Designation: E 1381 – 95

An American National Standard

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

This standard is issued under the fixed designation E 1381; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification describes the electronic transmission of digital information between clinical laboratory instruments and computer systems. The clinical laboratory instruments under consideration are those that measure one or more parameters from one or more patient samples. Often they will be automated instruments that measure many parameters from many patient samples. The computer systems considered here are those that are configured to accept instrument results for further processing, storage, reporting, or manipulation. This instrument output may include patient results, quality control results, and other related information. Typically, the computer system will be a Laboratory Information Management System (LIMS).

1.2 The terminology of the Organization for International Standards (ISO) Reference Model for Open Systems Interconnection (OSI) is generally followed in describing the communications protocol and services. The electrical and mechanical connection between instrument and computer is described in the Physical Layer section. The methods for establishing communication, error detection, error recovery, and sending and receiving of messages are described in the Data Link Layer section. The data link layer interacts with higher layers in terms of sends and receives "messages," handles data link connection and release requests, and reports the data link status.

1.3 Specification E 1394 is concerned with message content in the interface between clinical instruments and computer systems. The major topics are found in the following sections:

2. Referenced Documents

2.1 *ASTM Standards:*

E 1394 Specification for Transferring Information Between Clinical Instruments and Computer Systems[2]

2.2 *ANSI Standards:*[3]

X3.4-1986 American National Standard Code for Information Systems—Coded Character Sets—7-Bit American National Standard Code for Information Interchange (7-Bit ASCII)

X3.15-1976 American National Standard for Bit Sequencing of the American National Standard Code for Information Interchange in Serial-by-Bit Data Transmission

X3.16-1976 American National Standard Character Structure and Character Parity Sense for Serial-by-Bit Data Communication in the American National Standard Code for Information Interchange

2.3 *ISO Standard:*[3]

International Standard ISO 7498-1984(E), Information Processing Systems—Open Systems Interconnection—Basic Reference Model, International Organization for Standardization

2.4 *Other Document:*[4]

EIA-232-D-1986 Interface Between Data Terminal Equipment and Data Circuit-Terminating Equipment Employing Serial Binary Data Interchange

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[1] This specification is under the jurisdiction of ASTM Committee E31 on Healthcare Informatics and is the direct responsibility of Subcommittee E31.13 on Clinical Laboratory Systems.

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[2] *Annual Book of ASTM Standards*, Vol 14.01.

[3] Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

[4] Available from Electronics Industries Association, 2001 I Street, N.W., Washington, DC 20006.

3. Terminology

3.1 *receiver*—the device that responds to the sender and accepts the message.

3.2 *sender*—the device that has a message to send and initiates the transmission process.

3.3 The parts of a communication between instrument and computer are identified by the following terms. The parts are hierarchical and are listed in order of most encompassing first.

3.4 *session*—a total unit of communication activity, used in this standard to indicate the events starting with the establishment phase and ending with the termination phase, as described in subsequent sections.

3.5 *message*—a collection of related information on a single topic, used here to mean all the identity, tests, and comments sent at one time. When used with Specification E 1394, this term means a record as defined by Specification E 1394.

3.6 *frame*—a subdivision of a message, used to allow periodic communication housekeeping such as error checks and acknowledgements.

4. Significance and Use

4.1 Nearly all recent major clinical instruments have provision for connection to a computer system, and in nearly all laboratories that have implemented a LIMS, there is a need to connect the laboratory's high volume automated instruments to the LIMS so that results can be transferred automatically. To accomplish this connection, both the instrument and the computer must have compatible circuits and appropriate software, and there must be a proper cable to connect the two systems.

4.1.1 Without this standard specification, the interface between each different instrument and each different computer system is likely to be a different product. This increases the cost, the chances for compatibility problems, and the difficulty of specifying and designing a proper system. In addition, interfaces for every instrument-computer combination may not be available, forcing expensive and time-consuming custom development projects.

4.2 This standard specification defines the electrical parameters, cabling, data codes, transmission protocol, and error recovery for the information that passes between the instrument and the laboratory computer. It is expected that future products from instrument manufacturers and computer system developers, released after the publication of this specification, will conform to this specification, and that will lead to plug-together compatibility of clinical instruments and computer systems.

5. Physical Layer

5.1 *Overview*—The mechanical and electrical connection for serial binary data bit transmission between instrument and computer system is described in the physical layer. The technology is point-to-point, a direct connection between two devices.

5.2 *Electrical Characteristics*—The voltage and impedance levels for the generator and receiver circuits are as specified in the EIA-232-D-1986 standard.

5.2.1 *Signal Levels*:

5.2.1.1 For the data interchange circuits, a marking condition corresponds to a voltage more negative than minus three volts with respect to signal ground at the interface point. A spacing condition corresponds to a voltage more positive than plus three volts with respect to signal ground at the interface point.

5.2.1.2 Binary state ONE (1) corresponds to the marking condition; binary state ZERO (0) corresponds to the spacing condition.

5.2.1.3 The signal levels conform to the EIA-232-D-1986 standard.

5.2.2 *Character Structure*:

5.2.2.1 The method of data transmission is serial-by-bit start/stop. The order of the bits in a character is:

(1) One start bit, corresponding to a binary 0,

(2) The data bits of the character, least significant bit transmitted first,

(3) Parity bit,

(4) Stop bit(s), corresponding to a binary 1.

5.2.2.2 The time between the stop bit of one character and the start bit of the next character may be of any duration. The data interchange circuit is in the marking condition between characters.

5.2.2.3 Even parity corresponds to a parity bit chosen in such a way that there are an even number of ONE bits in the sequence of data bits and parity bit. Odd parity corresponds to an odd number of ONE bits when formed in the same way.

5.2.2.4 All devices must be capable of sending and receiving characters consisting of one start bit, eight data bits, no parity bit, and one stop bit.

5.2.2.5 The default character structure consists of one start bit, eight data bits, no parity bit, and one stop bit. Eight data bit character sets are allowed but not specified by this standard. Other character structures can be used for specialized applications, for example, seven data bits, odd, even, mark or space parity, or two stop bits.

5.2.2.6 The character bit sequencing, structure, and parity sense definitions conform to ANSI standards X3.15-1976 and X3.16-1976.

5.2.3 *Speed*:

5.2.3.1 The data transmission rate for instruments shall be at least one of these baud rates: 1200, 2400, 4800, or 9600 baud. The preferred rate is 9600 baud and should be the default setting of the instrument when more than one baud rate is available. The computer system must have the capability for all four baud rates.

5.2.3.2 Devices may optionally have the capability for other baud rates such as 300, 19 200, and 38 400 baud for use in specialized applications.

5.2.4 *Interface Connections*:

5.2.4.1 The conforming connection specified here defines the point of interconnection between the domain of the instrument and domain of the computer system. (See Fig. 1 and Fig. 2.) Within the domain of either device, any appropriate connection system may be used, preferably with suitable cable locking hardware.

5.2.4.2 The conforming connection utilizes a 25-position connector. The connector contact assignments are listed in

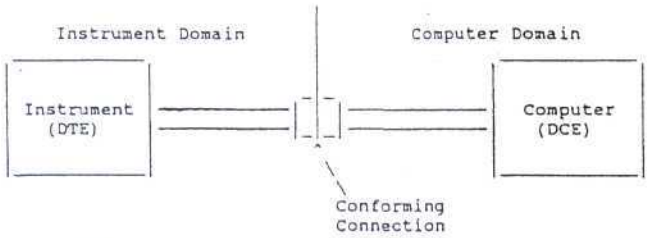


FIG. 1 Connector Strategy for Instrument Computer Connection—Cable Mounted

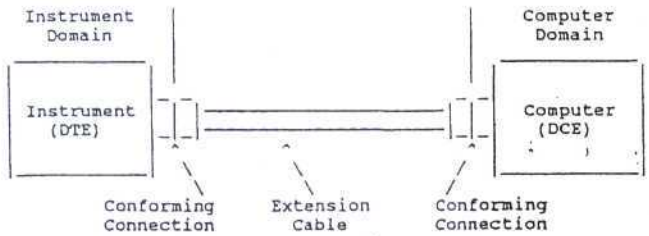


FIG. 2 Connector Strategy for Instrument Computer Connections—Chassis Mounted

Table 1. Connector contacts not listed are unused. The connector contact assignments conform to the EIA-232-D-1986 stan- for the circuits that are used.

.2.4.3 Contact 1 is the shield connection, it connects to the instrument's (the DTE) frame. The shield connection is left open at the computer (the DCE) to avoid ground loops. There will be no connections on any other pins. All other pins will be open circuits.

5.3 *Mechanical Characteristics*:

5.3.1 *Connector*:

5.3.1.1 The conforming connector associated with the instrument is a commercial type DB-25P (subminiature D male) style connector. The conforming connector associated with the computer is a commercial type DB-25S (subminiature D female) style connector. The connector dimensions must correspond to those given in the EIA-232-D-1986 standard.

5.3.1.2 When the conforming connector of the instrument is cable mounted, it shall be configured with a locking device such as No. 4-40 or M-3 thread female screw locking hardware. When the conforming connector of the computer is cable mounted, it shall be configured with a locking device such as No. 4-40 or M-3 thread male screw locking hardware. (See Fig. 1.)

5.3.1.3 When the conforming connector of either device is chassis mounted, it shall be configured with devices such as No. 4-40 or M-3 thread female screw locking hardware. The mating cable connector shall use devices such as No. 4-40 or M-3 thread male screw locking hardware. (See Fig. 2.)

TABLE 1 Connector Contact Assignments

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

5.3.1.4 When the conforming connector of the instrument is cable mounted and the conforming connector of the computer is chassis mounted, then a change in the cable mounted locking hardware is necessary.

5.3.2 *Cable*—Any extension cables to connect the instrument to the computer require a female connector on one end to mate with the instrument and a male connector on the other end to mate with the computer. Detailed requirements of an interconnecting cable are undefined but good engineering practice should be followed in selecting the cable and connectors. Shielded cable and connectors may be necessary to suppress electromagnetic interface (EMI). Low capacitance cable may be necessary for long cable lengths or the higher data rates. Appropriate connector locking hardware should be used at the conforming connectors.

6. Data Link Layer

6.1 *Overview*—The data link layer has procedures for link connection and release, delimiting and synchronism, sequential control, error detection, and error recovery.

6.1.1 Link connection and release establish which system sends and which system receives information. Delimiting and synchronism provide for framing of the data and recognition of frames. Sequence control maintains the sequential order of information across the connection. Error detection senses transmission or format errors. Error recovery attempts to recover from detected errors by retransmitting defective frames or returning the link to a neutral state from otherwise unrecoverable errors.

6.1.2 The data link layer uses a character-oriented protocol to send messages between directly connected systems. (See ANSI X3.4-1986. Also, see Appendix X1 for the coding of the ASCI characters.) Some restrictions are placed on the characters which can appear in the message content.

6.1.3 The data link mode of operation is one-way transfer of information with alternate supervision. Information flows in one direction at a time. Replies occur after information is sent,

never at the same time. It is a simplex stop-and-wait protocol.

6.1.4 At times, the two systems are actively operating to transfer information. The remainder of the time the data link is in a neutral state. See the state diagram in Annex A1.

6.1.5 There are three distinct phases in transferring information between instrument and computer system. In each phase, one system directs the operation and is responsible for continuity of the communication. The three phases assure the actions of sender and receiver are coordinated. The three phases are establishment, transfer, and termination.

6.2 *Establishment Phase (Link Connection)*:

6.2.1 The establishment phase determines the direction of information flow and prepares the receiver to accept information.

6.2.2 The sender notifies the receiver that information is available. The receiver responds that it is prepared to receive before information is transmitted.

6.2.3 A system which does not have information to send normally monitors the data link to detect the establishment phase. It acts as a receiver, waiting for the other system.

6.2.4 The system with information available initiates the establishment phase. After the sender determines the data link is in a neutral state, it transmits the <ENQ> transmission control character to the intended receiver. Sender will ignore a ponses other than <ACK>, <NAK>, or <ENQ>.

6.2.5 Upon receiving the <ENQ>, the receiver prepares to receive information. All other characters are ignored. It replies with the <ACK> transmission control character signifying it is ready. With this sequence of events, the establishment phase ends and the transfer phase begins.

6.2.6 A receiver that cannot immediately receive information, replies with the <NAK> transmission control character. Upon receiving <NAK>, the sender must wait at least 10 s before transmitting another <ENQ>.

6.2.7 Systems not having the ability to receive information always respond to an <ENQ> by replying with a <NAK>. Systems not having the ability to send information never transmit an <ENQ>.

6.2.7.1 *Contention*—Should both systems simultaneously transmit an <ENQ>, the data link is in contention. The instrument system has priority to transmit information when contention occurs. Contention is resolved as follows:

(1) Upon receiving a reply of <ENQ> to its transmitted <ENQ>, the computer system must stop trying to transmit; it must prepare to receive. When the next <ENQ> is received, it replies with an <ACK> or <NAK> depending on its readiness to receive.

(2) Upon receiving a reply of <ENQ> to its transmitted <ENQ>, the instrument must wait at least 1 s before sending another <ENQ>.

6.3 *Transfer Phase*— During the transfer phase, the sender tr nits messages to the receiver. The transfer phase contin- u. ntil all messages are sent.

6.3.1 *Frames*—Messages are sent in frames, each frame contains a maximum of 247 characters (including frame overhead). Messages longer than 240 characters are divided between two or more frames.

6.3.1.1 Multiple messages are never combined in a single frame. Every message must begin in a new frame.

6.3.1.2 A frame is one of two types, an intermediate frame or an end frame. Intermediate frames terminate with the characters <ETB>, checksum, <CR> and <LF>. End frames terminate with the characters <ETX>, checksum, <CR> and <LF>. A message containing 240 characters or less is sent in a single end frame. Longer messages are sent in intermediate frames with the last part of the message sent in an end frame. The frame structure is illustrated as follows:

<STX> FN text <ETB> C1 C2 <CR> <LF> ← intermediate frame

<STX> FN text <ETX> C1 C2 <CR> <LF> ← end frame

where:

<STX>	=	Start of Text transmission control character
FN	=	single digit Frame Number 0 to 7
text	=	*Data Content of Message*
<ETB>	=	End of Transmission Block transmission control character
<ETX>	=	End of Text transmission control character
C1	=	most significant character of checksum 0 to 9 and A to F
C2	=	least significant character of checksum 0 to 9 and A to F
<CR>	=	Carriage Return ASCII character
<LF>	=	Line Feed ASCII character

6.3.2 *Frame Number*— The frame number permits the receiver to distinguish between new and retransmitted frames. It is a single digit sent immediately after the <STX> character.

6.3.2.1 The frame number is an ASCII digit ranging from 0 to 7. The frame number begins at 1 with the first frame of the Transfer phase. The frame number is incremented by one for every new frame transmitted. After 7, the frame number rolls over to 0, and continues in this fashion.

6.3.3 *Checksum*—The checksum permits the receiver to detect a defective frame. The checksum is encoded as two characters which are sent after the <ETB> or <ETX> character. The checksum is computed by adding the binary values of the characters, keeping the least significant eight bits of the result.

6.3.3.1 The checksum is initialized to zero with the <STX> character. The first character used in computing the checksum is the frame number. Each character in the message text is added to the checksum (modulo 256). The computation for the checksum does not include <STX>, the checksum characters, or the trailing <CR> and <LF>.

6.3.3.2 The checksum is an integer represented by eight bits, it can be considered as two groups of four bits. The groups of four bits are converted to the ASCII characters of the hexadecimal representation. The two ASCII characters are transmitted as the checksum, with the most significant character first.

6.3.3.3 For example, a checksum of 122 can be represented as 01111010 in binary or 7A in hexadecimal. The checksum is transmitted as the ASCII character 7 followed by the character A.

6.3.4 *Acknowledgments*— After a frame is sent, the sender stops transmitting until a reply is received.

6.3.4.1 The receiver replies to each frame. When it is ready

to receive the next frame, it transmits one of three replies to acknowledge the last frame. This reply must be transmitted within the timeout period specified in 6.5.2.

6.3.4.2 A reply of <ACK> signifies the last frame was received successfully and the receiver is prepared to receive another frame. The sender must increment the frame number and either send a new frame or terminate.

6.3.4.3 A reply of <NAK> signifies the last frame was not successfully received and the receiver is prepared to receive the frame again.

6.3.4.4 A reply of <EOT> signifies the last frame was received successfully, the receiver is prepared to receive another frame, but is a request to the sender to stop transmitting. (See the following section on receiver interrupts.)

6.3.5 *Receiver Interrupts*—The receiver interrupt is a means for the receiver to request the sender to stop transmitting messages as soon as possible.

6.3.5.1 During the transfer phase, if the receiver responds to a frame with an <EOT> in place of the usual <ACK>, the sender must interpret this reply as a receiver interrupt request. The <EOT> is a positive acknowledgment of the end frame, signifies the receiver is prepared to receive next frame, and is a request to the sender to stop transmitting.

6.3.5.2 The sender does not have to stop transmitting after ..iving the receiver interrupt request. If the sender chooses to ignore the <EOT>, the receiver must re-request the interrupt for the request to remain valid.

6.3.5.3 If the sender chooses to honor the receiver interrupt request, it must first enter the termination phase to return the data link to the neutral state. This gives the receiver an opportunity to enter the establishment phase and become the sender. The original sender must not enter the establishment phase for at least 15 s or until the receiver has sent a message and returned the data link to the neutral state.

6.4 *Termination Phase (Link Release)*—The termination phase returns the data link to the clear or neutral state. The sender notifies the receiver that all messages have been sent.

6.4.1 The sender transmits the <EOT> transmission control character and then regards the data link to be in a neutral state. Upon receiving <EOT>, the receiver also regards the data link to be in the neutral state.

6.5 *Error Recovery*— Methods are described which enable both sender and receiver to recover, in an orderly way, from errors in data transmission.

6.5.1 *Defective Frames*— A receiver checks every frame to guarantee it is valid. A reply of <NAK> is transmitted for invalid frames. Upon receiving the <NAK>, the sender retransmits the last frame with the same frame number. In this way, transmission errors are detected and automatically corrected.

6.5.1.1 Any characters occurring before the <STX> or <EOT> or after the end of the block character (the <ETB> or `TX>) are ignored by the receiver when checking the frame. frame should be rejected because:

(1) Any character errors are detected (parity error, framing error, etc.),

(2) The frame checksum does not match the checksum computed on the received frame,

(3) The frame number is not the same as the last accepted frame or one number higher (modulo 8).

6.5.1.2 Upon receiving a <NAK> or any character except an <ACK> or <EOT> (a <NAK> condition), the sender increments a retransmit counter and retransmits the frame. If this counter shows a single frame was sent and not accepted six times, the sender must abort this message by proceeding to the termination phase. An abort should be extremely rare, but it provides a mechanism to escape from a condition where the transfer phase cannot continue.

6.5.2 *Timeouts*—The sender and receiver both use timers to detect loss of coordination between them. The timers provide a method for recovery if the communication line or the other device fails to respond.

6.5.2.1 During the establishment phase, the sender sets a timer when transmitting the <ENQ>. If a reply of an <ACK>, <NAK>, or <ENQ> is not received within 15 s, a timeout occurs. After a timeout, the sender enters the termination phase.

6.5.2.2 During the establishment phase, if the computer (as receiver) detects contention, it sets a timer. If an <ENQ> is not received within 20 s, a timeout occurs. After a timeout, the receiver regards the line to be in the neutral state.

6.5.2.3 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 s, a timeout occurs. After a timeout, the sender aborts the message transfer by proceeding to the termination phase. As with excessive retransmissions of defective frames, the message must be remembered so it can be completely repeated.

6.5.2.4 During the transfer phase, the receiver sets a timer when first entering the transfer phase or when replying to a frame. If a frame or <EOT> is not received within 30 s, a timeout occurs. After a timeout, the receiver discards the last incomplete message and regards the line to be in the neutral state.

6.5.2.5 A receiver must reply to a frame within 15 s or the sender will timeout. A receiver can delay its reply for up to 15 s to process the frame or to otherwise go busy. Longer delays cause the sender to abort the message.

6.5.2.6 Receivers that cannot process messages fast enough to keep up with a sender may cause message buffer overflows in the sender. A sender can normally store at least one complete message. Storage space for more than one outgoing message is desirable but optional.

6.6 *Restricted Message Characters*—The data link protocol is designed for sending character based message text. Restrictions are placed on which characters may appear in the message text. The restrictions make it simpler for senders and receivers to recognize replies and frame delimiters. Additional characters are restricted to avoid interfering with software controls for devices such as multiplexers.

6.6.1 A <LF> character is not permitted to appear in the message text; it can appear only as the last character of a frame.

6.6.2 None of the ten transmission control characters, the <LF> format effector control character, or four device control characters may appear in message text. The restricted characters are: <SOH>, <STX>, <ETX>, <EOT>, <ENQ>,

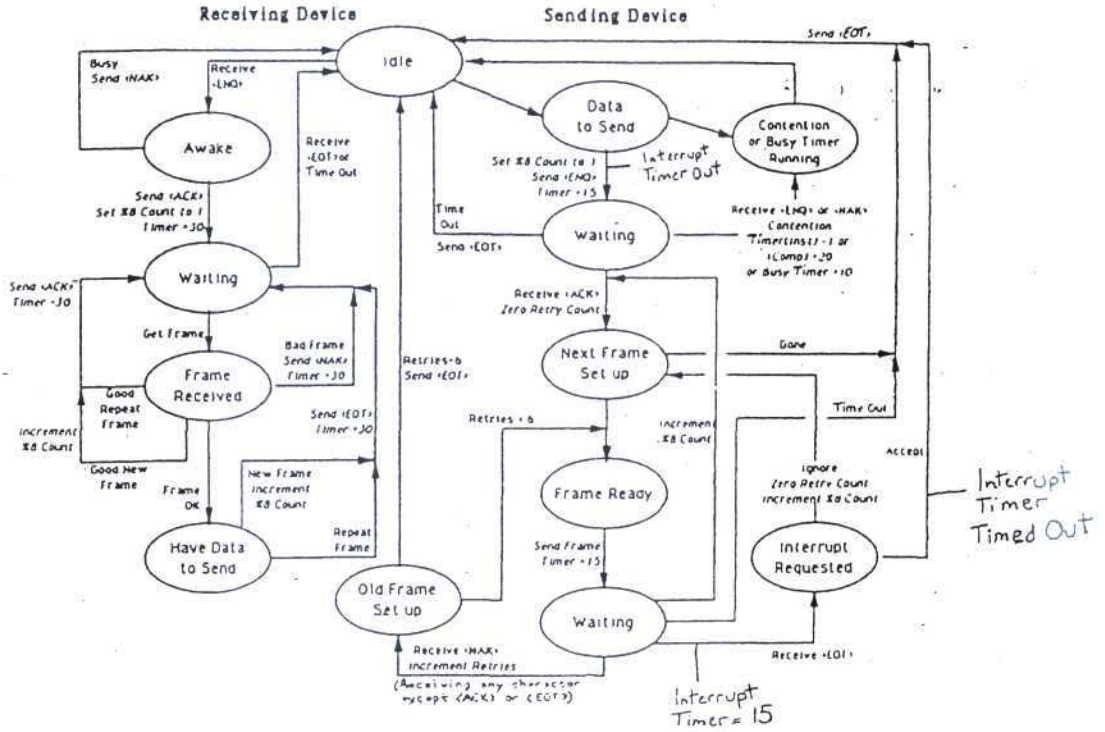
<ACK>, <DLE>, <NAK>, <SYN>, <ETB>, <LF>, <DC1>, <DC2>, <DC3>, and <DC4>.

ANNEX

(Mandatory Information)

A1. STATE DIAGRAM

A1.1 The state diagram is given in Fig. A1.1.



NOTE 1—"%8" represents modulo 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.

FIG. A1.1 State Diagram

APPENDIX

(Nonmandatory Information)

X1. SEVEN-BIT ASCII CODE CHARTS

X1.1 Character codes are given in Fig. X1.1 and Fig. X1.2.

| dec CHR |

↑ ↑ ASCII Character
↑ Decimal Character Code

000	NUL	016	DLE	032	SP	048	0	064	@	080	P	096	`	112	p
001	SOH	017	DC1	033	!	049	1	065	A	081	Q	097	a	113	q
002	STX	018	DC2	034	"	050	2	066	B	082	R	098	b	114	r
003	ETX	019	DC3	035	#	051	3	067	C	083	S	099	c	115	s
004	EOT	020	DC4	036	$	052	4	068	D	084	T	100	d	116	t
005	ENQ	021	NAK	037	%	053	5	069	E	085	U	101	e	117	u
006	ACK	022	SYN	038	&	054	6	070	F	086	V	102	f	118	v
007	BEL	023	ETB	039	'	055	7	071	G	087	W	103	g	119	w
008	BS	024	CAN	040	(	056	8	072	H	088	X	104	h	120	x
009	HT	025	EM	041	)	057	9	073	I	089	Y	105	i	121	y
010	LF	026	SUB	042	*	058	:	074	J	090	Z	106	j	122	z
011	VT	027	ESC	043	+	059	;	075	K	091	[	107	k	123	{
012	FF	028	FS	044	,	060	<	076	L	092	\	108	l	124	|
013	CR	029	GS	045	-	061	=	077	M	093	]	109	m	125	}
014	SO	030	RS	046	.	062	>	078	N	094	^	110	n	126	~
	SI	031	US	047	/	063	?	079	O	095	_	111	o	127	DEL

FIG. X1.1 Decimal Character Code

| hex CHR |

↑ ↑ ASCII Character
↑ Hexadecimal Character Code

00	NUL	10	DLE	20	SP	30	0	40	@	50	P	60	`	70	p
01	SOH	11	DC1	21	!	31	1	41	A	51	Q	61	a	71	q
02	STX	12	DC2	22	"	32	2	42	B	52	R	62	b	72	r
03	ETX	13	DC3	23	#	33	3	43	C	53	S	63	c	73	s
04	EOT	14	DC4	24	$	34	4	44	D	54	T	64	d	74	t
05	ENQ	15	NAK	25	%	35	5	45	E	55	U	65	e	75	u
06	ACK	16	SYN	26	&	36	6	46	F	56	V	66	f	76	v
07	BEL	17	ETB	27	'	37	7	47	G	57	W	67	g	77	w
08	BS	18	CAN	28	(	38	8	48	H	58	X	68	h	78	x
09	HT	19	EM	29	)	39	9	49	I	59	Y	69	i	79	y
0A	LF	1A	SUB	2A	*	3A	:	4A	J	5A	Z	6A	j	7A	z
0B	VT	1B	ESC	2B	+	3B	;	4B	K	5B	[	6B	k	7B	{
0C	FF	1C	FS	2C	,	3C	<	4C	L	5C	\	6C	l	7C	|
0D	CR	1D	GS	2D	-	3D	=	4D	M	5D	]	6D	m	7D	}
0E	SO	1E	RS	2E	.	3E	>	4E	N	5E	^	6E	n	7E	~
0F	SI	1F	US	2F	/	3F	?	4F	O	5F	_	6F	o	7F	DEL

FIG. X1.2 Hexadecimal Character Code

Designation: E 1394 – 97

An American National Standard

Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems[1]

This standard is issued under the fixed designation E 1394; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This standard covers the two-way digital transmission of remote requests and results between clinical instruments and computer systems. It is intended to document the common conventions required for the interchange of clinical results and patient data between clinical instruments and computer systems. This standard specifies the message content for transferring information between a clinical instrument and a computer system. It enables any two such systems to establish a logical link for communicating text to send result, request, or demographic information in a standard and interpretable form. This standard does not necessarily apply to general analytical instruments in an industrial analytical nor research and development setting.

1.2 This standard specification is intended to apply to the structure of messages exchanged between clinical instruments and computer systems by means of defined communications protocols. Low-level communications protocols and data transfer requirements are beyond the scope of this standard. A separate specification is available from ASTM detailing a standard for low-level data transfer communications (see Specification E 1381).

1.3 This standard specifies the conventions for structuring the content of the message and for representing the data elements contained within those structures. It is applicable to all text oriented clinical instrumentation. It has been specifically created to provide common conventions for interfacing computers and instruments in a clinical setting. It would also be applicable to interfacing instruments in clinical practice settings, such as physicians' offices, clinics, and satellite laboratories.

2. Referenced Documents

2.1 *ASTM Standards:*

E 1238 Specification for Transferring Clinical Observations Between Independent Computer Systems[2]

E 1239 Guide for Description of Reservation/Registration-Admission, Discharge, Transfer (R-ADT) Systems for Automated Patient Care Information Systems[2]

E 1381 Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems[2]

2.2 *ANSI Standards:*[3]

X3.30 ANSI Information System Codes

X3.40 ANSI Information System Codes

X3.43 ANSI Information Systems Codes

X3.50 ANSI Information Systems Codes

2.3 *ISO Standards:*[4]

ISO 5218 Information Interchange-Representation of Human Sexes

ISO 2955-93 Information Processing—Representation of SI and Other Units in Systems with Limited Character Sets

ISO 8859-1: 1987 Information Processing—8-bit single-byte coded graphic character sets—Part 1: Latin Alphabet No. 1

2.3 *Other Standards:*

EIA/TIA-232-E

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *battery*—a group of tests ordered together, for example, an admitting battery. The term *battery* is used in the document synonomously with the term *profile* or *panel*. The test elements within a battery may be characteristic of a single physiologic system, for example, liver function tests, or many different physiologic systems. The battery is simply a convention by which a user can order multiple tests by specifying a single name.

3.1.2 *component field*—a single data element or data elements which express a finer aggregate or extension of data elements which precede it. For example, parts of a field or repeat field entry. As an example, the patient's name is recorded as last name, first name, and middle initial, each of which is separated by a component delimiter. Components cannot contain repeat fields.

3.1.3 *download*—data transmitted from a computer system to a clinical instrument.

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[2] *Annual Book of ASTM Standards*, Vol 14.01.

[3] Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

[4] Available from International Standards Organization, 1 Rue de Varembe, Case Postale 56, Crt1221, Geneva 20 Switzerland.

3.1.4 *field*—one specific attribute of a record which may contain aggregates of data elements further refining the basic attribute.

3.1.5 *message*—a textual body of information consisting of a header (H) record through a message terminator (L) record.

3.1.6 *record*—an aggregate of fields describing one aspect of the complete message.

3.1.7 *repeat field*—a single data element which expresses a duplication of the field definition it is repeating. Used for demographics, requests, orders and the like, where each element of a repeat field is to be treated as having equal priority or standing to associated repeat fields.

3.1.8 *test*—a determination of a single analyte or a combination of values from other determinations or observations which constitute a measure of a single system attribute.

3.1.9 *upload*—data transmitted from a clinical instrument to a computer system.

4. Significance and Use

4.1 *General Information*:

4.1.1 This specification provides for two-way transmission allowing for data-flow in either direction. It provides for sending demographic and test information to or from clinical instruments. This specification has sufficient flexibility to permit the addition of fields to existing record types or the creation of new record types to accommodate new test and reporting methodologies.

4.1.2 This specification is related to Specification E 1238. Both standards use positional convention to define the structure of messages that exchange information about clinical test requests and results. The set of conventions specifies a hierarchical set of records in which the records higher in the hierarchy contain information that is common to all records lower in the hierarchy and thus avoids redundancy in linking data together. The positional convention is simple and direct to implement, requiring only a sequence of strings each having variable length delimited fields which are positionally specified.

4.1.3 Specification E 1238, in its entirety, is not appropriate for use as a clinical instrument to computer system interface. The conventions of Specification E 1238 regarding record types and the organization of data elements within the records have been adhered to as closely as possible to ensure that common data elements defined there and used within instruments are specified as closely as possible. This facilitates the use of this specification consistent with Specification E 1238 in a number of settings. There are three compelling reasons for developing a separate standard which deviates from Specification E 1238.

4.1.3.1 The scope of Specification E 1238 is specifically targeted to accommodate information transfer between two independent computer systems requiring shared patient demographic and test result data. Specification E 1238 contains extensive requirements and limitations, much of which may be of little, if any, use by clinical instrument systems. Further, clinical instruments have test and instrument specific requirements outside the scope of Specification E 1238 and, as such, are not available within the existing Specification E 1238.

4.1.3.2 The structure of Specification E 1238 provides great flexibility in the ordering and reporting of test results and patient demographics. While this is appropriate for use by advanced computer systems of equivalent rank, Specification E 1238 clearly falls beyond the technical limitations of many clinical laboratory instruments. This specification attempts to identify, and simplify, all complex data structures and interface procedures and, where practical, restrict multiple procedural options to single procedures appropriate for the clinical instrument setting. Further, this specification has attempted to assign a master/slave hierarchy where conflicts may occur, assigning appropriate responsibility for data processing or reporting operations to the party (clinical instrument or computer system) better able to process a particular task. For example, in all cases involving the ordering or reporting of tests, the instrument manufacturer is solely responsible for assigning the test and result ID numbers (see 6.6.1). These reductions in flexibility directly result in increased structure and clarity, which is deemed more appropriate for ensuring successful interface implementation within the clinical instrument setting.

4.1.3.3 Specification E 1238 was developed independent of data protocol and transfer considerations. Specification E 1238 uses maximum field and record lengths. Combined with its record level checksum and error recovery facilities, Specification E 1238 may be implemented without a data protocol layer. By contrast, this message-content specification has been developed in cooperative effort with a correlative ASTM low-level data transfer and protocol specification. While each specification (message-content and low-level protocol) is designed to be independently implemented and maintained, the message-content specification presumes that a protocol layer exists that will handle record blocking/deblocking, error detection and recovery, and other associated data transport tasks. As such, all protocol level operations and limitations existing in Specification E 1238 are not applicable, and therefore not included in this document.

5. Information Requirements in Clinical Testing

5.1 *General Approach*:

5.1.1 Messages may contain one or more requests/results for one or more patients. Tests may be requested as groups of many individual tests. These groups are referred to as batteries. Examples of batteries are tests produced on a multichannel analyzer, such as a CHEM12, physiological groupings of tests (such as liver function tests) and Minimum Inhibitory Concentration tests (MIC's) in microbiology testing. The fact that a series of tests is contained in a battery does not imply that they are all performed on the same analytic instrument.

5.1.2 Messages consist of a hierarchy of records of various types. Records at level zero contain information pertaining to the sender identification and completion of transmission. Records at level one of the hierarchy contain information about individual patients. Records at level two contain information about test order requests and specimens. Records at level three contain information about test results.

5.1.3 Comment records may be inserted at any level in the hierarchy. A comment record always relates to the immediately preceding patient, order, result, scientific or manufacturer information record. Therefore, if a comment record were to follow a patient record (level one), then that comment record

Using the transmission example as given in 5.2.1 and as outlined in Fig. 2, the following record recovery examples would be valid.

Line Failure Occurs At:	Requires Retransmission Of:
A	A
B	A, B
C	A, B, C
D	A, B, C, D
E	A, B, C, D, E
F	A, B, E, F
G	A, B, E, F, G
H	A, G, H
I	A, G, H, I
J	A, G, H, I, J
K	A, G, H, I, J, K
L	A, G, H, I, J, K, L
M	A, G, H, L, M
N	A, G, M, N
O	A, N, O
P	A, N, O, P
Q	A, N, O, P, Q

6. Message Content—General Considerations

6.1 *Character Codes*:

6.1.1 All data shall be represented as eight-bit, single-byte, coded graphic character values as defined in ISO 8859-1:1987. The eight-bit values, within the range from 0 to 127 of ISO 8859-1:1987 correspond to the ASCII standard character set. Values from 0 to 31 are disallowed with the exception of 7 (BEL), 9 (Horizontal tab), 11 (Vertical tab), and 13 (CR), where 13 is reserved as a record terminator. Values from 32 to 126 and from 128 to 254 are allowed. Values 127 and 255 are also not allowed. It is the responsibility of the instrument vendor and computer system vendor to understand the representation of any extended or alternate character set being used. As an example, the numeric value 13.5 would be sent as four-byte value characters 13.5 or Latin-1(49), Latin-1(51), Latin-1(46), and Latin-1(53).

Allowed Characters:	7, 9, 11, 12, 13, 32–126, 128–254
Disallowed Characters:	0–6, 8, 10, 14–31, 127, 255

6.1.2 Within text data fields, only the Latin-1 characters 32–126 and the undefined characters 128–254 are permitted as usable characters (excluding those used as delimiter characters in a particular transmission). Furthermore, all characters used as delimiters in a particular transmission are excluded from the permitted range. The sender is responsible for screening all text data fields to ensure that the text does not contain those delimiters. Unless otherwise stated, contents of data fields shall be case sensitive.

6.2 *Maximum Field Lengths*—This specification assumes that all fields are variable in length. No storage is allocated (except for the delimiter) for a null field. When, for example, ten characters of data are entered within a field, only ten characters will be used. This specification does not define a maximum length for any field or record and relies upon the receiver's buffering capabilities, and the logical layer's transport facilities, to parse information into workable lengths for transmission and processing purposes. It is the responsibility of the instrument vendor and computer system vendor to agree on any arbitrary field or record truncation that may need to be imposed. It is recommended that the instrument vendor provide documentation disclosing any field or record limits that will be mandated by the clinical instrument.

6.3 *Maximum Record Length*—None imposed.

6.4 *Delimiters*:

6.4.1 Alphanumeric characters should not be used as delimiters because they are likely to appear within field content. Moreover, some alphabetic characters have special uses as follows:

H, P, O, R, C, Q, S, L, M	record type ID's
. Latin-1(46)	decimal point (period)
, Latin-1(44)	comma
S, P, R, C	priority codes
L, H, <, >, N, U, D, B, W	result codes
C, P, F, X, I, O	result status

For the purpose of providing examples, the following delimiters are used in this specification:

Field delimiter = vertical bar (|) Latin-1 (124)
Repeat delimiter = backslash (\) Latin-1 (96)
Component delimiter = caret (^) Latin-1 (94)
Escape delimiter = ampersand (&) Latin-1 (38)

6.4.2 *Record Delimiter*—Carriage return (13) shall be the delimiter for the end of any of the defined record types.

6.4.3 *Field Delimiter*—A single allowable character as defined in 6.1.1 excluding Latin-1(13) (carriage return), shall separate adjacent fields. The field delimiter is variable and defined in the message header. The same delimiter must be used in all records following a header and preceding a message terminator record.

6.4.4 *Repeat Delimiter*—A single allowable character as defined in 6.1.1 excluding Latin-1(13) and the value for the field delimiter defined in 6.4.3. The repeat delimiter must be defined in the message header and is used to separate variable numbers of descriptors for fields containing parts of equal members of the same set.

6.4.5 *Component Delimiter*—A single allowable character as defined in 6.1.1 excluding Latin-1(13) and the field and repeat delimiter values. The component delimiter is used to separate data elements of fields of a hierarchical or qualifier nature. For example the street, city, state, zip, etc. of an address field would be separated by component delimiters.

6.4.6 *Escape Delimiter*—A single allowable character, as defined in 6.1.1, excluding Latin-1(13) and the field, repeat, and component delimiter values. The escape delimiter is used within text fields to signify special case operations. Applications of the escape delimiter are optional and may be used or ignored at the discretion of either transmitter or receiver. However, all applications are required to accept the escape delimiter and use it to correctly parse fields within the record.

6.4.6.1 *Use of Escape Delimiter*—The escape delimiter may be used to signal certain special characteristics of portions of a text field (for example, imbedded delimiters, line feed, carriage return, etc). An escape sequence consists of the escape delimiter character followed by a single escape code ID (listed below), followed by zero or more data characters followed by another (closing) occurrence of the escape delimiter character. No escape sequence may contain a nested escape sequence. The following escape sequences are pre-defined.

&H&	start highlighting text
&N&	normal text (end highlighting)
&F&	imbedded field delimiter character
&S&	imbedded component field delimiter character
&R&	imbedded repeat field delimiter character

&E&	imbedded escape delimiter character
&Xhhhh&	hexadecimal data

NOTE 1—Any number of hexadecimal digits (0–9, A–F) may follow (that is, &XA& could equal line feed).

&Zcccc&	Local (manufacturer defined) escape sequence

NOTE 2—Any number of legal characters may follow.

6.4.7 *Specification of Delimiters*—The actual delimiters to be employed in a given transmission shall be specified in the header message. It is the responsibility of the sender to avoid the inclusion of any delimiter characters within the field contents. The receiving computer will determine what characters to use by reading the specifications of the header it receives. See 6.4.1 for examples of delimiters used for this document.

6.4.8 *Delimiters for Null Values*—Fields shall be identified by their position, obtained by counting field delimiters from the front of the record. This position-sensitive identification procedure requires that when the contents of the field are null, its corresponding field delimiter must be included in the record to ensure that the i'th field can be found by counting $(i-1)$ delimiters. Delimiters are not included for trailing null fields; that is, if the tenth field was the last field containing data, the record could terminate after the tenth field, and therefore would contain only nine delimiters.

6.4.9 *Fields of No Concern to the Receiving System*—Transmitted records may include more fields than are required by a receiving system. When processing a message, the receiving system may ignore any field it does not require. Fields must always be transmitted, however, in the positional order specified.

6.4.10 *Fields with Null Values*:

6.4.10.1 A system may transmit a null value for a field because (*1*) it does not know the value, (2) it knows the value is irrelevant to the receiving system, or (*3*) the value has not changed since the last transmission, or any combination thereof. To exemplify case (*3*), a lab within a tightly linked hospital network may never transmit the patient's birthdate, sex, or race in the patient record when transmitting the order and result records to the requesting system, because it knows that the hospital registry system always broadcasts new or changed patient data to the receiving system.

6.4.10.2 Because the sending system can use null values to indicate no change, a null value does not overwrite existing data in the receiving system. In rare circumstances, for example, if a system erroneously sent a patient's birthdate when the birthdate was actually unknown, the receiving system should replace its existing value for a field with a null value.

6.4.10.3 A field containing only a pair of double quotes (Latin-1(34)) should be treated as an instruction to the receiver that the existing contents pertaining to that field definition should be deleted.

6.5 *Data Record Usage Overview*—Data shall be exchanged in records of different types. Each record is introduced by field (number one) identifying the record type, and terminated by a carriage return. The following record types are defined.

NOTE 3—The record type ID field shall be case insensitive.

6.5.1 *Message Header Record (H)*—This record shall contain information about the sender and the receiver, that is, it shall identify the instrument(s) and the computer systems whose records are being exchanged. It also defines the field, repeat field, and component field delimiter characters.

6.5.2 *Patient Identifying Record (P)*—This record type contains information about an individual patient

6.5.3 *Test Order Record (O)*—When sent from the computer system to the instrument, this record shall represent a test order and may be followed by one or more result records which would contain information pertinent to the test being ordered. When sent by the instrument to the computer system, it shall provide information about the specimen/test request, and may be followed by result records (at least one record for each test within the ordered batteries).

6.5.4 *Result Record (R)*—Each result record shall contain the results of a single analytic determination.

6.5.5 *Comment Record (C)*—Comment records shall apply to any other record except the message trailer record. They may be free standing messages sent to or from the instrument, unrelated to a particular patient or test procedure.

6.5.6 *Request Information Record (Q)*—This record shall be used to request information for new tests, for tests previously ordered, and possibly for tests previously reported. A single request information record may request demographic information, or results for an individual test, multiple test, or all tests for a single date, a series of dates, or a range of dates, or both, and for an individual patient, group of patients, individual specimens, groups of specimens, etc.

6.5.7 *Scientific Record (S)*—This record shall be used to exchange results between clinical sites for the purposes of proficiency testing or method development.

6.5.8 *Manufacturer Information Record (M)*—This record, which is similar to the comment record, may be used to send complex structures where use of the existing record types would not be appropriate. The fields within this record type are defined by the manufacturer.

6.6 *Common Field Types*:

6.6.1 *Universal Test ID*—This field is defined as a four part field with provisions to further define the test identification via use of component fields. The test ID field is used to identify a test or battery name. The four parts which are defined below are the universal test identifier, the test name, the test identifier type and the manufacturer defined test code. All test ID parts must be separated by a component delimiter and are position dependent. As an example, additional information which may be included in this field type are instrument ID, organism ID (for sensitivity tests), well number, cup number, location number, tray number, bar code number, etc. It is the responsibility of the instrument manufacturer to define the data content of the test ID field. When the test ID is used in the result record, there must be sufficient information within the test ID field to determine the relationship of the test result to the test, battery or batteries ordered.

6.6.1.1 *Universal Test ID (Part 1)*—This is the first component of the test ID field. This field is currently unused but reserved for the application of a universal test identifier code, should one system become available for use at a future time.

6.6.1.2 *Universal Test ID Name (Part 2)*—This would be the test or battery name associated with the universal test ID code described in 6.6.1.1.

6.6.1.3 *Universal Test ID Type (Part 3)*—In the case where multiple national or international coding schemes exist, this field may be used to determine what coding scheme is employed in the test ID and test ID name fields.

6.6.1.4 *Manufacturer's or Local Code (Part 4)*—This is the code defined by the manufacturer. This code may be a number, characters, or multiple test designator based on manufacturer defined delimiters (that is, AK.23.34-B). Extensions or qualifiers to this code may be followed by subsequent component fields which must be defined and documented by the manufacturer. For example, this code may represent a three part identifier such as—Dilution^ Diluent^ Description.

6.6.2 *Dates and Times*—In all cases, dates shall be recorded in the YYYYMMDD format as required by ANSI X3.30. December 1, 1989 would be represented as 19891201. When times are transmitted, they shall be represented as HHMMSS, shall be linked to dates as specified by ANSI X3.43. Date and time together shall be specified as up to a fourteen-character string: YYYYMMDDHHMMSS.

6.6.2.1 *Time Zone*—The time zone may be optionally appended to the date/time field in the format + HHMM or – HHMM as appropriate. The default time zone is that of the sender.

6.6.3 *Telephone Numbers*—Phone numbers shall be recorded as free text, which may contain extensions such as area code, country code, beeper number, hours to call, etc.

6.6.3.1 *Multiple Phone Numbers*—When multiple telephone numbers apply, they may be included in one field and separated from each other by repeat delimiters. The first such entry is considered the primary or the daytime number.

6.6.4 *Fixed Measurements and Units*—When a field contains a specific observation, for example, patient's weight, patient's height, or collection volume, the default units of measurement for that observation are specified in the field definition. When the observation is measured in the default units, the units need not be transmitted. If the measure is recorded in units different from the default, for example, if the weight is measured in pounds rather than kilograms, the measurement units must be transmitted. In this case the units are transmitted in the same field as the measurement. The units follow the measure and are separated from it by a component delimiter, for example, 100^lb. Units should be expressed in ISO standard abbreviations in accordance with ISO 2955.

6.6.5 *Addresses*—An address occupies a single field in a record. The address may be comprised of five components (street address, city, state, zip, or postal code, and country code) separated by component delimiters so that the receiving party can break them into separate fields as needed. An example would be 52 Hilton Street #B42^ Chicago^ IL^ 60305^ USA. The country need only be transmitted when it cannot be assumed from the context. The components of this field are position dependent.

6.6.6 *Provider and User ID's*—Physician's and other care givers' codes may be transmitted as internal code numbers, as full names, or both, as mutually agreed upon between the sender and the receiver. When both the name and ID number are sent, ID numbers should come first and be separated from the name by a component delimiter. Each component of the name is also separated by a component delimiter. The order of the components of the name shall be (*1*) last name, (*2*) first name, (*3*) middle initial or name, (*4*) suffix, for example, Jr., Sr., etc., and (*5*) title, for example, Dr., Mr., etc. Thus, if Dr. John G. Jones, Jr. had an identifier of 401-0, his number and name would be transmitted as 401-0^JONES^JOHN^G^JR^DR. When necessary, more than one ID may be sent within one field. Multiple IDs in one field are separated by repeat delimiters.

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

6.7 *Examples of Basic Record Types*—The following examples are given for a set of transmitted results for a given patient. These will show how the employment of the conventions defined lead to a valid message. In these examples the first two fields of each line (record) of the message body contain the record type and the integer record sequence number (excepting the header record). Carriage return is indicated by <CR>. To simplify the example, all the components of each record have not been included. Ellipses (...) are used to indicate fields that are left out and comments are enclosed in square brackets. Record hierarchical levels are shown by indentation.

NOTE 4—You may wish to study the record definitions outlined in Section 7 before reviewing the samples shown in Figs. 3-11. Trailing fields, unused, may or may not have field delimiters transmitted. Both cases should be handled by the receiving parser.

7. Message Header Record

7.1 *General*—The header shall contain identifiers of both the sender and the receiver. The message header is a level zero record and must be followed at some point by a message terminator record before ending the session or transmitting

```
H|\^&<CR>
    P|1<CR>
        O|1|||^^^A1<CR>
            R|1||0.356<CR>
    P|2|<CR>
        O|1|||^^^A2<CR>
            R|1||1.672<CR>
    .
    .
    P|96<CR>
        O|1|||^^^H12<CR>
            R|1||0.402<CR>
L|1<CR>
```

NOTE 1—This sample is not recommended for implementation.
NOTE 2—Direction: instrument to computer system.
FIG. 3 Minimal Implementation (No Patient ID or Specimen ID)

```
H|\^&<CR>
    P|1<CR>
        O|1|927529|||^^^A1\^^^A2<CR>
            R|1|^^^A1|0.295|||||||19890327132247<CR>
            R|2|^^^A2|0.312|||||||19890327132248<CR>
    P|2|<CR>
        O|1|927533|||^^^A3\^^^A4<CR>
            R|1|^^^A3|1.121|||||||19890327132422<CR>
            R|2|^^^A4|1.097|||||||19890317132423<CR>
L|1<CR>
```

FIG. 4 No Patient ID; Specimen ID and Multiple Results Shown

another header record. This record type must always be the first record in a transmission.

7.1.1 *Record Type ID*—The character H identifies the record as a message header record.

7.1.2 *Delimiter Definition*—The five Latin-1 characters that immediately follow the H (the header ID) define the delimiters to be used throughout the subsequent records of the message. The second character in the header record is the field delimiter, the third character is the repeat delimiter, the fourth character is the component delimiter, and the fifth is the escape character. A field delimiter follows these characters to separate them from subsequent fields. Another way to view this is that the first field contains H and the second field contains the repeat, component and escape delimiters. Using the example delimiters, the first six characters in the header record would appear as follows: H|\^&|.

7.1.3 *Message Control ID*—This is a unique number or other ID that uniquely identifies the transmission for use in network systems that have defined acknowledgment protocols that are outside of the scope of this specification. Note that this is the third field.

7.1.4 *Access Password*—This is a level security/access password as mutually agreed upon by the sender and receiver. If this security check fails, the transmission will be aborted and the sender will be notified of an access violation.

7.1.5 *Sender Name or ID*—The purpose of this field is to define the manufacturer/instrument(s) specific to this line. Using repeat and/or component delimiters this field may reflect software or firmware revisions, multiple instrument available on the line, etc.

7.1.6 *Sender Street Address*—This text value shall contain the street address of the sender as specified in 6.6.5.

7.1.7 *Reserved Field*—This field is currently unused but reserved for future use.

7.1.8 *Sender Telephone Number*—This field identifies a telephone number for voice communication with the sender as specified in 6.6.3.

7.1.9 *Characteristics of Sender*—This field contains any characteristics of the sender such as, parity, checksums, optional protocols, etc. necessary for establishing a communication link with the sender.

7.1.10 *Receiver ID*—This text value includes the name or other ID of the receiver. Its purpose is verification that the transmission is indeed for the receiver.

7.1.11 *Comment or Special Instructions*—This text field shall contain any comments or special instructions relating to the subsequent records to be transmitted.

7.1.12 *Processing ID*—Indicates how this message is to be processed:

P–Production: Treat message as an active message to be completed according to standard processing.

T–Training: Message is initiated by a trainer and should not have an effect on the system.

D–Debugging: Message is initiated for the purpose of a debugging program.

Q–Quality Control: Message is initiated for the purpose of transmitting quality control/quality assurance or regulatory data.

7.1.13 *Version No.*—This value identifies the version level of the specification. This value is currently E 1394–97.

7.1.14 *Date and Time of Message*—This field contains the date and time that the message was generated using the format specified in 6.6.2.

8. Patient Information Record

8.1 *General*—Each line of the patient record shall begin with a record type and end with a carriage return.

8.1.1 *Record Type*—The character P identifies the record as a patient record.

8.1.2 *Sequence Number*—For the first patient transmitted, 1 shall be entered, for the second, 2, ... until the last as defined in 6.6.7.

8.1.3 *Practice Assigned Patient ID*—This identifier shall be the unique ID assigned and used by the practice to identify the patient and his/her results upon return of the results of testing.

8.1.4 *Laboratory Assigned Patient ID*—This identifier shall be the unique processing number assigned to the patient by the laboratory.

8.1.5 *Patient ID No. 3*—This field shall be optionally used for additional, universal or manufacturer defined identifiers (such as Social Security Account No.), as arranged between transmitter and receiver.

8.1.6 *Patient Name*—The patient's name shall be presented in the following format: last name, first name, middle name or initial, suffix, and title, and each of these components shall be separated by a component delimiter as described in 6.6.6.

8.1.7 *Mother's Maiden Name*—The optional mother's maiden name may be required to distinguish between patients with the same birthdate and last name when registry files are very large. This name shall be presented as the mother's maiden surname, for example, Thompson.

8.1.8 *Birthdate*—The birthdate shall be presented in the standard format specified in 6.6.2.

8.1.9 *Patient Sex*—This field shall be represented by M, F, or U.

8.1.10 *Patient Race-Ethnic Origin*—The following examples may be used:

W–white
B–black
O–asian/pacific islander
NA–native american/alaskan native
H–Hispanic

Full text names of other ethnic groups may also be entered. Note that multiple answers are permissible, separated by a component delimiter.

8.1.11 *Patient Address*—This text value shall record the street address of the patient's mailing address as defined in 6.6.5.

8.1.12 *Reserved Field*—This field is reserved for future expansion.

```
H|\^&||PSWD|Harper Labs|2937 Southwestern Avenue^Buffalo^NY^73205||319 412-9722||||P|1394-97|19890314<CR>
Q|1|^032989325 | ^032989327| ALL||||||||0<CR>
L|1|N<CR>
```

FIG. 5 Request from Analyzer for Test Selections on Specimens 032989325-032989327

```
H|\^&||PSWD|Harper Labs|2937 Southwestern Avenue^Buffalo^NY^73205||319 412-9722||||P|1394-97|19890314<CR>
    P|1|2734|123|306-87-4587|BLAKE^LINDSEY^ANN^MISS<CR>
        O|1|032989325||^^^BUN|R<CR>
        O|2|032989325||^^^ISE|R<CR>
        O|3|032989325||^^^HDL\^^^GLU|R<CR>
    P|2|2462|158|287-17-2791|POHL^ALLEN^M.<CR>
        O|1|032989326||^^^LIVER\^^^GLU|S<CR>
    P|3|1583|250|151-37-6926|SIMPSON^ALBERT^^MR<CR>
        O|1|032989327||^^^CHEM12\^^^LIVER|R<CR>
L|1|F<CR>
```

FIG. 6 Response from Computer System for Previous Request

```
H|\^&||PSWD|Harper Labs|2937 Southwestern Avenue^Buffalo^NY^73205||319 412-9722||||P|1394-97|19890314<CR>
    P|1|2734|123|306-87-4587|BLAKE^LINDSEY^ANN^MISS<CR>
        C|1|L|Notify IDC if tests positive|G<CR>
        O|1|032989325||^^^BUN|R<CR>
            R|1|^^^BUN|8.71<CR>
                C|1|I|TGP^Test Growth Positive|P<CR>
                C|2|I|colony count >10,000|P<CR>
        O|2|032989325||^^^ISE|R<CR>
            R|1|^^^ISE^NA|139|mEq/L<CR>
            R|2|^^^ISE^K|4.2|mEq/L<CR>
            R|3|^^^ISE^CL|111|mEq/L<CR>

        O|3|032989325||^^^HDL|R<CR>
            R|1|^^^HDL|70.29<CR>
        O|4|032989325||^^^GLU|R<CR>
            R|1|^^^GLU|92.98<CR>
                C|1|I|Reading is Suspect|I<CR>
    P|2|2462|158|287-17-2791|POHL^ALLEN^M.<CR>
        O|1|032989326||^^^LIVER|S<CR>
            R|1|^^^LIVER^AST|29<CR>
            R|2|^^^LIVER^ALT|50<CR>
            R|3|^^^LIVER^TBILI|7.9<CR>
            R|4|^^^LIVER^GGT|29<CR>
        O|2|032989326||^^^GLU|S<CR>
            R|1|^^^GLU|91.5<CR>
    P|3|1583|250|151-37-6926|SIMPSON^ALBERT^^MR<CR>
        O|1|032989327||LIVER|R<CR>
            R|1|^^^AST|28<CR>              [Test ID field Implicitly Relates to LIVER order ]
            R|2|^^^ALT|49<CR>
            R|3|^^^TBILI|7.3<CR>
            R|4|^^^GGT|27<CR>
        O|2|032989327||CHEM12|R<CR>
            R|1|^^^CHEM12^ALB-G|28<CR>     [Test ID field Explicitly Relates to CHEM12 order ]
            R|2|^^^CHEM12^BUN|49<CR>
            R|3|^^^CHEM12^CA|7.3<CR>
            R|4|^^^CHEM12^CHOL|27<CR>
            R|5|^^^CHEM12^CREAT|4.2<CR>
            R|6|^^^CHEM12^PHOS|12<CR>
            R|7|^^^CHEM12^GLUHK|9.7<CR>
            R|8|^^^CHEM12^NA|138.7<CR>
            R|9|^^^CHEM12^K|111.3<CR>
            R|10|^^^CHEM12^CL|6.7<CR>
            R|11|^^^CHEM12^UA|7.3<CR>
            R|12|^^^CHEM12^TP|9.2<CR>
L|1<CR>
```

FIG. 7 Results from Given Ordered Test Selections Shown in Various Formats

8.1.13 *Patient Telephone Number*—Patient's telephone number formatted as defined in 6.6.3.

8.1.14 *Attending Physician ID*—This field shall identify the physician(s) caring for the patient as either names or codes, as agreed upon between the sender and the receiver. Identifiers or names, or both, should be separated by component delimiters as specified in 6.6.6. Multiple physician names (for example, ordering physician, attending physician, referring physician)

```
H|\^&||PSWD|Harper Labs|2937 Southwestern Avenue^Buffalo^NY^73205||319 412-9722||||P|1394-97|19890314<CR>
    Q|1|032989326||ALL<CR>
L|1<CR>
```

FIG. 8 Request from Computer System to Instrument for Previously Run Results

```
H|\^&||PSWD|Harper Labs|2937 Southwestern Avenue^Buffalo^NY^73205||319 412-9722||||P|1394-97|19890314<CR>
  P|1|2462|158|287-17-2791|POHL^ALLEN^M.<CR>
    O|1|032989326|||^^^LIVER|S<CR>
      R|1|^^^AST|29<CR>
      R|2|^^^ALT|50<CR>
      R|3|^^^TBILI|7.9<CR>
      R|4|^^^GGT|29<CR>
    O|2|032989326|||^^^GLU|S<CR>
      R|1|^^^GLU|91.5<CR>
L|1|F<CR>
```

FIG. 9 Reply to Result Request

```
H|\^&||Password1|Micro1|||||LSI1||P|1394-94|19890501074500<CR>

  P|1||52483291||Smith^John|Samuels|19600401|M|W|4526 C Street^Fresno^CA^92304||(402)782-
  3424X242|542^Dr. Brown|||72^in.|175^lb.||Penicillin|||19890428|IP|Ward1||||C|M|WSP||ER|PC^Prompt Care<CR>

    O|1|5762^01||^^^BC^BloodCulture^POSCOMBO|R|198905011530|198905020700|||456^Farnsworth|N|||-
    198905021130|BL^Blood|123^Dr. Wirth|||||||Instrument#1|||ER|N<CR>

      R|1|^^^Org#|51^Strep Species|||N<CR>
      R|2|^^^Bio|BH+^Beta Hemolytic|||N<CR>
L|1<CR>
```

FIG. 10 Microbiology Order and Result-Download of Demographics and Order

```
H|\^&||Password1|Micro1|||||LSI1||P|1394-94|19890501074500<CR>
  P|1||52483291<CR>
    O|1|5762^01||^^^BC^^POSCOMBO|||||||||||BL||||||||||F<CR>
      R|1|^^^ORG#|103^Group D Entero<CR>
      R|2|^^^AM^MIC|>16<CR>
      R|3|^^^AM^INTERP1|++<CR>
      R|4|^^^AM^DOSAGE1|PO 250-500 mg  Q6h<CR>
      R|5|^^^AM^DOSAGE1^COSTCODE|$25<CR>
      R|6|^^^AM^INTERP2|+++<CR>
      R|7|^^^AM^DOSAGE2|IV 1.0-2.0 gm  Q4h<CR>
      R|8|  ^^^P^MIC|<0.25<CR>
       R|9|^^^P^INTERP1|++<CR>
      R|10|^^^P^DOSAGE1|PO 250-500 mg  Q6h<CR>
      R|11|^^^P^DOSAGE1^COSTCODE|$25<CR>
      R|12|^^^P^INTERP2|+++<CR>
      R|13|^^^P^DOSAGE2|IM 0.9-1.2 MIL U Q6-12h<CR>
       .
       .
       .
      R|90|^^^BIOTYPE|102-34021<CR>
L|1<CR>
```

FIG. 11 Microbiology Order and Result-Upload of Finalized Results

shall be separated by repeat delimiters.

8.1.15 *Special Field 1*—An optional text field for vendor use (each laboratory can use this differently).

8.1.16 *Special Field 2*—An optional text field for vendor use.

8.1.17 *Patient Height*—(Default in cms.) An optional numeric field containing the patient's height. The default units are centimetres. If measured in terms of another unit, the units should also be transmitted as specified in 6.6.4.

8.1.18 *Patient Weight*—An optional numeric field containing the patient's weight. The default units are kilograms. If measured in terms of another unit, for example, pounds, the unit name shall also be transmitted as specified in 6.6.4. Height and weight information is not currently required by all laboratories but is of value in estimating normative values based upon body surface area.

8.1.19 *Patient's Known or Suspected Diagnosis*—This value should be entered either as an ICD-9 code or as free text. If multiple diagnoses are recorded, they shall be separated by repeat delimiters.

8.1.20 *Patient Active Medications*—Or those suspected, in overdose situations. The generic name shall be used. This field is of use in interpretation of clinical results.

8.1.21 *Patient's Diet*—This optional field in free text should be used to indicate such conditions that affect results of testing, such as 16 hr fast (for triglycerides), no red meat (for hemocult testing).

8.1.22 *Practice Field No. 1*—A text field for use by the practice, the optional transmitted text will be returned with the results.

8.1.23 *Practice Field No. 2*—Same as 8.1.22.

8.1.24 *Admission and Discharge Dates*—These values shall be represented as specified in 6.1. The discharge date, when included, follows the admission date and is separated from it by a repeat delimiter.

8.1.25 *Admission Status*—This value shall be represented by the following minimal list or by extensions agreed upon between the sender and receiver: OP (outpatient), PA (pre-admit), IP (inpatient), ER (emergency room).

8.1.26 *Location*—This text value shall reflect the general clinic location or nursing unit, or ward or bed or both of the patient in terms agreed upon by the sender and receiver.

8.1.27 *Nature of Alternative Diagnostic Code and Classifiers*—This field relates to 8.1.28. It identifies the class of code or classifiers that are transmitted, for example, DRGs, or in the future, AVG's (ambulatory visitation groups), etc.

8.1.28 *Alternative Diagnostic Code and Classification*—

Alternative diagnostic codes and classifications, for example, DRG codes, can be included in this field. The nature of the diagnostic code is identified in 8.1.27. If multiple codes are included, they should be separated by repeat delimiters. Individual codes can be followed by optional test descriptors (when the latter are present) and must be separated by component delimiters.

8.1.29 *Patient Religion*—When needed, this value shall include the patient's religion. Codes or names may be sent as agreed upon between the sender and the receiver. Full names of religions may also be sent as required. A list of sample religious codes follows:

P	Protestant
C	Catholic
M	Church of the Latter Day Saints (Mormon)
J	Jewish
L	Lutheran
H	Hindu

8.1.30 *Marital Status*—When required, this value shall indicate the marital status of the patient as follows:

M	married
S	single
D	divorced
W	widowed
A	separated

8.1.31 *Isolation Status*—Isolation codes indicate precautions that must be applied to protect the patient or staff against infection. The following are suggested codes for common precaution. Multiple precautions can be listed when separated by repeat delimiters. Full text precautions may also be sent.

ARP	antibiotic resistance precautions
BP	blood and needle precautions
ENP	enteric precautions
NP	precautions for neutropenic patient
PWP	precautions for pregnant women
RI	respiratory isolation
SE	secretion/excretion precautions
SI	strict isolation
WSP	wound and skin precautions

8.1.32 *Language*—The value of this field indicates the patient's primary language. This may be needed when the patient is not fluent in the local language.

8.1.33 *Hospital Service*—This value indicates the hospital service currently assigned to the patient. Both code and text may be sent when separated by a component delimiter as in 6.6.6.

8.1.34 *Hospital Institution*—This value indicates the hospital institution currently assigned to the patient. Both code and text may be sent when separated by a component delimiter as in 6.6.6.

8.1.35 *Dosage Category*—This value indicates the patient dosage group. For example, A–ADULT, P1–PEDIATRIC (1–6 months), P2–PEDIATRIC (6 months–3 years), etc. Subcomponents of this field may be used to define dosage subgroups.

9. Test Order Record

9.1 *General*—The test order record defines the attributes of a particular request for a clinical instrument's services and contains all specimen information. An order record will be generated by the computer system to request a given test, battery, or set of tests. The information in an order record will usually apply to a single specimen. However, there is not necessarily a one-to-one relationship between specimen and tests ordered. Different test batteries will usually be ordered within different order records even when they can be performed on a single specimen. In this case, the specimen information is duplicated in each of the order records that employ that specimen.

9.2 *Multiple Orders*—More than one test or test battery may be ordered on a single order record by using repeat delimiters between the individual tests ordered in that record. However, in such cases, all other attributes stored within the order record must be the same for all the tests ordered within that record. Thus, if one wishes to order one test as a STAT or immediate test and another as a routine test, two separate order records would be required. In the case that a test battery requires more than one specimen, such as is true for creatinine clearances, information about each of the test specimens may be included in the single order record identifying multiple specimens using the repeat delimiter within the specimen ID field.

9.2.1 Although multiple tests or test batteries can be on a single order record, when reporting the results, the instrument shall produce a separate order record for each unique battery, copying the appropriate specimen information from the original order record into each of the new order records.

9.2.2 In the event that a test battery cannot be performed, for example, because of hemolysis, the order record will be returned to the computer system with the report type indicator X to indicate that it was not done. In this case, no result records will be transmitted.

9.2.3 When test analyses are successfully performed, the message returned to the computer system will include the order record followed by result records for each separate observation requested by that order. The number of such result records will depend upon the number of individual measurements performed in the analysis. Four test result records would follow the order record for an electrolytes test. Twelve result records will follow the order record for an SMA12.

9.2.4 Test batteries that require multiple specimens for their performance would similarly be followed by a series of result records corresponding to the number of individual measurements obtained. The manufacturer must ensure that the test ID field within each result record contains sufficient information to relate the individual test measurements to the specific tests, batteries and specimens ordered.

9.2.5 Microbiological culture results are different. A new order record should be created for each panel of antimicrobial sensitivities, although multiple batteries/panels may be ordered on a single order record if desired. The series of antimicrobial sensitivities for any single sensitivity analysis will be reported as separate result records, one for each result element or combination of elements (antimicrobic, MIC, interpretation, etc.). Thus, the antimicrobial sensitivity appears logically very much like an extended SMA12 result with separate result records for each separate result from each antibiotic tested. Once again, the test ID field within the result records must contain sufficient information to relate the individual test measurements with the appropriate antibiotic test and battery ordered.

9.3 *General Applications*—The order record may be used in

four different circumstances:

9.3.1 It is sent by the computer system to request a ticular set of instrument tests.

9.3.2 It is transmitted back to the computer system as part of the results. If the ordered instrument analyses can be completed, the instrument sends back the order record along with the result records according to the hierarchy described in this specification. If results cannot be produced, for example, because the specimen is hemolyzed, the lab transmits the order with an appropriate report type (see 9.4.26) to indicate this problem, but no result records are transmitted.

9.3.3 The order record is transmitted back to the computer system in response to a request information query. In this case, it has the same form as in 9.3.2.

9.3.4 The instrument is requesting demographic or tests-ordered information from the computer system.

9.4 *Field Definitions*—The order record is comprised of the following fields:

9.4.1 *Record Type ID*—The character assigned to the order record shall be O.

9.4.2 *Sequence Number*—This field shall be represented as described in 6.6.7.

9.4.3 *Specimen ID*—This text field shall represent a unique identifier for the specimen assigned by the computer system and returned by the instrument. If the specimen has multiple components further identifying cultures derived from it, these component identifiers will follow the specimen ID and be parated by component delimiters. For example, the specimen may contain the specimen number followed by the isolate number, well or cup number (for example, 10435A^01^64).

9.4.4 *Instrument Specimen ID*—This text field shall represent a unique identifier assigned by the instrument, if different from the computer system identifier, and returned with results for use in referring to any results.

9.4.5 *Universal Test ID*—This field shall use universal test ID as described in 6.6.1.

9.4.6 *Priority*—Test priority codes are as follows:

S–stat
A–as soon as possible
R–routine
C–callback
P–preoperative

If more than one priority code applies, they must be separated by repeat delimiters.

9.4.7 *Requested/Ordered Date and Time*—The contents of this field shall be represented as specified in 6.6.2 and will denote the date and time the test order should be considered ordered. Usually this will be the date and time the order was recorded. This is the date and time against which the priorities should be considered. If the ordering service wants the test performed at a specified time in the future, for example, a test to be drawn two days in the future at 8 pm, the future date and time should be recorded here. Note that the message header data and the future date and time should be recorded here. Further, note that the message header record date and time (see 7.1.14) indicates the time the order was transmitted to or from the instrument.

9.4.8 *Specimen Collection Date and Time*—This field shall represent the actual time the specimen was collected or obtained.

9.4.9 *Collection End Time*—This field shall contain the end date and time of a timed specimen collection, such as 24-h urine collection. The value shall be specified according to 6.6.2.

9.4.10 *Collection Volume*—This value shall represent the total volume of specimens such as urine or other bulk collections when only aliquot is sent to the instrument. The default unit of measure is millilitres. When units are explicitly represented, they should be separated from the numeric value by a component delimiter, for example, 300^g. Units should follow the conventions given in 6.6.4.

9.4.11 *Collector ID*—This field shall identify the person and facility which collected the specimen. If there are questions relating to circumstances surrounding the specimen collection, this person will be contacted.

9.4.12 *Action Code*—This field shall indicate the action to be taken with respect to the specimens that accompany or precede this request. The following codes shall be used:

C–cancel request for the battery or tests named
A–add the requested tests or batteries to the existing specimen with the patient and specimen identifiers and date-time given in this record
N–new requests accompanying a new specimen
P–pending specimen
L–reserved
X–specimen or test already in process.
Q–treat specimen as a Q/C test specimen.

9.4.13 *Danger Code*—This field representing either test or a code shall indicate any special hazard associated with the specimen, for example, a hepatitis patient, suspected anthrax.

9.4.14 *Relevant Clinical Information*—Additional information about the specimen would be provided here and used to report information such as amount of inspired O_2 for blood gasses, point in menstrual cycle for cervical pap tests or other conditions that influence test interpretations.

9.4.15 *Date/Time Specimen Received*—This optional field shall contain the actual log-in time recorded in the laboratory. The convention specified in 6.6.2 shall be used.

9.4.16 *Specimen Descriptor*—This field may contain two separate elements, specimen type and specimen source as defined in 9.4.16.1 and 9.4.16.2. The components must be separated by component delimiters.

9.4.16.1 *Specimen Type*—Samples of specimen culture types or sources would be blood, urine, serum, hair, wound, biopsy, sputum, etc.

9.4.16.2 *Specimen Source*—This is always the second component of the specimen descriptor field and is used specifically to determine the specimen source body site (for example, left arm, left hand, right lung).

9.4.17 *Ordering Physician*—This field shall contain the name of the ordering physician in the format outlined in 6.6.6.

9.4.18 *Physician's Telephone Number*—This field shall contain the telephone number of the requesting physician and will be used in responding to callback orders and for critically abnormal results. Uses the format given in 6.6.3.

9.4.19 *User Field No. 1*—Text sent by the requestor should be returned by the sender along with the response.

9.4.20 *Users Field No. 2*—Similar to 9.4.19.

9.4.21 *Laboratory Field No. 1*—An optional field definable

for any use by the laboratory.

9.4.22 *Laboratory Field No. 2*—Similar to 9.4.21.

9.4.23 *Date/Time Results Reported or Last Modified*—This field is used to indicate the date and time the results for the order are composed into a report, or into this message or when a status as defined in 9.4.26 or 10.1.9 is entered or changed. When the computer system queries the instrument for untransmitted results, the information in this field may be used to control processing on the communications link. Usually, the ordering service would only want those results for which the reporting date and time is greater than the date and time the inquiring system last received results. Dates and times should be recorded as specified in 6.6.2.

9.4.24 *Instrument Charge to Computer System*—This field contains the billing charge or accounting reference by this instrument for tests performed.

9.4.25 *Instrument Section ID*—This identifier may denote the section of the instrument where the test was performed. In the case where multiple instruments are on a single line or a test was moved from one instrument to another, this field will show which instrument or section of an instrument performed the test.

9.4.26 *Report Types*—The following codes shall be used:

O	order record; user asking that analysis be performed
C	correction of previously transmitted results
P	preliminary results
F	final results
X	order cannot be done, order cancelled
I	in instrument pending
Y	no order on record for this test (in response to query)
Z	no record of this patient (in response to query)
Q	response to query (this record is a response to a request-information query)

9.4.27 *Reserved Field*—This field is unused but reserved for future expansion.

9.4.28 *Location or Ward of Specimen Collection*—This field defines the ward of specimen collection if different from the patient ward.

9.4.29 *Nosocomial Infection Flag*—This field is used for epidemiological reporting purposes and will show whether the organism identified is the result of a nosocomial (hospital acquired) infection.

9.4.30 *Specimen Service*—In cases where an individual service may apply to the specimen collected, and the service is different from the patient record service, this field may be used to define the specific service responsible for such collection.

9.4.31 *Specimen Institution*—In cases where the specimen may have been collected in an institution, and the institution is different from the patient record institution, this field may be used to record the institution of specimen collection.

10. Result Record

10.1 *General*—The result record shall include the following fields:

10.1.1 *Record Type ID*—Coded as R.

10.1.2 *Sequence Number*—Shall be assigned as described in 6.6.7.

10.1.3 *Universal Test ID*—This field shall use the universal test IDs described in 6.6.1.

10.1.4 *Data or Measurement Value*—Whether numeric, text, or coded values, the data shall be recorded in ASCII text notation. If the data result contains qualifying elements of equal stature, these should be separated by component delimiters. This applies strictly to results of identical nature (that is, this field may not contain implied sub-values). Use of components within this field should be avoided whenever possible.

10.1.4.1 Multiple results or values, observed, calculated or implied, for a single test order (for example, MIC or interpretation codes from a single antibiotic sensitivity test) must be reported in separate result records with each result definition defined uniquely by the test ID field as given in 10.1.3. Correspondingly, the test ID field (10.1.3) must be sufficiently descriptive to determine the placement of the data value with reference to the original test order record and to other result records associated with said test order record.

10.1.5 *Units*—The abbreviation of units for numeric results shall appear here. ISO standard abbreviations in accordance with ISO 2955 should be employed when available, for example, use mg rather than milligrams. Units can be reported in upper or lower case.

10.1.6 *Reference Ranges*:

10.1.6.1 This value shall be reported in the following sample format: (lower limit to upper limit; example: 3.5 to 4.5). The range definition can be included by text description. See 10.1.6.2. If a toxic substance, then the upper limit of the range identifies the toxic limit. If the substance being measured is a drug, the lower limits identify the lower therapeutic bounds and the upper limits represent the upper therapeutic bounds above which toxic side effects are common.

10.1.6.2 A result may have multiple ranges, for example, an observation may have a physiologic and a therapeutic range, for example, serum magnesium is being used to treat eclampsia. When multiple ranges are sent, they shall be separated by repeat delimiters. Each range can also have a text description. The text description follows immediately after the range and is separated from it by a component delimiter. Most results will only have one normal range transmitted.

10.1.7 *Result Abnormal Flags*—This field shall indicate the normalcy status of the result. The characters for representing significant changes either up or down or abnormal values shall be:

L–below low normal
H–above high normal
LL–below panic normal
HH–above panic high
<–below absolute low, that is off low scale on an instrument
>–above absolute high, that is off high scale on an instrument
N–normal
A–abnormal
U–significant change up
D–significant change down
B–better, use when direction not relevant or not defined
W–worse, use when direction not relevant or not defined

When the instrument can discern the normal status of a textual report, such as microbiologic culture, these should be reported as N when normal and A when abnormal.

10.1.8 *Nature of Abnormality Testing*—The kind of normal testing performed shall use the following representation: A, denotes that an age based population was tested, S, sex-based population, and R, a race based population. As many of the codes as apply shall be included. For example, if sex, age, and

race normals were tested, an (A\S\R) would be transmitted. N ⁱ⁻ ⁿlies that generic normal range was applied to all patient .imens.

10.1.9 *Result Status*—The following codes shall be used.

C–correction of previously transmitted results
P–preliminary results
F–final results
X–order cannot be done
I–in instrument, results pending
S–partial results
M–this result is a MIC level
R–this result was previously transmitted
N–this result record contains necessary information to run a new order

NOTE 5—For example, when ordering a sensitivity, the computer system may download a result record containing the organism type, or species, identified in a previous test.

Q—this result is a response to an outstanding query
V—operator verified/approved result
W—Warning: Validity is questionable

10.1.10 *Date of Change in Instrument Normative Values or Units*—This field shall remain empty if there are no relevant normals or units. Otherwise, it shall be represented as in 6.6.2. A change in this data from that recorded in the receiving system's dictionary indicates a need for manual review of the results to detect whether they can be considered the same as preceding ones.

10.1.11 *Operator Identification*—The first component identifies the instrument operator who performed the test. The second component identifies the verifier for the test.

10.1.12 *Date/Time Test Started*—Date and time the instru- ⁿnt started the test results being reported. Date and times should be reported as specified in 6.6.2.

10.1.13 *Date/Time Test Completed*—Date and time the instrument completed the test results being reported. Date and times should be reported as specified in 6.6.2.

10.1.14 *Instrument identification*—Identifies the instrument or section of instrument that performed this particular measurement.

11. Comment Record

11.1 *General*—Comment records may be inserted anywhere except after the message terminator record. Each comment record shall apply to the first non-comment record preceding it. The comment record shall include the following fields:

11.1.1 *Record Type ID*—This record type shall be denoted by C.

11.1.2 *Sequence Number*—As defined in 6.6.7.

11.1.3 *Comment Source*—Comment origination point:

P	practice
L	computer system
I	clinical instrument system

11.1.4 *Comment Text*—Where comment codes/mnemonics are used, the code should be sent first, followed, if desired, by the comment text and separated by a component delimiter as given in 6.6.6.

11.1.5 *Comment Type*—The following codes may be used to ıalify comment record types:

G	generic/free text comment
T	test name comment
P	positive test comment
N	negative test comment
I	instrument flag(s) comment

12. Request Information Record

12.1 *General*—The request information record is used by either clinical instrument or computer system to remotely request information from the reciprocal system.

NOTE 6—Only one request record may be outstanding at a time. the receiver of a request record must terminate the request, when finished, by means of the message terminator record, or the sender must cancel the request before sending a second logical request.

The request record shall include the following fields:

12.1.1 *Record Type ID*—coded as Q.

12.1.2 *Sequence Number*—as given in 6.6.7.

12.1.3 *Starting Range ID Number*:

12.1.3.1 This field may contain three or more components to define a range of patients/specimens/manufacturers selection criteria. The first component is the computer system patient ID No. The second component is the computer system specimen ID No. Any further components are manufacturer defined and for use in request sub-result information (that is, an individual isolate/battery for a specimen number). These components are position dependent. A list of sample IDs could be requested by the use of the repeat delimiter to separate IDs.

12.1.3.2 When ALL is entered, and the computer system is sending the request record, it is taken to mean all specimen results ordered by the inquiring system. If the instrument is generating the request record, then it is taken to mean all demographics and tests being ordered should be sent to the instrument at this time. The request is then interpreted for that identified subset of specimens as further modified by the test specifications and date ranges as described below.

12.1.3.3 This specification does not address how long data is to be retained by an instrument, nor does it require that the instrument provide the search services implied by some of the field contents. The appropriate response for a request for results is simply the return of a subset of results that are currently in storage and can be practically retrieved.

12.1.4 *Ending Range ID Number*—Similar to 12.1.3. If a single result or specimen demographic or test order is being requested then this field may be left blank.

12.1.5 *Universal Test ID*—As described in 6.6.1. This field may alternatively contain multiple codes separated by repeat delimiters, or the field may contain the text ALL, which signifies a request for all results on all tests or batteries for the patients/specimens/tests defined in 12.1.3 and 12.1.4 and within the dates described in 12.1.6 and 12.1.7.

12.1.6 *Nature of Request Time Limits*—Specify whether the date and time limits specified in 12.1.7 and 12.1.8 refer to the specimen collect or ordered date (see 9.4.8) or test date (see 9.4.23): S indicates the specimen collect date; R indicates the result test date. If nothing is entered, the date criteria are assumed to be the result test date.

12.1.7 *Beginning Request Results Date and Time*—This field shall represent either a beginning (oldest) date and time for which results are being requested or a single date and time. The field may contain a single date and time or multiple individual dates and times separated by repeat delimiters. Each date and time shall be represented as specified in 6.6.2.

12.1.7.1 If no date and time is included, the instrument should assume that the computer system wants results going as far into the past as is possible and consistent with the criteria specified in other fields.

12.1.8 *Ending Request Results Date and Time*—This field, if not null, specifies the ending or latest (or most recent) date and time for which results are being requested. Date and time shall be represented as in 6.6.2.

12.1.9 *Requesting Physician Name*—This field identifies the individual physician requesting the results. The identity of the requesting physician is recorded as specified in 6.6.6.

12.1.10 *Requesting Physician Telephone Number*—As specified in 6.6.3.

12.1.11 *User Field No. 1*—User defined field.

12.1.12 *User Field No. 2*—User defined field.

12.1.13 *Request Information Status Codes*—The following codes shall be used:

C—correction of previously transmitted results
P—preliminary results
F—final results
X—results cannot be done, request cancelled
I—request results pending
S—request partial/unfinalized results
M—result is a MIC level
R—this result was previously transmitted
A—abort/cancel last request criteria (allows a new request to follow)
N—requesting new or edited results only
O—requesting test orders and demographics only (no results)
D—requesting demographics only (for example, patient record)

13. Message Terminator Record

13.1 *General*—This is the last record in the message. A header record may be transmitted after this record signifying the start of a second message.

13.1.1 *Record Type ID*—Coded as L.

13.1.2 *Sequence Number*—As described in 6.6.7. (For this record type, the value of this field should always be 1.)

13.1.3 *Termination Code*—Provides explanation of end of session.

Nil, N—normal termination
T—sender aborted
R—receiver requested abort
E—unknown system error
Q—error in last request for information
I—no information available from last query
F—last request for information processed

NOTE 7—F, I, or Q will terminate a request and allow processing of a new request record.

14. Scientific Record

14.1 *General*—The scientific record exchanges the test data on clinical laboratory/instrument performance, quality assurance, or method development. It contains information in addition to the analyte measures found in the result record, although there are common elements in the two records.

14.1.1 *Record Type ID*—This field shall be identified by the character S.

14.1.2 *Sequence Number*—The sequence number shall be assigned as described in 6.6.7.

14.1.3 *Analytical Method*—This text field shall conform to Appendix I of Elevitch and Boroviczeny.

14.1.4 *Instrumentation*—This text field shall be represented by an ID composed of the manufacturer and instrument codes connected by a dash (Latin-1(45)). These codes shall conform to Appendix I of Elevitch and Boroviczeny.

14.1.5 *Reagents*—This text field shall include a list of constituent reagent codes, separated by subfield ID. These codes shall conform to the scheme of The American Chemical Society.

14.1.6 *Units of Measure*—The units of measure shall be represented as specified in 10.1.5.

14.1.7 *Quality Control*—Specifications to be developed.

14.1.8 *Specimen Descriptor*—This field shall use the convention described in 9.4.16.

14.1.9 *Reserved Field*—Reserved for future expansion.

14.1.10 *Container*—Specifications to be developed.

14.1.11 *Specimen ID*—This text field shall represent a unique specimen identifier assigned by the originator and returned by the receiving instrument.

14.1.12 *Analyte*—Specifications to be developed.

14.1.13 *Result*—This numeric field shall represent the determined value of the analyte.

14.1.14 *Result Units*—This field shall be represented as described in 10.1.5.

14.1.15 *Collection Date and Time*—This field shall be represented in accordance with 6.6.2.

14.1.16 *Result Date and Time*—This field shall be represented in accordance with 6.6.2.

14.1.17 *Analytical Preprocessing Steps*—This text field shall contain the description of any preprocessing steps.

14.1.18 *Patient Diagnosis*—This field shall be represented as IDC-9-CM codes.

14.1.19 *Patient Birthdate*—This should be represented as specified in 8.1.8.

14.1.20 *Patient Sex*—This field shall be represented in accordance with 8.1.9.

14.1.21 *Patient Race*—This should be represented in accordance with 8.1.10.

15. Manufacturer Information Record

15.1 *General*—This record is provided solely for custom use by the instrument or computer system manufacturer. It has no inherent hierarchical level and may be inserted at any point except immediately following a message terminator record. It is recommended that this record type not be implemented unless all other possibilities have been exhausted. This record shall include the following:

15.1.1 *Record type ID*—Coded as M.

15.1.2 *Sequence Number*—As defined in 6.6.7.

APPENDIX

(Nonmandatory Information)

X1. COMPARISON OF SPECIFICATIONS E 1238 AND E 1394

X1.1 Table X1.1 shows the major differences in requirements between Specifications E 1238 and E 1394. Other modifications and additions have been made. Not all of the fields required in Specification E 1238 are required in this specification. It is the responsibility of the user of this standard to compare the requirements of these two specifications and the changes that have been incorporated since the last issue.

TABLE X1.1 Requirement Comparison Between Specifications E 1238 and E 1394

Requirement	E 1238	E 1394
Addenda record	Yes (see 5.2 and 6.5.9)	No
Maximum record length	Yes (see 6.2 and Table 1)	No
Maximum field length	Yes (see 6.2 and Table 1)	No
Error check record	Yes (see 5.3)	no
Extended character set	No	Yes (see 6.1)
Latin-1(10) linefeed	Yes (see 6.1.1)	No
Record Type M	No	Yes (see 6.4)
Repeat delimiter	[A]	Yes (see 6.4.4)
Component delimiter	[B]	Yes (see 6.4.5)
Escape delimiter	No	Yes (see 6.4.6
Linked results	Yes (see 9.4.27)	No
Multiple specimen orders	Yes (see 9.4.29)	No
Universal Test ID	3-part (see 6.6.1)	4-part[C] (see 6.6.1)
Time fields	HHMM (see 6.6.2.1)	HHMMSS with optional time zone (see 6.6.2)
Result record representation[D]	Multiple parts permitted (see 10.1.4.2)	Single analytic result value (see 10.1.4)
Manufacturer's or local code	No	Yes—must be defined and documented by manufacturer (see 6.6.1.4)
Source of specimen	Specimen type and location (see 9.4.16)	Specimen descriptor (see 9.4.16)

[A] In Specification E 1238, this delimiter is referred to as a subfield delimiter.
[B] In Specification E 1238, this delimiter is referred to as a sub-subfield delimiter.
[C] Manufacturer-defined test code added.
[D] This record was modified and renamed in Specification E 1394.