communication interface between the external LIS and the ARCHITECT System. It does not simulate the software behavior internal to those devices.

Using the simulator

Using the simulator includes selecting a database, configuring and connecting to a communication port, installing and deleting assay information, and other various activities prior to developing or testing the LIS functionality. The simulator can be started by running the executable IcwSim.exe located in the C:\SCC Simulator (LIS Vendors) folder.

Selecting simulator database

The connection status and simulator database selection of the simulator is displayed for the user in the status window of the application. The fields for the status window are as follows: Current View, Connection Status, Communication Port, Baud Rate, and Selected Database. The database can be selected by using the **Browse for DB** icon on the main application window tool bar (*Figure 5.1*) or by selecting **File**, **Select Database** (*Figure 5.2*). Navigate to **C:\SCCSimulator(LISVendors)\ BlankIcwSimDb.mdb**. Once the selection is made, the Current View status bar field displays **RESULTS**, indicating the results view is displayed, and the Selected Database status bar field displays the selected database name (*Figure 5.3*).

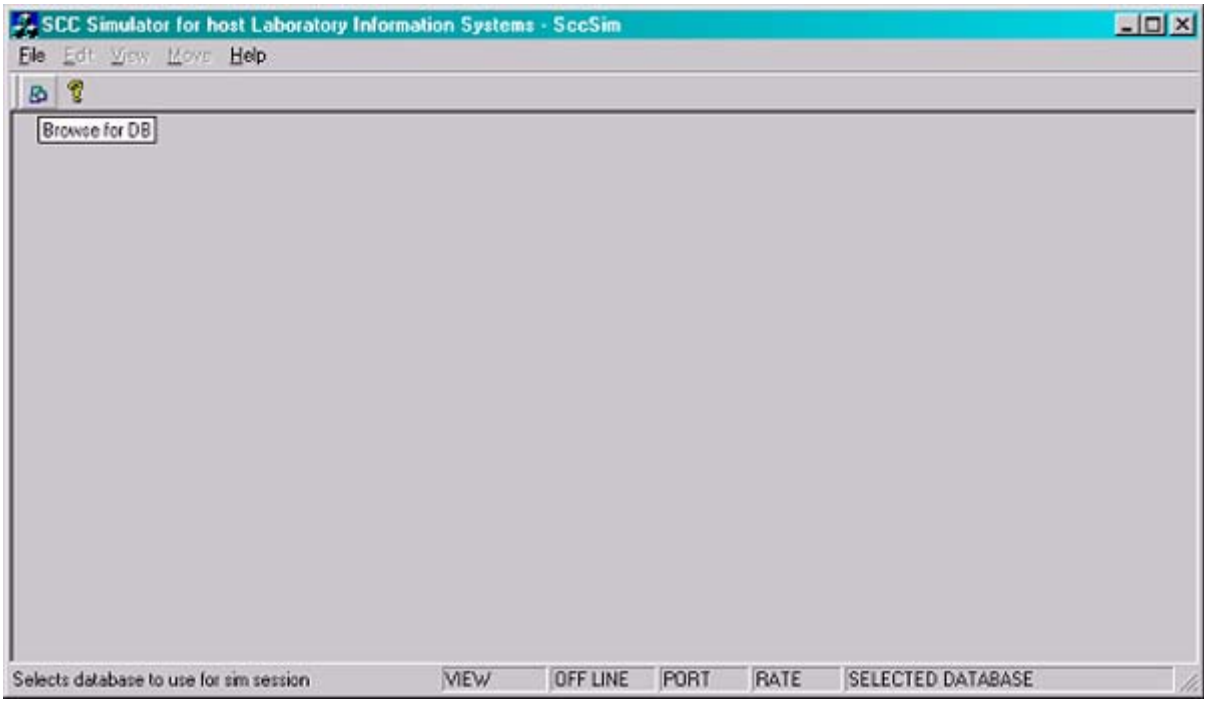


Figure 5.1: SCC Simulator Database Selection

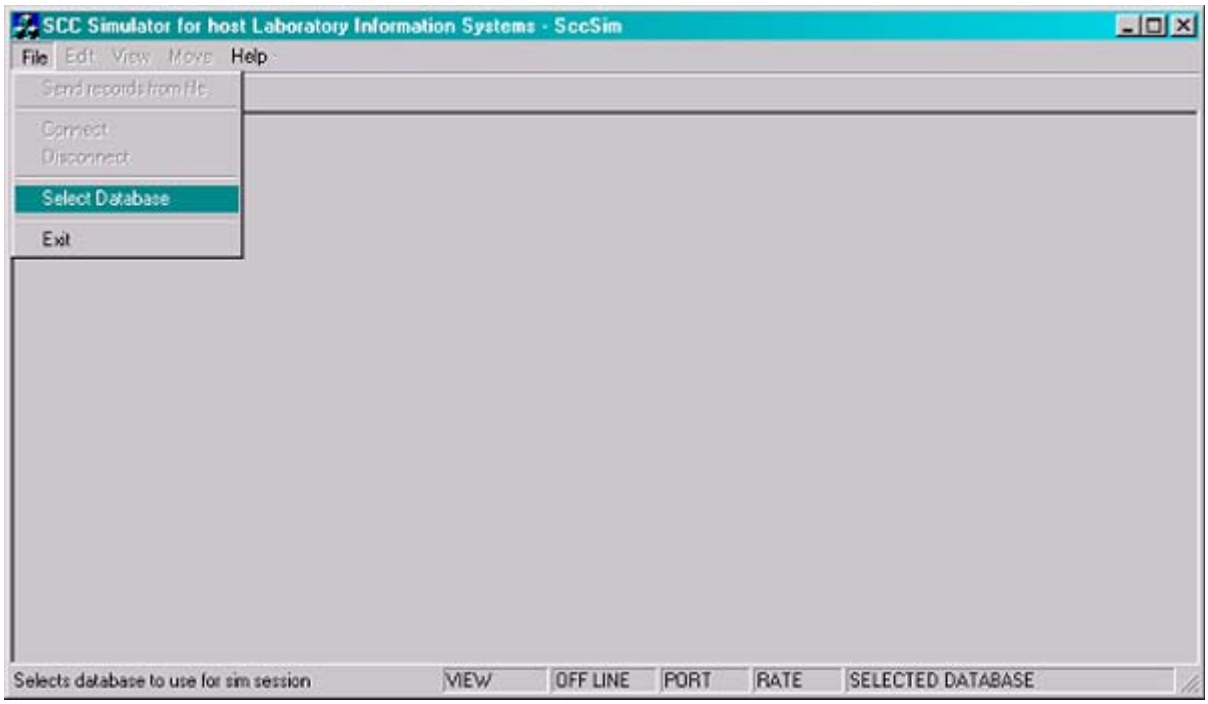


Figure 5.2: SCC Alternate Database Selection

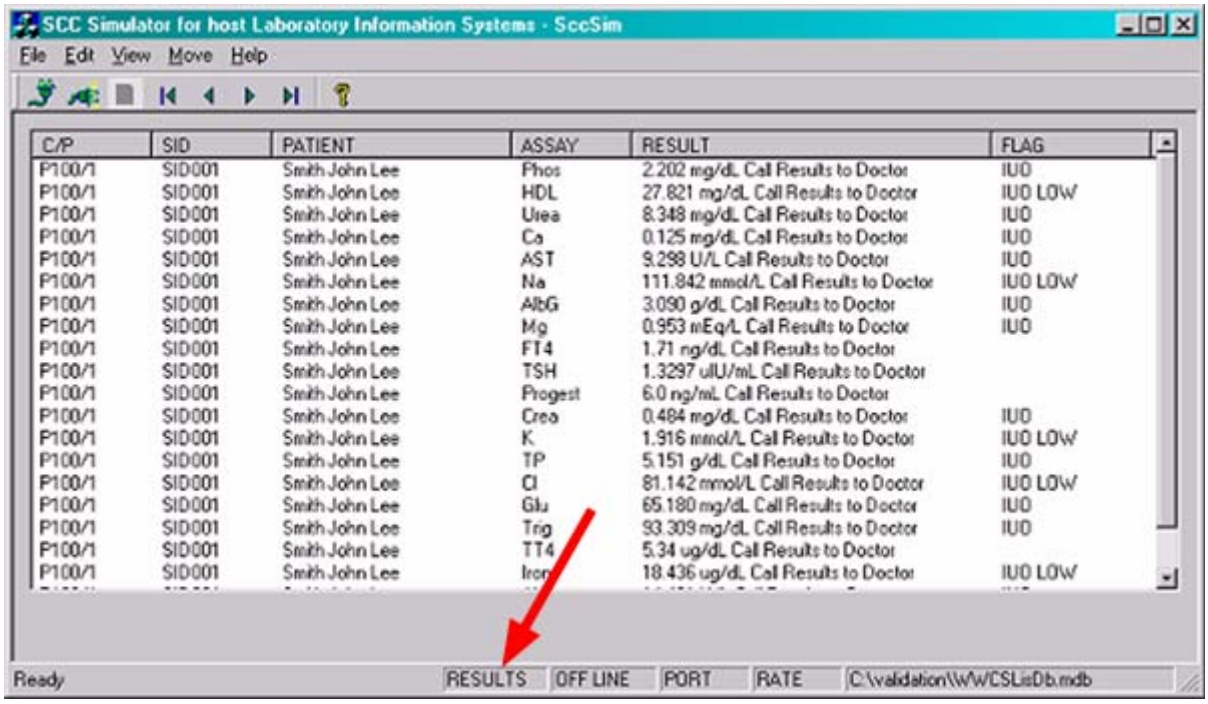


Figure 5.3: SCC Simulator after Database Selection

Configuring communication ports

The user can configure a communication port for the SCC Simulator by selecting **Edit**, **Comm** (*Figure 5.4*). The communication settings window (*Figure 5.5*) displays, allowing the user to configure the following port attributes:

Communication ports [1-10]

- Baud rate [1200, 2400, 4800, 9600, 14400, 19200, 28800, 38400, 57600, 115200]
- Data bits [7, 8]
- Parity [even, odd, none]
- Stop bits [1, 2]

The communications settings window (*Figure 5.5*) also has a **Reset To Defaults** button allowing the user to reset the communication settings to the following default port attributes

Communication port	2
Baud rate	9600
Data bits	8
Parity	none
Stop bits	1

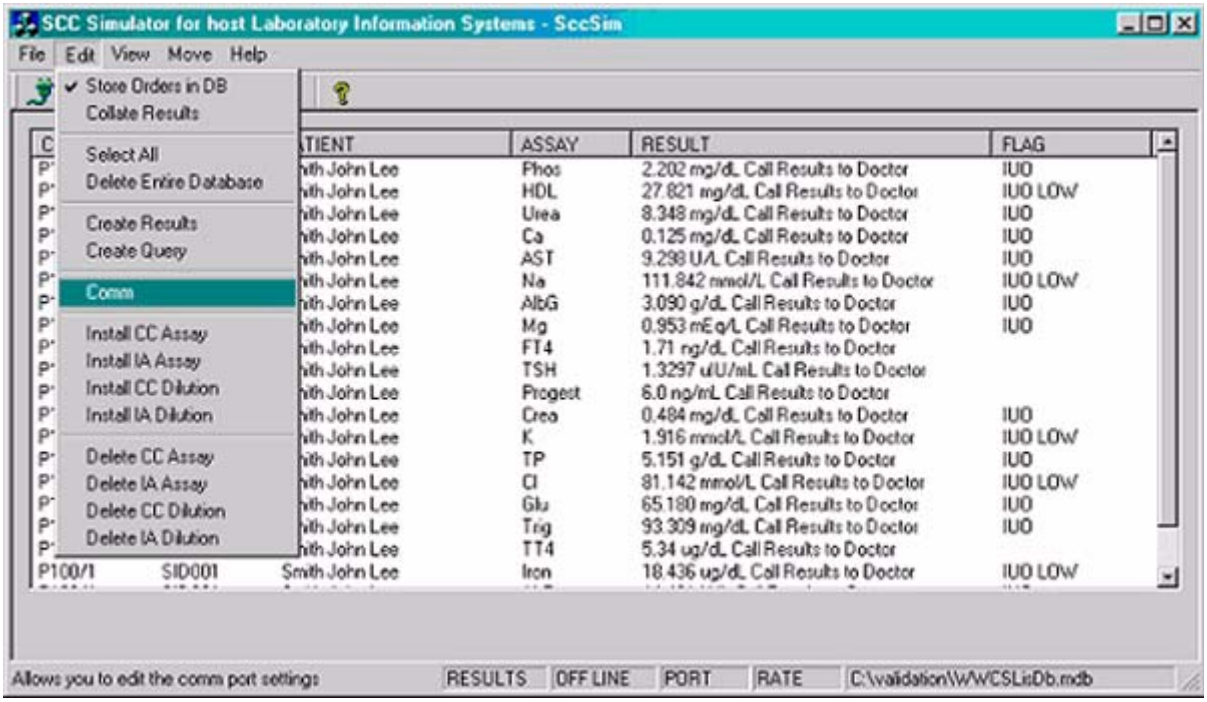


Figure 5.4: Configure Communication Port

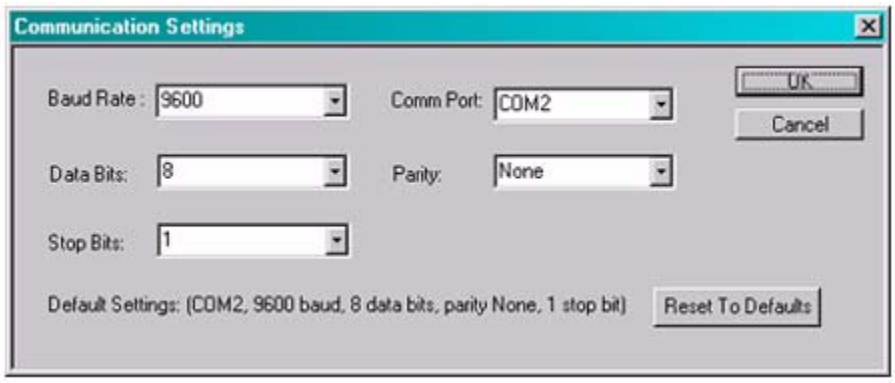


Figure 5.5: Communications Settings window

Connecting to the communication port

The SCC Simulator main application window status bar provides the connection status of the communication port. Prior to connecting to the communication port, the SCC Simulator connection status field displays **OFF LINE**, the communication port status field displays **PORT**, and the baud rate status field displays **RATE** (*Figure 5.6*). Once the user selects the communication settings used in the SCC Simulator session, the user can connect to the communication port by pressing the **Connect** icon on the main application window tool bar (*Figure 5.7*), or by selecting **File**, **Connect** (*Figure 5.8*). After the connection is established, the main application status window connection status field displays **ON LINE**, the communication port status field displays **COM#** (# is 1-10), and the baud rate status field displays one of the following baud rate values (1200, 2400, 4800, 9600, 14400, 19200, 28800, 38400, 57600, 115200) (*Figure 5.9*).

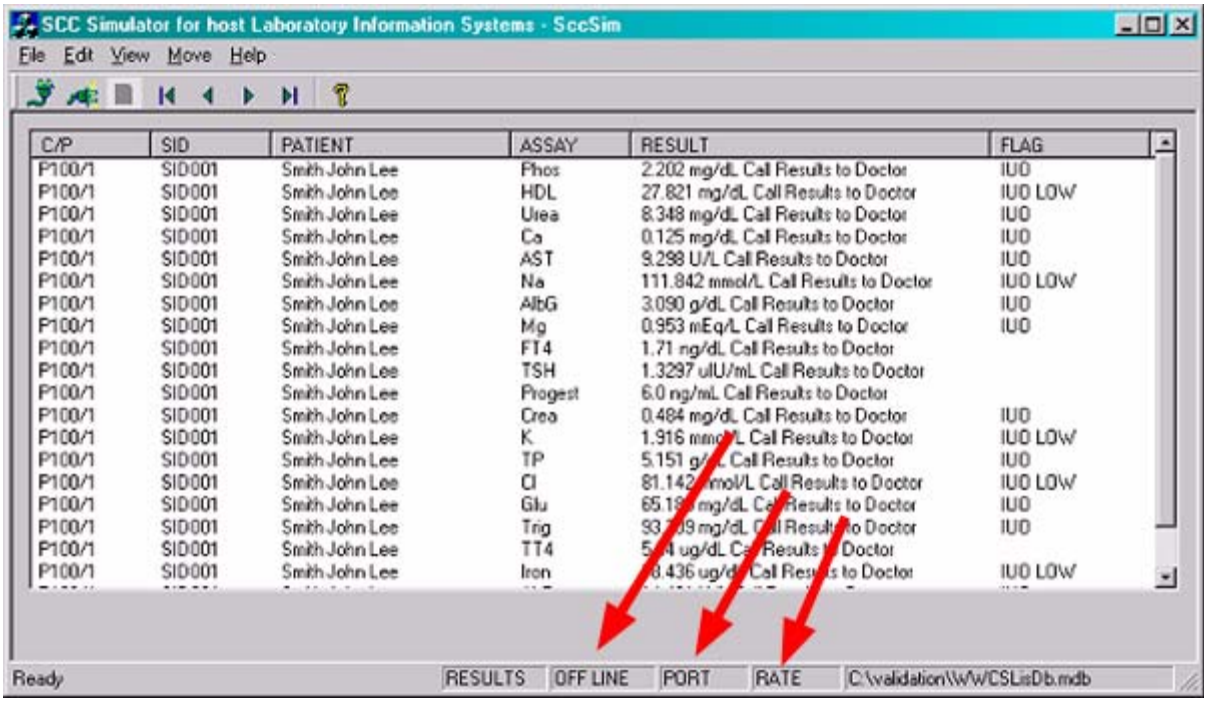


Figure 5.6: Application Window Prior to Connection

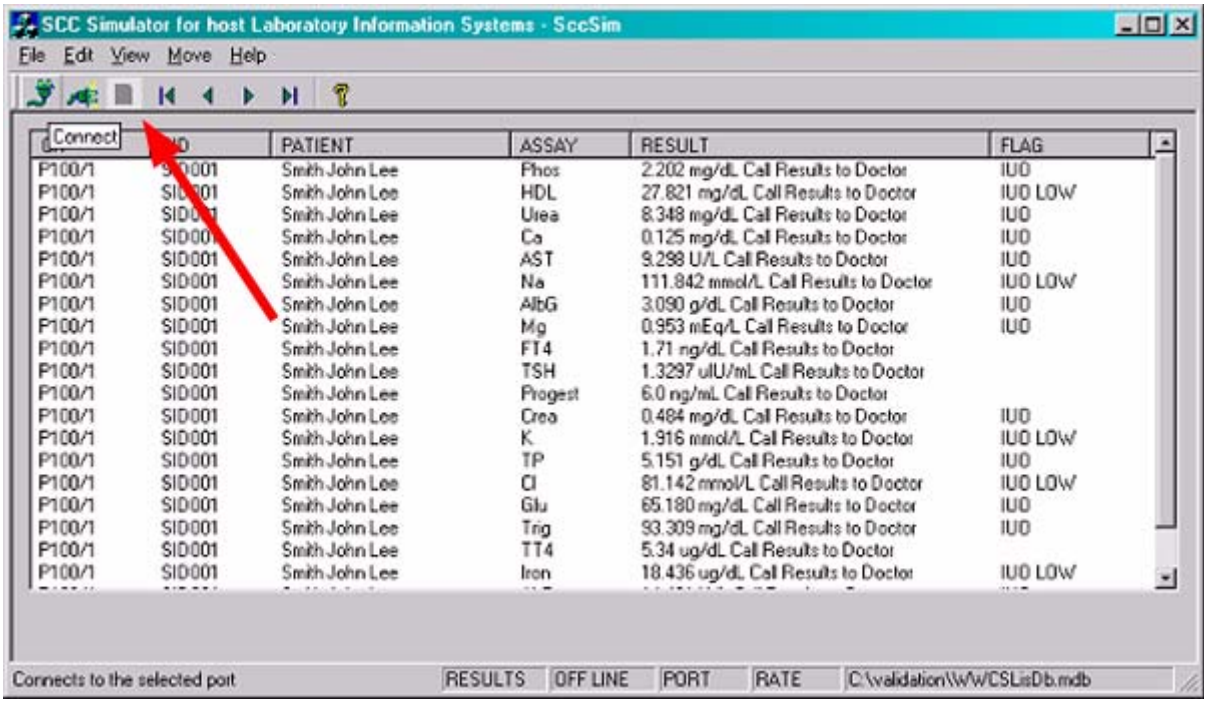


Figure 5.7: Connecting through Tool Bar Icon

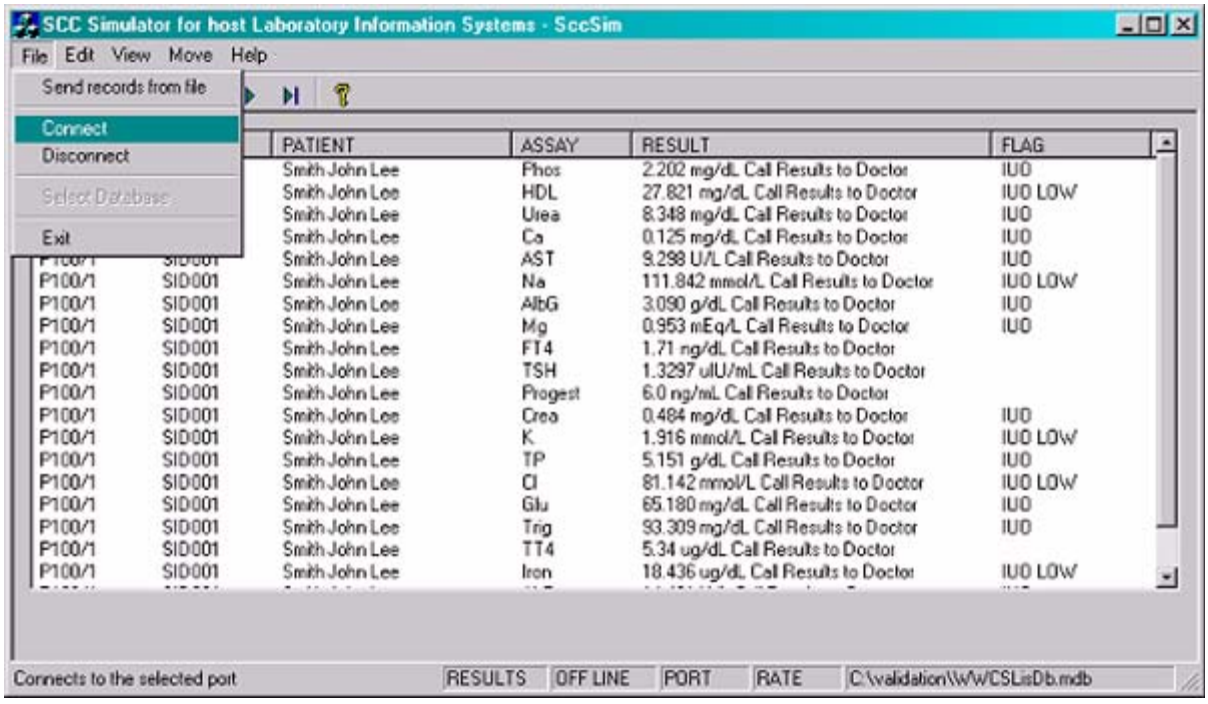


Figure 5.8: Connecting through the Main Menu

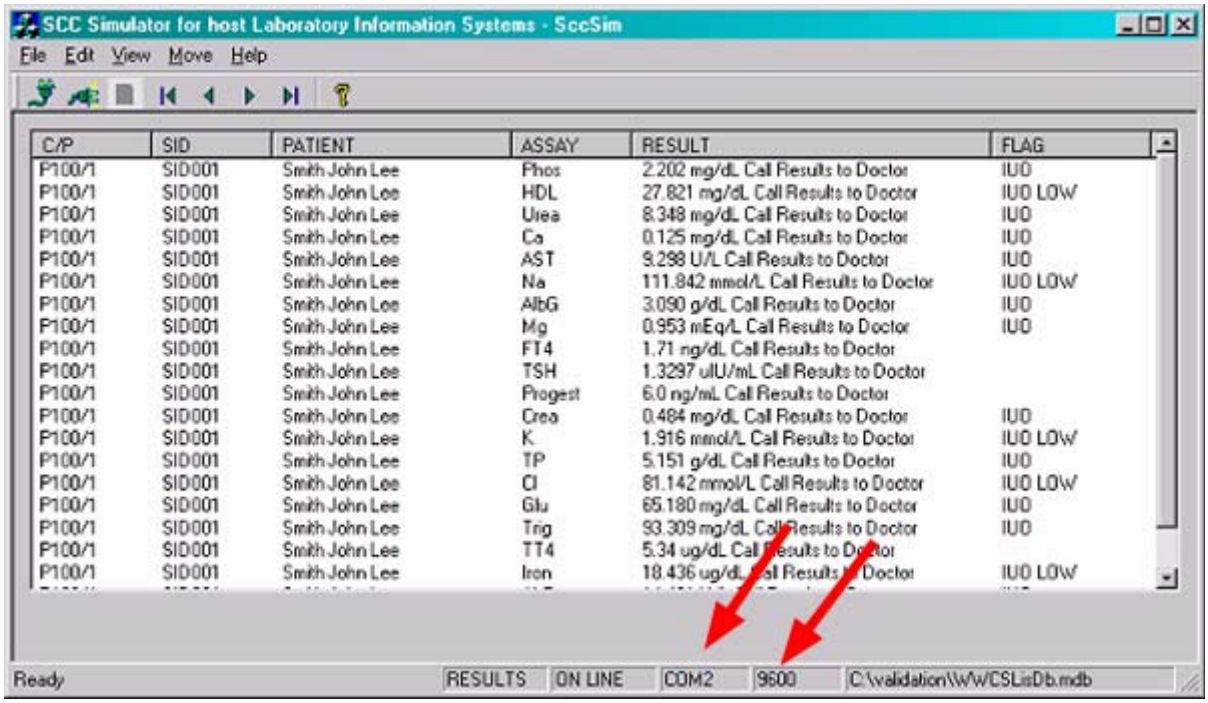


Figure 5.9: Application Window after Connection

Store received orders

The SCC Simulator provides the ability for the user to store orders or discard them. The SCC Simulator automatically selects storing received orders to the database when the application is started (*Figure 5.10*). If **Store Orders in DB** is checked, orders are stored in the database. The user can change this selection by selecting **Edit**, **Store Orders in DB** (*Figure 5.11*). Selecting this menu item toggles storing of orders to the database (*Figure 5.12*). In either case, the low-level result records are logged to the SCC Message Log.

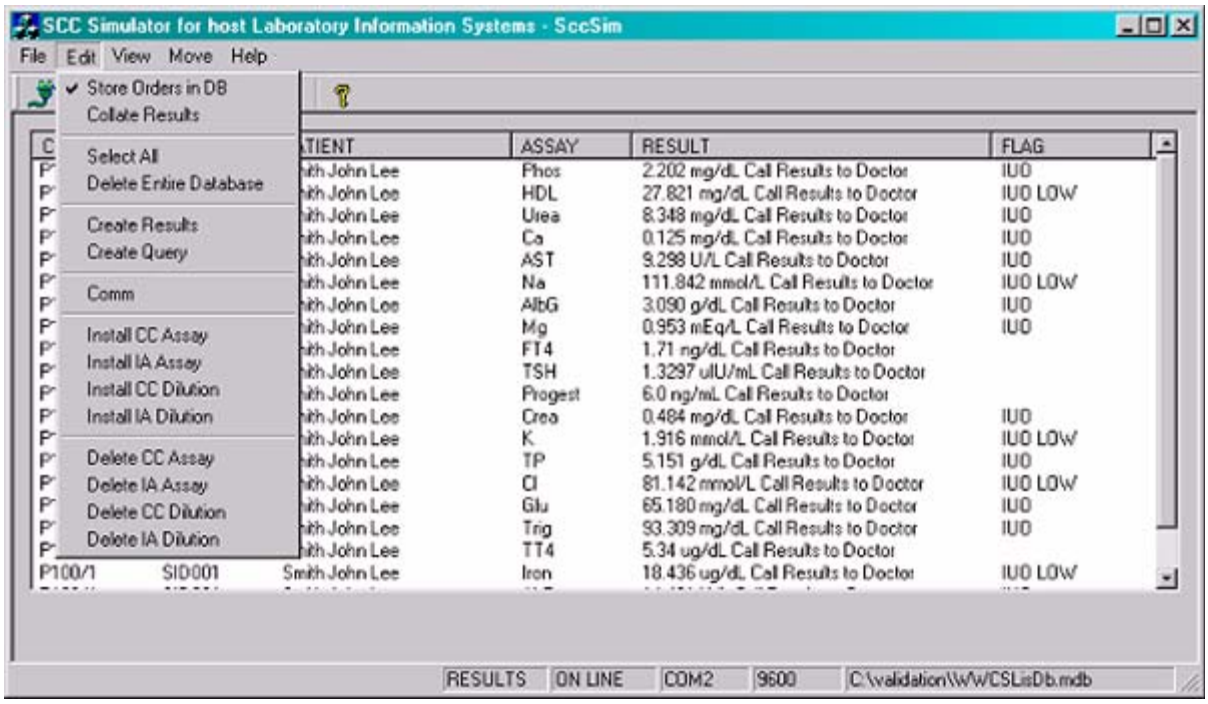


Figure 5.10: Storing Orders to the Database

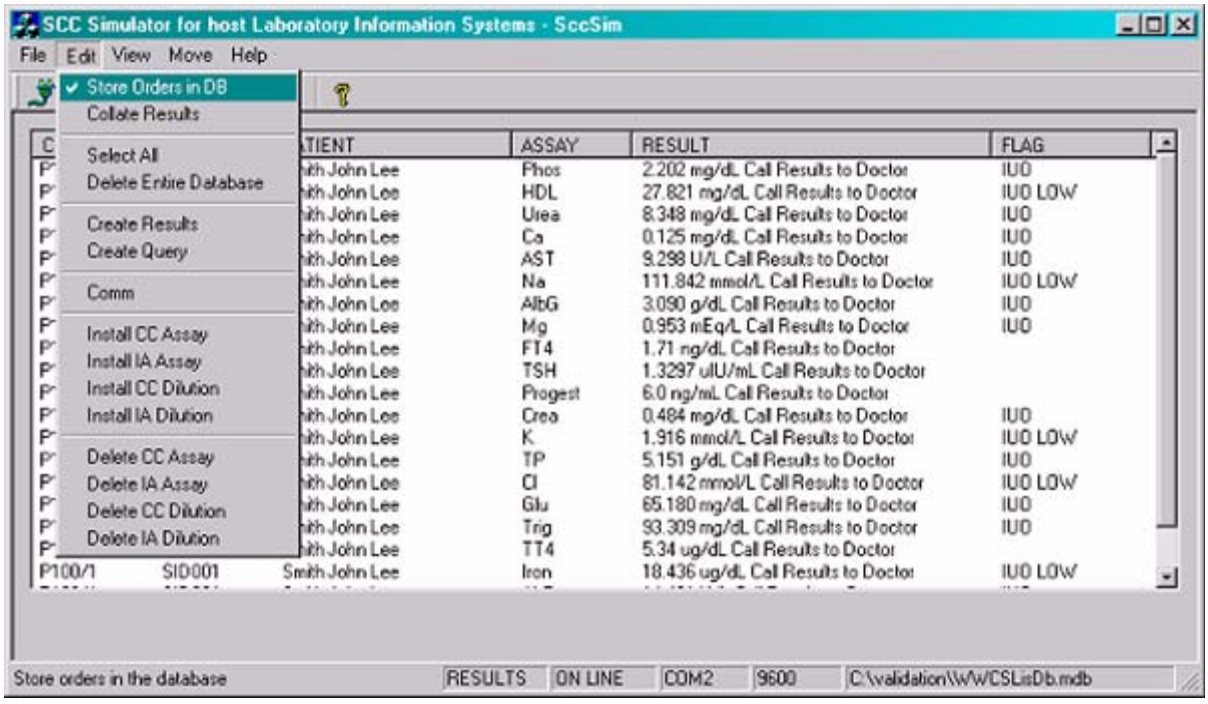


Figure 5.11: Deselecting Storing Orders to the Database

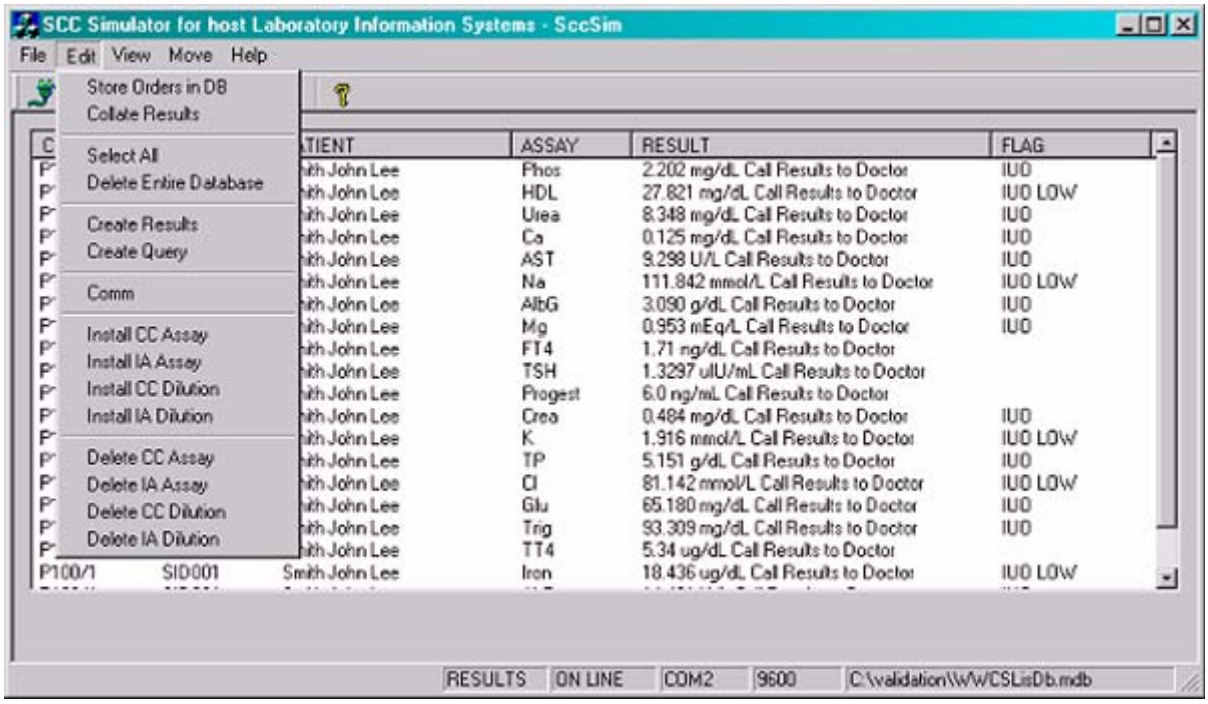


Figure 5.12: View after Toggle of Store Orders in DB

Collate results

The SCC Simulator provides the ability for the user to collate results that are sent to the LIS. The SCC Simulator defaults to not collating results when the application is started (*Figure 5.13*). Results are only collated if **Collate Results** is checked. The user can change this by selecting **Edit**, **Collate** (*Figure 5.14*). Selecting this menu item toggles the selection of the Collate Results menu item (*Figure 5.15*).

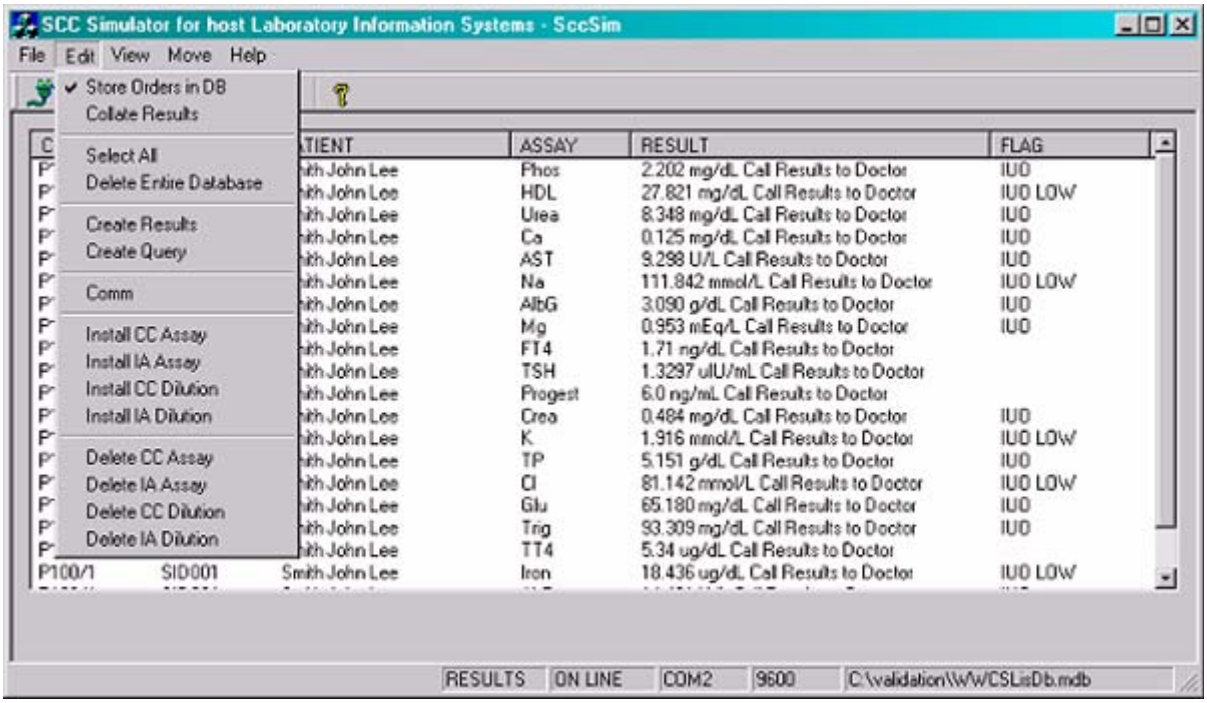


Figure 5.13: Collated Results

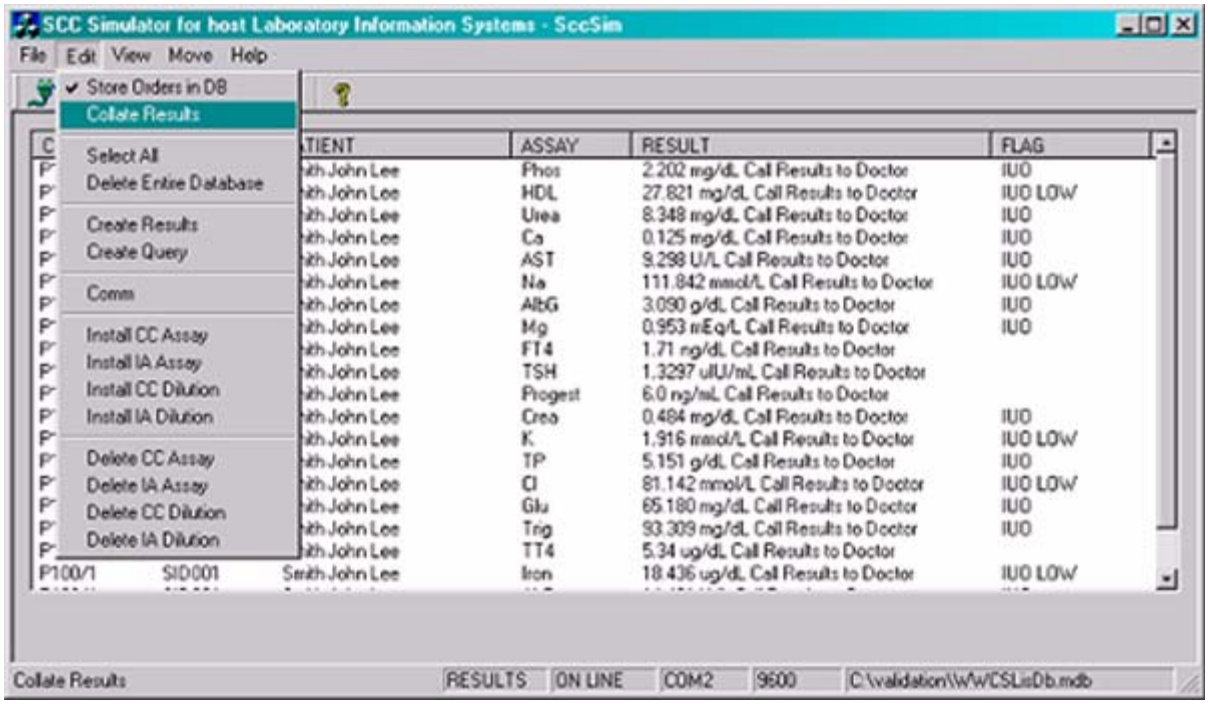


Figure 5.14: Selecting Collated Results

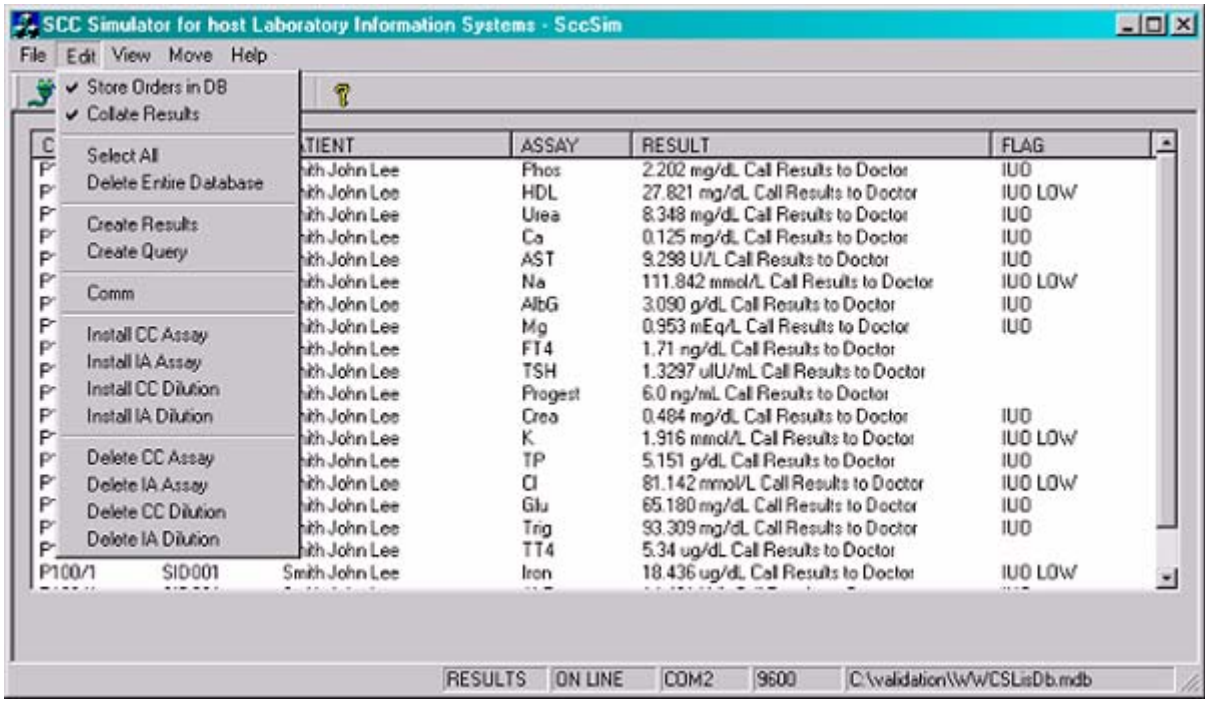


Figure 5.15: After Selection of Collate Results

Selecting views

The SCC Simulator supports multiple views [RESULTS VIEW, QUERIES VIEW, and ORDERS VIEW] that can be displayed based on user input through the user interface. The default view [RESULTS VIEW] is displayed immediately after the user has selected a database (*Figure 5.3*). The user can change the displayed view by selecting **View**, **Queries** (*Figure 5.16*).

The QUERIES VIEW displays in the main application window (*Figure 5.17*). The user can change to the ORDERS VIEW by selecting **View**, **Order From DB** (*Figure 5.18*). The ORDERS VIEW displays in the main application window (*Figure 5.19*). The display can be changed back to the RESULTS VIEW by selecting **View**, **Results**.

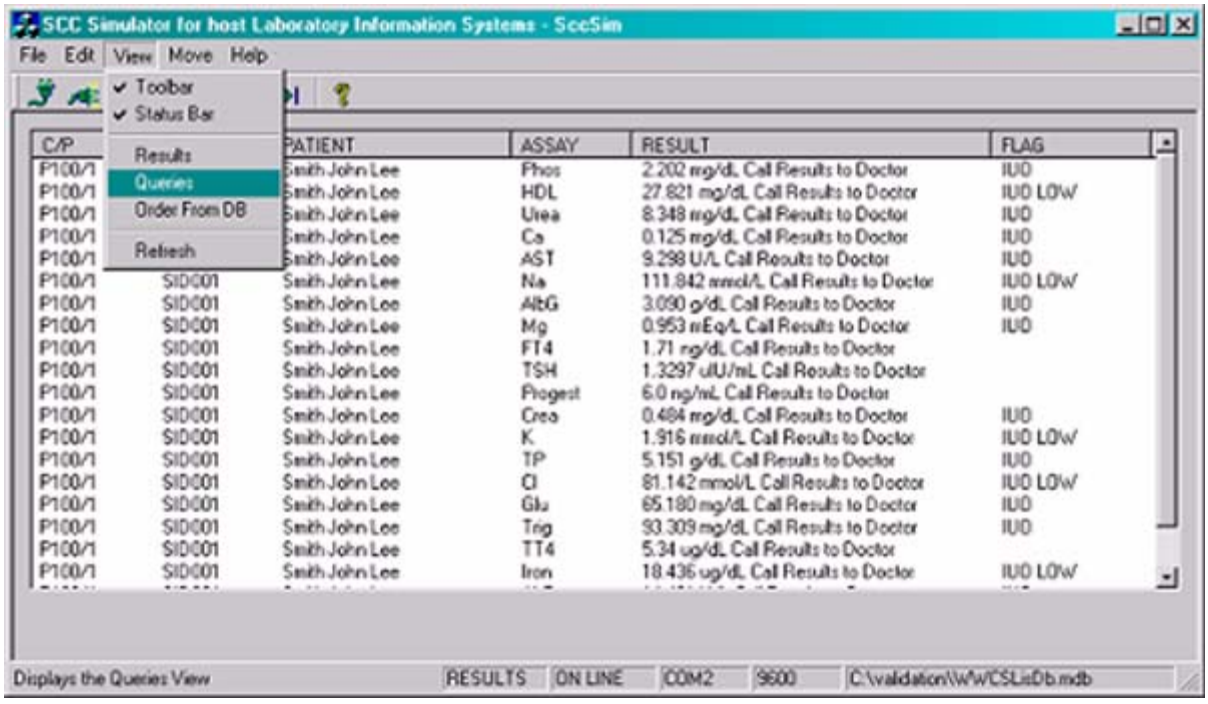


Figure 5.16: Selecting the Queries View

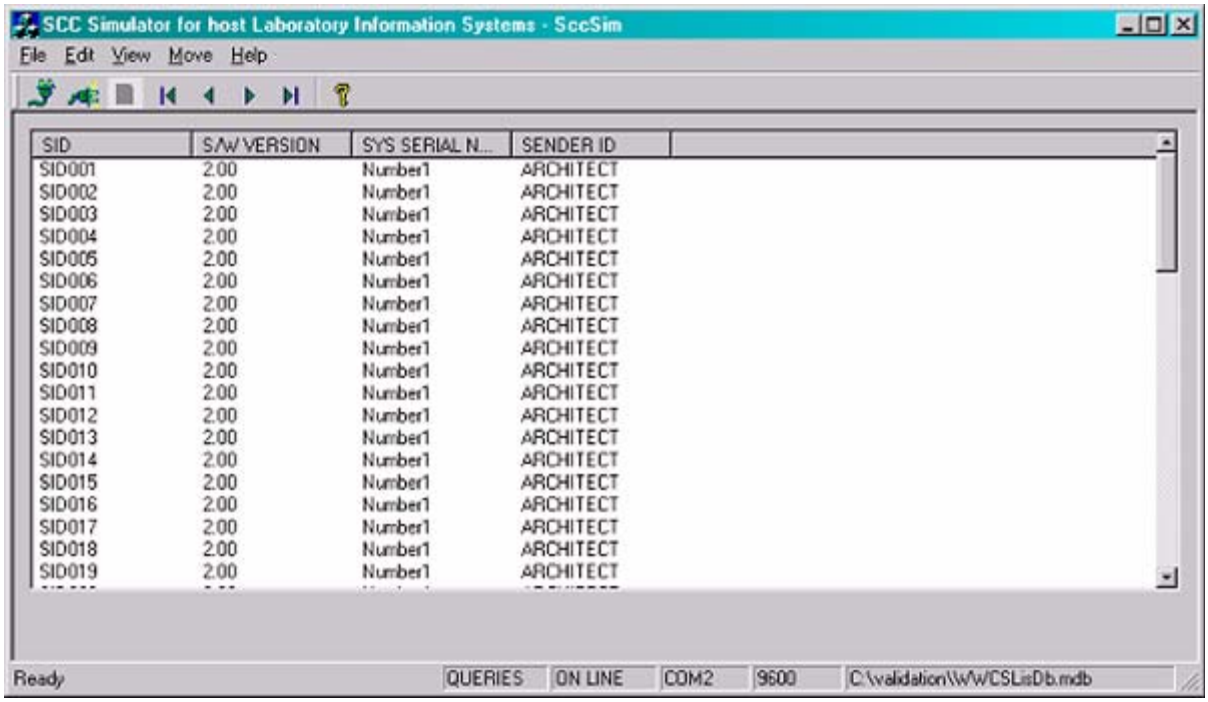


Figure 5.17: Queries View

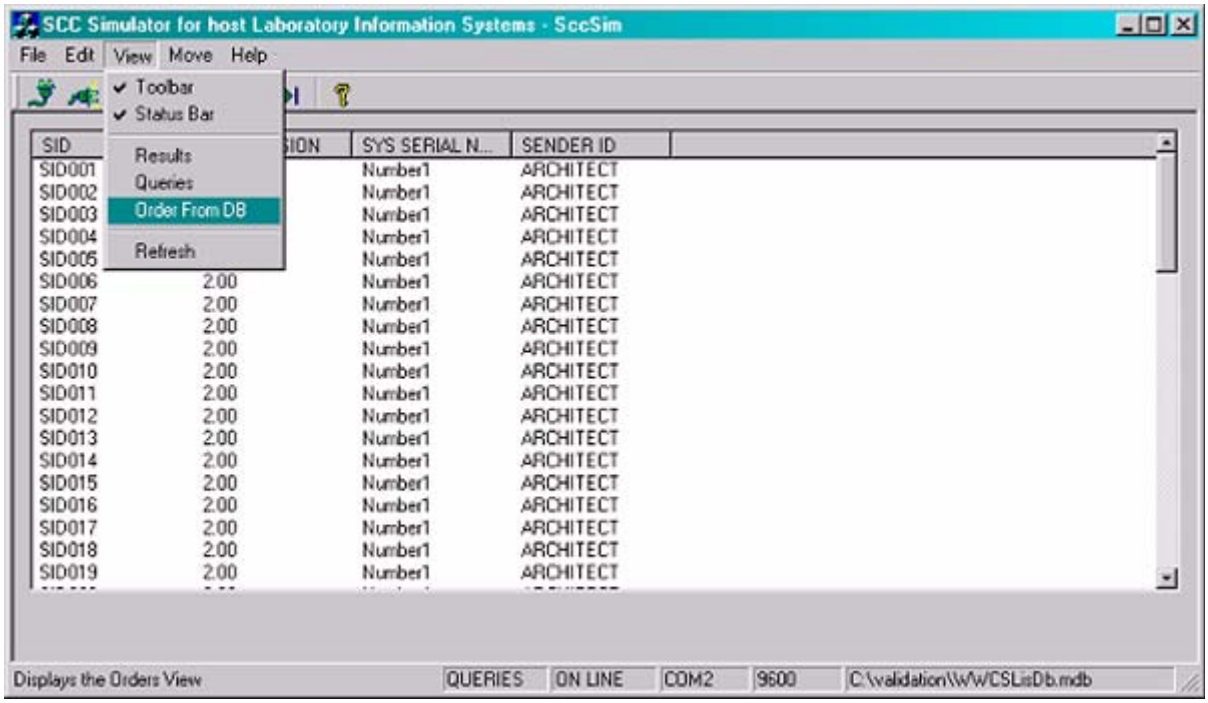


Figure 5.18: Selecting the Orders View

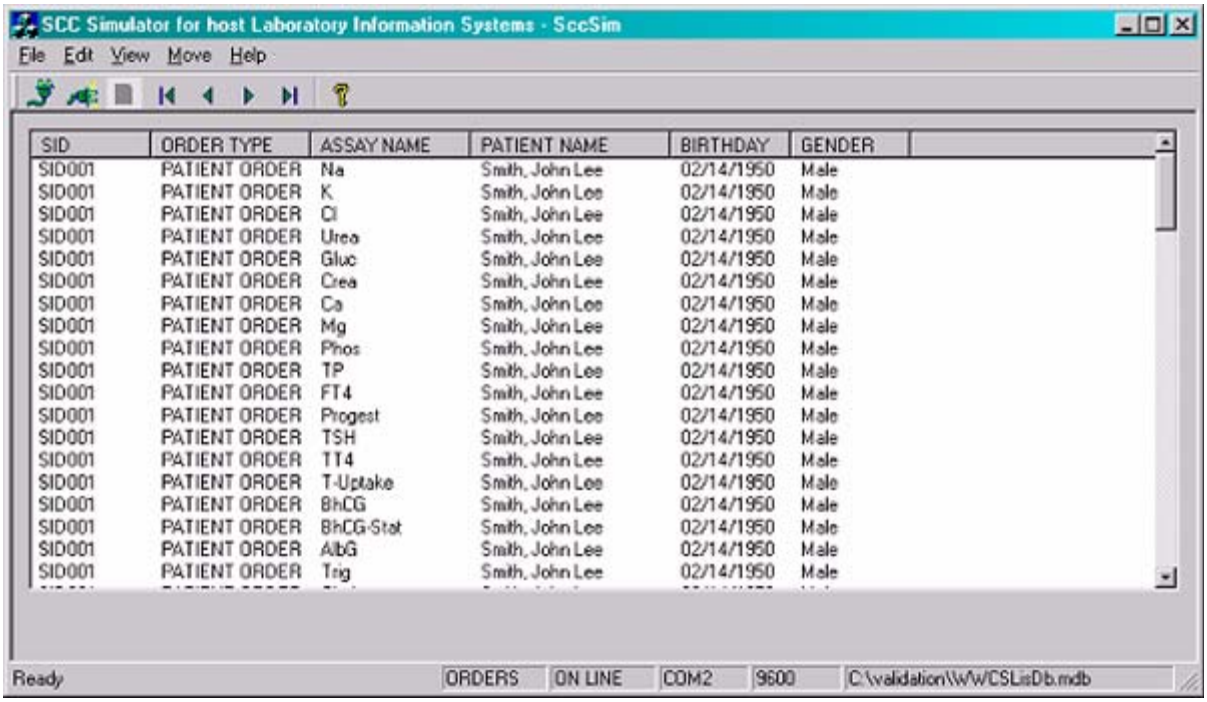


Figure 5.19: Orders View

Refresh views

The Simulator enables the Refresh icon on the main application toolbar if any orders have been received (*Figure 5.20*). The Simulator also enables the Refresh icon if the user has created any results or queries. The user can refresh the current view by pressing the Refresh icon on the main application window toolbar (*Figure 5.21*) or by selecting **View**, **Refresh** (*Figure 5.22*). The simulator disables the Refresh icon and updates the current view (*Figure 5.23*). Note the current view is updated, but no new information may show up because the Refresh icon is enabled if any new data has been received (i.e. queries). The user may have to change the view to see the new information. Also, the new data received is placed at the bottom of the database list. Therefore, the user may have to select the last records to view the new data.

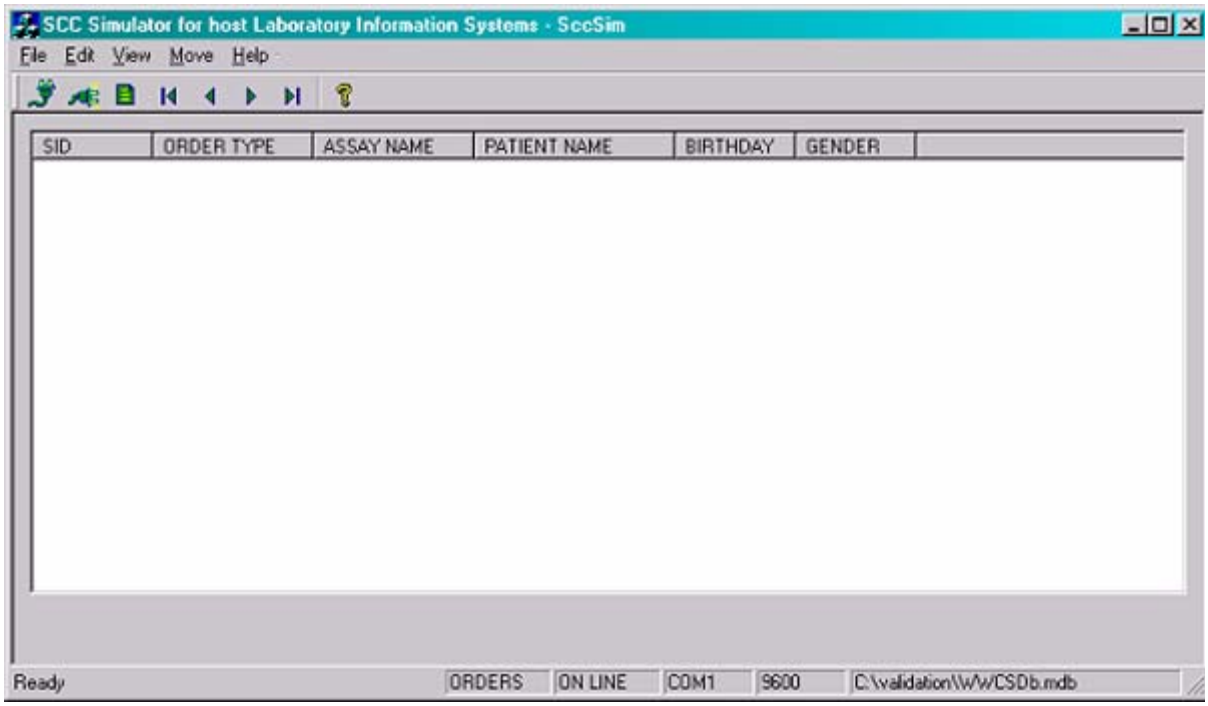


Figure 5.20: Refresh Notification

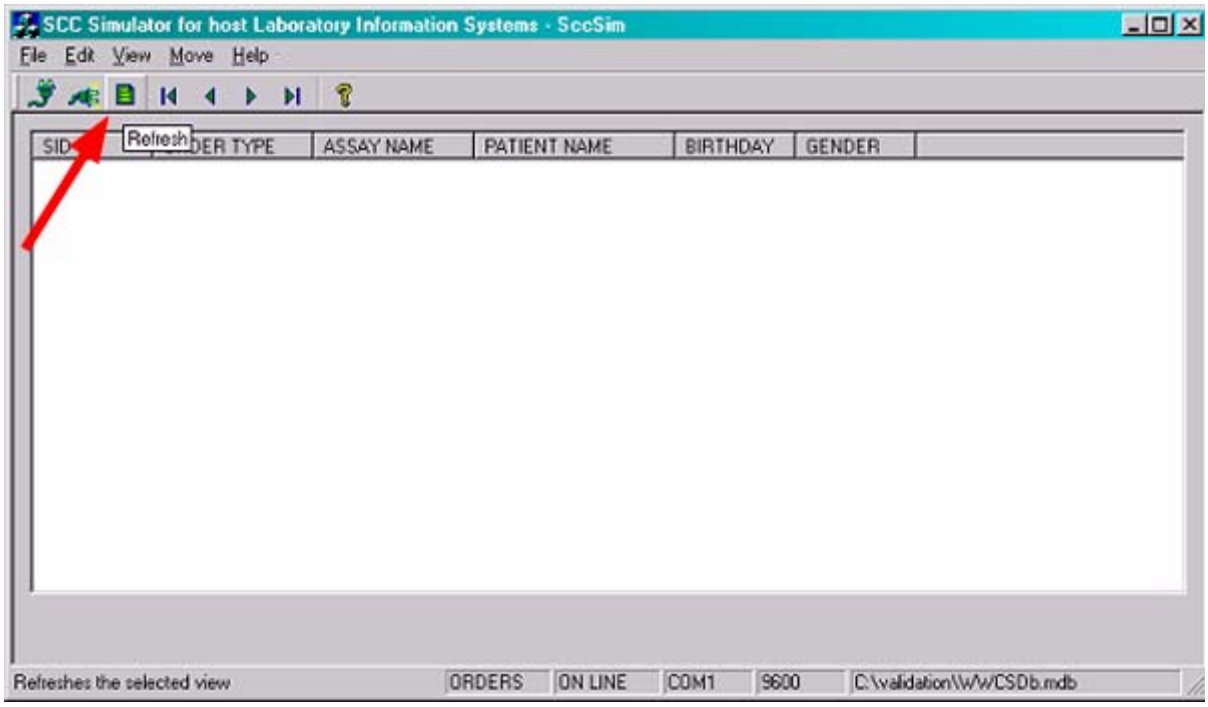


Figure 5.21: Refreshing the View From Toolbar

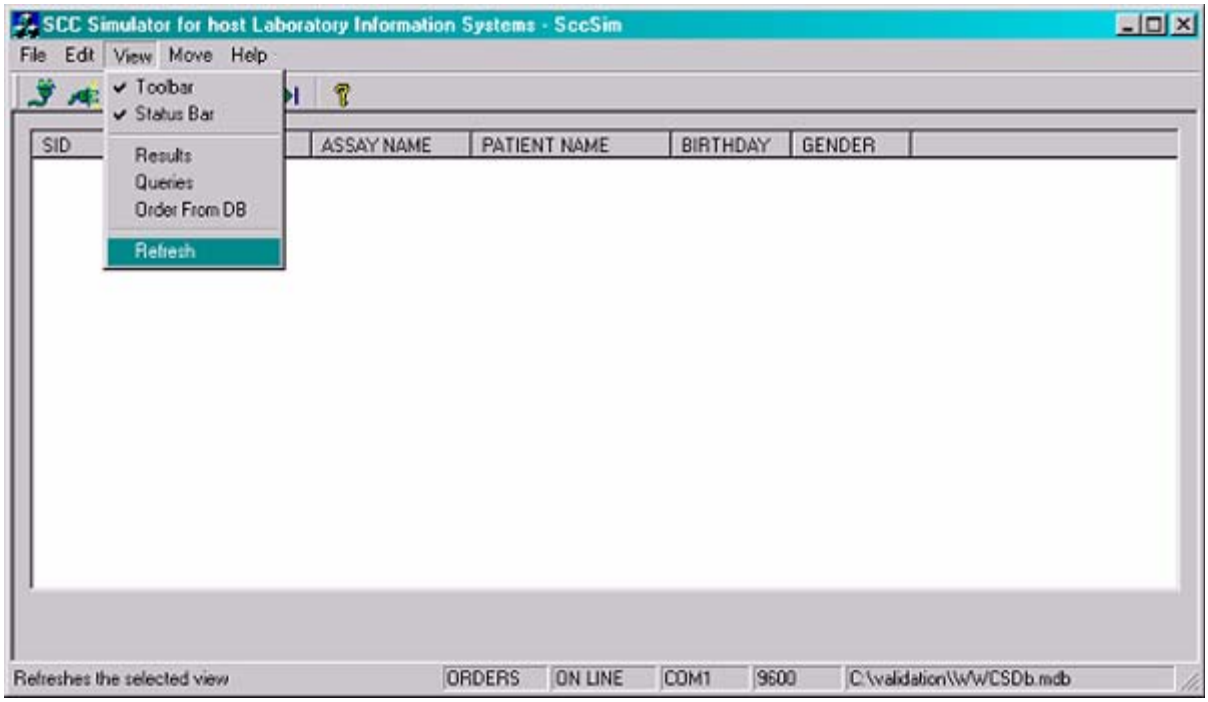


Figure 5.22: Refreshing the View From Menu

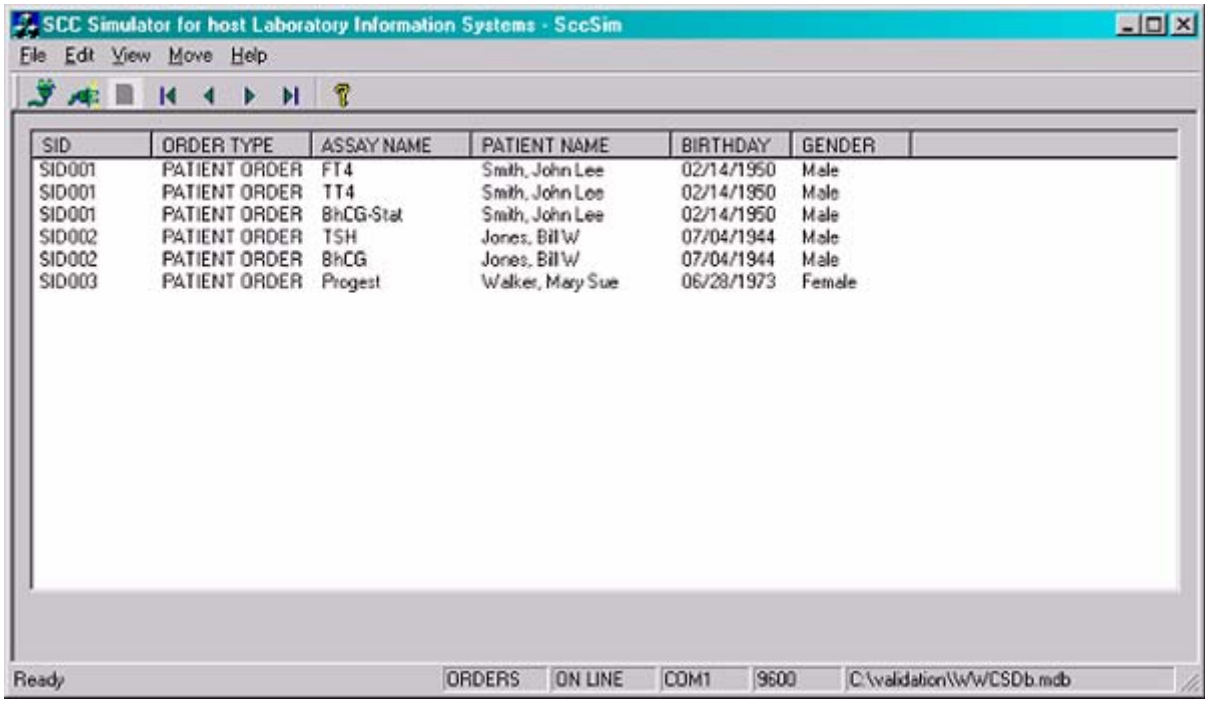


Figure 5.23: Refreshed View

Installing assays

The SCC Simulator provides a user interface to install Immunoassay and Clinical Chemistry assays in order to create control and patient results. The user can request to install a Clinical Chemistry assay or Immunoassay assay by selecting **Edit**, **Install CC Assay** or **Install IA Assay** (*Figure 5.24*). The simulator displays the Install Assay window allowing the user to install an assay name and assay number (*Figure 5.25*). After the user installs the assay, the assay name displays in the Available Assays/Tests list in the Create Results window. For more information, see Creating results, page 5-25.

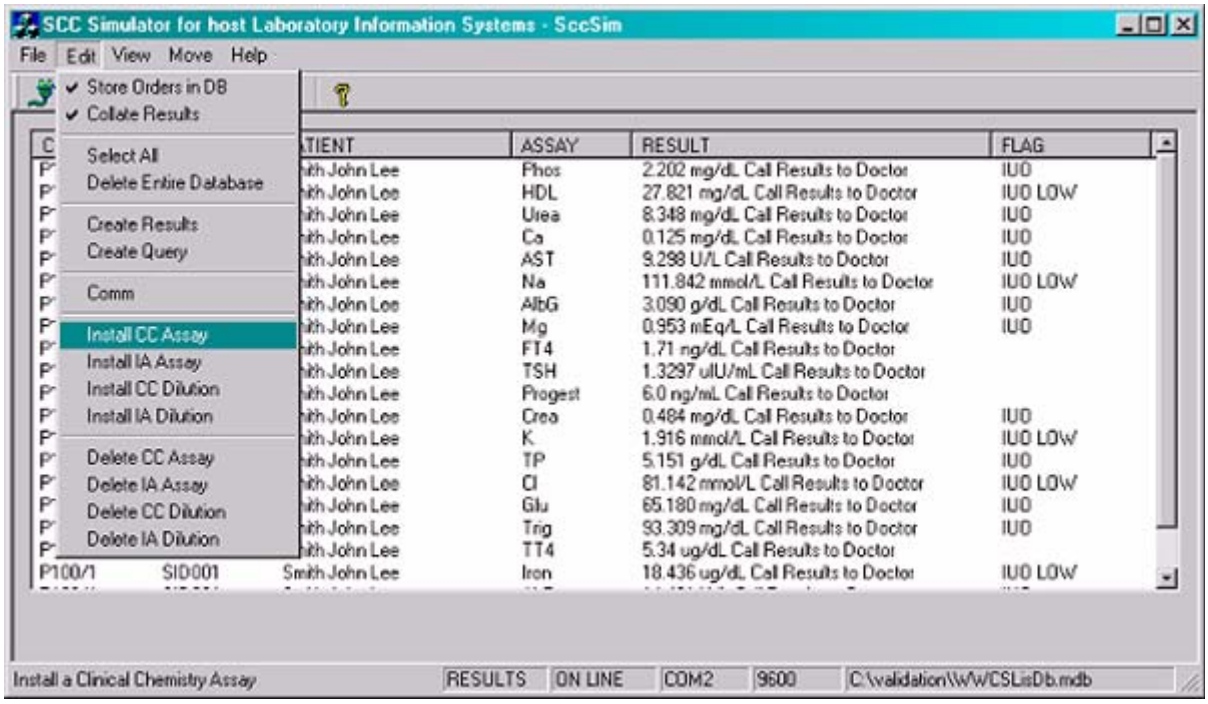


Figure 5.24: Install Assay

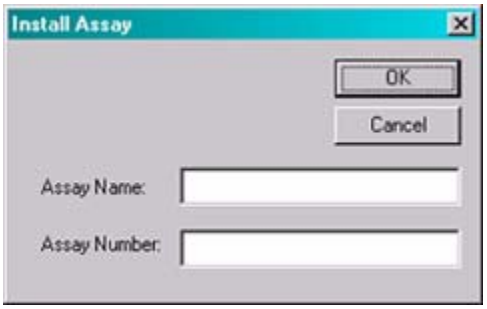


Figure 5.25: Install Assay Window

Installing dilution names

The SCC Simulator provides a user interface to install Immunoassay and Clinical Chemistry dilution names in order to create control and patient results. The user can install a Clinical Chemistry dilution name or Immunoassay dilution name by **Edit**, **Install CC Dilution** or **Install IA Dilution** (*Figure 5.26*). The simulator displays the Install Assay Dilution window, allowing installation of a Dilution Name (*Figure 5.27*). After the user installs the dilution name, the dilution name displays in the Dilution Name list in the Create Results window. For more information, see Creating results, page 5-25.

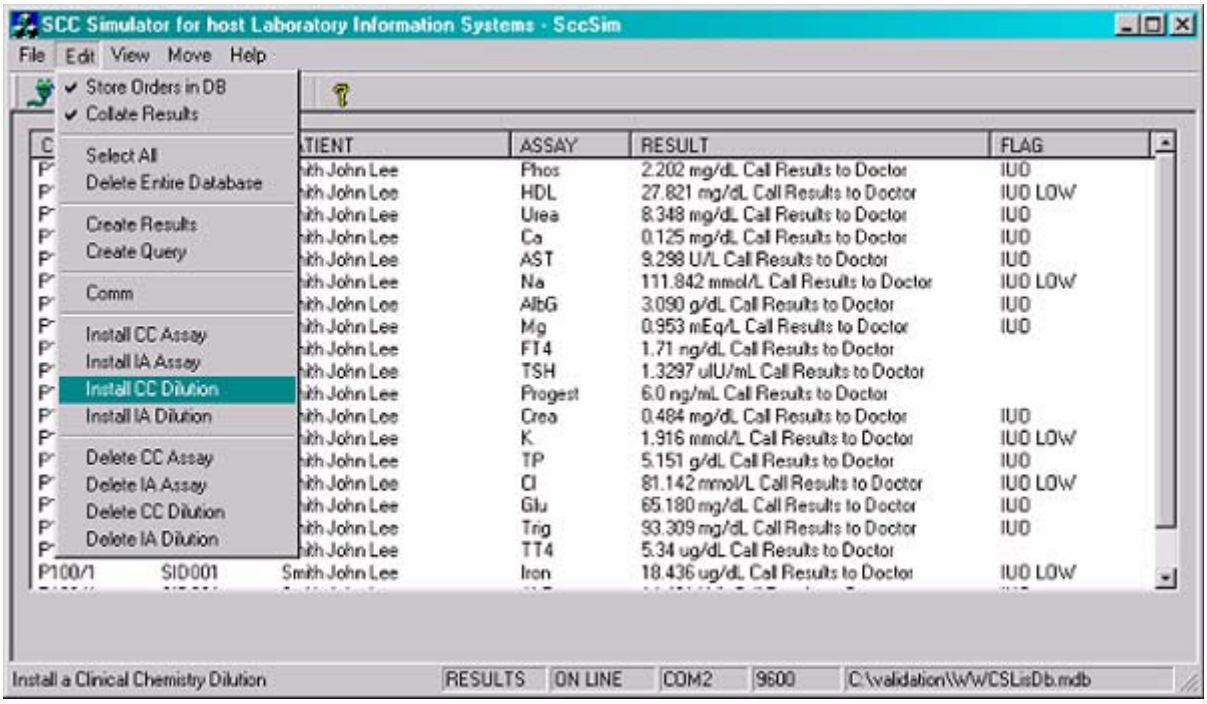


Figure 5.26: Install Dilution

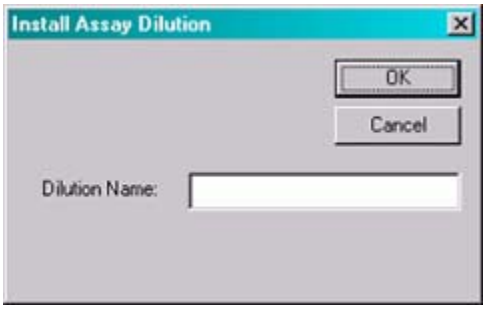


Figure 5.27: Install Assay Dilution Window

Deleting assays

The SCC Simulator provides a user interface to delete Immunoassay and Clinical Chemistry assays. The user can request to delete a Clinical Chemistry assay or Immunoassay by selecting **Edit**, **Delete CC Assay** or **Delete IA Assay** (*Figure 5.28*). The simulator displays the **Delete Assay** window and allows the user to delete an **Assay Name** (*Figure 5.29*). After the user deletes the assay, the assay name no longer displays in the Available Assays/Tests list in the **Create Results** window. For more information, see Creating results, page 5-25.

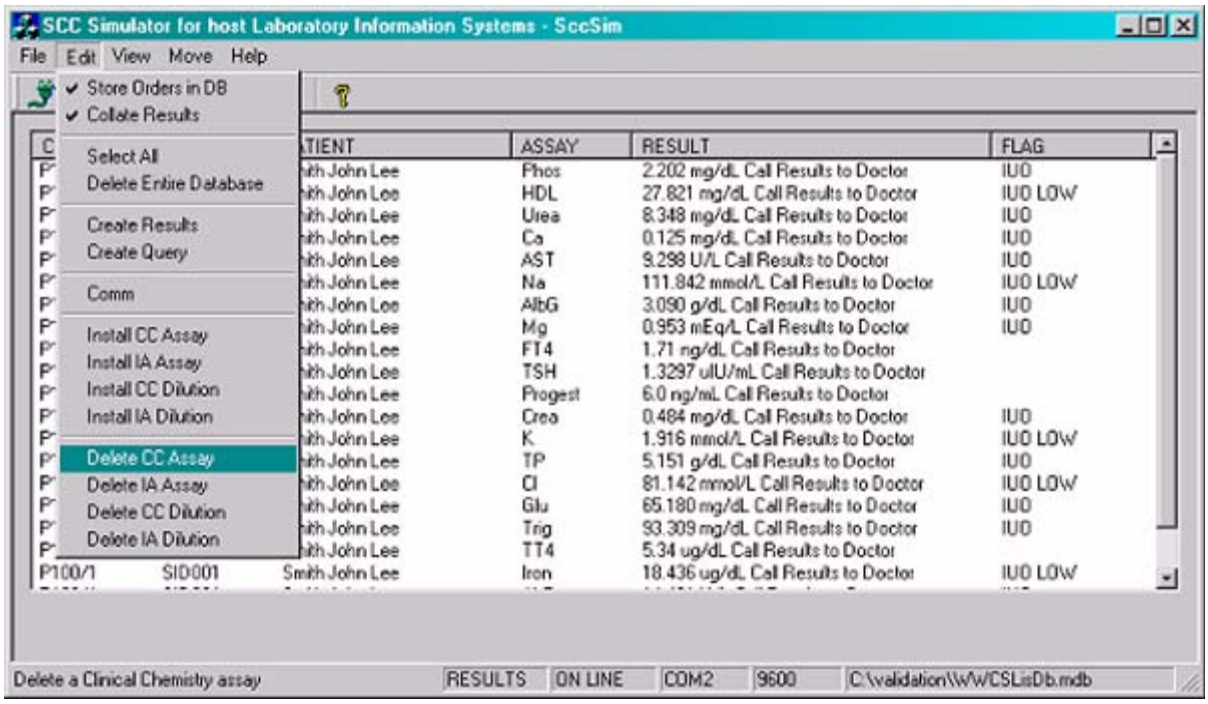


Figure 5.28: Delete Assay

Figure 5.29: Delete Assay Window

Deleting dilution names

The SCC Simulator provides a user interface to delete Immunoassay and Clinical Chemistry dilution names. The user can delete a Clinical Chemistry dilution name or Immunoassay dilution name by selecting **Edit**, **Delete CC Dilution** or **Delete IA Dilution** (*Figure 5.30*). The simulator displays the Delete Dilution window allowing the user to delete a Dilution Name (*Figure 5.31*). After the user deletes the dilution name, the dilution name no longer displays in the Dilution Name list in the Create Results window. For more information, see Creating results, page 5-25.

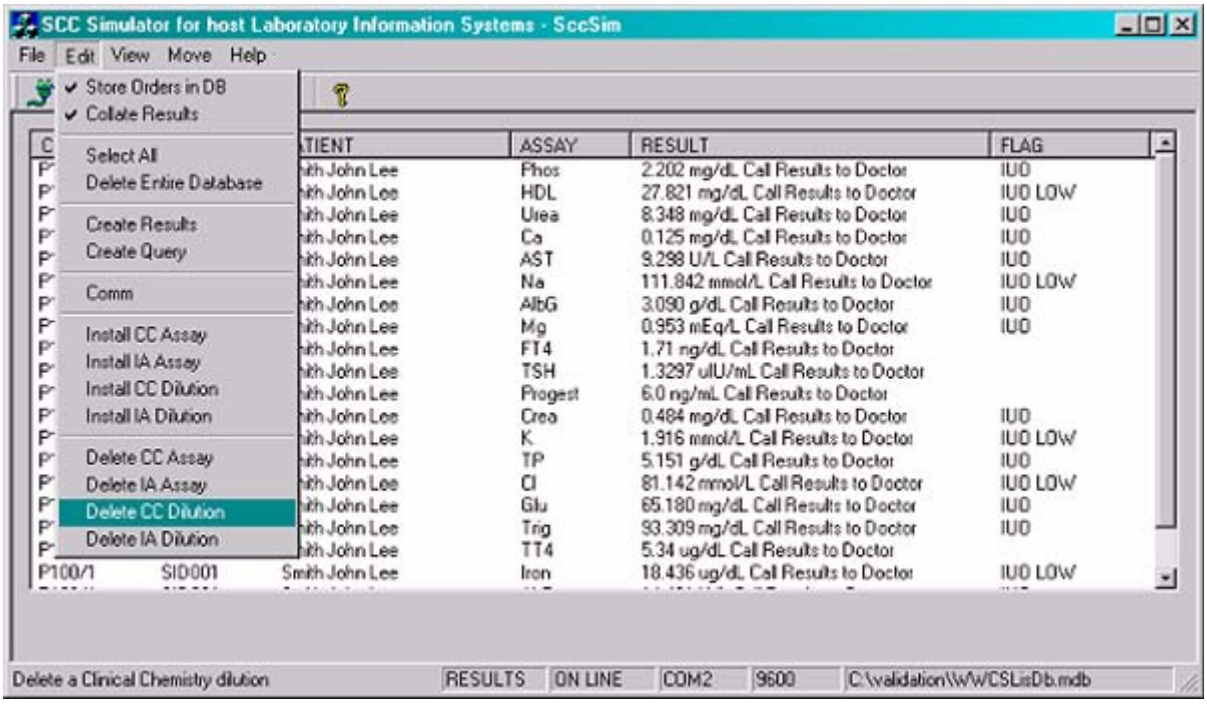


Figure 5.30: Delete Dilution Name

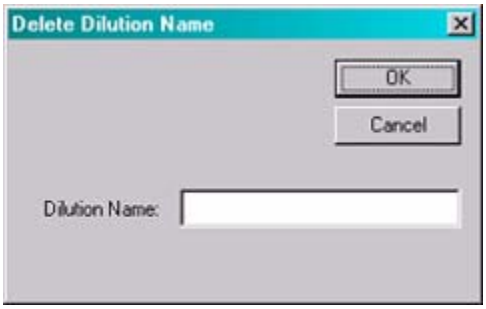


Figure 5.31: Delete Dilution Window

Creating results

The SCC Simulator provides the user the capability to create control and patient results against installed assays and dilution names and store created results in the user-selected database. The user navigates to the Create Results window through the Edit menu and selecting the Create Results menu item (*Figure 5.32*). Once the Create Results window is displayed (*Figure 5.33*), the user has the ability to create control or patient results against the displayed assays and dilution names. The Create Results window allows the user to create results to be stored in the database (*Figure 5.33*). The form allows the user to specify information for results on a particular instrument and demographic information related to the patient. Once the information has been specified, the user can select Create Result to add the result or results to the database. The results stored in the database are used to send to the LIS in response to orders that have been received. Note that the results sent to the LIS are not automatically sent in response to an order.

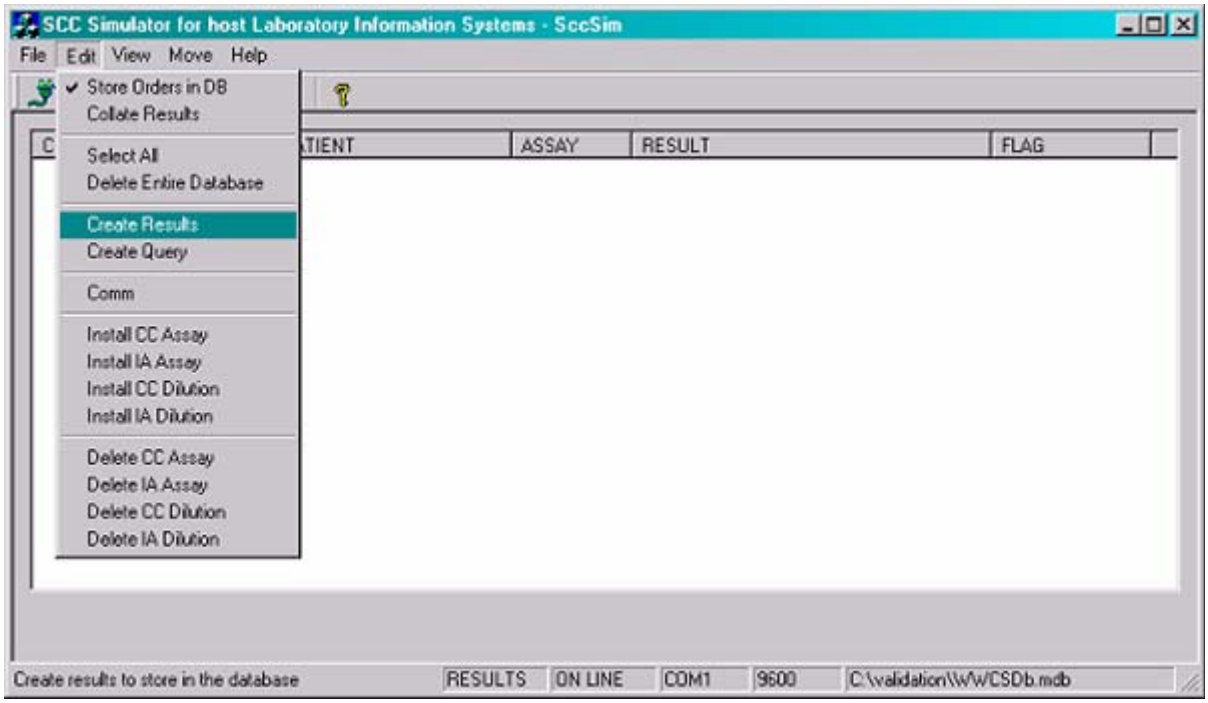


Figure 5.32: Selecting the Create Results Window

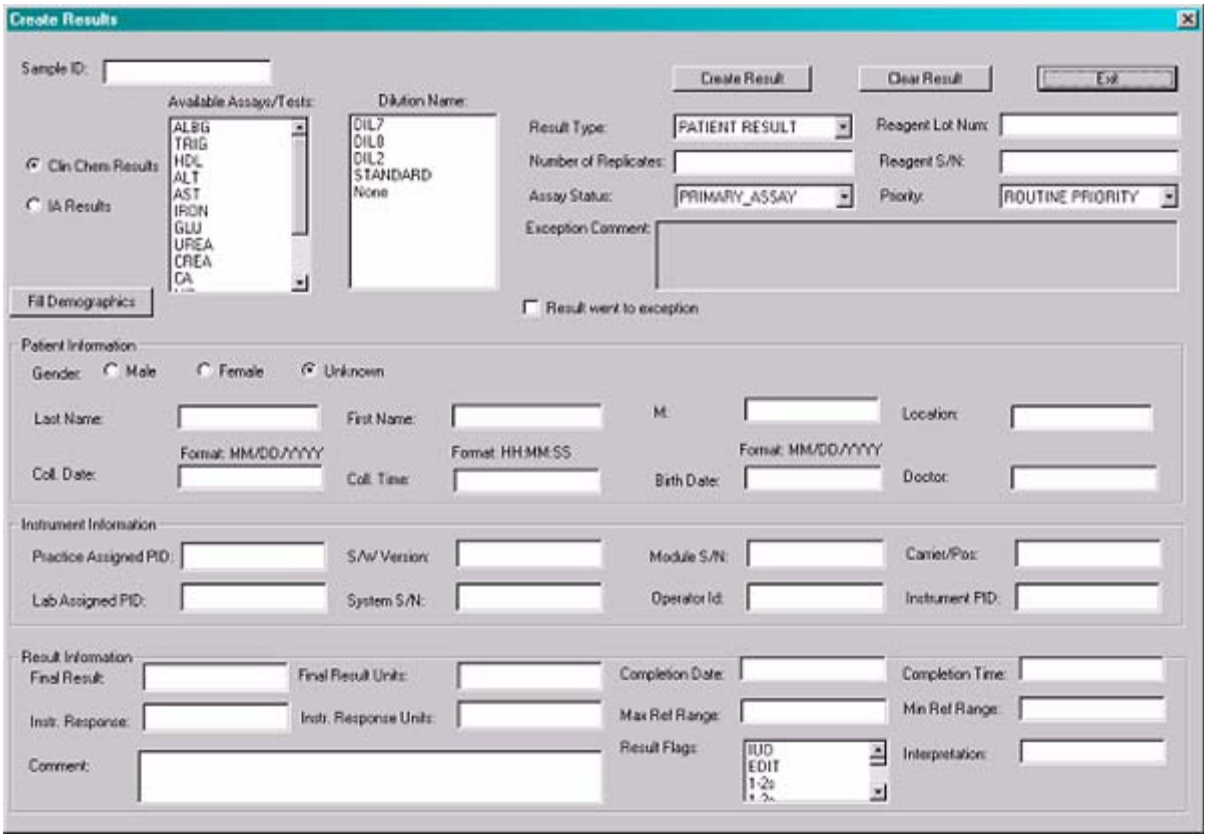


Figure 5.33: Create Results Window

Creating queries

The SCC Simulator provides the user the capability to create queries to be stored in the user-selected database and sent to the LIS for solicitation of orders against a SID. The user navigates to the Create Query window through the Edit menu and selecting the Create Query menu item (*Figure 5.34*). Once the Create Query window is displayed (*Figure 5.35*), the user has the ability to create a query for a particular SID. The Create Query window allows the user to create a query to be stored in the database (*Figure 5.35*). The form allows the user to specify information for a query on a particular instrument with version information. Once the information has been specified, the user can select Create Query to add the query to the database. The queries stored in the database are used to send to the LIS in order to solicit orders for a particular SID.

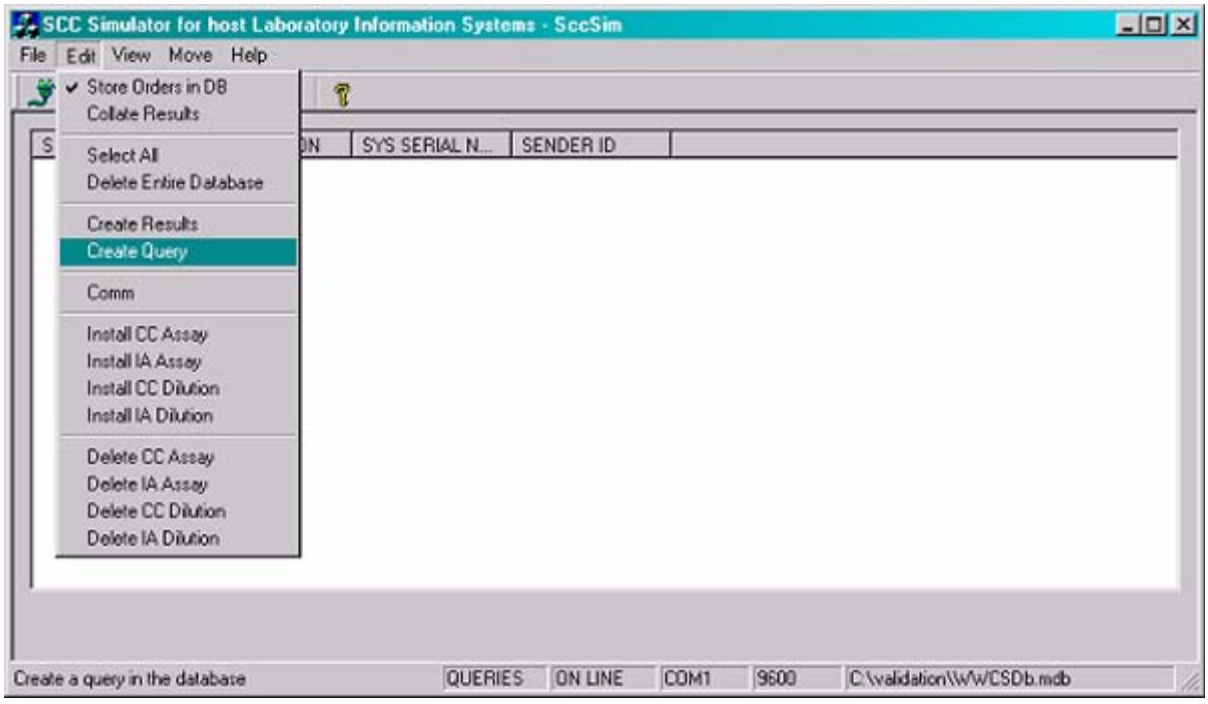


Figure 5.34: Selecting the Create Query Window

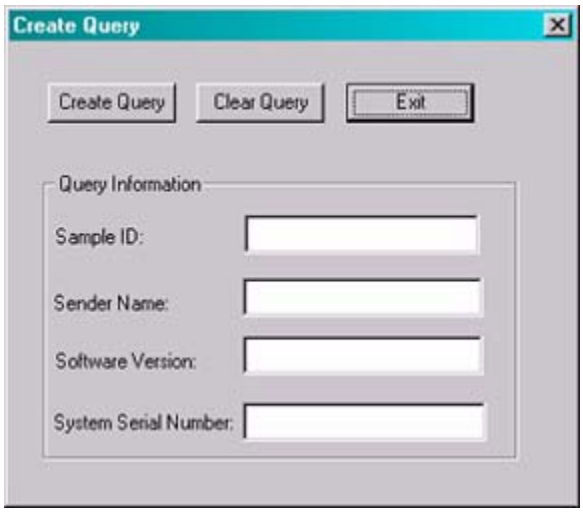


Figure 5.35: Create Query Window

Order filtering

The SCC Simulator allows the user to select different filter options in the ORDERS view. In order to change filter options, the user needs to navigate to the ORDERS view. For more information, see Selecting views, page 5-16. The filter options allow for easier selection of orders to view. The filter options display with a right mouse click in the

ORDERS view. Select the Filter Options menu item (*Figure 5.36*). This displays the Order View Filter Options Window (*Figure 5.37*). The filter options window allows the user to filter options based on Creation Order (*Figure 5.37*), Assay Name (*Figure 5.39*), or SID (*Figure 5.41*). *Figure 5.38* shows the Order View with a filter option that is based on Creation Order. *Figure 5.40* shows the Order View with a filter option that is based on Assay Name TT4. *Figure 5.42* shows the Order View with a filter option based on SID002. Note that if a SID is not given with the filter option based on SID, the Order View is sorted alphabetically by SID name (*Figure 5.43*). The same is true for a filter option based on Assay Name and no Assay Name is given. The Order View is sorted alphabetically by Assay Name (*Figure 5.44*). The default filter option on application startup is Creation Order (*Figure 5.38*).

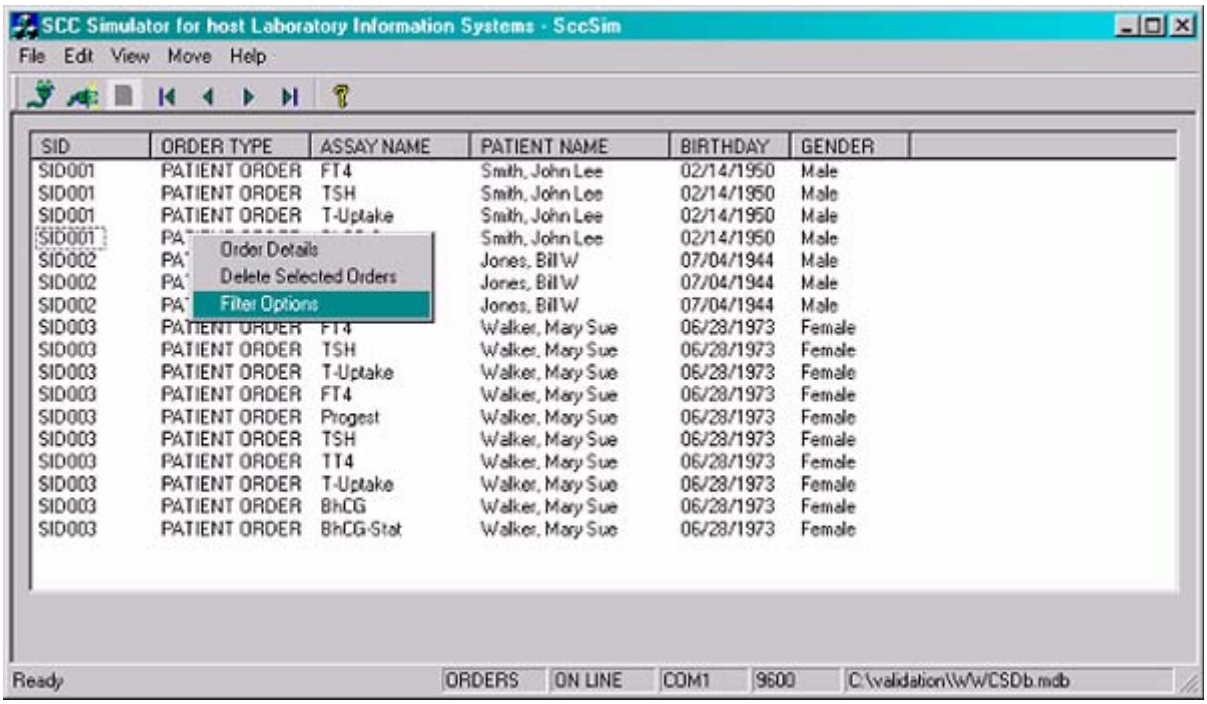


Figure 5.36: Selecting Order View Filter Options

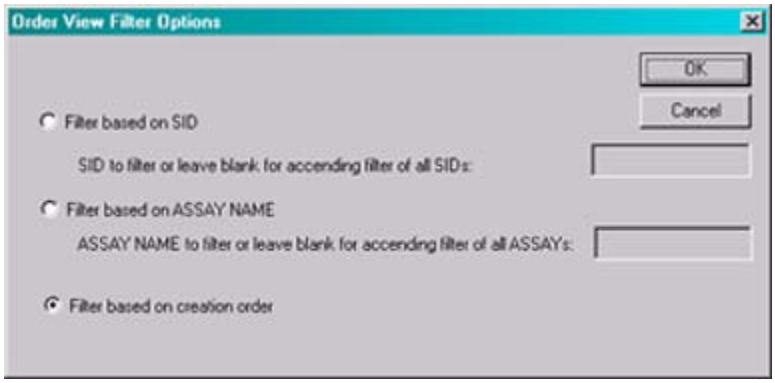


Figure 5.37: Filter Options Window Creation Order Selected

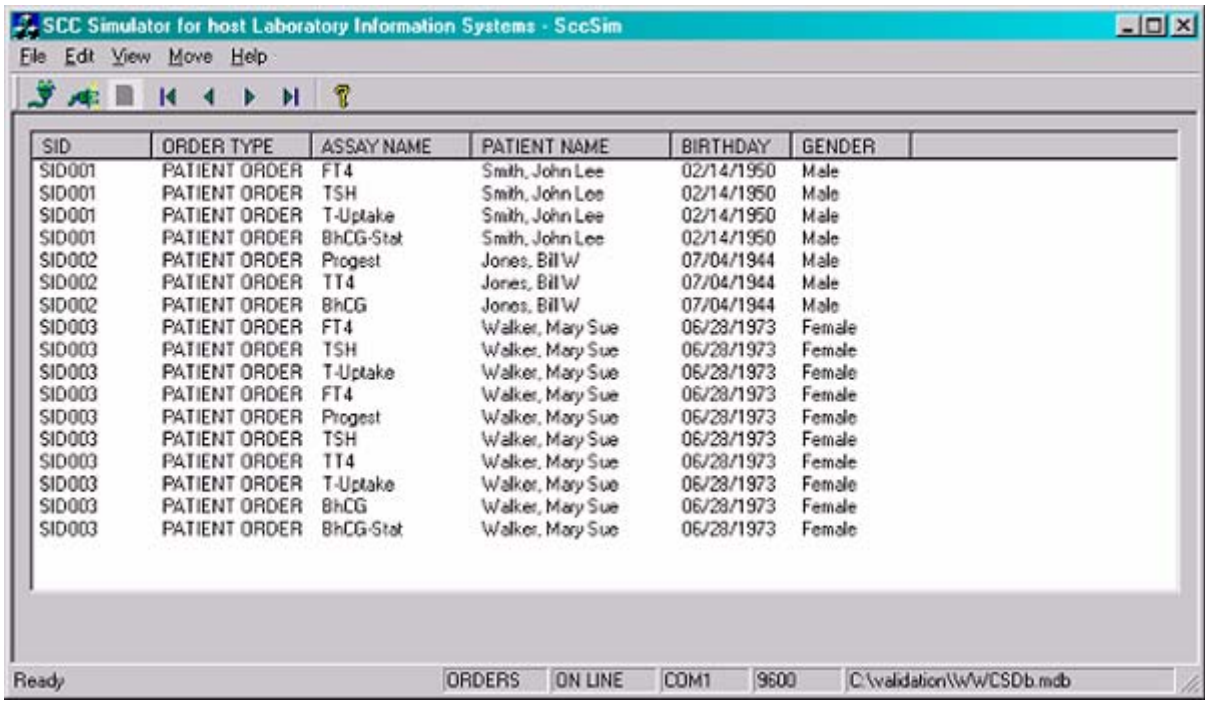


Figure 5.38: Order View Filtered Based On Creation Order

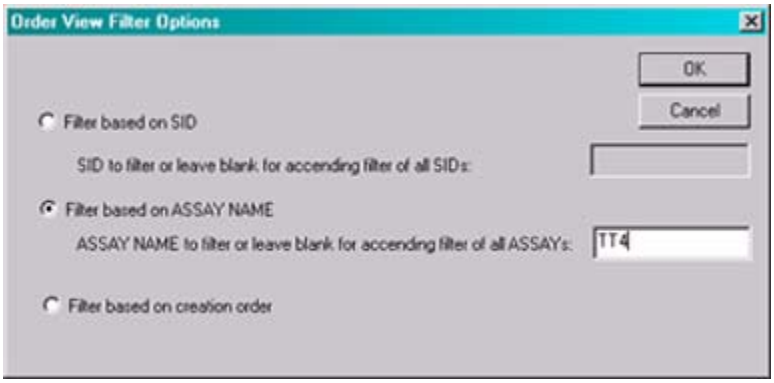


Figure 5.39: Filter Options Window with Assay Name Selection

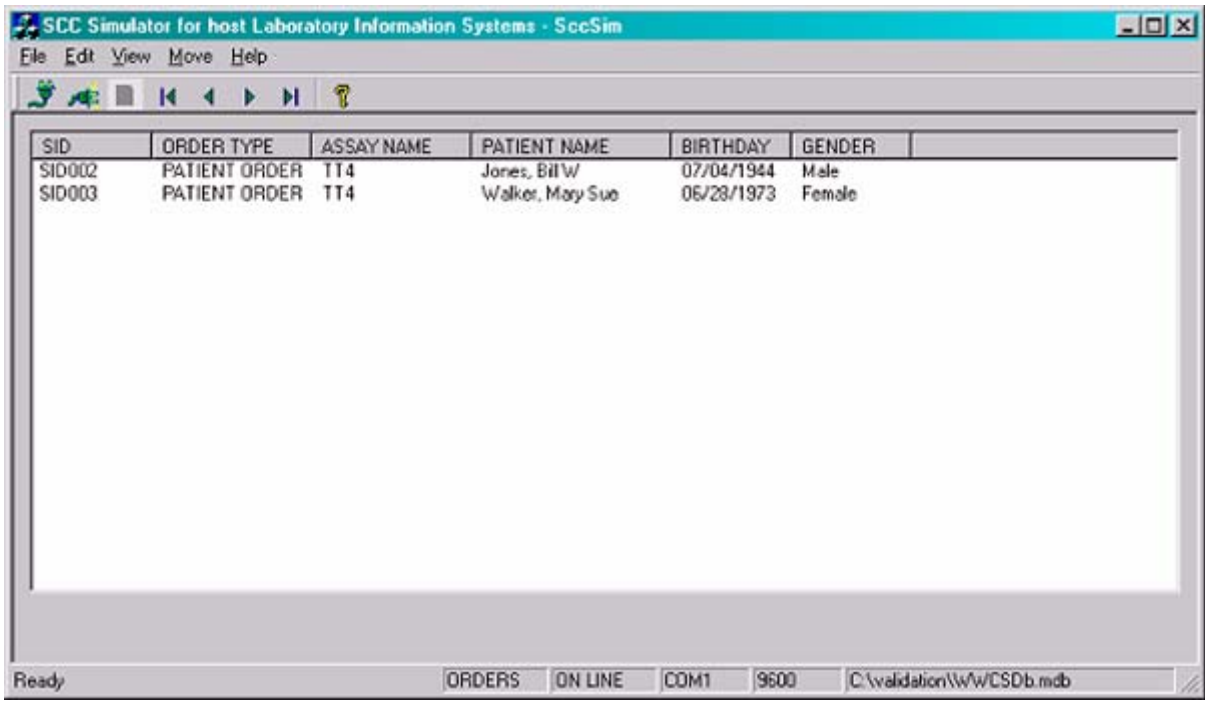


Figure 5.40: Order View with Assay Name as Filter Option

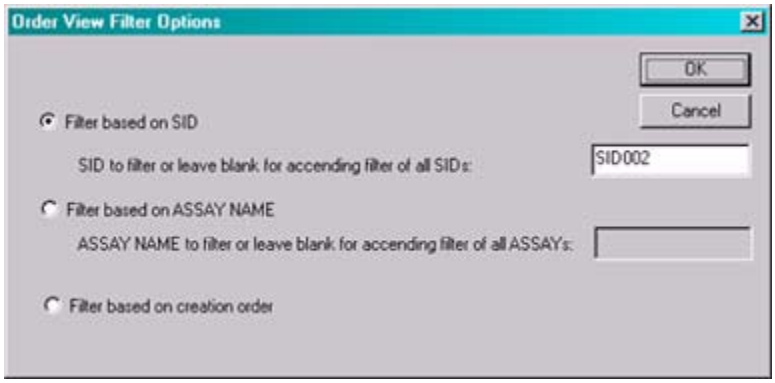


Figure 5.41: Filter Options Window with Filtering based on SID

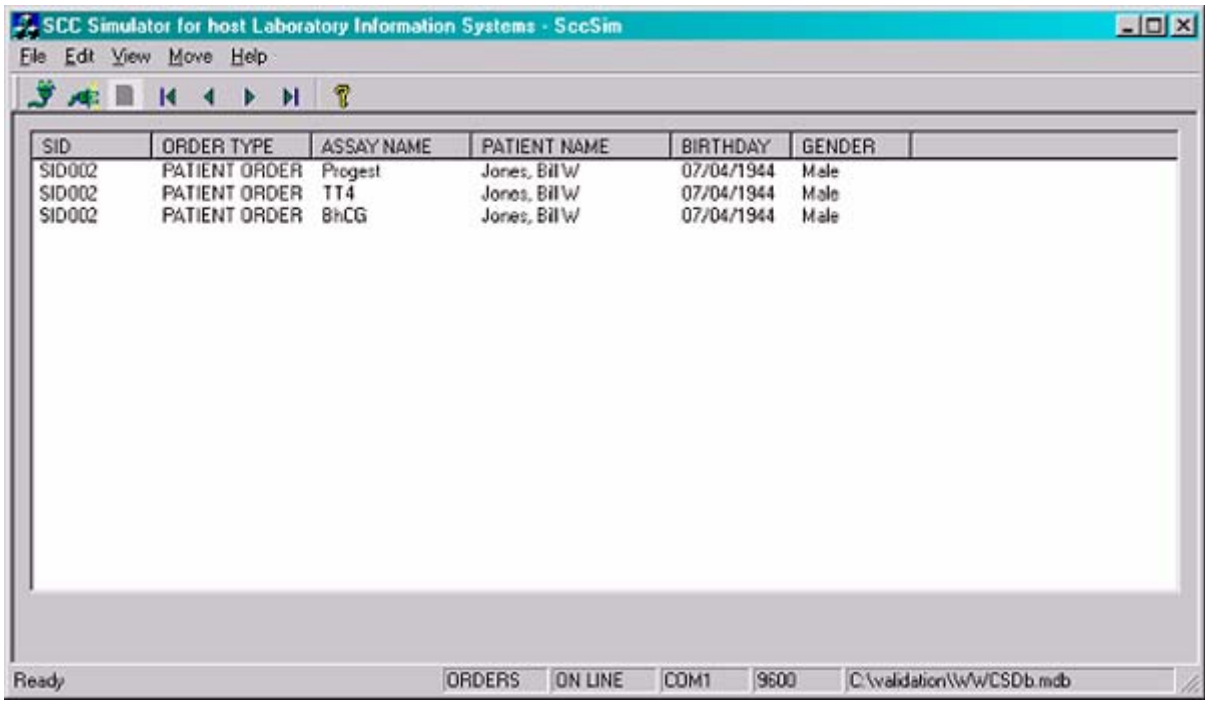


Figure 5.42: Order View with SID as Filter Option

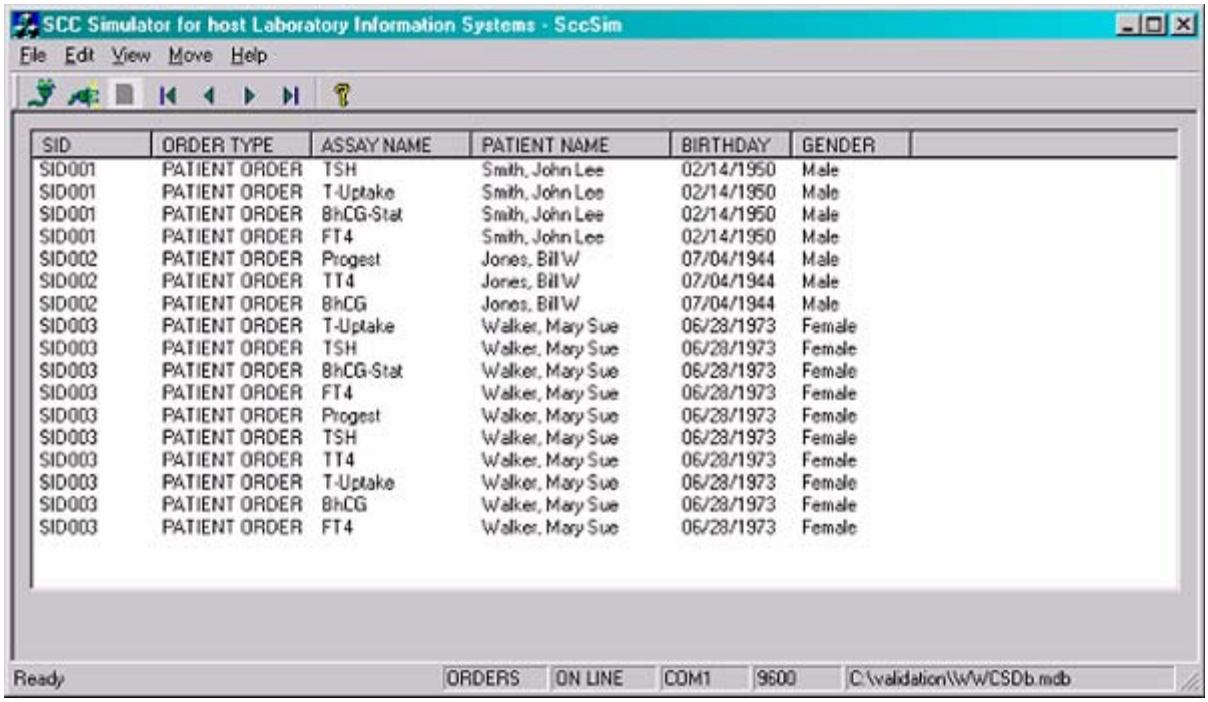


Figure 5.43: SID is Filter Option with No SID Given

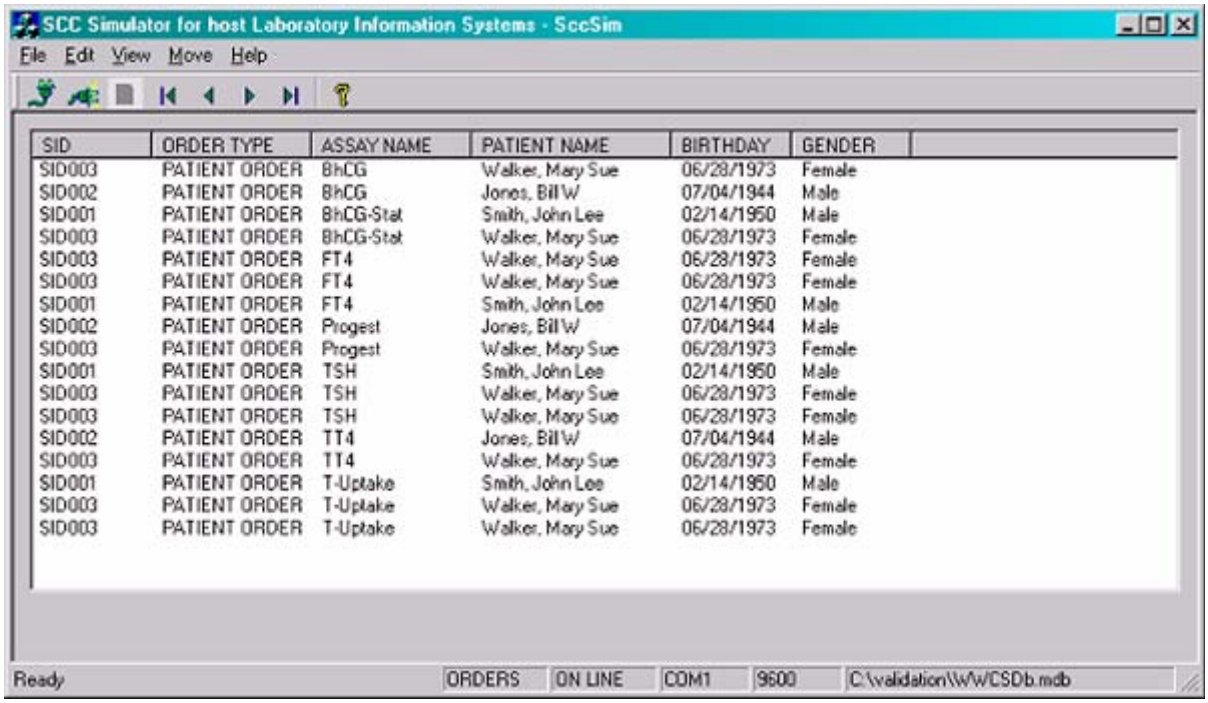


Figure 5.44: Assay Name is Filter Option with No Assay Name Given

Deleting items from the database

The SCC Simulator provides the user with the capability to delete items from the user-specified database based on the current view [RESULTS, QUERIES, ORDERS] in one of the following ways:

- The user can request the Simulator delete all the records for the currently selected view by selecting **Edit**, **Delete Entire Database** (*Figure 5.45*). *Figure 5.46* illustrates the view after the deletions have been made.
- The user can select one or multiple items in the currently displayed view [RESULTS, QUERIES, ORDERS] and request the simulator to delete the selected items by a right mouse click on one of the selected items, which displays a popup menu. Select **Delete Selected Items** [RESULTS, QUERIES] (*Figure 5.47* - *Figure 5.48*). A similar mechanism is used to delete selected items in the ORDERS VIEW except the **Delete Selected Orders** menu item is selected in the popup menu.

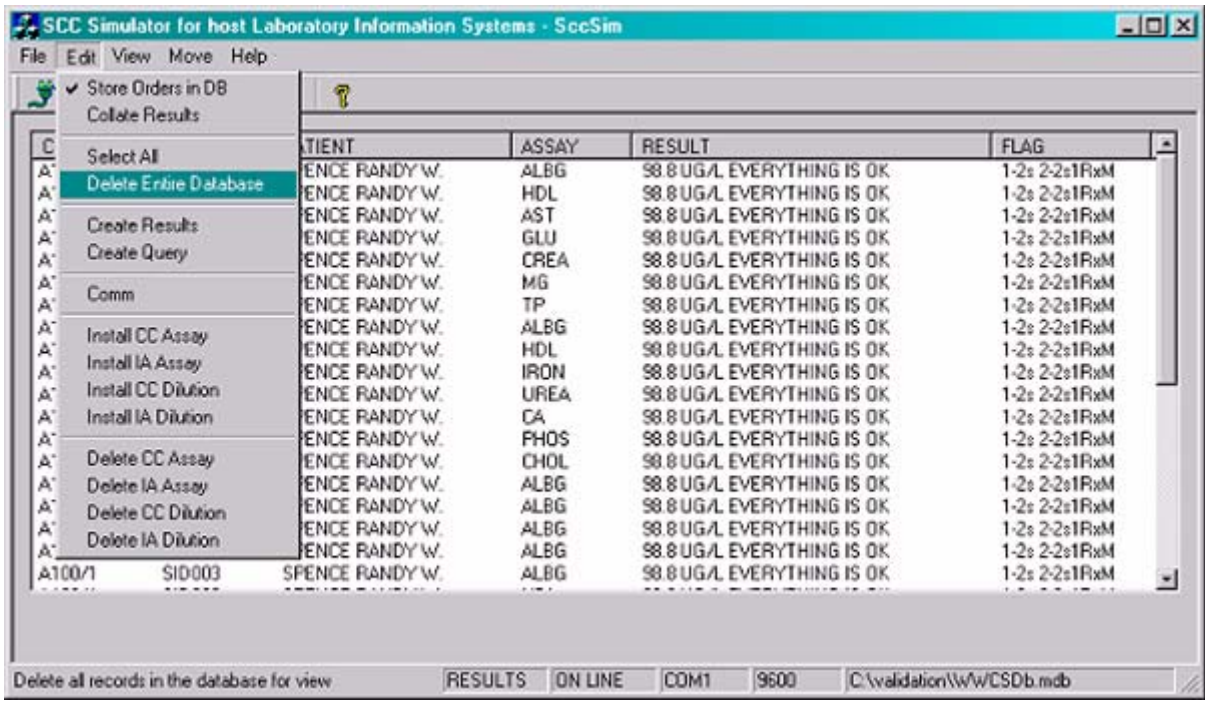


Figure 5.45: Delete Entire Database for Selected View

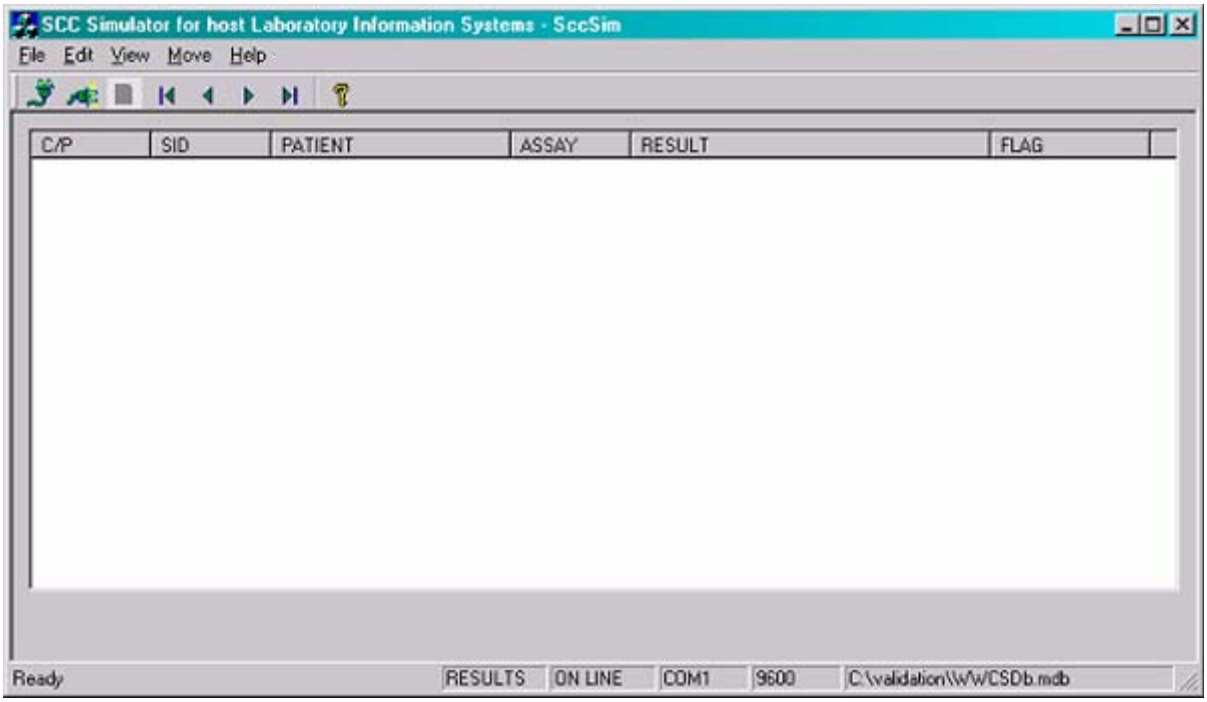


Figure 5.46: View after Deletion of Entire Database

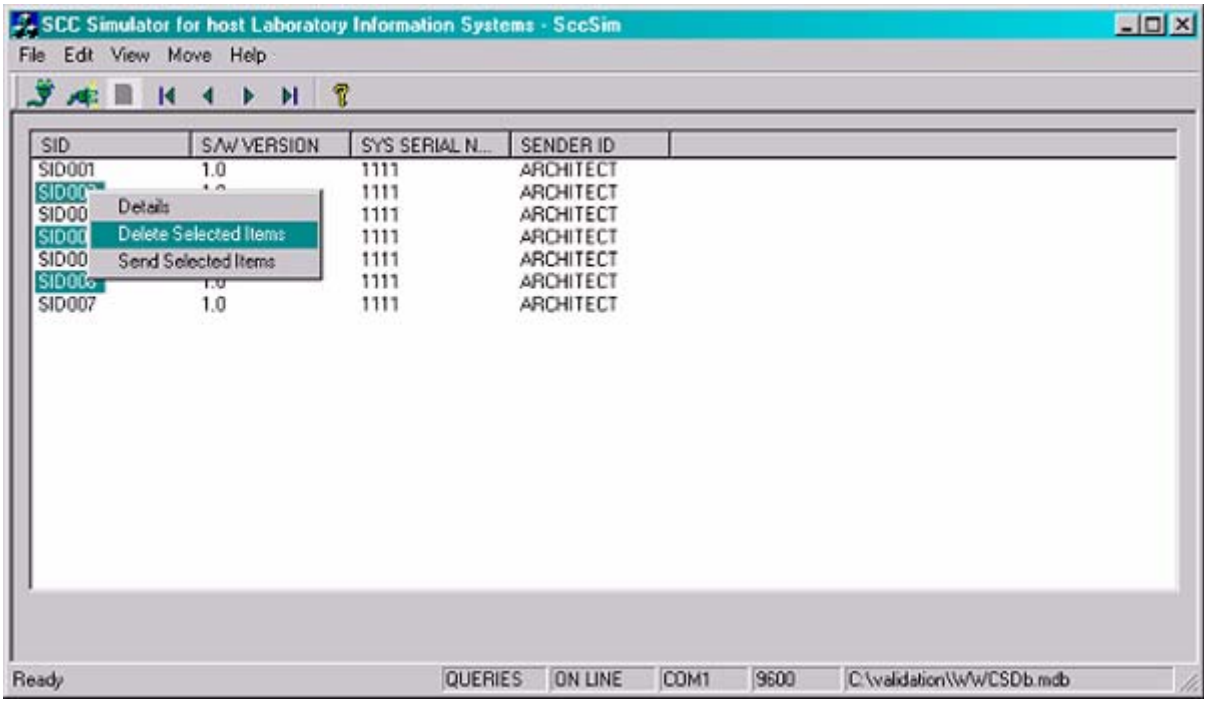


Figure 5.47: Deletion of Selected Items on a View

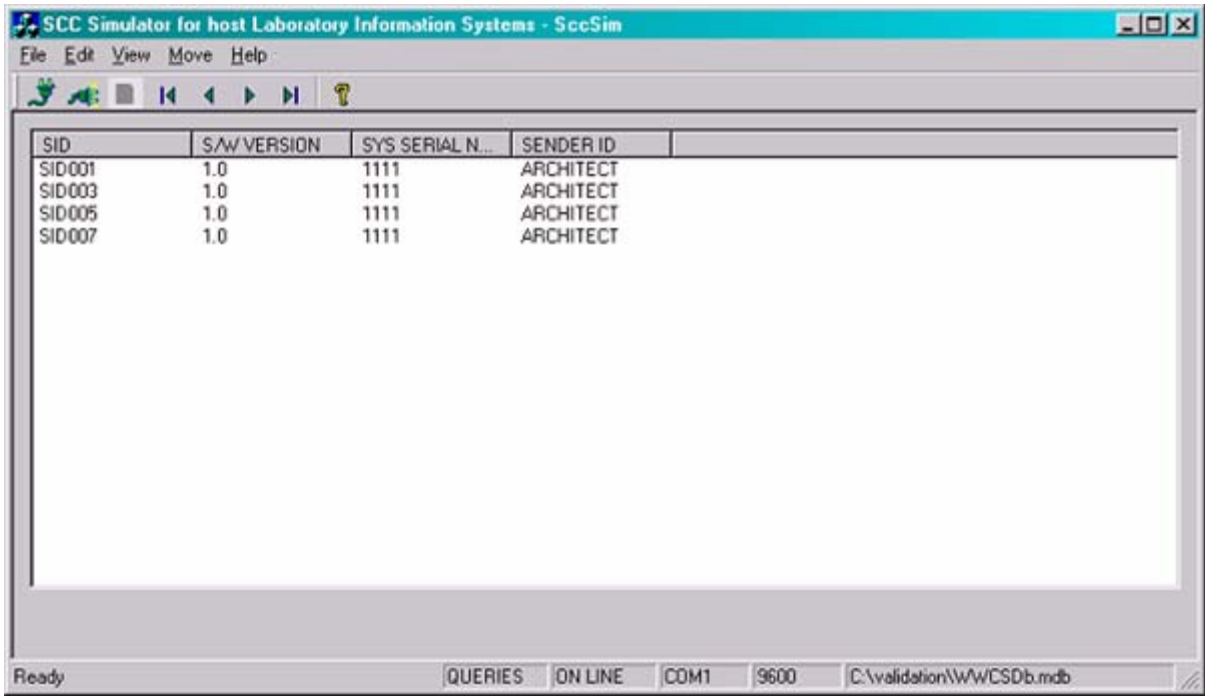


Figure 5.48: View after Deletion of Selected Items

Viewing item details from the database

The SCC Simulator provides the user with the capability to view one or multiple item details from the user-specified database based on the current view [RESULTS, QUERIES, ORDERS]. The user can request the Simulator to select all the records for the currently selected view by selecting **Edit**, **Select All** (*Figure 5.49*). *Figure 5.50* illustrates the view after the selections have been made. The user can also select one or multiple items in the currently displayed view [RESULTS, QUERIES, ORDERS]. The user can then right click on one of the selected items to display a popup menu. Select **Details** (*Figure 5.51*, *Figure 5.53*) [RESULTS, QUERIES] or **Order Details** (*Figure 5.55*) [ORDERS]. This displays the details form for that view (*Figure 5.52*, *Figure 5.54*, *Figure 5.56*).

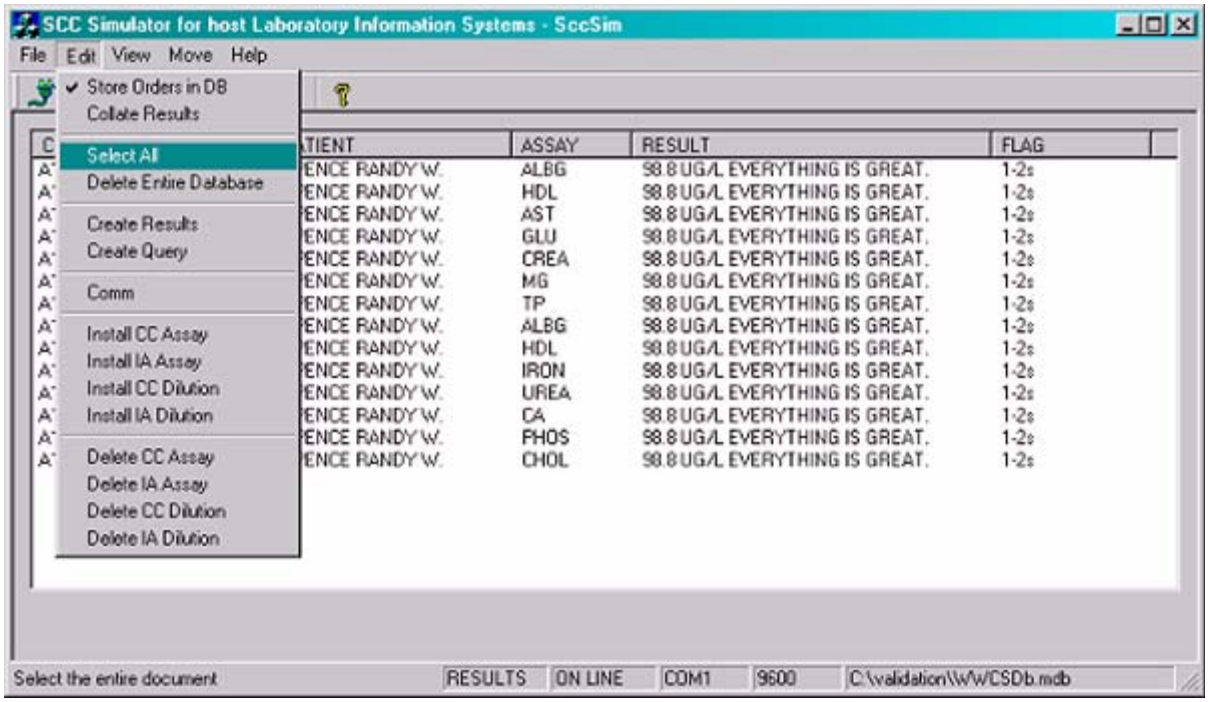


Figure 5.49: Select All Items in a View

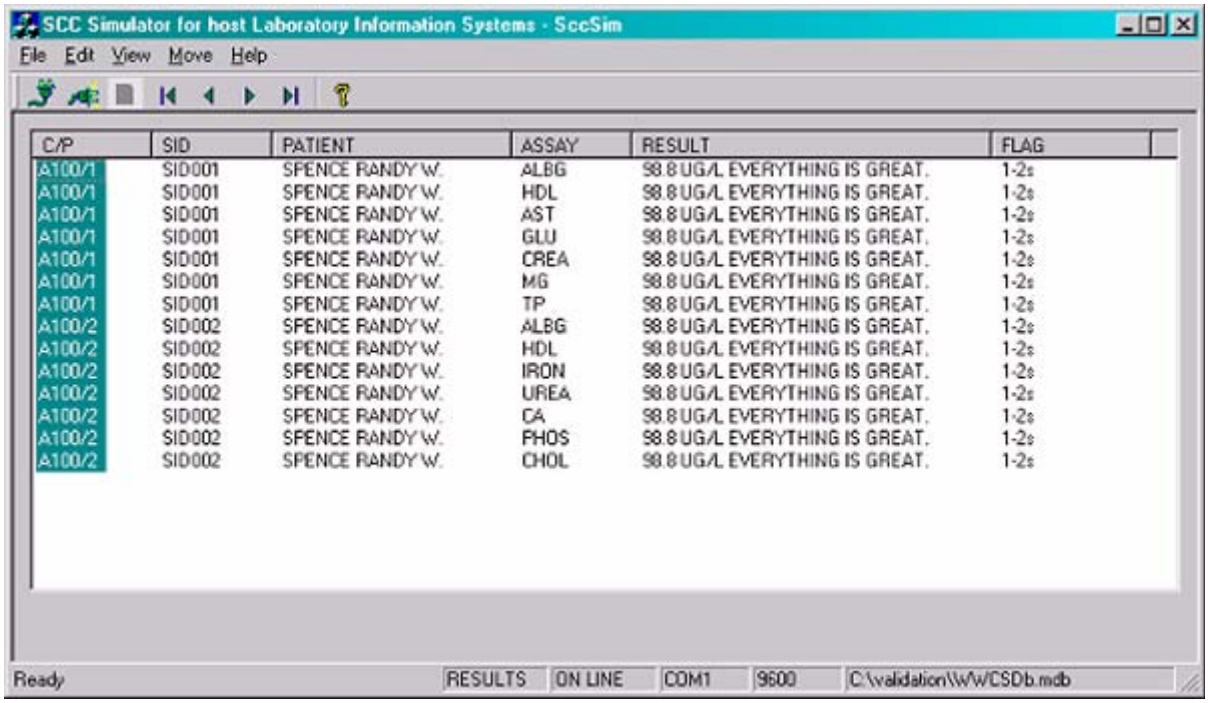


Figure 5.50: View after a Select All

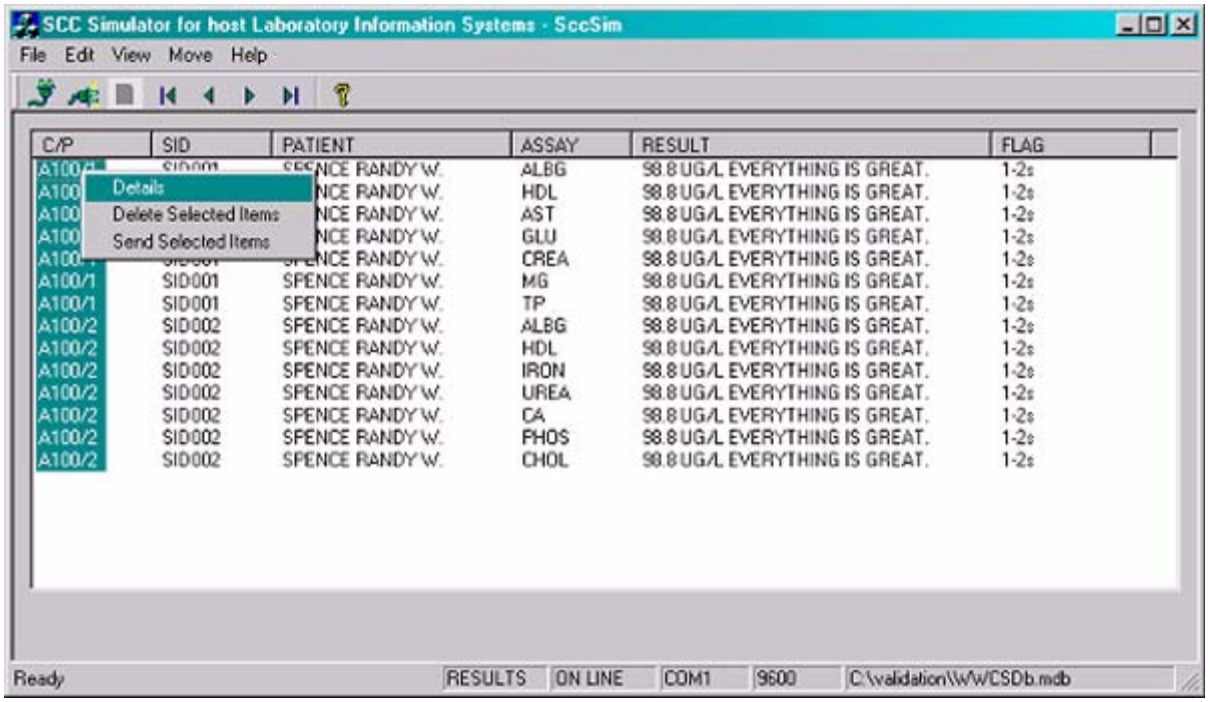


Figure 5.51: Select Details for View

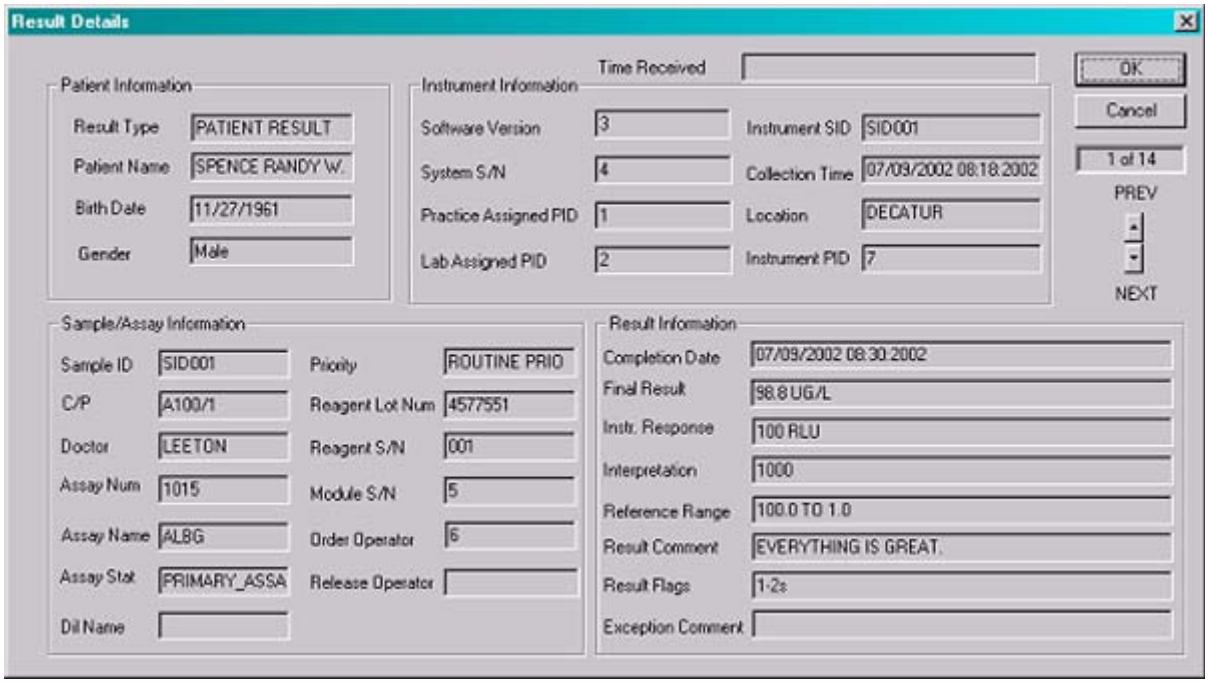


Figure 5.52: Details Form for Results View

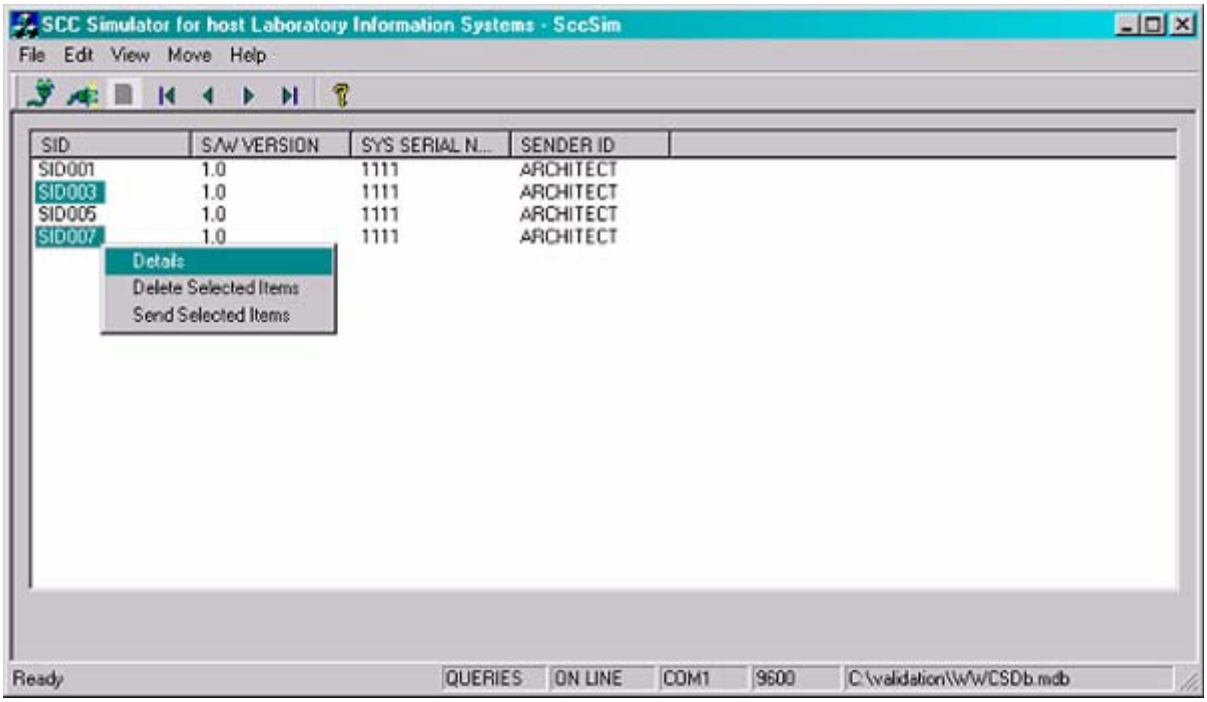


Figure 5.53: Selected Items Details for Queries

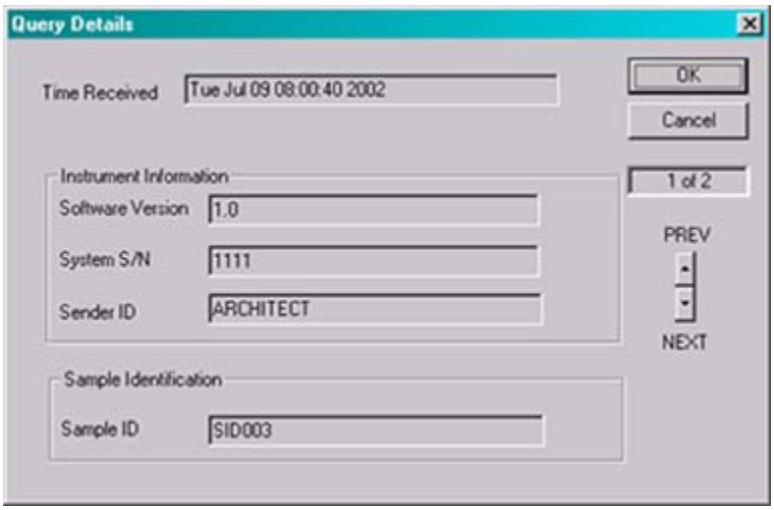


Figure 5.54: Query View Details

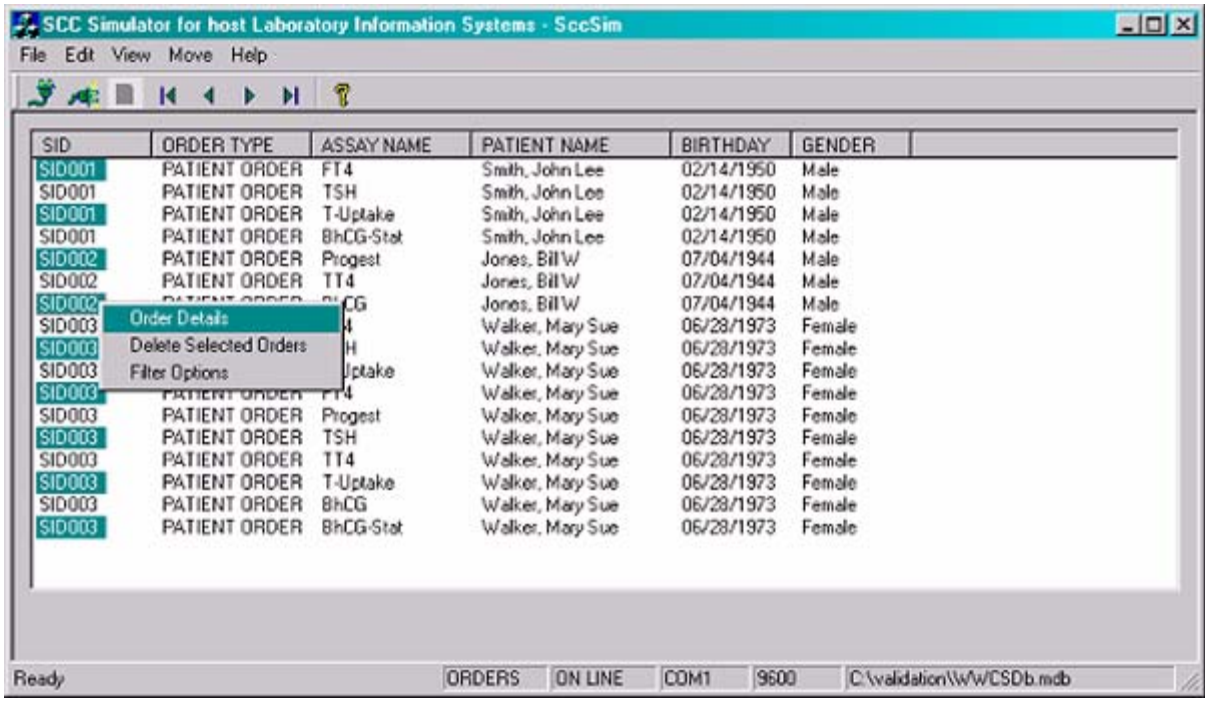


Figure 5.55: Selected Item Details for Orders

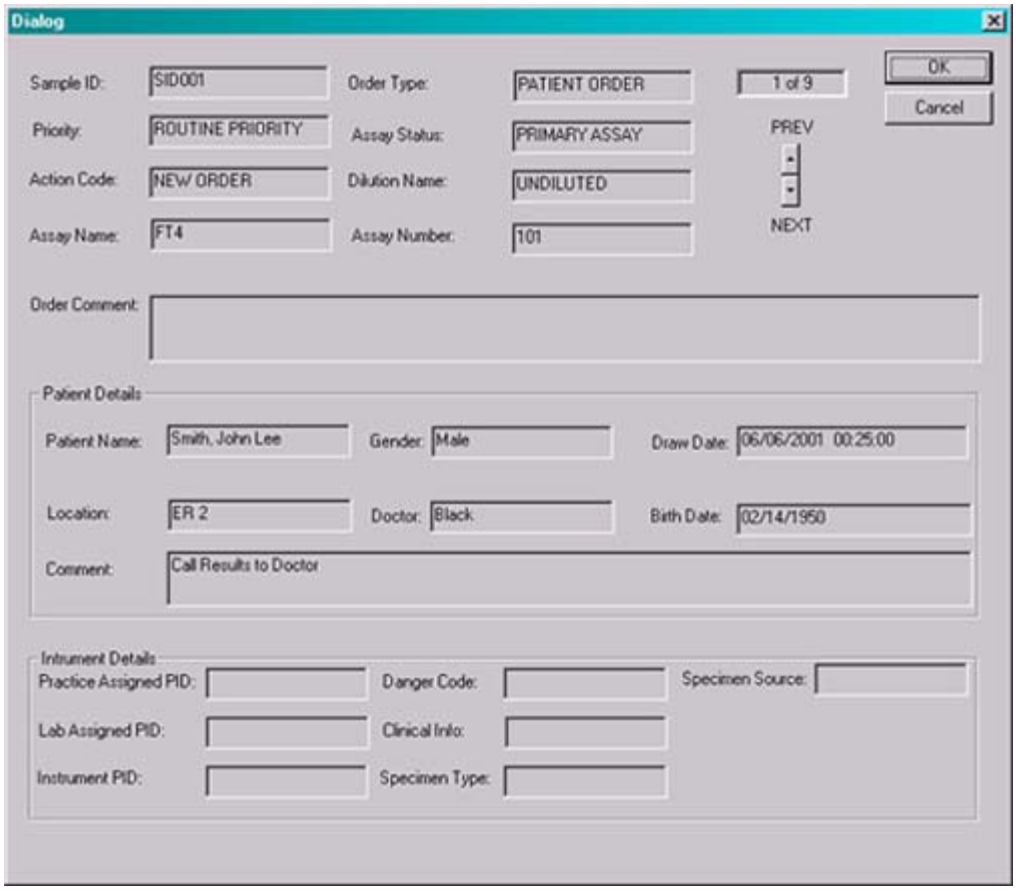


Figure 5.56: Order View Details

Disconnecting from the communication port

The SCC Simulator main application window status bar provides the connection status of the communication port. Prior to disconnecting from the communication port, the SCC Simulator status window displays **ON LINE**. The user can disconnect from the communication port by pressing the DisConnect icon on the main application window tool bar (*Figure 5.57*), or by selecting **File**, **Disconnect** (*Figure 5.58*). After the disconnection, the main application status window connection status field changes to **OFF LINE**.

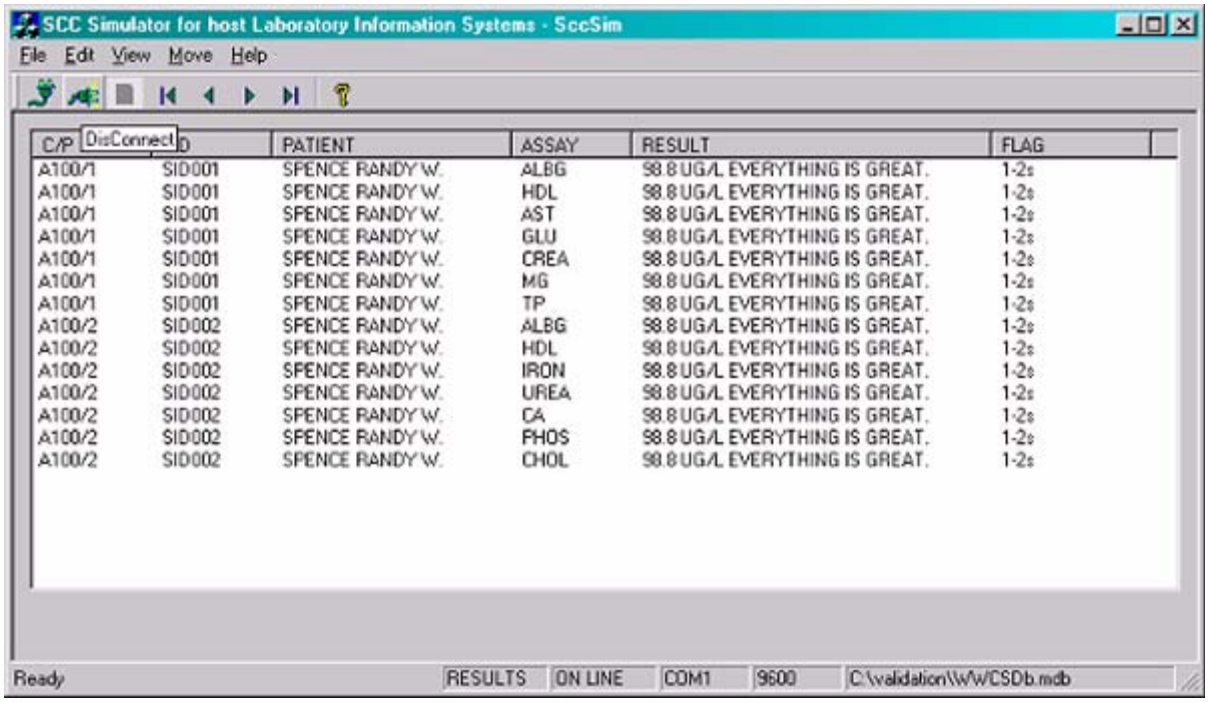


Figure 5.57: Prior to Disconnecting from a Communication Port

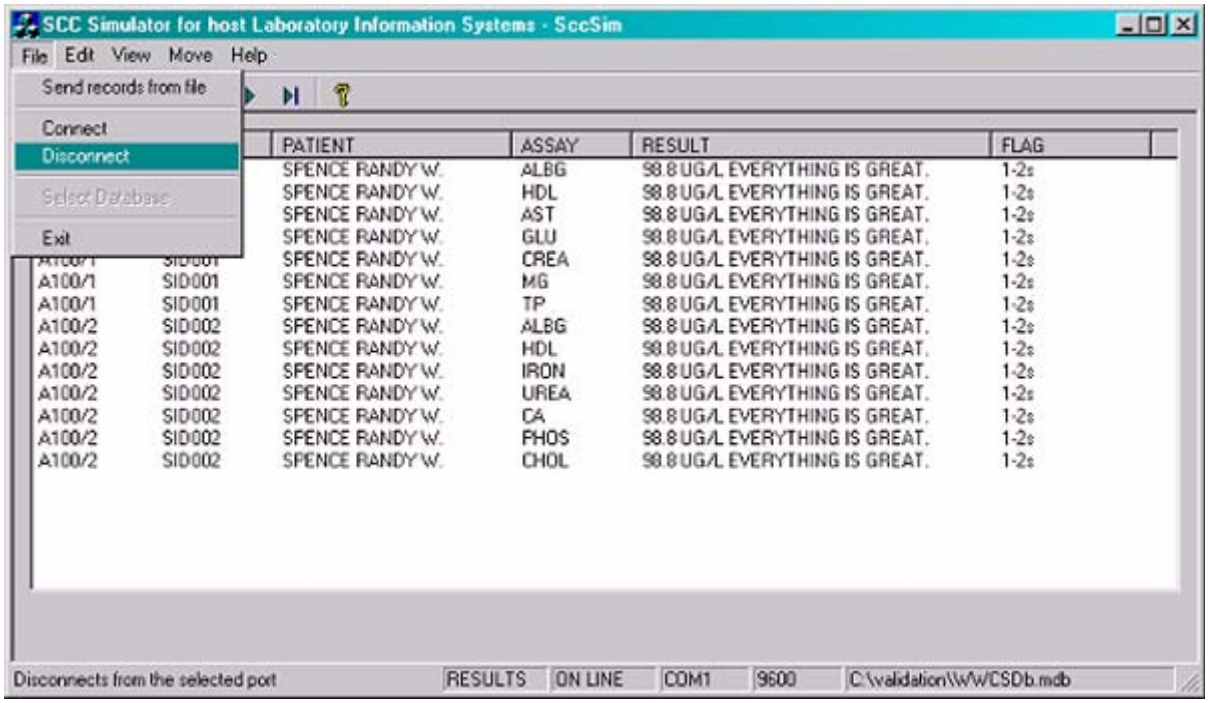


Figure 5.58: Disconnect Through Menu

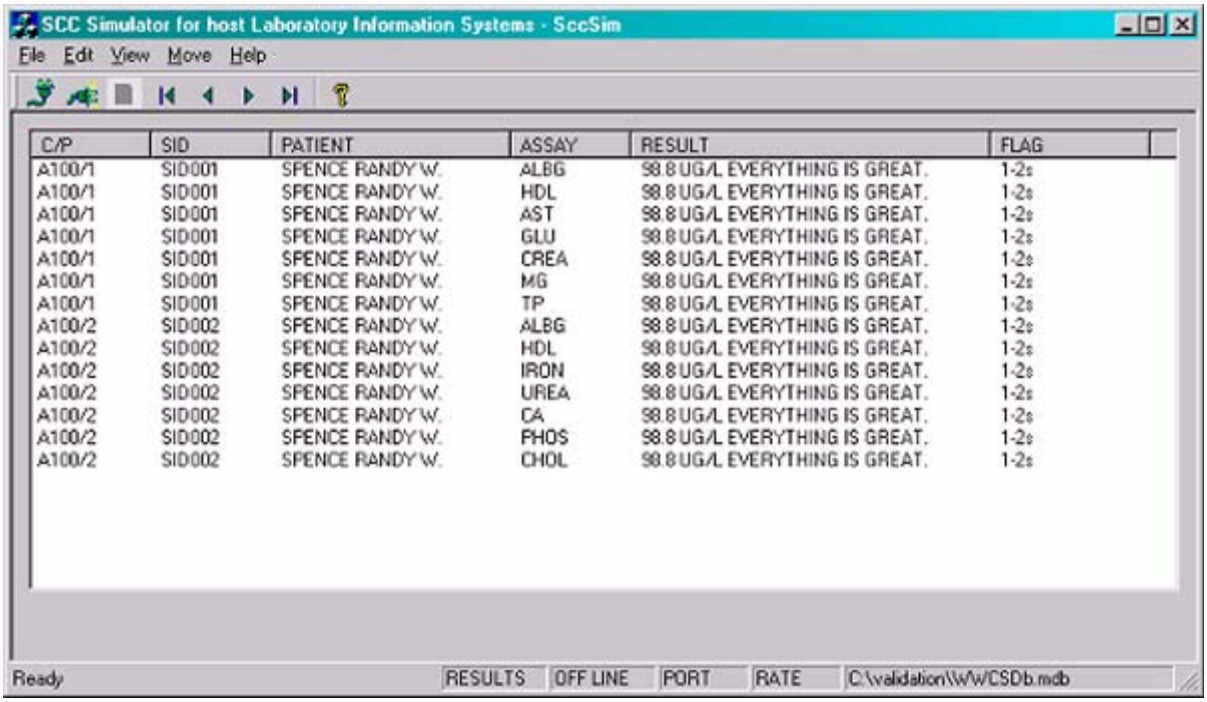


Figure 5.59: After Disconnecting from a Communication Port

Sending results or queries to a host

The SCC Simulator provides the user the capability to send results or queries to an LIS provided they are in the [RESULTS or QUERIES] view and the simulator is connected to a communication port. The user can select one or multiple items in the currently displayed view [RESULTS or QUERIES]. Once the selections are made, right mouse click on one of the selected items, and select **Send Selected Items** from the popup menu (*Figure 5.60*, *Figure 5.61*) [RESULTS, QUERIES]. The simulator sends the selected items.

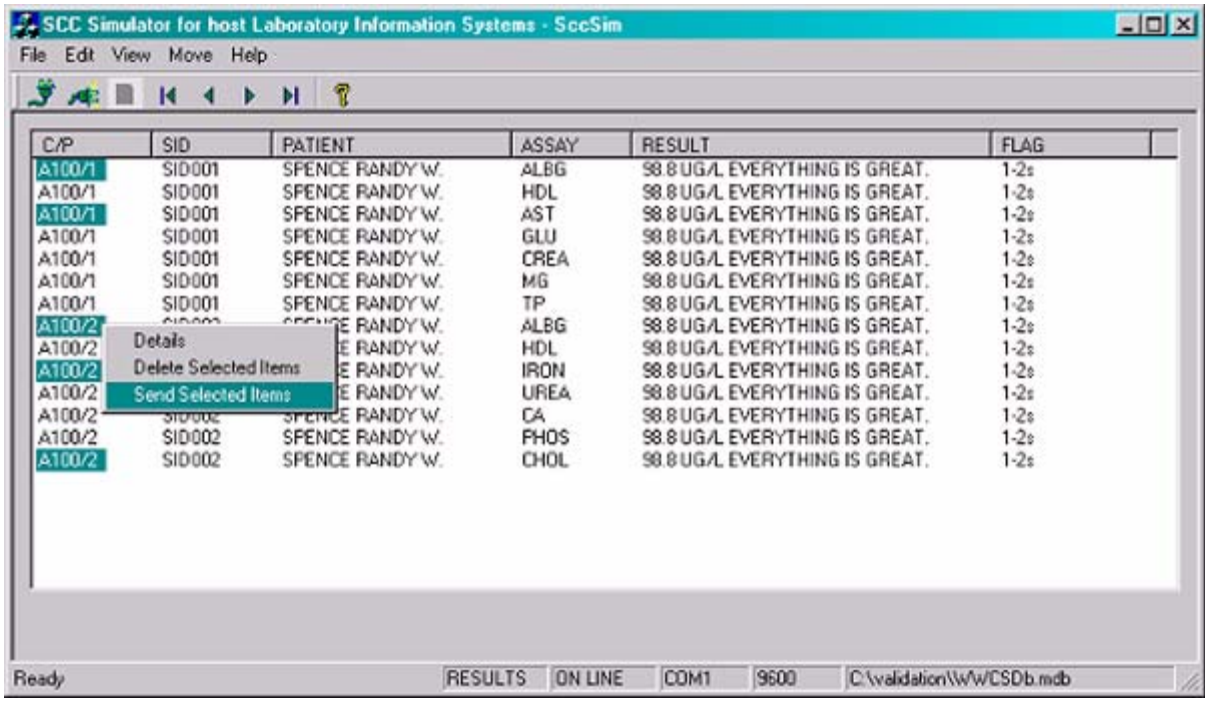


Figure 5.60: Send Selected Results

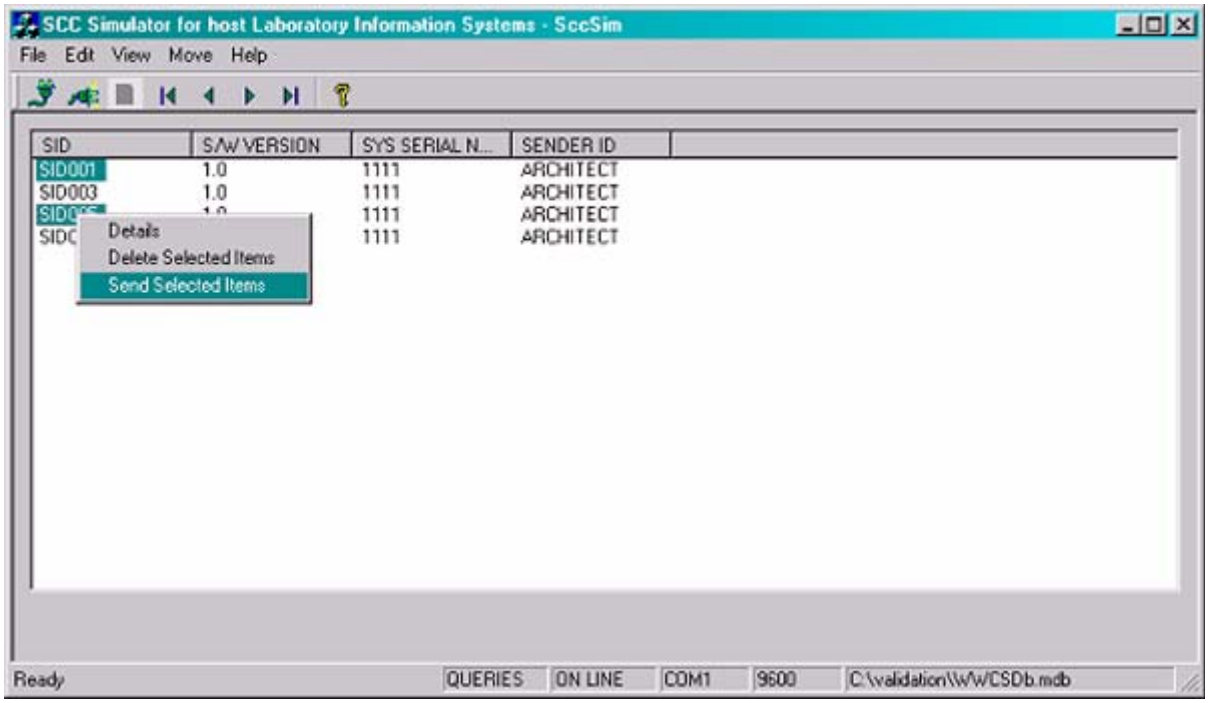


Figure 5.61: Send Selected Queries

NOTES

Introduction

This section provides a comparison of RS-232 interface specifications between the ARCHITECT System and the AxSYM System including:

- A functional comparison between the two systems.
- A document comparison between the Abbott Standard Interface RS-232 Manuals of the two systems covering *Section 2: System-specific Outgoing Messages* and *Section 3: System-specific Incoming Messages*.

NOTES

Functional Comparison

Background

As the ARCHITECT System is primarily designed for high volume immunoassay markets, its Host Interface is also designed to enhance the speed and the data communicated with a host system.

The following is a brief description of the major functional differences between the ARCHITECT System and AxSYM System.

Physical Layer

Speed

AxSYM System

Supported baud rates are:

1200, 2400, 4800, 9600, 19200

ARCHITECT System

Supported baud rates are:

1200, 2400, 4800, 9600, 14400, 19200, 28800, 38400, 57600, 115200

Host Interface Port

AxSYM System

The Host Interface Port is one of the eight interface ports located on the back of the AxSYM System.

ARCHITECT System

The COM5 Port is used as the Host Interface Port and is located at the back of the System Control Center (SCC).

Data Link Layer

Establishment Phase

AxSYM System

During the Establishment Phase, if the AxSYM System has information to transmit, it attempts to establish a connection with an external host every 60 seconds.

ARCHITECT System

During the Establishment Phase, if the ARCHITECT System has information to transmit, it attempts to establish a connection with a host every 30 seconds.

If, after ten unsuccessful attempts to establish the connection with the host system *(e.g.*, the host system is down), the ARCHITECT System displays an alert message, and discontinues attempts to establish a connection with the host system.

In the case of discontinuation of attempts, the Host Interface Port is disabled and the user must re-enable Host Communication.

Message Content Layer

Canceling of Test Orders

AxSYM System

AxSYM does not currently support the ability for a host to cancel a previously downloaded test order through the use of the Action Code field.

ARCHITECT System

ARCHITECT currently supports the ability for a host to cancel a previously down-loaded test order through the use of the Action Code field. Refer to Section 3: ARCHITECT System-specific Incoming Messages, Test Order Records.

Transmission Modes

AxSYM System

Has two separate options for transmission as:

- Select Transmit Approved Patient Results to Host: ON/OFF

If set to ON, the AxSYM System sends patient results to the host computer upon approval.
Default = OFF.

- Select Accept Order Requests from Host:
  ON/OFF

  If set to ON, the AxSYM System is enabled to receive orders from a host computer.
  Default = OFF

ARCHITECT System

Provides a single option for both transmission modes as:

- Host type: ASTM/Serial or None
  Query mode: On/Off

  If set to ASTM/Serial, the ARCHITECT System is enabled to receive test orders downloaded from the host system and send approved results to the host system.
  If set to Query mode: On, the ARCHITECT System is enabled to receive test orders downloaded from the host system or queries and send approved results to the host system.
  Default = OFF.

The ARCHITECT System also provides options for transmitting results to the host. Refer to the ARCHITECT System Operations Manual for information on these options.

Transmission of Multiple Flags

AxSYM System

Provides an option to configure the Transmission of Multiple Result Flags to the Host (ON/OFF) in the result record type F (final).

If set to OFF, the AxSYM System sends the highest priority result flag to be transmitted to the host.

If set to ON, all result flags (up to 12 characters) are transmitted to the host separated by Component Delimiters (^).

There is no requirement for all component delimiters (^) to be present.

ARCHITECT System

Automatically sends result related flags in the Result Record Type F. All flags are transmitted to the host separated by Component Delimiters (^).

Comment Record

AxSYM System

- **For Outgoing messages:** Allows at least 100 characters maximum in the comment record to be sent to the host system.
- **For Incoming messages:** Not supported.

ARCHITECT System

- **For Outgoing messages:** Allows at least 260 characters maximum in the comment record to be sent to the host system.
- **For Incoming messages:** Allows 50 characters maximum in the comment record to be sent from the host system. The comment may be associated with and follow either a patient record or a test order record.

Query Mode

AxSYM System

If a Query Request is not responded to by either Orders or a Negative Query Response, the AxSYM System discontinues waiting for the response, and no longer issues Query Requests for the remainder of the current run.

ARCHITECT System

Allows three consecutive Query time-out errors (pre-defined by the system) occurring due to the inability of the host system to reply within the Query time-out period configured via the “Host query timeout” option on the Configure host-release mode dialog window. If this number is reached, the system alerts the user about the encountered error, and disables the query mode.

Logical Transmission Error Recovery Requirements

AxSYM System

- **Incoming messages:** During transmission failure, expects to receive the whole message that was unsuccessfully received.
- **Outgoing messages:** During transmission failure, retransmits the whole message that was unsuccessfully transmitted.

ARCHITECT System

- **Incoming messages:** stores segments of the message as received, according to the following criteria:

– At decremental changes in the hierarchical level. Any unsaved data is saved prior to this record.

– At receipt of a test order. Any unsaved test order record and associated comment record(s) received prior to this record are saved.

According to the hierarchical record level requirements, all logical records necessary to reach the point [record] where transmission failure occurred must be retransmitted.

An example message, showing save points, is provided below at left. A list of which records would need resending in case of transmission failure is shown at right.

Line #	Record Type(Level)	Increment	Action of Host:
A	Header	(Level 0)+0	
B	Patient1	(Level 1)+1	
C	Order 1	(Level 2)+1	
D	Order 2	(Level 2)+0 ←	at this
E	Comment1	(Level 3)+1	
F	Order 3	(Level 2)-1 ←	at this point,
G	Comment1	(Level 3)+1	
H	Patient2	(Level 2)-2 ←	at this point,
I	Order 1	(Level 2)+1	
J	Order 2	(Level 2)+0 ←	at this point,
K	Comment1	(Level 3)+1	
L	Patient3	(Level 1)-2 ←	at this point,
M	Comment1	(Level 2)+1	
N	Order1	(Level 2)+0	
O	Comment1	(Level 3)+1	
P	Terminator	(Level 0)-3 ←	at this point,

(Terminator record is assumed as saved.)

Line # where failure occurred	ARCHITECT would require retransmission of:
A	A
B	AB
C	ABC
D	ABCD
E	ABDE
F	ABDEF
G	ABFG
H	ABFGH
I	AHI
J	AHIJ
K	AHJK
L	AHJKL
M	ALM
N	ALMN
O	ALMNO
P	ALMNOP

Figure 6.1: Example of Logical Transmission Error Recovery (Incoming)

- **Outgoing messages:** Data is presumed to be saved at the host whenever any decremental change in the hierarchical level is observed.

  The example below illustrates the decremental change in the hierarchical level that defines the point where the data is presumed to be saved at the host. At these level changes, all the data received, not including the record at which the decremental change occurred, is saved. In the example below at the left, storage would occur at points E, G, I, M, O, Q, and T.

  In order to fulfill hierarchical record level requirements, all logical records necessary to reach the restart record point are sent prior to transmitting the record where line failure originally occurred. A list of which records would be resent in case of a transmission failure is shown at the right.

Line #	Record Type(Level)	Increment	Action of Host:
A	Header	(Level 0)+0	
B	Patient1	(Level 1)+1	
C	Order 1	(Level 2)+1	
D	Result1	(Level 3)+1	
E	Order 2	(Level 2)-1 ←	at this
F	Comment1	(Level 3)+1	
G	Order 3	(Level 2)-1 ←	at this
H	Comment1	(Level 3)+1	
I	Patient2	(Level 2)-2 ←	at this point, saves G thru H
J	Order 1	(Level 2)+1	
K	Result1	(Level 3)+1	
L	Comment1	(Level 4)+1	
M	Result2	(Level 3)-1 ←	at this
N	Result3	(Level 3)+0	
O	Order2	(Level 2)-1 ←	at this
P	Comment1	(Level 3)+1	
Q	Patient3	(Level 1)-2←	at this
R	Order1	(Level 2)+1	
S	Result1	(Level 3)+1	
T	Terminator	(Level 0)-3 ←	at this

(Terminator record is assumed as saved.)

Line # where failure occurred	ARCHITECT would require retransmission of:
A	A
B	AB
C	ABC
D	ABCD
E	ABCDE
F	ABEF
G	ABEFG
H	ABGH
I	ABGHI
J	AIJ
K	AIJK
L	AIJKL
M	AIJKLM
N	AIJMN
O	AIJMNO
P	AIOP
Q	AIOPQ
R	AQR
S	AQRS
T	AQRST

Figure 6.2: Example of Logical Transmission Error Recovery (Outgoing)

Other specific field format and content differences

Please refer to the respective RS-232 Manuals. A comparison of these sections follows.

Document Comparison

System-Specific Outgoing Messages

The following information provides a comparison between Section 4 of the ARCHITECT System vs. AxSYM System Abbott Standard Interface RS-232 Manuals:

Overview

The following section outlines the ASTM records and field contents needed to establish communication from the ARCHITECT / AxSYM System to a host computer.

For information on communicating from the host to the ARCHITECT / AxSYM System, refer to System-Specific Incoming Messages in the respective Abbott Standard Interface RS-232 Manuals.

Communication: (ARCHITECT vs. AxSYM) to Host

Transmission of Patient Results, Quality Control Results, and Order Query Requests utilize the high level ASTM records and fields described in this section. Unused fields are not listed.

Results Transmission Mode

Single Results

Transmission of single results is the same for both systems.

Collated Results

ARCHITECT System**:**

If the user-configurable option “Approved Patient Results” is set to “Collated”, multiple ASTM records are sent within a host session. The record hierarchy is as follows:

Message Header Record
Patient Information Record
Test Order Record (Result)
Result Record (Final)
Comment Record (optional)
Result Record (Interpretation - optional)
Result Record (Preliminary - optional)
Test Order Record (Exception)
Comment Record
Test Order Record (Result)
Result Record (Final)
Comment Record (optional)
Result Record (Interpretation - optional)
Result Record (Preliminary - optional)
Message Terminator Record

The ARCHITECT System collates all the results for a sample and transmits to the host only after the last test for that sample has been completed and released, including reruns. The ARCHITECT System sends one patient information record per session.

AxSYM System:

The AxSYM System collates all the results for a sample and transmits to the host only after the last test for that sample has been completed and released. The AxSYM System collates multiple patient information records within one session.

Order Query Transmission

Order Query transmission is the same for both systems.

ASTM Record Formats

The following sections detail the formats for these ASTM records:

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

ASTM records that are not used:

- Scientific Record
- Manufacturer Information Record

Message Header Record

The following table details the format of the Message Header Record sent by the ARCHITECT System or AxSYM System to the Host.

Table 6.1: Message Header: ARCHITECT / AxSYM System to Host

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
7.1.1	Record Type ID (Same for both)	1	H	Header
7.1.2	Delimiter Definition (Same for both)	4	|	Field delimiter: vertical bar
			\	Repeat delimiter: backslash
			^	Component delimiter: caret
			&	Escape delimiter: ampersand
7.1.5	Sender Name or ID	ARCHITECT: 9	ARCHITECT	Instrument Name
		AxSYM 5	AxSYM	
	Software Version (Same for both)	4	^Version Number (numeric)	Version number in the format 1.23
	Serial Number	ARCHITECT: 25	^Serial Number (alphanumeric)	ARCHITECT: SCC Serial Number
		AxSYM: 10		AxSYM: Instrument Serial Number
	Interface Version (Same for both)	16	^Interface Version (alphanumeric)	Record types the system supports
7.1.12	Processing ID	1	P	ARCHITECT: Production: Treat message as an active message to be completed according to standard processing AxSYM: Patient results
			AxSYM: Q	AxSYM: Quality Control results
7.1.13	Version No. (Same for both)	1	1	Mandatory Field
7.1.14	Date and Time (Same for both)	14	YYYYMMDDHHMMSS	Date and Time of transmission in ASTM format.

```
H|\^&|||ARCHITECT^1.00^123456789^H1P1O1R1C1Q1L1|||||||P|1|19930330133346[CR]
```

Figure 6.3: Example of Message Header Record: ARCHITECT System to Host

```
H|\^&|||AxSYM^1.00^1234567-89^H1P1O1R1C1Q1L1|||||||P|1|19930330133346[CR]
```

Figure 6.4: Example of Message Header Record: AxSYM System to Host

Patient Information Record

The following table details the format of the Patient Information Record sent by the ARCHITECT System or AxSYM System to the Host.

Table 6.2: Patient Information Record: ARCHITECT / AxSYM System to Host

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
8.1.1	Record Type	1	P	Patient
8.1.2	Sequence Number	ARCHITECT: 5	ARCHITECT: 1 to 65535	Must be consistent with sequence number rules.
		AxSYM: 1	AxSYM: 1 to n	n represents any number.
8.1.3	Practice-Assigned Patient ID	ARCHITECT: 20	Printable String	Returned unchanged during transmission to the host
		AxSYM: 15	(Any character)	Always returned unchanged to the host.
8.1.4	Laboratory-Assigned Patient ID	ARCHITECT: 20	Printable String	Returned unchanged during transmission to the host
		AxSYM: 15	(Any character)	Always returned unchanged to the host.
8.1.5	Patient ID No. 3	ARCHITECT: 20	Printable String	Optional for Patient test orders
		AxSYM: 15	(Any character)	Instrument PID assigned by operator.

Table 6.2: Patient Information Record: ARCHITECT / AxSYM System to Host *(continued)*

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
8.1.6	Patient Name	ARCHITECT: 20	Last (printable string)	• Last, first, and middle patient name ARCHITECT ONLY: • Optional for Patient test orders • Empty for Control test orders
		AxSYM: 15	Last (any character)	
		ARCHITECT: 20	^First (printable string)	
		AxSYM: 20	^First (any character)	
		ARCHITECT: 12	^Middle (printable string)	
		AxSYM: 1	^Middle Initial (any character)	
ARCHITECT: 8.1.8	Birth date	8	YYYYMMDD ≥18000101 date≤current system date	• Patient birth date • Optional for Patient test orders • Empty for Control test orders.
ARCHITECT: 8.1.9	Patient Gender	1	M, F, U	• Patient's gender (Male, Female, or Unknown) • Optional for Patient test orders. • Empty for Control orders • Field is returned unchanged in transmission to the host for patient test orders placed from the host.
ARCHITECT: 8.1.14	Doctor	20	Printable String	Patient Doctor's name • Field contains the data displayed in the optional Doctor attribute on the UI for Patient Test Orders if "Transmit to host: Doctor, location and draw date/time" configuration option is On. • Field is empty for patient test orders if "Transmit to host: Doctor, location and draw date/time" configuration option is Off. • Field is empty for Control test orders

Table 6.2: Patient Information Record: ARCHITECT / AxSYM System to Host *(continued)*

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
ARCHITECT: 8.1.26	Location	20	Printable String	The general clinic location or nursing unit, or ward or bed or both of the patient. • Field contains the data displayed in the optional Location attribute on the UI for Patient Test Orders if "Transmit to host: Doctor, location and draw date/time" configuration option is ON. • Field is empty for patient test orders if "Transmit to host: Doctor, location and draw date/time" configuration option is Off. • Field is empty for Control test orders

```
P|1|||PID13|Patient^Im^A||19320122|F|||||Dr.Amesbury||||||||||||ParkClinic[CR]
```

Figure 6.5: Example of Patient Information Record: ARCHITECT System to Host

```
P|1|||PID13|PATIENT^IM^A[CR]
```

Figure 6.6: Example of Patient Information Record: AxSYM System to Host

Test Order Record

The following table details the format of the Test Order Record sent by the ARCHITECT System or AxSYM System to the Host.

Table 6.3: Test Order Record: ARCHITECT / AxSYM System to Host

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
9.4.1	Record Type	1	O	Order
9.4.2	Sequence Number	ARCHITECT: 5	1 to 65535	Must be consistent with sequence number rules.
		AxSYM: 1	1 to n	n represents any number

Table 6.3: Test Order Record: ARCHITECT / AxSYM System to Host *(continued)*

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
9.4.3	Specimen ID	ARCHITECT: 20 AxSYM: 15	ARCHITECT: Printable String AxSYM: any character	Sample ID downloaded from Host, returned unchanged to the host
9.4.4	ARCHITECT: Instrument specimen ID	20	Printable String	Instrument Specimen ID, Carrier_ID, and Position are returned for all specimens tested, although Instrument Specimen ID may be different than Specimen ID in 9.4.3 if changed by operator or scanned by the instrument
	Carrier ID	4	^alphanumeric	
	Position	2	^numeric	
	AxSYM: Instrument specimen ID	15	any character	Instrument Sample ID, segment, and position are returned for all specimens tested, although Instrument Sample ID may be different than Sample ID in 9.4.3 if changed by the operator. NOTE: The information in the Segment/Position portion of the field is invalid for Control Orders.
	^location_ID	1	^segment (Alphanumeric)	
	^position	2	^position (Numeric)	
9.4.5	Universal Test ID Code	ARCHITECT: 4 AxSYM: 3	^^^Assay Number (numeric)	Specific number that identifies the test
	Name	ARCHITECT: 10 AxSYM: 9	^Assay Name (printable string) ^Assay Name (alphanumeric)	Test name
	Assay Protocol	10	ARCHITECT: ^Dilution (printable string) AxSYM: ^Dilution (Alphanumeric)	Dilution protocol name
	ARCHITECT: Assay Status	1	^Status (P or C)	Assay status: • P or p if assay is installed as the primary version • C or c if the assay is installed as the correlation version
9.4.6	Priority (Same for both)	1	S or s *or* R	STAT ARCHITECT: R or any other character

Table 6.3: Test Order Record: ARCHITECT / AxSYM System to Host *(continued)*

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
ARCHITECT: 9.4.8	Collection Date and Time	14	YYYYMMDDHHMMSS ≥ 19700101000000 and ≤ current system date	Date and time of sample collection • Field contains the data displayed in the optional Draw date/time attribute on the UI for Patient Test Orders if "Transmit to host: Doctor, location and draw date/time" configuration option is ON. • Field is empty for Patient Test Orders if "Transmit to host: Doctor, location and draw date/time" configuration option is OFF. • Field is Empty for Control Test Orders
9.4.12	Action Code (Same for both)	1	Q	• Quality Control Result • Empty for Patient result
9.4.26	Report Types (Same for both)	1	F *or* X	Final Result Test could not be performed

```
O|1|SID13|SID3^A123^5|^^^123^Assay1^UNDILUTED^P|R||20010223081223|||||||||||||||||F[CR]
```

Figure 6.7: Example of Test Order Record: ARCHITECT System to Host

```
O|1|SID13|SID13^A^1|^^^16^Assay1^NEAT|R|||||||||||||||||||F[CR]
```

Figure 6.8: Example of Test Order Record: AxSYM System to Host

Result Record

The following table details the format of the Result Record sent by the ARCHITECT System or AxSYM System to the Host.

Table 6.4: Result Record: ARCHITECT / AxSYM System to Host

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
10.1.1	Record Type (Same for both)	1	R	Result
10.1.2	Sequence Number	ARCHITECT: 5	1 to 65535	Must be consistent with sequence number rules.
		AxSYM: 1	1 to n	n represents any number

Table 6.4: Result Record: ARCHITECT / AxSYM System to Host *(continued)*

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
10.1.3	Universal Test ID Code	ARCHITECT: 4 AxSYM: 3	^^^Assay Number (numeric)	Specific number that identifies the test
	Name	ARCHITECT: 10 AxSYM: 9	^Assay Name (printable string) ^Assay Name (alphanumeric)	Test name
	Assay Protocol	10	ARCHITECT: ^Dilution (printable string) AxSYM: ^Dilution (alphanumeric)	Dilution protocol name
	ARCHITECT: Assay Status	1	^ Status (P or C)	Assay Status: • P if assay is installed as primary version • C if assay is installed as correlation version
	ARCHITECT: Reagent Lot	15	^ alphanumeric	Reagent Master Lot # (empty for calculated results)
	ARCHITECT: Reagent Serial Number	5	^ alphanumeric	Serial number of reagent kit used to process the test result (empty for calculated results)
	ARCHITECT: Control Lot Number	20	printable string	Lot number of the control material (empty for patient results and calculated results)
	AxSYM: Test_Qualifier		^^	Always null
	Result Type	1	ARCHITECT: ^F AxSYM: F *or*	ARCHITECT: • Final result concentration or result value AxSYM: • Final result concentration
			P *or*	ARCHITECT: • Preliminary instrument result (RLU, mV, Abs) AxSYM: • Preliminary instrument result (rate or mP)
			I	Interpreted result

Table 6.4: Result Record: ARCHITECT / AxSYM System to Host *(continued)*

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
10.1.4	Data Value	ARCHITECT: 20	ARCHITECT: Printable String	For Result Type F (concentration value if within dynamic range) including < or >
				For Result Type P (numeric response)
				For Result Type I (interpretation)
		AxSYM: 15	AxSYM: Numeric	For Result Type F
			AxSYM: Numeric Response	For Result Type P (Float decimal position or comma for both Result Type F and P.)
			AxSYM: Interpretation String	For Result Type I
10.1.5	Units	7	ARCHITECT: Result Units (printable string)	Result Type F
			AxSYM: Concentration Units	
			or	
			ARCHITECT: RLU or mV or Abs	Result Type P
			AxSYM: Rate or mP or Percent	
			or Empty	Result Type I
10.1.6	Reference Ranges	ARCHITECT: at least 35	Normal/Therapeutic Ranges ARCHITECT ONLY: (Printable string formatted as minimum value to maximum value)	For Result Type F for Patient Result
			or	
		AxSYM: 25	AxSYM: Control Range	For Result Type F for QC Result
			ARCHITECT ONLY: Control Range (Printable string formatted as minimum value to maximum value)	For Result Type F for Control Result
			or Empty	For Result Type I or P and for Result Type F, if range undefined.

Table 6.4: Result Record: ARCHITECT / AxSYM System to Host *(continued)*

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
10.1.7	Result Abnormal Flags	ARCHITECT: 25	IUO EDIT 1-2s 1-3s 2-2s1R1M 2-2s1RxM 2-2sxR1M R-4s 4-1s1M 4-1sxM 10-x1M 10-xxM EXP EXPC A#1 A#2 CNTL < or > INDX FLEX LL or HH PSHH LOW or HIGH CORR	For Result Type F: This field can be blank or can contain one or more result flags. Multiple flags are sent separated by component delimiters (which are used as a repeat delimiter). For Result Type P and I: This field is blank. The following flags are Westgard analysis flags and only display if the result is a control: 1-2s, 1-3s, 2-2s1R1M, 2-2s1RxM, 2-2sxR1M, R-4s, 4-1s1M, 4-1sxM, 10-x1M, 10-xxM
		AxSYM: 12	EX QC < or > LL or HH L or H	For Result Type F: If configured for multiple result flags, this field can be blank or can contain one or more result flags (separated by a component delimiter). For Result Type P and I: This field is blank.
10.1.9	Result Status (Same for both)	1	F *or* R	Final Results Previously Transmitted Results
10.1.11	Operator Identification	ARCHITECT: 12	Order Operator ID (printable string)	ID of Operator logged into system at time of order
			^Release Operator ID (printable string)	ID of Operator logged in at time of result release
		AxSYM: 6	printable string	
10.1.13	Date/Time Test Complete (Same for both)	14	YYYYMMDDHHMMSS	
ARCHITECT: 10.1.14	Instrument Identification	25	Alphanumeric	Serial # of the module which performed the test.

```
R|1|^^^16^TSH^DIL1^P^12345AB89^12345^^F|28.275|mIU/mL|30.000TO500.000|EXP^LOW|
|F||OP345^OP346||19930330132949|IA200A345[CR]
```

Figure 6.9: Example of Result Record: ARCHITECT System to Host

```
R|1|^^^16^Assay1^UNDILUTED^^F|28.275|mIU/mL|30.000 TO 500.000|EX^L||F||||19930330132949[CR]
```

Figure 6.10: Example of Result Record: AxSYM System to Host

ARCHITECT:

The following list of field contents of 10.1.7 (Result Abnormal Flags) are not part of the ASTM standard: EXP, CNTL, CORR, the Westgard Analysis flags (1-2S, 1-3S, 2-2S 1R 1M, 2-2S 1R xM, 2-2S xR 1M, R-4S, 4-1S 1M, 4-1S xM, 10x 1M, 10x xM), IUO, EXPC, A#1, A#2, FLEX, EDIT, and PSHH.

Comment Record

AxSYM:

A Comment Record follows a Result Record if information is entered into the comment section of the Results Review screen.

The following table details the format of the Comment Record sent by the ARCHITECT System or AxSYM System to the Host.

Table 6.5: Comment Record: ARCHITECT / AxSYM System to Host

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
11.1.1	Record Type (Same for both)	1	C	Comment
11.1.2	Sequence Number	ARCHITECT: 5	1 to 65535	Must be consistent with sequence number rules
		AxSYM: 1	1 to n	n represents any number
11.1.3	Comment Source (Same for both)	1	I	Instrument
11.1.4	Comment Text	ARCHITECT: at least 260	Printable String	Result Comment or Exception String
		AxSYM: 100		

Table 6.5: Comment Record: ARCHITECT / AxSYM System to Host

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
11.1.5	Comment Type (Same for both)	1	G *or* I	Result Comment Exception String

```
C|1|I|Example Result Comment|G[CR]
```

Figure 6.11: Example of Comment Record: ARCHITECT / AxSYM System to Host

Request Information Record

The following table details the format of the Request Information Record sent by the ARCHITECT System or AxSYM System to the Host.

ARCHITECT

The following table details the exact format of the Request Information Record which shall be sent by the ARCHITECT System to the Host.

Table 6.6: Request Information Record: ARCHITECT / AxSYM System to Host

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
12.1.1	Record Type ID (Same for both)	1	Q	
12.1.2	Sequence Number (Same for both)	1	1	Always contains 1
12.1.3	ARCHITECT: ID Number	20	^Specimen ID	Sample ID read from the bar code label on the sample tube
	AxSYM: Starting Range ID Number	15		
12.1.5	Universal Test ID	ARCHITECT: 3	^^^ALL	System always requests that ALL outstanding orders be sent
		AxSYM: [blank]		
12.1.13	Status Code (Same for both)	1	O	System only requests Orders

```
Q|1|^SID12345||^^^ALL||||||||O[CR]
```

Figure 6.12: Example of Request Information Record: ARCHITECT / AxSYM System to Host

Message Terminator Record

The following table details the format of the Message Terminator Record sent by the ARCHITECT System or AxSYM System to the Host.

Table 6.7: Message Terminator Record: ARCHITECT / AxSYM System to Host

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
13.1.1	Record Type (Same for both)	1	L	Last
13.1.2	Sequence Number (Same for both)	1	1	

```
L|1[CR]
```

Figure 6.13: Example of Terminator Record: ARCHITECT / AxSYM System to Host

System-Specific Incoming Messages

The following information provides a comparison between system-specific incoming messages in the ARCHITECT System and AxSYM System Abbott Standard Interface RS-232 Manuals.

Overview

The following section outlines the ARCHITECT / AxSYM System records and field contents needed to establish communication from a host computer to the ARCHITECT / AxSYM System.

For information on communicating from the ARCHITECT / AxSYM System to a host computer, refer to ***System-Specific Outgoing Messages*** in the respective Abbott Standard Interface RS-232 Manuals.

Communication: Host to the System (ARCHITECT vs. AxSYM)

Transmission of Patient Demographics, Patient ID, Sample ID, Test Orders, and Query Responses utilize the high level ASTM records and fields described in this section. Unlisted fields are ignored by the ARCHITECT / AxSYM System.

Transmission of patient orders to the ARCHITECT / AxSYM System from the host takes place according to the following logical record hierarchy.

ARCHITECT:

Message Header Record

Patient Information Record

Test Order Record

Patient Information Record

Test Order Record

Test Order Record

Comment Record (optional)

Patient Information Record

Comment Record (optional)

Test Order Record

Test Order Record

Message Terminator Record

AxSYM:

Message Header Record

Patient Information Record

Test Order Record

Message Terminator Record

Both

Transmission of a negative Query Response (those responses that indicate that the Query Request SID is unknown, or has no outstanding orders) utilize the following logical record hierarchy.

Message Header Record

Request Information Record

Message Terminator Record

NOTE: In the case of a negative Query Response, the Request Information Record is a copy of the original record sent from ARCHITECT / AxSYM System, with the Status Code field set to X.

ARCHITECT:

An error is logged and the remainder of the message—up to the message terminator record—is ignored if the ARCHITECT System receives a record that:

- Is missing a required field as defined in this section
- Is not defined for ARCHITECT System incoming messages
- Has an invalid sequence number

- Has one or more fields or components that do not conform to requirements as defined further in this section

Records that were received prior to this record are accepted and processed further.

Format Detail

The ARCHITECT / AxSYM System recognizes fields when parsing for the following records:

- Message Header Record
- Patient Information Record
- Request Information Record
- Test Order Record
- Comment Record [ARCHITECT System ONLY]
- Message Terminator Record

ARCHITECT:

The following records are not used by the ARCHITECT System:

- Scientific Record
- Manufacturer Information Record

AxSYM:

All other fields are ignored regardless of content.

The following records are ignored by the AxSYM System:

- Comment Record
- Scientific Record
- Manufacturer Information Record

Message Header Record

Table 6.8: Message Header: Host to ARCHITECT / AxSYM System

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
7.1.1	Record Type (Same for both)	1	H or h	Header
7.1.2	Delimiter Definition	ARCHITECT: 4 AxSYM: [blank]		Bytes 2 and 6 of the record must be the same.

Table 6.8: Message Header: Host to ARCHITECT / AxSYM System *(continued)*

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
7.1.12	Processing ID	1	P or p	ARCHITECT: Production: Treat message as an active message to be completed according to standard processing
				AxSYM: Processing ID
7.1.13	Version Number (Same for both)	1	1	Must be 1

```
H|\^&|||||||||P|1[CR]
```

Figure 6.14: Example of Message Header Record: Host to ARCHITECT / AxSYM System

Processing ID must be P and Version Number must be 1 or the message "Message Header Record to Terminator Record" is ignored.

ASTM Fields 7.1.1, 7.1.2, 7.1.12, and 7.1.13 of the Message Header Record are all required by the ARCHITECT / AxSYM System.

Patient Information Record

The following table details the format of the Patient Information Record sent by the Host to the ARCHITECT System or AxSYM System.

Table 6.9: Patient Information Record: Host to ARCHITECT / AxSYM System

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
8.1.1	Record Type (Same for both)	1	P or p	Patient
8.1.2	Sequence Number (Same for both)	5	1 to 65535	Must be consistent with sequence number rules
8.1.3	Practice-Assigned Patient ID	ARCHITECT: 20	Printable String	• Returned unchanged during transmission to the host • Optional for Patient test orders • Empty for Control test orders
		AxSYM: 15	Any character	Returned unchanged during transmission to the host.

Table 6.9: Patient Information Record: Host to ARCHITECT / AxSYM System *(continued)*

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
8.1.4	Laboratory-Assigned Patient ID	ARCHITECT: 20	Printable String	• Returned unchanged during transmission to the host • Optional for Patient test orders • Empty for Control test orders
		AxSYM: 15	Any character	Returned unchanged during transmission to the host.
8.1.5	Patient ID No. 3	ARCHITECT: 20	Printable String	• Optional for Patient test orders • Empty for Control test orders
		AxSYM: 15	Any character	See note below.
8.1.6	Patient Name	ARCHITECT: 20	ARCHITECT: Last (printible string)	ARCHITECT: • Last, first, and middle patient name for Patient test orders • Empty for Control test orders AxSYM: • Last, first, and middle initial of the patient name.
		AxSYM: 15	AxSYM: Last (any character)	
		20	ARCHITECT: ^First (printible string)	
			AxSYM: First (any character)	
		ARCHITECT: 12	ARCHITECT: ^Middle (printible string)	
		AxSYM: 1	AxSYM: Middle initial (any character)	
ARCHITECT: 8.1.8	Birth Date	8	YYYYMMDD ≥18000101 ≤current system date	• Patient birth date • Optional for Patient test orders • Empty for Control test orders.
ARCHITECT: 8.1.9	Patient Sex	1	M, F, U	• Patient sex (Male, Female, Unknown) • Optional for Patient test orders • Empty for Control test orders.

Table 6.9: Patient Information Record: Host to ARCHITECT / AxSYM System *(continued)*

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
ARCHITECT: 8.1.14	Doctor	20	Printable String	Patient Doctor's name • Field contains the data displayed in the optional Doctor attribute on the UI for Patient Test Orders if "Transmit to host: Doctor, location, and draw date/time" configuration option is On. • Field is empty for patient test orders if "Transmit to host: Doctor, location, and draw date/time" configuration option is Off. • Field is empty for Control test orders.
ARCHITECT: 8.1.26	Location	20	Printable String	The general clinic location or nursing unit, or ward or bed or both, of the patient. • Field contains the data displayed in the optional Location attribute on the UI for Patient Test Orders if "Transmit to host: Doctor, location, and draw date/time" configuration option is On. • Field is empty for patient test orders if "Transmit to host: Doctor, location and draw date/time" configuration option is Off. • Field is empty for Control test orders.

Examples:

Patient Test Order

```
P|1|Practice PID|Lab PID||Doe^John^Q||19320122|F|||||Dr. Amesbury||||||||||||ParkClinic[CR]
```

Figure 6.15: Example of Patient Information Record: (Patient Test Ordering): Host to ARCHITECT System

```
P|1|Practice PID|Lab PID||Doe^John^Q[CR]
```

Figure 6.16: Example of Patient Information Record: (Patient Test Ordering): Host to AxSYM System

Control Test Order

```
P|1[CR]
```

Figure 6.17: Example of Patient Information Record (Control Test Ordering): Host to ARCHITECT System

NOTE: The field contents of Practice Assigned Patient ID (8.1.3) shall be copied into the Patient ID No. 3 field upon transmission back to the host (8.1.5) if the field contents of both the Laboratory Assigned Patient ID (8.1.4) and the Patient ID No. 3 (8.1.5) are blank. The field contents of Laboratory Assigned Patient ID (8.1.4) shall be copied into Patient ID No. 3 field upon transmission back to the host (8.1.5), if the field contents of the Patient ID No. 3 (8.1.5) are blank.

Test Order Record

ARCHITECT:

The ARCHITECT System Control Center accepts unsolicited Patient and Control test orders from the LIS regardless of whether the host query option is enabled or not.

Replicates for an assay may be ordered using one of the two methods:

- Use of Repeat Delimiter in Universal Test ID (Field 5) of Test Order Record.
- Multiple Order Records containing Action Code A for Patient test orders.

AxSYM:

A host-defined panel is not recognized by the AxSYM System. Panels must be converted into individual tests and then regrouped into predefined panels by the host computer.

Replicates for an assay may be ordered using one of two methods:

1. Use of Repeat Delimiter in Universal Test ID (Field 12).
2. Multiple Order Records containing Action Code “A.”

   NOTE: The only field in which the AxSYM System supports the repeat delimiter, within Incoming Messages, is the Universal Test ID of the Test Order Record.

The following table details the format of the Test Order Record sent by the Host to the ARCHITECT System or AxSYM System.

Table 6.10: Test Order Record: Host to ARCHITECT / AxSYM System

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
9.4.1	Record Type (Same for both)	1	O or o	Order
9.4.2	Sequence Number (Same for both)	5	1 to 65535	Must be consistent with sequence number rules
9.4.3	ARCHITECT: Specimen ID	20	Printable String	Sample ID downloaded from Host
	Carrier ID	4	^alphanumeric	Carrier ID and position are ignored on input
	Position	2	^numeric	
	AxSYM: Specimen ID ^location_ID ^position	15	Specimen	Sample ID downloaded from Host. Location and position are ignored on input.
9.4.4	ARCHITECT: Instrument specimen ID	N/A	N/A	Field ignored on input
	Carrier ID			
	Position			
	AxSYM: Instrument specimen ID ^location_ID ^position			
9.4.5	ARCHITECT: Universal Test ID (The only required component of this field is the assay number)	4	^^^(numeric)	Specific number that identifies the test
		10	^(printable string)	Test name
		10	^(printable string)	Dilution protocol name
		1	^(P, p, C, or c)	Assay status: • P or p if the assay is installed as the primary version • C or c if the assay is installed as the correlation version
	AxSYM: Universal Test ID	N/A	^^^Assay Number ^Name ^Dilution	Specific number that identifies the test Test Name Dilution Protocol (The only required component of this field is the assay number.)
9.4.6	Priority (Same for both)	1	S	STAT (otherwise blank for Routine)

Table 6.10: Test Order Record: Host to ARCHITECT / AxSYM System *(continued)*

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
ARCHITECT: 9.4.8	Collection Date and Time	14	YYYYMMDDHHMMSS ≥ 19700101000000 and ≤ current system date	Date and time of sample collection • Field contains the data displayed in the optional Draw date/time attribute on the UI for Patient Test Orders if "Transmit to host: Doctor, location and draw date/ time" configuration option is ON. • Field is empty for Patient Test Orders if "Transmit to host: Doctor, location, and draw date/time" configuration option is OFF. • Field is Empty for Control Test Orders
9.4.12	Action Code	1	N *or* A *or* Q *or* ARCHITECT ONLY: C	ARCHITECT: New order for a patient sample AxSYM: New Patient or New Order for an existing Sample ARCHITECT: Unconditional Add order for a patient sample. AxSYM: Add order for Patient ARCHITECT: Control Sample AxSYM: Quality Control Cancel or Delete the existing order
9.4.13	Danger Code	ARCHITECT: 15	Printable String	Part of the Test Order Comment Field (optional)
		AxSYM: [blank]	Alphanumeric	Part of the Sample Comment Field
9.4.14	Clinical Information	ARCHITECT: 15	Printable String	Part of the Test Order Comment Field (optional)
		AxSYM: [blank]	Alphanumeric	Part of the Sample Comment Field
9.4.16	ARCHITECT: Specimen Type	5	Printable String	Part of the Test Order Comment Field (optional)
	Specimen Source	15	^Printable String	
	AxSYM: Specimen Descriptor Specimen Type Specimen Source	[blank]	^Alphanumeric ^Alphanumeric ^Alphanumeric	Part of the Sample Comment Field

Table 6.10: Test Order Record: Host to ARCHITECT / AxSYM System *(continued)*

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
9.4.26	Report Types (Same for both)	1	O or o *or* Q or q	Order Order in response to a Query Request.

```
O|1|MCC1||^^^16\^^^606|||20010223081223||||A|Hep|lipemic||serum|||||||||Q[CR]
```

Figure 6.18: Example of Test Order Record: Host to ARCHITECT System

```
O|1|OMEGA_1||^^^16\^^^606|||||||Q|||||||||||||O[CR]
```

Figure 6.19: Example of Test Order Record: Host to AxSYM System

AxSYM only:

ASTM Fields 9.4.1, 9.4.2, 9.4.3, 9.4.5, 9.4.12, and 9.4.26 of the Test Order Record are required by the AxSYM System.

Text in fields 9.4.13, 9.4.14 and two components of field 9.4.16 (Refer to Table 5.3), limited to a maximum of 50 characters in length, is placed sequentially in the Comment field of an AxSYM System order.

If a dilution is specified for supported assays, the dilution is run. If a dilution is not specified, default dilution is ordered for that assay.

If the field content of 9.4.12 (Action Code) is N, the test order is considered a new patient. However, if the sample and test already exists in the host input spool, an error message is generated on the instrument and the test order record is ignored.

If the field content of 9.5.12 (Action Code) is A, the test order is processed as a patient request. If the sample exists, the test requests is added to the sample. If the sample does not exist, a patient request is created.

If the field content of 9.5.12 (Action Code) is Q the sample is created and verified as a control for the requested analytes. If verified, the QC tests is created.

ARCHITECT:

If a dilution is specified for supported assays, the dilution is run. If a dilution is not specified, default dilution is ordered for that assay.

If the field content of 9.4.12 (Action Code) is **N** for Patient test orders, the test order is considered a new test. However, if the same test order for this sample ID already exists (Pending, Scheduled, or Running), the system considers this an invalid request and error message is generated.

If the field content of 9.4.12 (Action Code) is **A**, the test order shall be processed as a mandatory added test order. It shall be added to the test order list regardless of whether or not the same test order exists (Pending, Scheduled, or Running) in the instrument's database.

If the field content of 9.4.12 (Action Code) is **C**, the test order shall be processed as a request to cancel the specified test order. The instrument shall cancel the first pending test order found, from its pending test order list which has the same SID, Assay Number, Dilution Name, and Assay Status. If no such order is found, the system ignores this request.

If the field content of 9.5.12 (Action Code) is **Q**, the sample is established and verified as a control for the requested analytes. If verified, the QC tests are created.

ARCHITECT ONLY: Comment Record

The following table details the exact format of the Comment Record which shall be sent by the host to the ARCHITECT System.

Table 6.11: Comment Record: Host to ARCHITECT System

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
11.1.1	Record Type	1	C or c	Comment
11.1.2	Sequence Number	5	1 to 65535	Must be consistent with sequence number rules
11.1.3	Comment Source	1	L	Computer system
11.1.4	Comment Text	50	Printable characters	Comment text
11.1.5	Comment Type	1	G	Generic comment

```
Q|1|^SID1234||^^^ALL||||||||X[CR]
```

```
C|1|L|Example Comment|G[CR]
```

Figure 6.20: Example of Comment Record: Host to ARCHITECT System

When the Comment Record follows a patient record, the comment in 11.1.4 refers to that patient sample and is duplicated in the comment field for each test order for that patient sample.

When the Comment Record follows a test order, it refers only to that test order.

The following comment text—limited to a maximum of 50 characters in length—is placed in the comment field of an ARCHITECT System test order in the following sequence:

1. Text in field 11.1.4 (refer to table 5.9 – Comment Record) of one or more comment records associated with the patient record.

   then

2. Text in fields 9.4.13, 9.4.14 and two components of 9.4.16 (refer to table 5.3 – Test Order Record).

   then

3. Text in field 11.1.4 of one or more comment records associated with the test order.

Negative Query Response Record, ARCHITECT

Request Information Record, AxSYM

ARCHITECT:

The system shall accept a Negative Query Response from the Host system. The Negative Query Response is used to indicate that an earlier Query Request from the system resulted in no orders being sent, either due to:

- The sample ID specified in the original Query Request was unknown to the Host system

  or

- The sample ID specified had no outstanding orders at the time the Query Request was received.

The following table details the exact format of the Negative Query Response Record which shall be sent by the Host to the system

Table 6.12: Request Information Record: Host to AxSYM System Negative Query Response Record: Host to ARCHITECT System

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
12.1.1	Record Type ID (Same for both)	1	Q or q	

Table 6.12: Request Information Record: Host to AxSYM System Negative Query Response Record: Host to ARCHITECT System *(continued)*

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
12.1.2	Sequence Number (Same for both)	1	1	Always contains 1
12.1.3	ARCHITECT: ID Number	20	^Specimen ID (printable string)	Sample ID that was originally sent by the system
	AxSYM: Starting Range ID Number	15	^Specimen ID	
12.1.5	Universal Test ID	ARCHITECT: 3	^^^ALL	Field contents originally sent by the system
		AxSYM: [blank]		
12.1.13	Status Code (Same for both)	1	X	Indicates that either the Sample ID is unknown to the Host, or there are no outstanding orders for the specified Sample ID

ARCHITECT

```
Q|1|^SID1234||^^^ALL||||||||X[CR]
```

Figure 6.21: Example of Negative Query Response Record: Host to ARCHITECT System

AxSYM

```
Q|1|^SID12345||^^^ALL||||||||X[CR]
```

Figure 6.22: Example of Request Information Record: Host to AxSYM System

The system shall discontinue waiting for either Test Orders or a Negative Query Response in response to an earlier issued Query Request, as defined in the user-configurable option “Host query timeout”.

After a predefined number of allowed consecutive host time-out errors, the software shall:

- Log an error
- Disable the query mode

AxSYM:

The only form of the Request Information Record that is supported by AxSYM as an incoming transmission, is that of the Negative Query Response. The Negative Query Response is used to indicate that an earlier Query Request from the AxSYM System results in no orders being sent. This can be due to (1) the Sample ID specified in the original Query Request was unknown to the Host system, or (2) the Sample ID specified has no outstanding orders at the time the Query Request was received.

The Negative Query Response is essentially a copy of the original Query Request with the Status Code set to X.

Message Terminator Record

The following table details the exact format of the Message Terminator Record which shall be sent by the Host to the system.

Table 6.13: Message Terminator Record: Host to ARCHITECT System

ASTM Field	Field Name	Maximum Characters	Field Contents	Field Description
13.1.1	Record Type	1	L	Last
13.1.2	Sequence Number	1	1	Must be 1

```
L|1[CR]
```

Figure 6.23: Example of Message Terminator Record: Host to ARCHITECT System

NOTES

ASTM Standard E1394-91 and CLSI (NCCLS) LIS2-A2 (second edition) Comparison

Table A.1: Message Header Record

ASTM E 1394-91	CLSI LIS2-A2	Field Name
7.1.1	6.1	Record Type ID
7.1.2	6.2	Delimiter Definition
7.1.3	6.3	Message Control ID
7.1.4	6.4	Access Password
7.1.5	6.5	Sender Name or ID
7.1.6	6.6	Sender Street Address
7.1.7	6.7	Reserved Field
7.1.8	6.8	Sender Telephone Number
7.1.9	6.9	Characteristics of Sender
7.1.10	6.10	Receiver ID
7.1.11	6.11	Comment or Special Instructions
7.1.12	6.12	Processing ID
7.1.13	6.13	Version Number
7.1.14	6.14	Date and Time of Message

Table A.1: Patient Information Record

ASTM E 1394-91	CLSI LIS2-A2	Field Name
8.1.1	7.1	Record Type ID
8.1.2	7.2	Sequence Number
8.1.3	7.3	Practice-Assigned Patient ID
8.1.4	7.4	Laboratory-Assigned Patient ID
8.1.5	7.5	Patient ID Number 3
8.1.6	7.6	Patient Name
8.1.7	7.7	Mother's Maiden Name
8.1.8	7.8	Birth Date
8.1.9	7.9	Patient Sex
8.1.10	7.10	Patient Race-Ethnic Origin
8.1.11	7.11	Patient Address
8.1.12	7.12	Reserved Field
8.1.13	7.13	Patient Telephone Number
8.1.14	7.14	Attending Physician ID
8.1.15	7.15	Special Field 1
8.1.16	7.16	Special Field 2
8.1.17	7.17	Patient Height
8.1.18	7.18	Patient Weight
8.1.19	7.19	Patient's Known or Suspected Diagnosis
8.1.20	7.20	Patient Active Medication
8.1.21	7.21	Patient's Diet
8.1.22	7.22	Practice Field Number 1
8.1.23	7.23	Practice Field Number 2
8.1.24	7.24	Admission and Discharge Dates
8.1.25	7.25	Admission Status
8.1.26	7.26	Location
8.1.27	7.27	Nature of Alternative Diagnostic Code and Classifiers
8.1.28	7.28	Alternative Diagnostic Code and Classification
8.1.29	7.29	Patient Religion
8.1.30	7.30	Marital Status
8.1.31	7.31	Isolation Status
8.1.32	7.32	Language
8.1.33	7.33	Hospital Service
8.1.34	7.34	Hospital Institution
8.1.35	7.35	Dosage Category

Table A.2: Test Order Record

ASTM E 1394-91	CLSI LIS2-A2	Field Name
9.4.1	8.4.1	Record Type ID
9.4.2	8.4.2	Sequence Number
9.4.3	8.4.3	Specimen ID
9.4.4	8.4.4	Instrument Specimen ID
9.4.5	8.4.5	Universal Test ID
9.4.6	8.4.6	Priority
9.4.7	8.4.7	Requested/Ordered Date and Time
9.4.8	8.4.8	Specimen Collection Date and Time
9.4.9	8.4.9	Collection End Time
9.4.10	8.4.10	Collection Volume
9.4.11	8.4.11	Collector ID
9.4.12	8.4.12	Action Code
9.4.13	8.4.13	Danger Code
9.4.14	8.4.14	Relevant Clinical Information
9.4.15	8.4.15	Date/Time Specimen Received
9.4.16	8.4.16	Specimen Descriptor
9.4.17	8.4.17	Ordering Physician
9.4.18	8.4.18	Physician's Telephone Number
9.4.19	8.4.19	User Field Number 1
9.4.20	8.4.20	User Field Number 2
9.4.21	8.4.21	Laboratory Field Number 1
9.4.22	8.4.22	Laboratory Field Number 2
9.4.23	8.4.23	Date/Time Results Reported or Last Modified
9.4.24	8.4.24	Instrument Charge Information System
9.4.25	8.4.25	Instrument Section ID
9.4.26	8.4.26	Report Types
9.4.27	8.4.27	Reserved Field
9.4.28	8.4.28	Location of Specimen Collection
9.4.29	8.4.29	Nosocomial Infection Flag
9.4.30	8.4.30	Specimen Service
9.4.31	8.4.31	Specimen Institution

Table A.3: Result Record

ASTM E 1394-91	CLSI LIS2-A2	Field Name
10.1.1	9.1	Record Type ID
10.1.2	9.2	Sequence Number
10.1.3	9.3	Universal Test ID
10.1.4	9.4	Data or Measurement Value
10.1.5	9.5	Units
10.1.6	9.6	Reference Range
10.1.7	9.7	Result Abnormal Flag
10.1.8	9.8	Nature of Abnormality Testing
10.1.9	9.9	Result Status
10.1.10	9.10	Date of Change in Instrument Normative Values or Units
10.1.11	9.11	Operator Identification
10.1.12	9.12	Date/Time Test Started
10.1.13	9.13	Date/Time Test Completed
10.1.14	9.14	Instrument Identification

Table A.4: Comment Record

ASTM E 1394-91	CLSI LIS2-A2	Field Name
11.1.1	10.1	Record Type ID
11.1.2	10.2	Sequence Number
11.1.3	10.3	Comment Source
11.1.4	10.4	Comment Text
11.1.5	10.5	Comment Type

Table A.5: Request Information Record

ASTM E 1394-91	CLSI LIS2-A2	Field Name
12.1.1	11.1	Record Type ID
12.1.2	11.2	Sequence Number
12.1.3	11.3	Starting Range ID Number
12.1.4	11.4	Ending Range ID Number
12.1.5	11.5	Universal Test ID
12.1.6	11.6	Nature of Request Time Limits
12.1.7	11.7	Beginning Requests Results Date and Time
12.1.8	11.8	Ending Request Results Date and Time
12.1.9	11.9	Requesting Physician Name
12.1.10	11.10	Requesting Physician Telephone Number
12.1.11	11.11	User Field Number1
12.1.12	11.12	User Field Number 2
12.1.13	11.13	Request Information Status Codes

Table A.6: Message Terminator Record

ASTM E 1394-91	CLSI LIS2-A2	Field Name
13.1.1	12.1	Record Type ID
13.1.2	12.2	Sequence Number
13.1.3	12.3	Termination Code

Table A.7: Manufacture's Record

ASTM E 1394-91	CLSI LIS2-A2	Field Name
15.1.1	14	Record Type ID
15.1.2	14	Sequence Number
	*	* Configurable by manufacturer

NOTES

Revision history

The revision history table provides a high level summary of content that has changed in this document since the last revision (91407-107 November 2010).

Section	Description
Front matter	Updated: • Customer support • Trademark statement
How to Use this Manual	• Updated section numbers in description of the organization of the manual. • Deleted information on the data diskette containing the Instrument Specification File as it is no longer provided with this manual.
Section 1 Abbott Standard Interface	• Speed - updated references to Communication Setup to the ARCHITECT System Operations Manual. • Figure 1.25 CLSI Document LIS1-A Sender/Receiver State Diagram - corrected number of retries for Old Frame Set Up.
Section 2 Communication Setup	This section has been removed. Refer to your ARCHITECT System Operations Manual.
Section 3 ARCHITECT System-specific Outgoing Messages	This is now Section 2. • Replaced “Host Bidirectional Mode is On or Off with query” with “Connection status is Enabled”. • Replaced “Bidirectional Host Mode is transitioned to Off” and “Bidirectional Host Mode Off” with “Connection status is Disabled”.
Section 4 ARCHITECT System-specific Incoming Messages	This is now Section 3. • Replaced “Host Communication Mode to Off” with “Connection status to Disabled”. • ASI Code Pages for the ARCHITECT System - updated reference to Communication Setup to the ARCHITECT System Operations Manual.
Section 5 ARCHITECT System Support of ASI Options	This is now Section 4.
Section 6 Troubleshooting	This section has been removed. Refer to your ARCHITECT System Operations Manual.
Section 7 Abbott Host/Instrument Interface Tools	This is now Section 5. Deleted references to ASIST Tool.
Section 8 ARCHITECT System and AxSYM Comparison	This is now Section 6. • Updated section number references. • Message Content Layer/Transmission Modes and Query Mode - updated description for ARCHITECT System.

NOTES

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Electronics Industries Association. 1986. *EIA-232-D-1986 Interface Between Data Terminal Equipment and Data Circuit-Terminating Equipment Employing Serial Binary Data Interchange.*

Clinical and Laboratory Standards Institute (CLSI) LIS1-A. ***Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems***.

Clinical and Laboratory Standards Institute: LIS2-A2. ***Specification for Transferring Information Between Clinical Instruments and Computer Systems; Approved Standard - Second Edition***.

NOTES

Index

Glossary

Allowed Data Formats

All data is represented in ASCII format within the range 0 - 255.
Values 0 - 127 are defined by ANSI X3.4-196 Standard.
Values 128 - 255 are defined as needed by specific instruments.
Values 0 - 31 cannot be used, with the exception of 13 (<CR>). The value 13 is reserved as a record terminator.
Values 32 - 255 can be used, with the exception of 127 and 255. Within a data text field, only the ASCII characters 32 - 126 and 128 - 254 are permitted as usable characters. Characters used as delimiters in the transmission are excluded from the above permitted range. The sender is responsible for checking that a data text field does not contain any delimiters. The record identified fields (H, P, O, R, L, C, M, and Q) are always uppercase when output from the Abbott instrument. On input, both upper- and lowercase record identifiers are accepted. Fields and records are variable in length with no restriction placed on the maximum length of a field or record. The high-level protocol depends on the receiver's buffering capability and the low-level communication ability to divide the information into workable lengths for transmission and processing purposes. All Abbott Standard Interface RS-232 manuals provide the maximum allowable length of each field transmitted and received.

ASI

Abbott Standard Interface: Abbott's implementation of the American Society for Testing and Materials (ASTM) Standard.
E 1394-91, A Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems.
E1381-91, Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems.

Assay

Analysis to determine the presence, absence, or quantity of one or more analytes.

Assay calibration

The generation of a calibration curve for use in determining the concentration of an analyte present in samples.

Assay parameters

Settings that define specific characteristics or verify the performance of an assay.

Assay protocols

Assay processing steps that provide the system with information which allows pipetting, incubation, washing and reading to occur at specific volumes and times throughout the reaction sequence. Protocol types include: One-step, Two-step, and Pre-Treatment.

Assay settings

Individual settings within each assay configuration category which you can edit to meet your site-specific requirements.

ASTM

American Society for Testing and Materials. Consists of specifications that define the transferring of information between laboratory instruments and computer systems.

Bulk solutions

The solutions found in the supply and waste center which are used on the system (Pre-Trigger Solution, Trigger Solution, Wash Buffer).

Calibration curve

Created when an operator performs an assay calibration. Used for determining the concentration of analyte in a sample.

Calibrator

Material with a known concentration of specific analyte used to create a calibration curve.

Check boxes

A user interface input area where you can make one or more selections for an item. A black check mark in the box indicates that it has been selected.

Chemiluminescense	Emission of light produced by a chemical reaction.
CMIA	Chemiluminescent Microparticle Immunoassay; the detection technology the ARCHITECT System uses to perform automated immunoassays.
Configuration	The process by which you can edit System, Assay, and QC-Cal settings that provide the system with information to meet your site-specific requirements.
Consumables	Items that are exhausted in the process of running assays (reagents, calibrators, controls, bulk solutions, septums, replacement caps, sample cups, reaction vessels)
Control	Material with a known concentration of a specific analyte. Controls are run with patient samples and are used to monitor assay and system performance over time.
***c* System**	Refers to a *c* 8000 or *c* 16000 instrument.
Dialog windows	Overlay screens that display on top of, or in front of, full-frame screens. They provide additional information, details, or functions. They display after an item or function key has been selected on the primary full-frame screen.
Drop-down menu	List of items that display when an icon is selected that represents each of the screens available for the specific icon.
E1381-91 Frame	A frame is a subdivision of a message and allows transmission of up to 247 characters (240 data characters and 7 control characters). The Abbott instrument transmits one record per frame. Messages more than 247 characters long can be divided into multiple frames, as long as each frame contains only information from one record at a time.
E1381-91 Message	A block of data that is transmitted in a format consistent with the ASTM E 1381-91 Standard. Abbott ASI instruments use an E 1394-91 Record as the E1381-91 Message. Thus, an E1381-91 Message may be transmitted using multiple (one or more) frames, based on the length of the message.
E 1394-91 Message	A block of data that is transmitted in a format consistent with the ASTM E 1394-91 Standard. Data is transmitted in a series of records starting with a Header Record (H) and ending with a Terminator Record (L). When a transmission is lost, the Abbott instrument retransmits or accepts only complete messages.
E 1394-91 Record	An E1394 Record is a string of characters starting with a capital ASCII alphabet character and ending with a carriage return (ASCII 13), as defined by the ASTM E 1394-91 Standard.
Exceptions	Test orders that fail to complete.
Field	A subdivision of a record containing one specific piece of information, such as an address.
Full-frame screen	Screen displayed when a drop-down menu option is selected.
Function key zone	Located at the bottom of the software screens containing function keys associated with a particular screen.
Host	An auxiliary computer system that can communicate back and forth with the ARCHITECT System.
Icon	Symbol providing a graphic and name that represent a category of screens or additional functionality.

Icon zone	Located at the top of the software screens providing navigational and status indication support. Each icon in the icon zone has a drop-down menu that is displayed when you select the icon.
Immunoassay	Analytical procedure based on reactions between antigens and antibodies.
Information zone	The main area of the software screens containing information pertaining to a particular screen, including screen name.
***i* System**	Refers to a single or multi-module *i* 2000, *i* 2000_{SR}, or *i* 1000_{SR}.
Multi-module	ARCHITECT System configuration containing more than one (1) *i* 2000 processing module.
Popup windows	Overlay screens that display at the center of a full-frame screen and in front of the currently displayed window. All interaction with the user interface is suspended until you acknowledge the popup by selecting one of the buttons in the window.
Process path	A covered temperature controlled circular track that moves RVs; provides liquid aspiration, and wash points as necessary for the assay.
Processing center	Area in which assay processing activities take place. Contains the process path.
Processing module	Light sealed area where sample processing takes place. Functions that occur here include mixing and delivering of reagents, solutions, and samples, incubations, all optical reads and disposal of used RVs.
Processing module graphic	Located in the center of the Snapshot screen, and contains key information specific to the processing module, as well as navigational hot spots for accessing related screens.
Processing module status	Information regarding the operational mode of the processing module. Status types include: Offline, Stopped, Warming, Ready, Scheduled Pause, Running, Initializing, and Scanning.
Query Request	A message sent to the LIS requesting test orders for a specific sample ID.
Query Response	A message sent to the ARCHITECT System containing orders for the sample ID specified in the prior Query Request. A Query Response may also indicate that no orders are required at the time the Query Request was made.
Radio buttons	A user interface input area where you can only make one selection from multiple options. A black-filled circle indicates that it has been selected.
Reaction Vessel (RV)	A disposable that carries a specified volume of sample, reagent, and solution through the processing center path.
Reagent carousels	Carousels located in the refrigerated compartment of the processing center where reagent bottles are loaded.
Record	Related information which forms a subdivision of a complete ASTM message.
Repeat field	A single data element which expresses a duplication of the field definition it represents. It is used for demographics, requests, orders and the like, where each element of a repeat field is to be treated as having equal priority to associated repeat fields.

Reserved Characters
The following characters have special uses and should not be used for data:
Vertical Bar (|)
Backslash (\)
Ampersand (&)
Carriage Return (<CR>)
Caret (^)

Sample double load / Unload queues
Configured on multi-module systems to provide two load queue lanes with a capacity of up to 125 samples each (25 sample carriers) for a total capacity of 250 samples (50 sample carriers).

Sample handler
Module that transports samples from the load queue to the Processing Center queue and then to the unload queue.

Sample handler keypad
Used to provide extended system control center functionality at the sample handling center.

Sample handler status
Information regarding the operational mode of the sample handler. Status types include: Offline, Stopped, Ready, Running, and Load queue paused.

Sample load queue
Track on the left side of the processing module where sample carriers are loaded.

Sample load queue bar code reader
Used to scan carrier ID bar codes, carrier position bar codes, and primary tube bar codes to identify the sample.

Sample processing queue
Track in front of the processing module where sample carriers are transported from the load queue to the sample aspiration position and then down the track to the unload queue.

Sample syringe (SS)
Aspirates and dispenses sample by moving the piston in the syringe body.

Sample unload queue
Track on the right side of the processing module where sample carriers are unloaded

Serial port
A connection point between the ARCHITECT System and an external device.

Snapshot screen
The Main Menu screen of the ARCHITECT System. Monitors key system and processing module information. Also provides quick access to related screens through the use of icons and drop-down menus.

System control center
Computer workstation that provides a centralized interface by which the operator can control one or more processing modules.

System software
Software that controls operation of the ARCHITECT System.

System status
Information regarding the operational modes of the system. The processing module and the sample handler each have separate statuses.

Unicode
Character encoding scheme that supports internationalization of textual information. The encoding scheme uses 16 data bits to represent each character which provides for definition of 65536 unique characters.

User interface
Graphical screens that an operator uses to control and navigate through the ARCHITECT System software. Navigate by using a mouse, touch-screen monitor, and/or keyboard.