INTERNATIONAL STANDARD

ISO 18812

First edition
2003-03-15

Health informatics — Clinical analyser interfaces to laboratory information systems — Use profiles

Informatique de santé — Interfaces d'analyseur clinique pour systèmes d'information de laboratoire — Profils d'utilisation

Reference number
ISO 18812:2003(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 18812 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Introduction

This International Standard describes messages for the transfer of data between analytical instruments (AIs) and laboratory information systems (LISs).

AIs are mainly used in hospital laboratories to analyse samples from patients. Most of these are interfaced to LISs that process the result data and produce reports for use by healthcare practitioners. In the absence of standards for the interface, each LIS supplier has to write a new interface for each new analytical instrument. The cost of writing these interfaces can amount to between 10 % and 20 % of the total cost of the LIS. One of the most effective ways of reducing this cost is to implement a standard interface between the AI and the LIS.

In the early 1990s, the E31 committee of the American Society for Testing and Materials (ASTM) published a standard entitled *Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems* (ASTM E1394-91). This improved the situation by standardizing the format of the message and the syntax. It also attempted to standardize the data transferred in the messages, but suffered from implementation problems because:

— the vast choice of data items available gave implementers the choice to send the same data in many different ways;

— the relative lack of implementation guidelines meant that different implementers interpreted the same clauses of the standard in different ways;

— much of the information that is defined in the standard is intended for use in North America and does not cover international requirements.

The result of this is that each AI supplier has produced its own “standard”, based loosely on ASTM E1394. Whereas this has made interfacing easier for the analytical instrument suppliers, the LIS suppliers are still faced with the need to write a different interface for most of the analytical instruments installed in a given laboratory.

In particular, the LIS interface designer has to, in theory, take into account any implementation allowed by ASTM E1394. This means that even simple AIs are normally handled by using a hugely complex interface on the LIS.

ASTM E1394-91 was reissued with minor revisions in 1997 as ASTM E1394-97.

This International Standard is intended to make interfaces between AIs and LISs simpler to implement by

— defining standard ways of conveying the same information in the same circumstances;

— defining a series of levels of complexity so that it is possible to interface a simple AI using only easy-to-implement messages;

— adapting the original standard to cover actual requirements;

— giving advice and guidance on how particular data items and functions should be implemented so as to reduce misinterpretation.

This is done by defining a series of standard messages, each of which is a subset of a comparable ASTM E1394 message. These are detailed in Clause 6. Examples of scenarios covered by this International Standard, together with models and sequence diagrams, are given in Annex B. An informative implementation guide for both ASTM E1394 and this International Standard is given in Annex C.

There is a trend for all clinical laboratories to be certified or accredited under a suitable quality management scheme. ISO/IEC 17025 require the laboratory to keep records of certain data. This means that, for the support of the users when conforming to the standard, the instruments and LIS have to be capable of handling this data (input, storage, validation, output), and also of transmitting it. This is especially important in functions that produce large amounts of data that cannot be handled effectively without automated processing. Typically, this is a task for the LIS, but certain items have to originally come from the instrument. ASTM E1394 does not explicitly handle data needed for quality management. In principle, it is capable of doing so, but the needed fields have to be defined.

This has been achieved in this International Standard by making recommendations as to which fields shall be implemented in order to satisfy the needs of quality management. These are identified in the implementation guideline included as Annex C.

This International Standard includes provisions for using existing ASTM E1394 records and fields to meet quality management requirements.

This International Standard defines records that are subsets of records defined in ASTM E1394. Therefore, all implementations conforming to this International Standard also conform to ASTM E1394. It should be noted, however, that not all implementations that conform to ASTM E1394 will conform to this International Standard.

Those not familiar with some of the concepts, e.g. profiling, described here should first refer to Annex A.

Health informatics — Clinical analyser interfaces to laboratory information systems — Use profiles

1 Scope

This International Standard specifies general messages for electronic information exchange between analytical instruments (AIs) and laboratory information systems (LISs) within a clinical laboratory. It is applicable to the specialities of clinical chemistry/biochemistry, haematology, toxicology, microbiology, virology and immunology. It is not applicable to the blood transfusion and blood bank speciality

This International Standard covers the specification of messages used by communicating parties and the syntax in which they are communicated. It does not cover the transport mechanisms used for the message interchange.

This International Standard is applicable only to character-based message information. It is not applicable to the communication of graphical or image information.

NOTE The provisions for this International Standard have been validated in the domains and for the purposes described above. However, messages conforming to this International Standard may be considered by some user communities to meet their needs for purposes outside this scope. Use of the messages in these circumstances is not precluded by the scope.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ASTM E1394-97 [1)], *Standard Specification for Transferring Information between Clinical Instruments and Computer Systems*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
analyte
component indicated in the name of a measurable quantity

3.2
analytical instrument
AI
named set of equipment that provides implementations of laboratory services

NOTE 1 In ASTM E1394, the term “Clinical Laboratory Instrument” or “Clinical Instrument” is used.

1) Available from www.astm.org.

NOTE 2 Workstations in laboratories can carry out communication between AIs and LISs. Such workstations can assume the dual role of both posing as an LIS to an AI, and as an AI to an LIS. Therefore, a workstation connected between an AI and an LIS may, in some circumstances, be considered as an AI, or, in other circumstances, as a LIS.

3.3
battery
group of analytical instrument investigations ordered together

NOTE This supplies a convention by which the user (the LIS) can order multiple analytical instrument investigations by specifying a single name.

3.4
component
single data element or data elements that express a finer aggregation or extension of data elements that precede it

NOTE A part of a field or repeat field entry is a component. As an example, the patient's name is recorded as three components: last name, first name and middle initial, each of which is separated by a component delimiter (components cannot contain repeat fields).

3.5
download
transmission of data from an LIS to an AI

3.6
field
specific attribute of a record that may contain a single data element or aggregates of data elements

3.7
laboratory information system
LIS
information system which can provide services to one or more analytical instruments

NOTE 1 In ASTM E1394, the term “Computer System” is used.

NOTE 2 Workstations in laboratories can carry out communication between AIs and LISs. Such workstations can assume the dual role of both posing as an LIS to an AI, and as an AI to an LIS. Therefore, a workstation connected between an AI and an LIS may, in some circumstances, be considered as an AI, or, in other circumstances, as an LIS.

3.8
loadlist
subset of one or more worklists specifically assigned to an analytical instrument

3.9
order
set of one or more analytical instrument investigation requests submitted to an analytical instrument

3.10
profile
restricted subset of a standard intended for a particular purpose

3.11
record
aggregate of fields describing one aspect of the complete message

3.12
repeat field
field containing one or more data elements, each of which is to be treated as having equal priority or standing

NOTE The repeat field is used for demographics, requests, orders, etc. For example, the repeat field “Test ID” may contain the three individual test IDs “Na”, “K” and ”Ca”.

3.13
request
request for a single laboratory service and a corresponding analytical instrument procedure to be carried out in respect of a specified subject of investigation

3.14
result
set of information including all essential or useful data relevant to the result of a single analytical instrument investigation and a corresponding analytical instrument procedure

3.15
sample
one or more parts taken or to be taken from a system and intended to provide information on that system or on a subsystem, or to provide a basis for decision on either of these

NOTE 1 In this context, “system” refers to a system under investigation, e.g. a human body, rather than a computer system.

NOTE 2 The term "specimen" is used in ASTM E1394 to denote the term “sample”.

3.16
test
determination of a single analyte or a combination of values from other determinations or observations that constitute a measure of a single system attribute

NOTE In this context, “system” refers to a system under investigation, e.g. a human body, rather than a computer system.

3.17
trigger event
action or event causing a message to be sent

3.18
upload
transmission of data from an AI to an LIS

3.19
worklist
defined set of requested analytical instrument investigations that can be assigned to an analytical instrument

4 Domains

4.1 User domain

This International Standard has been specifically created to provide common conventions for interfacing AIs and LISs in a clinical laboratory environment. It is also applicable to the interfacing of AIs to computers in other clinical practice settings, such as physicians' offices, clinics and satellite laboratories. It is not applicable to applications with a continuous flow of results from only one (or a few) implicitly identified subjects of investigation, such as is found in the monitoring of vital signs. It may not be applicable to situations where the AI is remote from the laboratory that controls it, i.e. near patient testing (NPT) or point of care (POC) AIs.

4.2 Interface domain

This applies to communication between parties where one party will assume the role of an AI and the other party will assume the role of an LIS. It is therefore also intended for communication involving independent workstations in the laboratory environment where these are capable of carrying out functions of communication between AIs and LISs. Such workstations may assume the dual role of both posing as an LIS to an AI, and as an AI to an LIS.

5 Conformity

Messages for transmission of information between AIs and LISs covered in this International Standard shall use only the message types, records, fields and values specified in Clause 6.

Implementations conforming to this International Standard shall be in accordance with one of the profiles specified in Clause 6.

Conformity to a profile specified in Clause 6 shall entail support of the messages and records defined for that profile in 6.3, and the sequence of messages for that profile specified in 6.4.

When claiming conformity to this International Standard, implementations shall state to which of the profiles defined in Clause 6 the messages conform.

6 Profiles

6.1 General

This clause specifies the profiles to which implementations shall conform. For each profile it specifies

— the messages that shall be supported;

— the message sequence that shall be supported;

— the records allowed within each message;

— the optionality of the fields within the message;

— the values allowed within each field.

The sequence of messages that shall be supported by each profile are specified in 6.4.

6.2 Message descriptions

An overview of each message is given in Table 1.

Table 1 — Message descriptions

Message identifier	Message title	Comment
M1	Result	For sending results from AI to LIS
M2	Results by query	For sending results from AI to LIS in response to a query for results message (M6) sent from LIS to AI[a]
M3	Results by query	For sending results from LIS to AI in response to a query for results message (M6) sent from AI to LIS[a]
M4	Order	For sending orders from LIS to AI, either unsolicited or in response to a query for order message (M5)
M5	Query for order	For sending a query for an order from AI to LIS
M6	Query for results	For sending a query for results from LIS to AI, or AI to LIS

[a] ASTM E1394 requires different fields to be supported for records containing results in response to queries and different fields depending on the direction of the response message. There are no such requirements for order messages.

6.3 Profile descriptions

The messages included in each profile, the direction of message flow and the records included in each message are specified in Table 2.

Table 2 — Profile descriptions

Profile	Description	Direction[a]	Message[b]	Record[c]
P1	Simple profile for the transfer of results from AI to LIS	AI → LIS	M1: Result	H, L, P, O, R, C
P2	Simple profile for the transfer of orders from the LIS to the AI, and for the transfer of results from the AI to the LIS	LIS → AI	M4: Order	H, L, P, O, C
		AI → LIS	M1: Result	H, L, P, O, R, C
P3	Bidirectional query profile for the transfer of order queries from the AI to the LIS, orders from the LIS to the AI, and results from the AI to the LIS	AI → LIS	M5: Query for order	H, L, Q
		LIS → AI	M4: Order	H, L, P, O, C
		AI → LIS	M1: Result	H, L, P, O, R, C
P4	Bidirectional query profile for the transfer of order queries from the AI to the LIS, orders from the LIS to the AI, result queries from the LIS to the AI, orders from the LIS to the AI, and results from the AI to the LIS	AI → LIS	M5: Query for order	H, L, Q
		LIS → AI	M4: Order	H, L, P, O, C
		AI → LIS	M1: Result	H, L, P, O, R, C
		LIS ↔AI	M6: Query for results	H, L, Q
		AI → LIS	M2: Results by query	H, L, P, O, R, C
		LIS → AI	M3: Results by query	H, L, P, O, R, C
P5	Implementation compliant only with ASTM E1394	either/both	(no restrictions)	(no restrictions)

a The sequence of messages that shall be supported by each profile is detailed in 6.4.

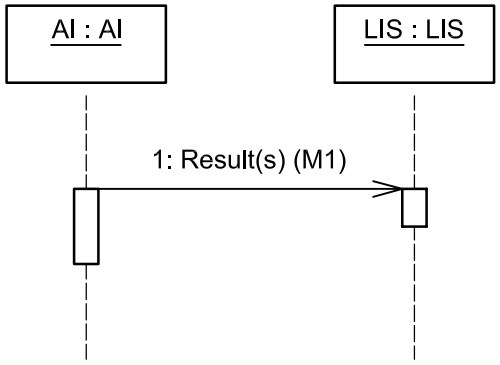
b The message identifiers correspond to the entries in Table 1.

c H = message header record; L = terminator record; P = patient information record; O = test order record; R = result record; C = comment record; Q = request information record.

6.4 Sequence diagrams

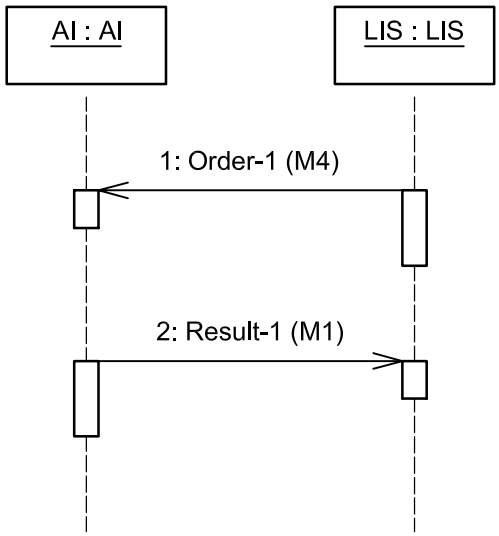
6.4.1 Profile P1

Implementations of profile P1 shall support the following sequence of messages.



6.4.2 Profile P2

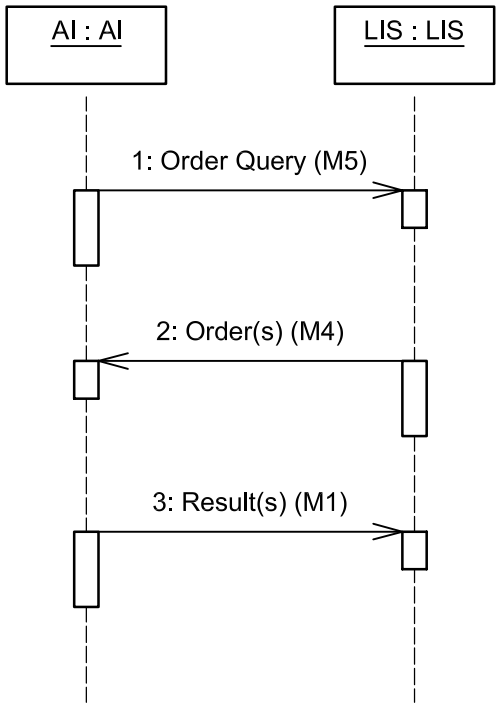
Implementations of profile P2 shall support the sequence of messages defined for profile P1 plus the following sequence of messages.



NOTE The message sequence defined above relates only to a single message-response sequence. It does not preclude many order messages being followed by many result responses, e.g. Order-1, Order-2, Order-3, Result-1, Result-2, Result-3; or Order-1, Order-2, Result-1, Order-3, Result-2, Result-3.

6.4.3 Profile P3

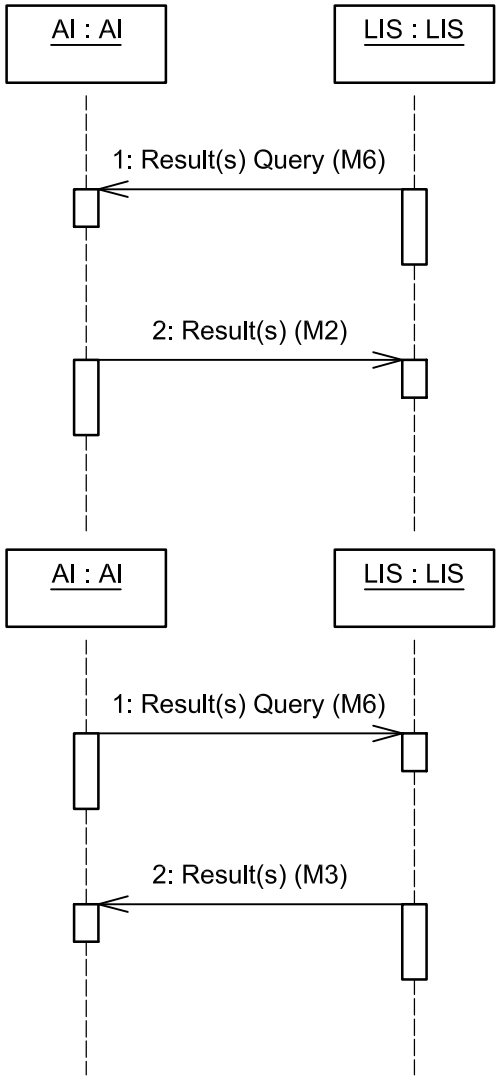
Implementations of profile P3 shall support the sequence of messages defined for profile P2 plus the following sequence of messages.



NOTE The message sequence defined above relates only to a single message-response sequence. It does not preclude, for example, many order query messages being followed by many order messages, followed by many results.

6.4.4 Profile P4

Implementations of profile P4 shall support the sequence of messages defined for profile P3 plus the following sequences of messages.



NOTE The message sequence defined above relates only to a single message-response sequence. It does not preclude, for example, many result query messages being followed by many result messages.

6.4.5 Profile P5

There are no restrictions on the message sequence that shall be supported by profile P5.

6.5 Attribute optionality and allowed values

The attribute optionality and allowed values are specified in Table 3.

Table 3 — Attribute optionality and allowed values

ASTM E1394 reference					Message identifier	M1	M2	M3	M4	M5	M6
					Message name/Attribute	Attribute optionality and allowed values[a]					
						Result	Result(s) by query	Result(s) by query	Order	Query for order(s)	Query for result(s)
Message header record											
H	7	1	1		Record type ID	M	M	M	M	M	M
H	7	1	2		Delimiter definition	M	M	M	M	M	M
H	7	1	5		Sender name or ID	O	O	O	O	O	O
H	7	1	6		Processing ID	O (P, Q)	O (P, Q)	O (P, Q)	O (P, Q)	O (P, Q)	O (P, Q)
H	7	1	10		Receiver ID	O	O	O	O	O	O
H	7	1	13		Version No.	O	O	O	O	O	O
H	7	1	14		Date and time of message	O	O	O	O	O	O
Patient information record											
P	8	1	1		Record type ID	M	M	M	M		
P	8	1	2		Sequence No.	M	M	M	M		
P	8	1	4		Laboratory assigned ID	D	D	D	O		
P	8	1	6		Patient name	D	D	D	O		
P	8	1	8		Birthdate	D	D	D	O		
P	8	1	9		Patient sex	D	D	D	O		
P	8	1	17		Patient height	D	D	D	O		
P	8	1	18		Patient weight	D	D	D	O		
P	8	1	26		Location	D	D	D	O		
Test order record											
O	9	4	1		Record type ID	M	M	M	M		
O	9	4	2		Sequence No.	M	M	M	M		
O	9	4	3		Sample ID	D	D	M	M		
O	9	4	4		Instrument sample ID	M	M	D	D		
O	9	4	5		Universal test ID	D	D	D	M		
O	9	4	6		Priority	O	O	O	O		
O	9	4	8		Sample collection date and time	D	D	D	O		
O	9	4	12		Action code	O (Q)	O (Q)	O (Q)	O (N, Q, C, A)		
O	9	4	13		Danger code	D	D	D	O		
O	9	4	16		Sample descriptor	D	D	D	O		
O	9	4	16	1	Sample type	D	D	D	O		
O	9	4	16	2	Sample source	D	D	D	O		
O	9	4	17		Ordering physician	D	D	D	O		

Table 3 — *(continued)*

ASTM E1394 reference					Message name/Attribute	Message identifier	M1	M2	M3	M4	M5	M6
							Attribute optionality and allowed values[a]					
							Result	Result(s) by query	Result(s) by query	Order	Query for order(s)	Query for result(s)
O	9	4	18		Physician telephone No.		D	D	D	O		
O	9	4	23		Date/Time results reported or last modified		O	O	O	O		
O	9	4	26		Report types		D	D	D	M (O, X, Z, Q)		
Result record												
R	10	1	1		Record type ID		M	M	M			
R	10	1	2		Sequence No.		M	M	M			
R	10	1	3		Universal test ID		M	M	M			
R	10	1	4		Data or measurement value		M	O	O			
R	10	1	5		Units		O	O	O			
R	10	1	7		Result abnormal flags		O	O	O			
R	10	1	9		Result status		O (P, F, M, R)	O (P, F, X, I, M, R, Q)	O (P, F, X, I, M, R, Q)			
R	10	1	11		Operator identification		O	O	O			
R	10	1	13		Date/Time test completed		O	O	O			
R	10	1	14		Instrument identification		O	O	O			
Comment record												
C	11	1	1		Record type ID		M	M				
C	11	1	2		Sequence No.		M	M				
C	11	1	4		Comment text		M	M				
C	11	1	5		Comment type		M (G, I)	M (G, I)				
Request information record												
Q	12	1	1		Record type ID						M	M
Q	12	1	2		Sequence No.						M	M
Q	12	1	3		Starting range ID No.						M	M
Q	12	1	4		Ending range ID No.						O	O
Q	12	1	5		Universal test ID						O	O
Q	12	1	13		Request information status codes						O (O, D)	M (P, F, I, M, N)

Table 3 — *(concluded)*

ASTM E1394 reference					Message identifier / Message name/Attribute	M1	M2	M3	M4	M5	M6
						Attribute optionality and allowed values[a]					
						Result	Result(s) by query	Result(s) by query	Order	Query for order(s)	Query for result(s)
Message terminator record											
L	13	1	1		Record type ID	M	M	M	M	M	M
L	13	1	2		Sequence	M	M	M	M	M	M
L	13	1	3		Termination code	M (N)	M (N)	M (N)	M (N)	M (N)	M (N)

[a] M = mandatory; O = optional; D = disallowed; values in brackets denote allowable values (from those specified in ASTM E1394).

Annex A
(informative)

How to read this International Standard

A.1 Introduction

The Introduction gives further background to the concepts behind this International Standard and explains the purpose of some of the other clauses.

A.2 Profiles

A.2.1 The concept of profiles

This International Standard consists of message definitions that are profiles of the ASTM E1394 standard. The concept of profiling standards is common in European and international standardization: a profile of a standard is a way of limiting the options within the standard so as to make it easier to use for a particular purpose.

As an example of this, consider a communications network standard that supports both local area networks (LANs) and wide area networks (WANs), but requires different options to be set depending on whether the standard is implemented for a LAN or a WAN. Then consider two implementations: one that has the options set for the LAN and another that has the options set for a WAN. Both implementations conform to the standard, but they are incompatible. The LAN implementation will not interwork with the WAN.

What is needed, therefore, is some way of specifying that one implementation conforms to the standard but has all the LAN options set, and the other conforms to the standard but has all the WAN options set. The way this is normally done is by specifying two profiles: the one with all the LAN options set may be called the LAN profile and the other with all the WAN options set may be called the WAN profile. Any implementation claiming conformance to the LAN profile should interwork with any other implementation claiming conformance to the LAN profile, and the same for the WAN profile. The LAN profile is not expected to work with the WAN profile.

The profiles, therefore, are a way of setting the options (or limiting the optionality) within the standard for a particular purpose.

A.2.2 Profiles of ASTM E1394

The ASTM E1394 standard was originally written to allow almost any type of AI to communicate with any type of LIS for almost any purpose. This has been its strength, the fact that it can be used in any situation. It has also been its weakness in that every implementation is different and cannot easily work with a different implementation. However, most implementations only need a limited range of the information that can be carried in ASTM E1394, and only need it for a limited number of purposes.

For example, many AIs are only capable of sending single results to a LIS and cannot receive messages. Therefore, they only need to use a very limited number of the facilities that ASTM E1394 offers, e.g.:

— message type: result message;

— record type: message header record, terminator record, patient information tecord, result record, comment record;

— field: basic fields consisting of patient identifier, test identifier, result value, free text comment, etc.

If the LIS knew that it was only required to support this very limited range of functions, the LIS end of the interface would be very simple. Unfortunately, however, ASTM E1394 implies that every interface has to be capable of supporting an enormous range of record types and fields for a huge variety of purposes. Therefore, the LIS interface has to be very complex, although in this case the complexity is unnecessary. It is impractical for the LIS interface to support every available option, so the LIS interface would be designed or configured specially to meet the needs of this simple AI. This keeps the cost and complexity down, but removes most of the benefits of standardization.

What is required, therefore, is a way of specifying a simple one-way AI interface, conforming to ASTM E1394, but only using those facilities required by typical unidirectional AIs. This could then be called the “simple unidirectional AI interface”. The supplier of the LIS would then be able to write his own “simple unidirectional AI interface” that could be used for all unidirectional AIs. On-site implementation of such interfaces would then become much easier and cheaper, with a much lower chance of errors.

This could then be called the “simple unidirectional AI profile” of ASTM E1394.

A.2.3 Need for a range of profiles

Obviously, the simple profile would only be usable for a limited range of AIs. Even simple, bidirectional AIs (i.e. those capable of receiving as well as transmitting messages) would not be able to use it. Many AIs would also need to support more complex features, wider ranges of information and queries from one side of the interface to another. However, nearly all these requirements can be satisfied by defining a range of profiles, e.g.:

— simple unidirectional AI profile: (as above; results from AI to LIS);

— simple bidirectional AI profile: (orders from LIS to AI, results from AI to LIS);

— bidirectional order query profile: (orders from LIS to AI, results from AI to LIS, order queries from AI to LIS);

— bidirectional order/result query profile: (orders from LIS to AI, results from AI to LIS, order queries from AI to LIS, result queries from LIS to AI).

All these profiles are much simpler than using the full ASTM E1394 standard. They should handle nearly all requirements for interfacing AIs to LISs. However, some complex AIs may need facilities not included in these profiles. These requirements would still be covered by ASTM E1394, but would not be covered by a profile. For convenience, it is possible to define a fifth profile that includes the whole of ASTM E1394. This gives a complete set of profiles:

— profile 1: simple unidirectional AI profile;

— profile 2: simple bidirectional AI profile;

— profile 3: bidirectional order query profile;

— profile 4: bidirectional order/result query profile;

— profile 5: the whole of ASTM E1394.

These are the profiles specified in Clause 6 of this International Standard. Each profile specifies:

— the messages supported in that profile;

— the direction in which each of the messages should flow;

— the records allowed in each message.

These are all specified in Table 2. Scientific and manufacturer records are not included in profiles 1 to 4, as they are rarely used and there seems to be no consistent way of using them.

This International Standard also specifies (6.4) the sequence of messages that shall be supported by each profile.

A.2.4 Limiting the fields and allowed values

Many of the fields specified in ASTM E1394 are never used in real implementations. Others are used rarely, some are used wrongly and some are used where a more commonly used field would be more appropriate. For this reason, many of the fields in messages specified by the profiles 1 to 4 are disallowed. These fields are specified in Table 3 of this International Standard.

Table 3 also shows where fields can only have specific values. This is because the other values allowed by ASTM E1394 have no known use or cannot be used safely (usually because the receiver of the information cannot interpret it or use it safely).

Profile 5 (the whole of ASTM E1394) has no such restrictions.

A.3 Claiming conformity

In the past, an AI interface could claim general conformity to ASTM E1394. Now the interface can claim conformity to one of the profiles specified in this International Standard, which should greatly limit the complexity of the LIS interface implementation. As all the profiles are perfect subsets of ASTM E1394, any implementation conforming to a profile is also in accordance with ASTM E1394. Therefore, any implementation conforming to this International Standard is also in accordance with ASTM E1394.

However, the implementations conforming to ASTM E1394 may not in general be in accordance with this International Standard.

Conformity to a profile specified in this International Standard consists of conformity to

— the messages allowed by the profile;

— the sequence of messages that shall be supported;

— the records allowed within each message;

— the optionality of the fields within the message;

— the values allowed within each field.

This is defined in Clause 5 of this International Standard.

A.4 Implementation guidelines

As well as defining the profiles above, this International Standard also gives guidelines for making interfaces easier to implement and more reliable. These include

— advice on further restricting the allowed values in certain fields;

— information on the interpretation of ASTM E1394;

— the circumstances in which certain fields should be used.

These guidelines are included in Annex C.

Annex B
(informative)

Scenarios and models

B.1 Overview

This annex shows the communication requirements supported by the use of profiles specified in this International Standard. These requirements are identified in scenarios, which do not, however, form an exhaustive list of circumstances in which these profiles are applicable.

The scenarios are described as text and as models using the Unified Modeling Language (UML).

In order to promote understanding, the scenarios are described in laboratory user terms in Clause B.2 and are then stated formally in Clause B.3. Clause B.4 shows use case models in UML and the corresponding sequence diagrams.

B.2 User-friendly scenarios

B.2.1 Introduction

This clause describes typical scenarios for information interchange between AIs and LISs in clinical laboratories.

B.2.2 Analytical instrument with positive sample identification, bidirectional communication in a chain

A varying number of tests are to be performed for a number of samples on a selective clinical chemistry AI. Each sample cup carries a bar code label for identification. The samples are placed in a chain and entered to the AI. For each sample, the following procedure is performed.

a) The AI reads the bar code label and transmits a message to the LIS asking for test requests for this sample.

b) LIS has to transmit the test orders for this sample to the AI within a given time window.

c) The AI starts performing the ordered tests. Each time a test is completed, the result will be transmitted to the LIS. LIS identifies the results with the help of sample ID and test ID.

d) The bar code label of the next sample is read by the AI. This typically happens during the processing of the previous one.

B.2.3 Analytical instrument with positive sample identification, bidirectional communication on a carousel

A varying number of tests are to be performed for a number of samples on a selective clinical chemistry AI. Each sample cup carries a bar code label for identification. The samples are placed on a carousel and entered to the AI. For each carousel, the following procedure is performed.

a) The AI reads the carousel ID and sends a message to LIS asking test orders for this carousel.

b) LIS downloads all sample IDs and test orders for these samples to the AI.

c) The requested tests for the samples are performed on the AI and the results are uploaded to the LIS. The LIS identifies the results with the help of sample ID and test ID.

d) When all the tests for this carousel have been performed, the AI reads the next carousel ID.

B.2.4 Batch analytical instrument, bidirectional communication

A number of tests are to be performed for a number of samples on a clinical chemistry AI. The samples are placed in a chain. The following procedure is carried out for each test.

a) A loadlist is printed out by the LIS to determine the sample positions. The samples are placed in their positions.

b) The AI sends a message to the LIS indicating which test will be done next.

c) The LIS sends the position numbers of all samples having this test requested.

d) The AI performs the test on each of these samples and transmits the results to the LIS. The LIS identifies the results with the help of the sample position number and test ID.

e) When all orders have been processed, the AI will initiate the next test.

B.2.5 Manual workplace, unidirectional communication

A single test is to be performed on a number of samples on a manual photometer workplace. The following procedure is carried out.

a) A worklist is printed out on the LIS. This list defines the sequential order of the samples.

b) After a test specific pre-treatment, the samples are measured on the photometer in the order of the workplace list.

c) As soon as a test is complete, the result is transmitted to the LIS. The LIS identifies the results with the help of the sequence number and test ID.

B.2.6 Haematology analytical instrument

Blood counts are to be done for a series of samples on an automatic cell counter. For one part of the samples, simple blood counts are requested and, for the other part, differential blood counts are requested. The samples are identified by their position in a chain. The following procedure is carried out.

a) LIS prints out a loadlist to determine the sample positions.

b) On an operator command on the LIS, the orders indicating which cell count is to be done are downloaded to the counter.

c) The counter performs the requested cell counts and transmits the results to the LIS.

B.2.7 Microbiology scenario

Samples are collected on special tubes used to detect bacterial infection in blood. The tubes are incubated in an instrument that will keep track of the tubes and, at regular intervals, inspect them for sign of bacterial growth. When growth is detected, the instrument will report this to the LIS. After a specific incubation time, the tubes without growth are reported negative and removed from the instrument.

B.3 Use case descriptions

B.3.1 Introduction

This clause describes typical scenarios for which the profiles defined in Clause 6 are valid. These scenarios are then modelled in Clause B.4.

The scenarios covered are

— Scenario 1a: unidirectional communication with sequential sample identification;

— Scenario 1b: unidirectional communication with positive sample identification;

— Scenario 2a: bidirectional communication, loadlisting a batch AI with sequential sample identification;

— Scenario 2b: bidirectional communication, positive sample ID and general order download to the AI;

— Scenario 3a: bidirectional communication with positive sample ID and specific order queries;

— Scenario 3b: bidirectional communication, positive sample ID and patient demographic order queries;

— Scenario 4a: bidirectional communication, query for results.

Each use case description includes

— a text description of the scenario;

— details of the dialogue between the AI and LIS;

— message examples in ASTM E1394 syntax.

B.3.2 Unidirectional communication

B.3.2.1 Scenario 1a: Unidirectional communication with sequential sample identification

One or more tests are to be performed on a number of samples on an analytical instrument. The AI may be of a very simple type, with little or no ability to store or process results, provide positive sample ID etc. The operator can only identify the sample on the AI by some positional or sequence information. This information may be a running sequence number, or a tray number and position in tray, etc. The information has to be handled in such a way that the LIS is able to identify the sample from the message information or the message sequence.

A workflow example is as follows.

a) The operator prints a worklist from the LIS.

b) The operator prepares the samples for analysis.

c) The samples are inserted into the AI and measurement is performed in the defined order.

d) When the test-result(s) are completed, the results are transmitted to the LIS, either automatically when completed or in some way initiated by an operator.

e) The LIS receives the result-messages and identifies the results by sequence or a positional code or number, and test ID contained in the message.

Dialogue:

AI	Direction	LIS	Message (see Table 1)	Trigger event
Sender	→	Receiver	M1: Result	Operator starts working.

Message examples:

```
H|\^&
P|1
O|1||235
R|1|^^^GLU|5.5
L|1|N
```

or:

```
H|\^&
P|1
O|1||^^34
R|1|^^^NA|139|mmol/L
R|2|^^^K|4.2|mmol/L
R|3|^^^CL|111|mmol/L
P|2
O|1||^^35
R|1|^^^K|4.8|mmol/L
L|1|N
```

or:

```
H|\^&|||4Z^SR-X1^123N44|||||||ENV13728^P1|19990315121500
P|1
O|1||^4^1
R|1|^^^SR|35|||>||F||JGG||19990315115800
P|2
O|1||^4^2
R|1|^^^SR|8||||F||JGG||19990315115800
P|3
O|1||^4^3
R|1|^^^SR|11||||F||JGG||19990315115800
L|1|N
```

B.3.2.2 Scenario 1b: Unidirectional communication with positive sample identification

One or more tests are to be performed on a number of samples on an analytical instrument. The AI may be of a simple type. The operator may identify the sample on the AI (e.g. keyboard, barcode reader) by positive sample identification (for example, sample number, request number). The identification number is used by the AI to identify the sample in the message information.

A workflow example is as follows.

a) The operator prepares the samples for analysis.

b) The samples are inserted into the AI and measurement is performed.

c) When the test-result(s) are completed, the results are transmitted to the LIS, either spontaneously or in some way initiated by an operator.

d) The LIS receives the result-messages and identifies the results by the identification number and test ID contained in the message.

Dialogue:

AI	Direction	LIS	Message (see Table 1)	Trigger event
Sender	→	Receiver	M1: Result	Operator starts working.

Message examples:

```
H|\^&
P|1
O|1||99038152
R|1|^^^pH|7,322
R|2|^^^pO2|11.2|kPa
R|3|^^^pCO2|5.8|kPa
R|4|^^^BE|-2|mmol/L
L|1|N
```

or:

```
H|\^&|||4Z^SR-X1^123N44|||||||ENV13728^P1|19990315121500
P|1
O|1||99042278^4^1
R|1|^^^SR|35|||>||F||JGG||19990315115800
P|2
O|1||99042344^4^2
R|1|^^^SR|8||||F||JGG||19990315115800
P|3
O|1||99043001^4^3
R|1|^^^SR|11||||F||JGG||19990315115800
L|1|N
```

B.3.3 Simple bidirectional communication

B.3.3.1 Scenario 2a: Bidirectional communication, loadlisting a batch AI with sequential sample identification

One or more tests are to be performed on a number of samples on an analytical instrument. The LIS has the capability of creating a loadlist of samples defining the positional information in the AI's input sample carrier. This may be a rack, a carrousel, a chain, plate etc. The information has to be handled in such a way that the LIS and the AI will be able to correctly identify the sample by the message information.

A workflow example is as follows.

a) The operator creates and prints a loadlist from the LIS.

b) The operator prepares the samples for analysis and loads the sample carrier(s).

c) The sample carriers are inserted into the AI.

d) The operator decides what test is to be done on the AI and instructs the LIS to download the positional information for the samples with the particular test requested.

e) The AI performs measurements on the particular samples ordered.

f) When the test-result(s) are completed, the results are transmitted to the LIS, either spontaneously or in some way initiated by an operator.

g) The LIS receives the result-messages and identifies the results by sequence or a positional code or number, and test ID contained in the message.

NOTE Operations d) to g) are repeated until all the tests are completed on the specific samples in the sample carrier. The test results may either be transmitted to the LIS [f)] as they are completed or when results for the whole sample are completed.

Dialogue:

AI	Direction	LIS	Message (see Table 1)	Trigger event
Receiver	←	Sender	M4: Order	Operator gives a download command to the LIS.
Sender	→	Receiver	M1: Result	Operator starts working.

Message examples:

(LIS)

```
H|\^&
P|1
O|1|99042123^9^1||^^^T3||||||||||||||||||O
P|2
O|1|99043874^9^2||^^^T3||||||||||||||||||O
P|3
O|1|99043531^9^3||^^^T3||||||||||||||||||O
P|4
O|1|99042997^9^4||^^^T3||||||||||||||||||O
L|1|N
```

(AI)

```
H|\^&
P|1
O|1||99042123^9^1
R|1|^^^T3|1.3
P|2
O|1||99043874^9^2
R|1|^^^T3|2.0
P|3
O|1||99043531^9^3
R|1|^^^T3|3.1|||>
P|4
O|1||99042997^9^4
R|1|^^^T3|1.2
L|1|N
```

B.3.3.2 Scenario 2b: Bidirectional communication, positive sample ID and general order download to the AI

A varying number of tests are to be performed for a number of samples on a selective AI.

Each sample cup or tube carries a bar code label for identification or, in some cases, the operator identifies the sample to the AI while loading a sample carrier (chain, rack, carousel, etc.). The operator performs an action in the LIS making a general download of all or a range of orders. The samples or sample carrier are placed in the sample input part of the AI and the operator starts the process of running the samples. After measurements are made, the AI will transmit the results to the LIS.

A workflow example is as follows.

a) The operator initiates a download of orders to the AI.

b) LIS will transmit the sample information and test orders for the samples to the AI.

c) The operator loads the AI with samples.

d) The AI reads a bar code label on the sample-tube.

e) The AI performs the ordered tests on the sample.

f) When test results are completed, the AI transmits the results to the LIS.

g) The LIS identifies the results in the message by the sample ID and test ID.

Dialogue:

AI	Direction	LIS	Message (see Table 1)	Trigger event
Receiver	←	Sender	M4: Order	Operator gives a download command to the LIS.
Sender	→	Receiver	M1: Result	Results completed on AI.

Message examples:

(LIS)

```
H|\^&
P|1||02095217784||OLSEN^CARL||19520902|M
O|1|99042123||^^^HB\^^^ERYT\^^^LEUK|S||19990316080000  cont..
 ||||||||||||||||||O
P|2||11126429753||DOE^WILLIAM||19641211|M
O|1|99046341||^^^HB\^^^TROMB|S||19990316080000  cont..
 ||||||||||||||||||O
L|1|N
```

(AI)

```
H|\^&
P|1|02095217784||OLSEN^CARL||19520902|M
O|1||99042123
R|1|^^^HB|14.5|g/dL||||F||BWD||19990316090200
R|1|^^^ERYT|6.5|10^12/L||||F||BWD||19990316090200
R|1|^^^LEUK|2.2|10^9/L||<||F||BWD||19990316090200
P|2|11126429753||DOE^WILLIAM||19641211|M
O|1||99046341
R|1|^^^HB|13.2|g/dL||||F||AS||19990316090800
R|1|^^^TROMB|354|10^9/L||||F||AS||19990316090800
L|1|N
```

B.3.4 Bidirectional communication with order query (P3)

B.3.4.1 Scenario 3a: Bidirectional communication with positive sample ID and specific order queries

A varying number of tests are to be performed for a number of samples on a selective AI.

Each sample cup or tube carries a bar code label for identification, or, in some cases, the operator identifies the sample to the AI while loading a sample carrier (chain, rack, carousel, etc.). The samples or sample carrier are placed in the sample input part of the AI and the operator starts the process of running the samples. After measurements are made, the AI will transmit the results to the LIS.

For microbiology blood culture investigations, the sample tubes are incubated on the AI. At specific intervals, the AI measures the growth and transmits positive or negative (growth or no growth) results to the LIS.

A workflow example is as follows.

a) The operator loads the AI with samples.

b) The AI reads a bar code label on the sample tube.

c) The AI transmits a message to the LIS asking for sample information and test requests for this sample.

d) LIS will transmit the sample information and test orders (if necessary) for this sample to the AI (see Notes 1 and 4).

e) The AI starts performing the ordered tests on the sample.

f) When test results are completed, the AI transmits the results to the LIS (see Note 2).

g) The LIS identifies the results in the message by the sample ID (and test ID if AI supports more than one test: see Note 4).

NOTE 1 On several AIs, this is a time-critical operation and some AIs will ignore the sample if the LIS does not respond within a specific time limit. Such requirements would normally be stated in the AI interface manual as special service requirements.

NOTE 2 The AI may transmit single results as they are completed or all results for one sample in each message.

NOTE 3 Operations b) to e) and operations f) to g) may be strictly sequential or independent of each other. In the most powerful AIs, the sample loading and request-query operations function completely independently of the result transmissions.

NOTE 4 For microbiology tests, there is often no specific test order or test ID, so this would not be transmitted.

Dialogue:

AI	Direction	LIS	Message (see Table 1)	Trigger event
Sender	→	Receiver	M5: Query for order	Operator loads samples on the AI.
Receiver	←	Responder	M4: Order	Response to an order query from the AI.
Sender	→	Receiver	M1: Result	Results completed on AI.

Message examples:

(AI)

```
H|\^&
Q|1|^99042718
L|1|N
```

(LIS)

```
H|\^&
P|1
O|1|99042718||^^^NA\^^^K\^^^CL||||||||||||||||||||O
L|1|N
```

(AI)

```
H|\^&
P|1
O|1||99042718
R|1|^^^NA|145|mmol/L
R|2|^^^K|4.5|mmol/L
R|3|^^^CL|101|mmol/L
L|1|N
```

Or:

(AI)

```
H|\^&|||CORP^HEMO^X-1000|||||||||19990316081200
Q|1|^99042278
Q|2|^99042399
Q|3|^99045188
Q|4|^99043001
L|1|N
```

(LIS)

```
H|\^&|||Z-Lab^STRATOS^V12.2+
P|1||02095217784||ERIKSEN^PETER||19520902|M
O|1|99042278||^^^HB\^^^ERYT\^^^LEUK|S||19990316080000  cont..
 ||||||||||||||||O
P|2||11126429753||HANSEN^NILS||19641211|M
O|1|99042399||^^^HB\^^^TROMB|S||19990316080000  cont..
 ||||||||||||||||O
P|3
O|1|99045188||||||||||||||||||||||Z
P|4||12107634451||MORGAN^JOHN||19761012|M
O|1|99043001||^^^HB\^^^ERYT\^^^LEUK|R||19990316080000  cont..
 ||||||||||||||||O
L|1|N
```

(AI)

```
H|\^&|||CORP^HEMO^X-1000||||||||ENV13728^P2|19990316092100
P|1|12107634451||MORGAN^JOHN||19761012|M
O|1||99043001
R|1|^^^HB|14.5|g/dL||||F||BWD||19990316090200
R|1|^^^ERYT|6.5|10^12/L||||F||BWD||19990316090200
R|1|^^^LEUK|2.2|10^9/L||<||F||BWD||19990316090200
L|1|N
```

Or:

(AI)

```
H|\^&|||BactComp^Supra2000^12556
Q|1|^19990278||||||||||O
Q|2|^19990399||||||||||O
L|1|N
```

(LIS)

```
H|\^&|||BioLab^LabPLUSS^V2.41
P|1||10114313984||Patterson^Charles||19431110|M
O|1|19990278||^^^BCULT|B||19990623093000||||||||||||||||||O
P|2||11126429753||Hansen^Nils||19641211|M
O|1|19990399||^^^BCULT|B||19990624080000||||||||||||||||||O
L|1|N
```

(AI)

```
H|\^&|||BactComp^Supra2000^12556
O|1||19990278
R|1|^^^BCULT|Neg|||||P||||19990625135500
O|2||19990399
```

```
R|1|^^^BCULT|Neg|||||P||||19990625135500
O|3||19990133
R|1|^^^BCULT|Pos|||||F||PJo||19990625135500
O|4||19990121
R|1|^^^BCULT|Neg|||||F||PJo||19990625135500
L|1|N
```

B.3.4.2 Scenario 3b: Bidirectional communication, positive sample ID and patient demographic order queries

A dedicated analytical instrument (electrophoresis instrument, amino acid analyser, blood culture incubator etc.) implements a message to query the LIS for patient demographic data.

Each sample tube, cup or bottle carries a bar code label for identification, or, in some cases, the operator identifies the sample to the AI while loading samples.

A workflow example is as follows.

a) The operator loads the AI with samples.

b) The AI reads a bar code label on the sample tube.

c) The AI transmits a message to the LIS asking for patient demographic information.

d) LIS transmits the information to the AI.

Dialogue:

AI	Direction	LIS	Message (see Table 1)	Trigger event
Sender	→	Receiver	M5: Query for order	Operator starts working running samples on the AI.
Receiver	←	Responder	M4: Order	Response to an order query from the AI.

Message examples:

(AI)

```
H|\^&
Q|1|^99045276|||||||||D
Q|2|^99044324|||||||||D
Q|3|^99044876|||||||||D
L|1|N
```

(LIS)

```
H|\^&
P|1
P|1||19127865399||FALK^ALLAN||19781219|M
O|1|99045276
P|2||20068154637||BROWN^ELSA||19810620|K
O|1|99044324
P|3||09078465134||BLAKE^GORDON||19840709|M
O|1|99044876
L|1|N
```

B.3.5 Bidirectional communication with order and result queries

B.3.5.1 Scenario 4a: Bidirectional communication, query for results

A specific AI is designed to only send messages to the LIS when prompted by the LIS. The interface is therefore designed to periodically query the AI for any new results. When the AI receives such a query, it will transmit the requested results to the LIS.

A workflow example is as follows.

a) The AI is continuously running tests on samples loaded in the AI.

b) The LIS will periodically (or initiated by an operator) query for new results.

c) The AI transmits the queried results to the LIS.

d) The LIS identifies the results in the message by the sample ID and test ID.

Dialogue:

AI	Direction	LIS	Message (see Table 1)	Trigger event
Receiver	←	Sender	M6: Query for results	Periodical query from the LIS.
Responder	→	Receiver	M2: Result by query	Queried results completed on AI.

Message examples:

(LIS)

```
H|\^&
Q|1|^ALL||||||||||F
L|1|N
```

(AI)

```
H|\^&
P|1|02095217784||OLSEN^CARL||19520902|M
O|1|99042123
R|1|^^^HB|14.5|g/dL||||F||BWD||19990316090200
R|1|^^^ERYT|6.5|10^12/L||||F||BWD||19990316090200
R|1|^^^LEUK|2.2|10^9/L||<||F||BWD||19990316090200
P|2|11126429753||DOE^WILLIAM||19641211|M
O|1||99046341
R|1|^^^HB|13.2|g/dL||||F||AS||19990316090800
R|1|^^^TROMB|354|10^9/L||||F||AS||19990316090800
L|1|N
```

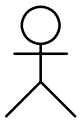
B.4 Use case and sequence diagrams

B.4.1 Introduction

The following use case diagrams are derived by a process of decomposition from the use case descriptions given in Clause B.3. The decomposition is intended to produce use cases focussed on one subject for communication, i.e. each leaf-level use case should involve a single actor and a single interaction in response to a single stimulus. However, there is not always an exact one-to-one relation between scenarios and the corresponding use case diagrams.

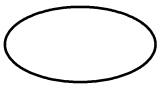
Interaction between objects can be expressed in UML with collaboration diagrams and/or sequence diagrams, collectively referred to as interaction diagrams. Collaboration diagrams illustrate the flow of messages between objects, using message sequence numbers to show explicit ordering. Sequence diagrams also illustrate this flow, but use vertical position to indicate time order. An interaction's collaboration diagram and sequence diagram are isomorphic: one can be automatically generated from the other, and changes to one are automatically reflected in its counterpart. In this document, sequence diagrams are used to indicate the time order for the exchange of messages between an AI and a LIS.

B.4.2 How to read the use case diagrams



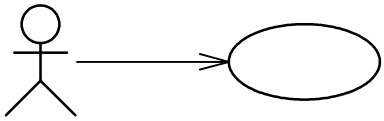
Actor

An actor is an object outside the domain of the system itself that interacts directly with the system. The users and any system that may interact with the system are the actors. In the following diagrams, the actor is the AI or the LIS



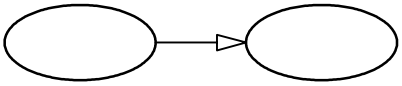
Use case

A use case is a sequence of transactions performed by a system in response to a triggering event initiated by an actor to the system. A use case contains all the events that can occur between an actor/use case pair, not necessarily the ones that will occur in any particular scenario. A use case contains a set of scenarios that explain various sequences of interaction within the transaction.



Association

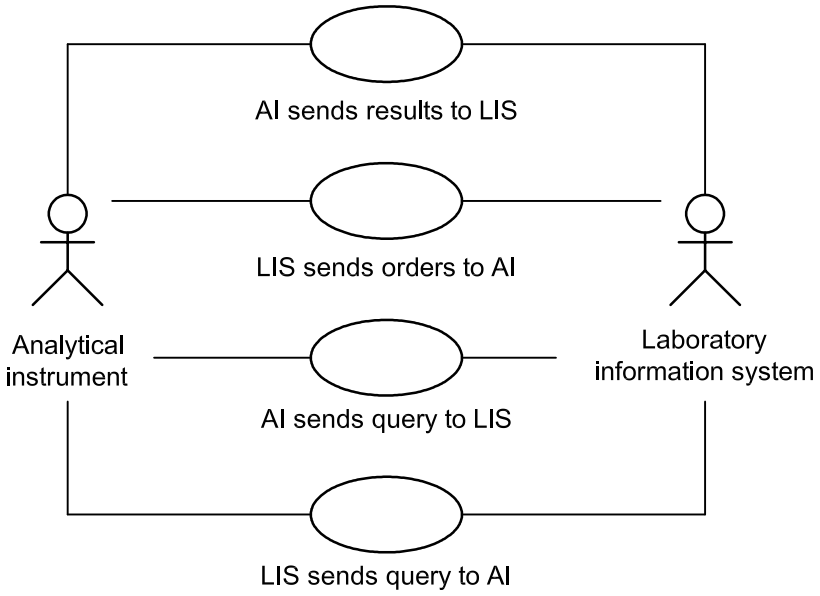
An association shows that an actor is connected with a use case. For example, the operator of the LIS may cause the LIS to transmit an order to the AI (see B.4.3).



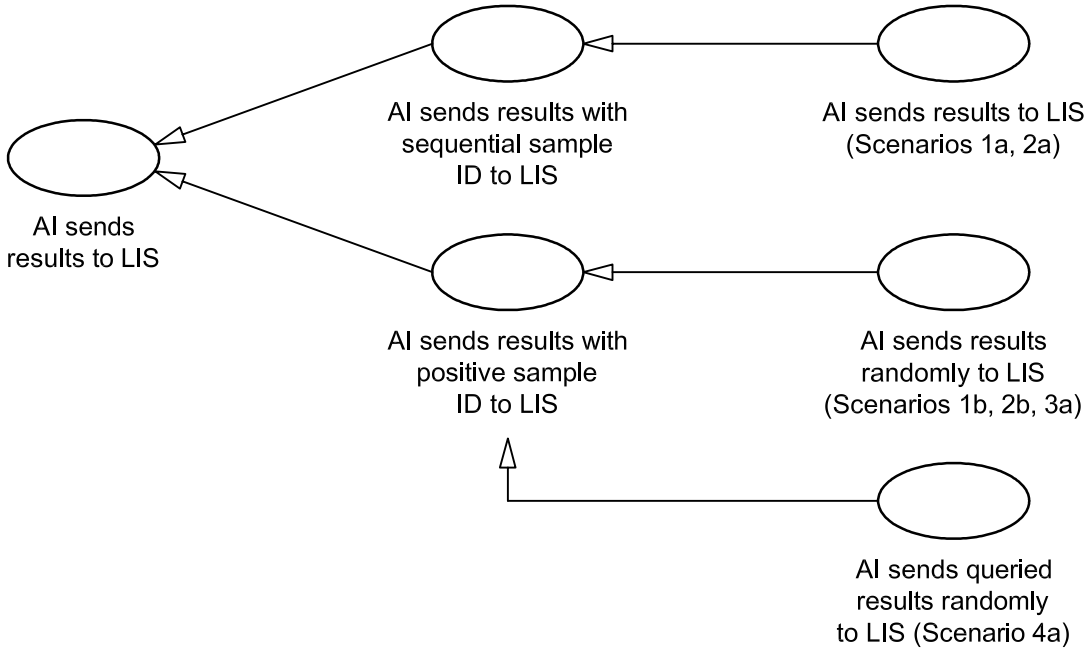
Generalize relationship

A generalized relationship between use cases shows that a use case can share the behaviour defined in the other use case. For example, “Order Transmission” is an example of “Perform Communication” in B.4.3.

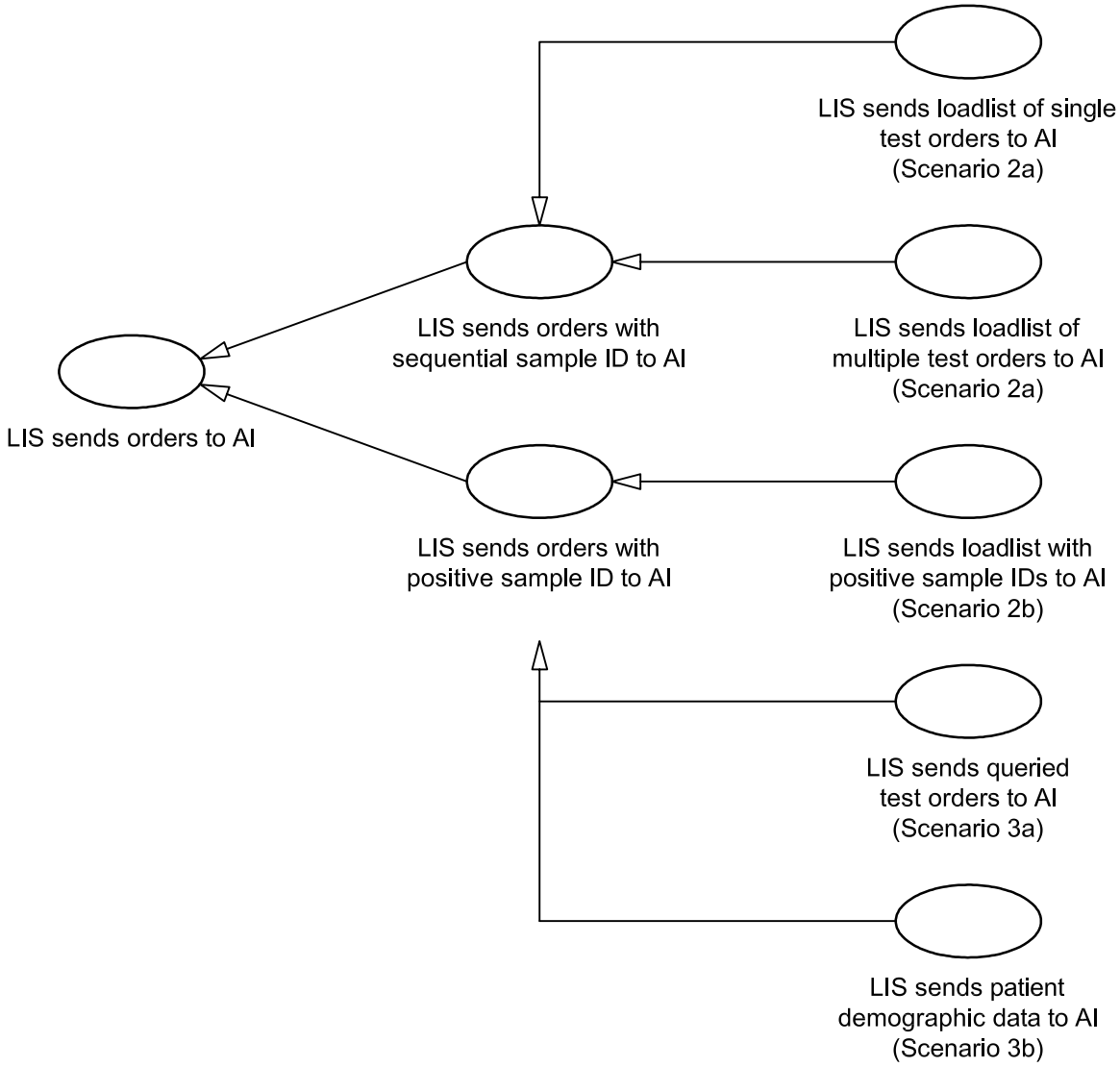
B.4.3 Use cases: General level



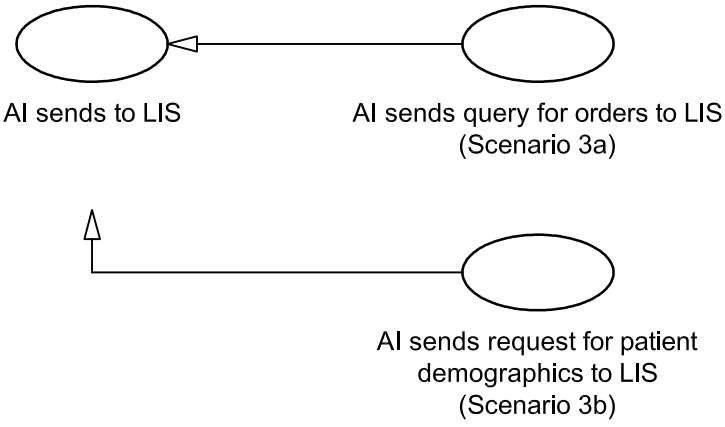
B.4.4 Use cases: AI sends results to LIS



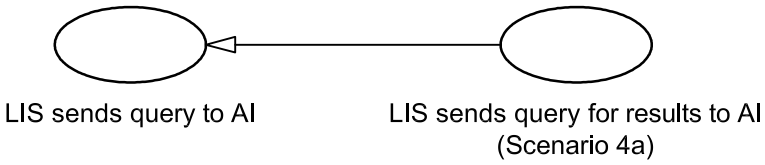
B.4.5 Use cases: LIS sends orders to AI



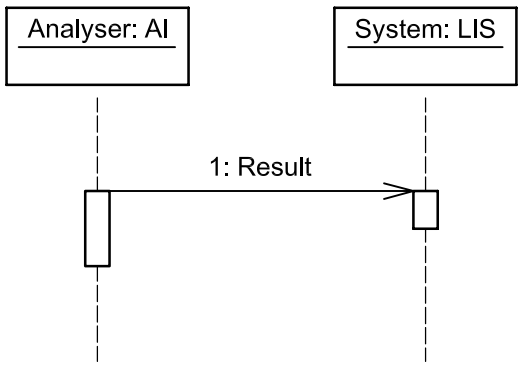
B.4.6 Use cases: AI sends query to LIS



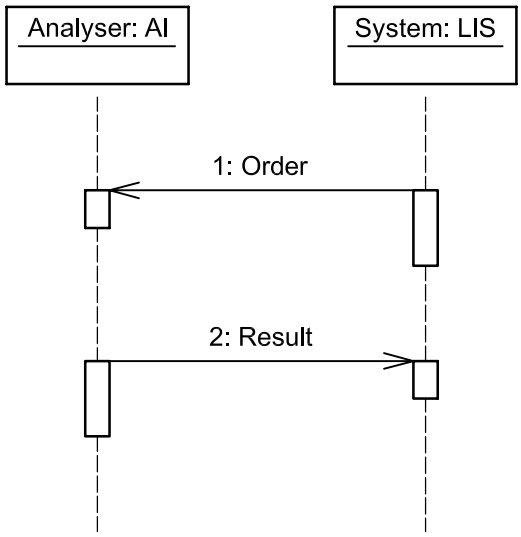
B.4.7 Use cases: LIS sends query to AI



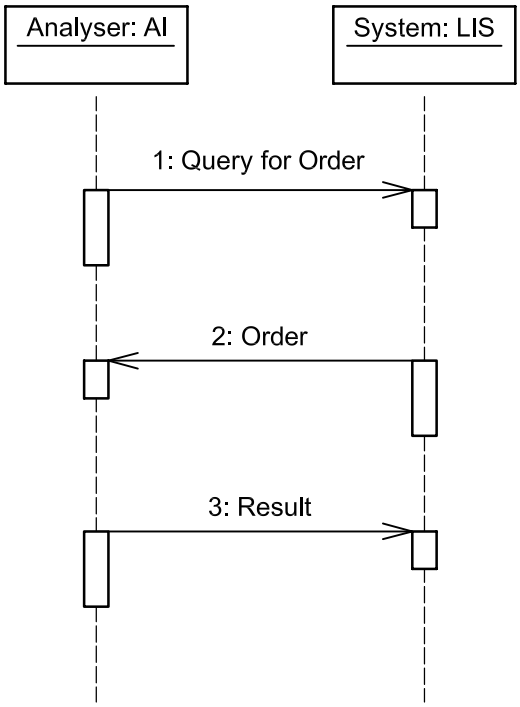
B.4.8 Sequence diagram: Scenarios 1a/1b



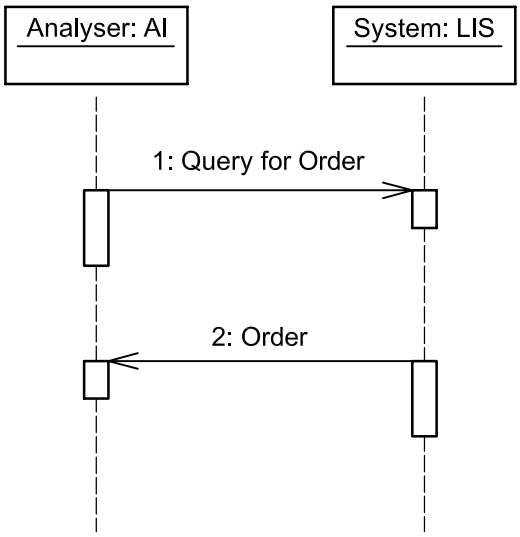
B.4.9 Sequence diagram: Scenarios 2a/2b



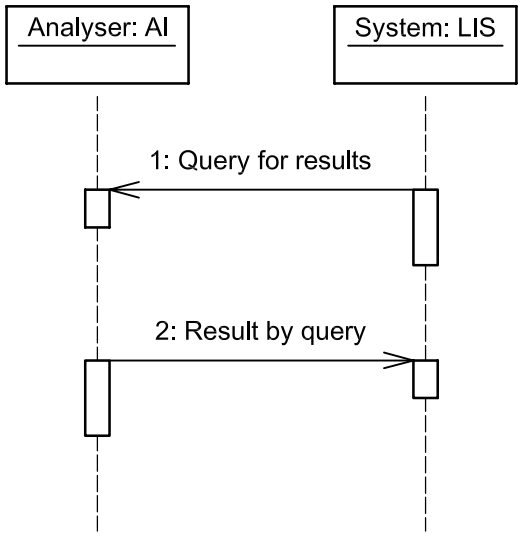
B.4.10 Sequence diagram: Scenario 3a



B.4.11 Sequence diagram: Scenario 3b



B.4.12 Sequence diagram: Scenario 4



Annex C
(informative)

Implementation guidelines

As discussed in the Introduction to this International Standard, different implementers interpret the same clauses of ASTM E1394 in different ways. Also, the vast choice of data items available gives implementers the ability to send the same data in many different ways. This can make the standard hard to implement and can result in communication problems.

This International Standard describes a number of profiles that improve this situation, but there are advantages to further explanation of the ASTM E1394 fields and records. This annex quotes all fields used in the standard and gives guidance, where appropriate, on how they should be implemented.

Table C.1 below deals with general considerations, e.g. common fields and formats. Tables C.2 to C.9 list all ASTM E1394 records, including all fields, and give guidelines for each.

Each table includes the following (where applicable):

— ASTM reference: paragraph number in ASTM E1394;

— field name: name of field in ASTM E1394;

— ASTM text: text quoted from ASTM E1394;

— use type: suggested limitations on use: mandatory (M), optional (O), disallowed (D). Where these differ between messages (M1 to M6 in Table 1), this is shown;

— content: suggested allowable values. Where these differ between messages (M1 to M6 in Table 1), this is shown;

— implementation guideline: guideline on how the field should be implemented to promote interworking.

As described in the Introduction to this International Standard, certain fields have to be transferred between the LIS and the AI to satisfy quality management requirements specified in ISO/IEC 17025. These are marked in the following tables using *italics*.

Table C.1 — General considerations for message content

ASTM reference	Field name	ASTM text	Implementation guideline
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. 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 13.1.3 and 13.1.4 and within the dates described in 12.1.6 and 12.1.7.	
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.	This is compatible with ISO 8601.

Table C.1 — *(continued)*

ASTM reference	Field name	ASTM text	Implementation guideline
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.	This field should correspond to the following format: Street & Street No. or PO box number^City^Area of country or county^Postal Code^Country This is as close as possible to European conventions, while retaining compatibility with ASTM E1394. The country need only be transmitted when it cannot be assumed from the context.
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). E.g. for the first patient transmitted, 1 shall be entered, for the second, 2, ... until the last as defined.	Maximum value is to be limited to 32768.
11.1.5	Comment Type	The following codes may be used to qualify 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	Use only G or I. T, P and N are covered by G and I.

Table C.2 — Message header record

ASTM reference	Field name	ASTM text	Use type	Content	Implementation guideline
7.1.1	Record Type ID		M	H	Use only capital letter
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 | \ ^ & |.	M	|\^&	Do not use delimiters other than |\^&. NOTE ASTM E1394 allows any non-alphanumeric characters from ISO 8859 to be used as delimiters. The standard, however, uses |\^& as examples and nearly all implementations use these.
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 acknowledgement protocols that are outside of the scope of this specification. Note that this is the third field.	D		Do not use. NOTE This field is not often used and, if used, has no clear meaning.
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.	D		NOTE There is no meaningful use in the current area of point to point connection.
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.*	*O*		*Should be used only to identify the AI or LIS. Repeat delimiters should not be used. The field should only contain Manufacturer Name; System Name; System Serial No, i.e. only 3 components and no repeat fields.* *This is required for quality management* *If Software Revision is required for tracing or debugging, this should be put in the Comment Record.*
7.1.5.1			O		1. component (manufacturer name).
7.1.5 2			O		2. component (system name).
7.1.5.3			O		3. component (system serial no).
7.1.6	Sender Street Address	This text value shall contain the street address of the sender as specified in 6.6.5.	D		See ASTM ref. 6.6.5.
7.1.7	Reserved Field	This field is currently unused but reserved for future use.	D		Do not use.

Table C.2 — *(continued)*

ASTM reference	Field name	ASTM text	Use type	Content	Implementation guideline
7.1.8	Sender Telephone Number	This field identifies a telephone number for voice communication with the sender as specified in 6.6.3.	O		As per ASTM E1394. This should not be used for the telephone number of the AI manufacturer.
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.	D		Do not use. This has no meaningful use. If the message is received correctly, get the message, the communication is already established.
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.*	*O*		*As 7.1.5.* *This is required for quality management*
7.1.10.1			O		Manufacturer name.
7.1.10.2			O		System name.
7.1.10.3			O		System ID.
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.	D		Do not use. NOTE Not used by any known AI.
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.	O	P or Q	Do not use repeats or component fields. If the field is empty or not present, P should be assumed. If Q is used, all the following messages are QC-messages. If T or D is used, the receiver should ignore the message. See also ASTM ref. 9.4.12.
7.1.13	Version No.	This value identifies the version level of the specification. This value is currently 1394-97	O	E 1394-97	As ASTM E1394. It is recommended that this field be always used.
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.*	*O*		*See ASTM ref. 6.6.2.* *This is required for quality management. It only identifies the date and time the record was assembled and transmitted rather than the date and time the analysis was done, so is to be used only as a starting point for identification of problems.*

Table C.3 — Patient information record

ASTM reference	Field name	ASTM text	Use type	Content	Implementation guideline
8.1.1	Record Type		M	P	Use only capital letter.
8.1.2	Sequence Number		M	1 ... n	See ASTM ref 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.	D		Do not use. This is useful for report generation, but not necessary for the communication between the LIS and AI.
8.1.4	Laboratory Assigned Patient ID	This identifier shall be the unique processing number assigned to the patient by the laboratory.	D (M1,2,3) O (M4)		As ASTM E1394, but repeat and component delimiters should not be used. May be alphanumeric.
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.	D		Do not use. This is not necessary for the communication between the AI and LIS.
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.	D (M1,2,3) O (M4)		
8.1.6.1			D (M1,2,3) O (M4)	Last Name	
8.1.6.2			D (M1,2,3) O (M4)	First Name	
8.1.6.3			D (M1,2,3) O (M4)	Middle Name or Initial.	
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.	D		Do not use. This is not necessary for the communication between the AI and LIS.
8.1.8	Birthdate	The birthdate shall be presented in the standard format specified in section 6.6.2.	D (M1,2,3) O (M4)	YYYY-MM-DD	Age should not be used. See ASTM reference 6.6.2.
8.1.9	Patient Sex	This field shall be represented by M, F, or U.	D (M1,2,3) O (M4)	M, F or U	This does not conflict with ISO 5218.

Table C.3 — *(continued)*

ASTM reference	Field name	ASTM text	Use type	Content	Implementation guideline
8.1.10	Patient Race-Ethnic Origin	The following examples may be used: W: White B: Black 0: 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.	D		Do not use. This is not necessary for the communication between the AI and LIS.
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.	D		Do not use. This is not necessary for the communication between the AI and LIS.
8.1.13	Patient Telephone Number	This text value shall record the street address of the patient's mailing address as defined in 6.6.5.	D		Do not use. This is not necessary for the communication between the AI and LIS.
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) shall be separated by repeat delimiters.	D		Do not use. This is not necessary for the communication between the AI and LIS. Only ordering physician (ASTM ref. 9.4.17) is useful.
8.1.15	Special Field 1	An optional text field for vendor use (each laboratory can use this differently).	D		Do not use. This has no meaningful use. If there is additional information to transmit, then the standard is to be changed.
8.1.16	Special Field 2	An optional text field for vendor use.	D		See ASTM ref. 8.1.15.
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.	D (M1,2,3) O (M4)		In Europe, use cm only.

Table C.3 — *(continued)*

ASTM reference	Field name	ASTM text	Use type	Content	Implementation guideline
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.	D (M1,2,3) O (M4)		Use kg as defaults units. In Europe use kg only.
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.	D		Do not use. This information can be handled better in the LIS. It is not required by the AI.
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.	D		Do not use (see ASTM ref. 8.1.19).
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)	D		Do not use (see ASTM ref. 8.1.19).
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.	D		Do not use (see ASTM ref. 8.1.19).
8.1.23	Practice Field No. 2	Same as section 8.1.22.	D		Do not use (see ASTM ref. 8.1.19).
8.1.24	Admission and Discharge Dates	These values shall be represented as specified in section 6.1. The discharge date, when included, follows the admission date and is separated from it by a repeat delimiter.			Do not use (see ASTM ref. 8.1.19).
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 preadmit, IP inpatient, ER emergency room.	D		Do not use (see ASTM ref. 8.1.19).
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.	D (M1,2,3) O (M4)		Current location as held by LIS.
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.	D		Do not use (see ASTM ref. 8.1.19).

Table C.3 — *(continued)*

ASTM reference	Field name	ASTM text	Use type	Content	Implementation guideline
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.	D		Do not use (see ASTM ref. 8.1.27).
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	D		Do not use (see ASTM ref. 8.1.19). Not required by the LIS or the AI.
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	D		Do not use (see ASTM ref. 8.1.19). Not required by the LIS or the AI.
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	D		Do not use. In modern laboratory medicine, every sample should be handled as if it were a “dangerous” sample. If the sample is known to be a dangerous sample, then sample should be marked as such, not the data records. See also 9.4.13.

Table C.3 — *(continued)*

ASTM reference	Field name	ASTM text	Use type	Content	Implementation guideline
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.	D		Do not use (see ASTM ref. 8.1.19). Not required by the LIS or the AI.
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.	D		Do not use (see ASTM ref. 8.1.19).
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.	D		Do not use (see ASTM ref. 8.1.19).
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. Sub-components of this field may be used to define dosage sub-groups.	D		Do not use (see ASTM ref. 8.1.19).

Table C.4 — Test order record

ASTM reference	Field name	ASTM text	Use type	Content	Implementation guideline
9.4.1	Record Type ID		M	O	Use only capital letter.
9.4.2	Sequence Number		M	1 ... n	See ASTM ref. 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 separated by component delimiters. For example, the specimen ID may contain the specimen number followed by the isolate number, well or cup number (for example, 10435A^01^64).	O (M1,2) M (M3,4)		Repeat fields should not be used, but components are used for microbiology.
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.	M (M1,2) O (M3,4)		
9.4.5	Universal Test ID	This field shall use universal test ID as described in section 6.6.1	D (M1,2,3) M (M4)		

Table C.4 — *(continued)*

ASTM reference	Field name	ASTM text	Use type	Content	Implementation guideline
9.4.6	Priority	Test priority codes are as follows: S: stat A: as soon as possible R: routine C: call-back P: preoperative If more than one priority code applies, they must be separated by repeat delimiters	O	S or R	LISs normally only recognize two priorities. Therefore only the following should be used: S: stat (do now) R: routine.
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.	D		Do not use. This information has no meaning for the AI.
9.4.8	Specimen Collection Date and Time	This field shall represent the actual time the specimen was collected or obtained.	D (M1,2,3) O (M4)		See ASTM ref. 6.6.2.
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.	D		Do not use. This information is not necessary for the AI. It would be used by the LIS.
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.	D		See ASTM ref. 9.4.9.
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.	D		See also ASTM ref. 9.4.17.

Table C.4 — *(continued)*

ASTM reference	Field name	ASTM text	Use type	Content	Implementation guideline
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.	O		If this test order is one QC order among non-QC orders, then this field should be "Q" AND field 7.1.12 should NOT be Q. If the message contains only QC orders, then ASTM ref. 7.1.12 and ASTM ref. 9.4.12 are to be Q. Q should always be used as indicated by ASTM E1394. All QC orders should use "Q".
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.	D (M1,2,3) O (M4)		As ASTM E1394.
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 gases, point in menstrual cycle for cervical pap tests or other conditions that influence test interpretations.	D		Do not use. Use comment record instead.
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 section 6.6.2 shall be used.	D		Do not use. This information can be handled better in the LIS. This information is not necessary for the AI.
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.	D (M1,2,3) O (M4)		The chemistry/ haematology specimen ID should be specified in the universal test ID. For microbiology, use as ASTM E1394, i.e. free text.
9.4.16.1	Specimen Type	Samples of specimen culture types or sources would be blood, urine, serum, hair, wound, biopsy, sputum, etc.	D (M1,2,3) O (M4)		

Table C.4 — *(continued)*

ASTM reference	Field name	ASTM text	Use type	Content	Implementation guideline
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).	D (M1,2,3) O (M4)		
9.4.17	Ordering Physician	This field shall contain the name of the ordering physician in the format outlined in 6.6.6.	D (M1,2,3) O (M4)		This should be used rather than the attending physician (8.1.14). See also ASTM ref. 9.4.11.
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 call-back orders and for critically abnormal results. Uses the format given in 6.6.3.	D (M1,2,3) O (M4)		
9.4.19	Users Field No. 1	Text sent by the requester should be returned with the sender along with the response.	D		Do not use. Use comment record instead.
9.4.20	Users Field No. 2	Similar to 9.4.19.	D		See ASTM ref. 9.4.19.
9.4.21	Laboratory Field No. 1	An optional field definable for any use by the laboratory.	D		Do not use.
9.4.22	Laboratory Field No. 2	Similar to 9.4.21.	D		Do not use.
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.	O		For chemistry/ haematology, do not use. For microbiology, it has possible use for interim reporting.
9.4.24	Instrument Charge to Computer System	This field contains the billing charge or accounting reference by this instrument for tests performed.	D		Do not use. This information has no meaning for the AI.
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.	D		Do not use. Use ASTM ref. 10.1.14 instead.

Table C.4 — *(continued)*

ASTM reference	Field name	ASTM text	Use type	Content	Implementation guideline
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: results cannot be done, request 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)	D (M1,2,3) M (M4)	O, X, Z, Q	
9.4.27	Reserved Field		D		Do not use.
9.4.28	Location or Ward of Specimen Collection	This field defines the ward of specimen collection if different from the patient ward.	D		Do not use. Not required by AI.
9.4.29	Nosocomial Injection 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.	D		Do not use. Not required by AI.
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.	D		Do not use. Not required by AI.
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	D		Do not use. Not required by AI.

Table C.5 — Result record

ASTM reference	Field name	ASTM text	Use type	Content	Implementation guideline
10.1.1	Record Type ID		M	R	Use only capital letter.
10.1.2	Sequence Number		M	1 ... n	See ASTM ref. 6.6.7.
10.1.3	Universal Test ID		M		See ASTM ref. 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.	M (M1) O (M2,3)		Do not use components.
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.	O		As ASTM E1394. This field is closely linked to the universal test ID.
10.1.6	Reference Ranges		D		Do not use.
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.	D		Do not use.
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 test description follows immediately after the range and is separated from it by a component delimiter. Most results will only have one normal range transmitted.	D		Do not use.

Table C.5 — *(continued)*

ASTM reference	Field name	ASTM text	Use type	Content	Implementation guideline
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.	O	< or >	Use only “<” or “>”. Other values have little or no meaning to most LISs.
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. N: implies that generic normal range was applied to all patient specimens. 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.	D		Do not use.

Table C.5 — *(continued)*

ASTM reference	Field name	ASTM text	Use type	Content	Implementation guideline
10.1.9	Result Status	The following codes shall be used. C: correction of previously transmitted results P: preliminary results F: final results X: results cannot be done, request will not be honoured 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 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	O	P, F, M, R in M1 P, F, X, I, M, R, Q in M2 and M3	
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 section 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.	D		See ASTM ref. 6.6.2.
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.*	*O*		*Operator validation of result should not be done on the AI.* *Required for quality management. In most cases, only the first component will be used, but on larger and more complex AIs it may be necessary to use the second as well.*
10.1.12	Date/Time Test Started	Date and time the instrument started the test results being reported. Date and times should be reported as specified in 6.6.2.	D		
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.	O		See ASTM ref. 6.6.2.

Table C.5 — *(continued)*

ASTM reference	Field name	ASTM text	Use type	Content	Implementation guideline
10.1.14	Instrument identification	Identifies the instrument or section of instrument that performed this particular measurement	O		*Required for quality management*.

Table C.6 — Comment record

ASTM reference	Field name	ASTM text	Use type	Content	Implementation guideline
11.1.1	Record Type ID		M	C	Use only capital letter.
11.1.2	Sequence Number		M	1 ... n	See ASTM ref. 6.6.7.
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.	M	Free text or code^text	Do not use more than two components. Repeats are not allowed.
11.1.5	Comment Type	The following codes may be used to qualify 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	M	G or I	Use only G or I. T, P and N are covered by G and I.

Table C.7 — Request information record

ASTM reference	Field name	ASTM text	Use type	Content	Implementation guideline
12.1.1	Record Type ID		M	Q	Use only capital letter.
12.1.2	Sequence Number		M	1 ... n	See ASTM ref. 6.6.7.
12.1.3	Starting Range ID Number		O		

Table C.7 — *(continued)*

ASTM reference	Field name	ASTM text	Use type	Content	Implementation guideline
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.	O		Use ASTM ref. 12.1.3.1 or ASTM ref. 12.1.3.2.
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.	O		Use ASTM ref. 12.1.3.1 or ASTM ref. 12.1.3.2.
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 by the instrument as mutually agreed upon between the instrument and laboratory or external computer system.	D		Do not use.
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.	O		
12.1.5	Universal Test ID	As described in section 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 13.1.3 and 13.1.4 and within the dates described in 12.1.6 and 12.1.7	O		See ASTM ref. 6.6.1. ALL means all tests.
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.	D		Do not use. Not used by any known AI.

Table C.7 — *(continued)*

ASTM reference	Field name	ASTM text	Use type	Content	Implementation guideline
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.	D		Do not use.
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.	D		Do not use.
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.	D		Do not use.
12.1.10	Requesting Physician Telephone number	As specified in 6.6.3.	D		Do not use.
12.1.11	User Field No. 1	User defined field.	D		Do not use.
12.1.12	User Field No. 2	User defined field.	D		Do not use.
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 result only O: requesting test orders and demographics only (no results) D: requesting demographics only (for example, patient record)	M	O,D in M5 P,F,I,M, N in M6	"D" should not be used.

Table C.8 — Message terminator record

ASTM reference	Field name	ASTM text	Use type	Content	Implementation guideline
13.1.1	Record Type ID		M	L	Use only capital letter.
13.1.2	Sequence Number		M	1	See ASTM ref. 6.6.7.
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 F, I, or Q will terminate a request and allow processing of a new request record.	M		N (normal): use as ASTM E1394. T should not be used.

Table C.9 — Scientific record

ASTM reference	Field name	ASTM text	Use Type	Content	Implementation guideline
14.1		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.			Do not use. Not necessary for AI-LIS communication and difficult to standardize, therefore should not be used in a standard interface.

Table C.10 — Manufacturer information record

ASTM reference	Field name	ASTM text	Use type	Content	Implementation guideline
15.1		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.			Do not use. Not necessary for AI-LIS communication and difficult to standardize, therefore should not be used in a standard interface.

Bibliography

[1] ISO 5218, *Information interchange — Representation of human sexes*

[2] ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

[3] ISO/IEC 8859-1:1998, *Information technology — 8-bit single-byte coded graphic character sets — Part 1: Latin alphabet No. 1*

[4] ISO 15189:2003, *Medical laboratories — Particular requirements for quality and competence*

[5] ISO/IEC 17025:—[2)], *General requirements for the competence of testing and calibration laboratories*

2) To be published as revision of ISO/IEC Guide 25:1990.

ICS 35.240.80

Price based on 52 pages