EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN/TC 251/N99-039
1999-05-28

CEN/TC 251
Health Informatics
Secretariat: SIS-HSS

TITLE/ SUBJECT: **First Working Document of Health Informatics - Instrument Interfaces to Laboratory Information Systems**

SOURCE: ***CEN/TC 251/WG IV Secretariat***

ACTION REQUIRED: ***REQUEST FOR COMMENTS BEFORE 1999-08-06***

CEN/TC 251 Secretariat: SIS-HSS (Swedish Healthcare Standards Institution)

Mail address:	Box 704 87	TC Secretary:	Karin Kajbjer
	SE-107 26 Stockholm, Sweden	Visiting and Courier mail:	Hornsgatan 20
Fax:	+46(0)8 702 4915	e-mail:	karin.kajbjer@hss.se
Tel:	+46(0)8 702 4916	Web site:	www.centc251.org

Request for comments on:

First Working Document of Health Informatics - Instrument Interfaces to Laboratory Information Systems

Comments may be received in any format, but preference is shown for comments to be in an electronic document with a file extension of .RTF attached to an email or sent on diskette to facilitate the process of compiling the comments and the responses to the comments. The use of the form below on the next page is much appreciated but commenters should feel free to approach the project leader by fax or even telephone.

Comments should be separated and numbered and preferably grouped.

The comments should contain, and be structured according to the following:

Author:

1. Author identification:
   Name, organisation, address, country, fax and phone number, e-mail
   Title: Comment on Red Cover Document
2. Author represents:Self or others.
   If others: name, organisation, address, country, fax and phone number, e-mail

Comment:

3. Comment text:
4. Reference to Working Document: document name, version, page, line number(s)
5. Reference to other documents: document name, version, chapter, page, line number(s)
6. Classification of each comment as one of the following:

(T)	**TYPO**	Technical, grammatical or typographical errors
(Q)	**QUERY**	Uncertain of meaning, or lack of clarity
(S)	**SUGGEST**	Suggestion for improvement which does not arise from any disagreement with the approach
(m)	**MINOR**	Minor disagreement with the approach taken or the terms of the standard. This indicates something which one feels needs discussion but which one does not necessarily oppose.
(M)	**MAJOR**	Serious disagreement with the approach taken or the terms of the standard. This indicates that failure to accept the change might lead to opposing the standard in principle. In this case reasons and useful explanations must be given as well as possible alternative solutions.

7. When making comments one should consider using examples of the problems one foresees, provide accurate references to other standards or other documents which illustrate a point (preferable enclose copies of such documents).
8. In addition to the comments on the current text, please suggest what kind of change you would like to see to accommodate your comments, with inclusion of proposed revised phrasing wherever possible.

Comments to First Working Document (FWD) of the draft European prestandard

Health Informatics - Instrument Interfaces to Laboratory Information Systems
produced by CEN/TC 251/WG IV with project team 36

Please send comments before 1999-08-06 to:

Martin Whittaker,
Touchstone Consultancy Ltd, Foundry Cottage, London Road, Hook
UK - RG27 9DJ
Telephone+44 (0)1256 765902, Fax +44 (0)1256 765902
email mjwhittaker@compuserve.com

Comments From

Name:

Address:

E-Mail:

Author represents:Self or other (please indicate organisation) :

Classification of comments

TYPO (T) Technical, grammatical or typographical errors

QUERY (Q) Uncertain of meaning or lack of clarity

SUGGEST (S) Suggestion for improvement which does not arise from any disagreement with the approach

MINOR (m) Minor disagreement with the approach taken or the terms of this European Prestandard. This indicates something which one feels needs discussion.

MAJOR (M) Serious disagreement with the approach taken or the terms of this European Prestandard.

UNCLASSIFIED (U)

Comment No	Page No	Line No	Category	Comment

EUROPEAN PRESTANDARD
PRENORME EUROPEENNE
EUROPÄISCHE VORNORM

FWD XXX
CEN TC 251 WGIV/N99-12
May 1999

UDC
Descriptors

English Version

Health Informatics

Instrument Interfaces to Laboratory Information Systems

First Working Document (FWD)
CEN TC251 WG IV
Drafted by CEN/TC 251/PT36

VERSION 1

1999-05-20

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung
Central Secretariat: Rue de Stassart 36, B-1050 Brussels, Belgium

Document history

Version	Date	Description
0.1	March 1999	Draft FWD for circulation to PT36
0.2	April 1999	Revised Draft FWD for circulation to PT36, including heavily revised definitions, new UFS section, and heavily revised implementation guide. Incorporates comments from Dr Arno Fraterman.
1	May 1999	FWD approved by WGIV for submission to TC 251 Secretariat to begin Request for Comment ("Red Cover") procedure. Revised for conformance with ISO format. Margins increased to allow printing of line numbers. Much of document put in Informative Annexes rather than the main document.

Contents

Foreword

This First Working Document has been produced by CEN/TC 251/PT36 “Instrument Interfaces to Laboratory Information Systems”.

??Text in Italics between double question marks represents editor's notes??

Project Team

Damon Berry	IE	Dublin Institute of Technology
Dr Arno Fraterman	D	Allgemeines Krankenhaus Hagen
Jens Gleditsch	N	Rikshospitalet, Oslo
Richard Hayes (Leader)	IE	Dublin Institute of Technology
Rauno Heinonen	D	Eppendorf-Netheler-Hinz GmbH
Thomas Norgall	D	Freidrich Alexander Universität Erlangen-Nürnberg
Uwe Okun	D	FREY Computersysteme GmbH
Martin Whittaker	UK	Touchstone Consultancy Ltd

Comments

Please send any comments on this document to

Martin Whittaker
Touchstone Consultancy Ltd

Tel +44 1256 765902
Fax +44 1256 766052
email calm@touchstone.uk.com
Web www.touchstone.uk.com

Introduction

This European Prestandard 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 medical practitioners. In the absence of standards for the interface, each LIS supplier must 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 published a standard "Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems (ASTM E1394 - 91)". This improved the situation by standardising the format of the message and the syntax. It also attempted to standardise 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 interpret 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 European requirements.

The result of this is that each AI supplier has produced his 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 particular laboratory.

In particular, the LIS interface designer must - in theory - allow for any implementation allowed by ASTM E1394. This means that even simple AIs are should be 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 European Prestandard

This European Prestandard 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 simple, easy to implement messages
- Adapting the original standard to cover European 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 message. These are detailed in clause 6. Examples of scenarios covered by this European Prestandard, together with models and sequence diagrams, are given in Annex A. An informative implementation guide for both ASTM E1394 and this European Prestandard is given in Annex B.

Quality Management

There is a trend for all European clinical laboratories to be certified or accredited under a suitable quality management scheme. In most European countries the scheme is actually based on EN 45001: 1989 General criteria for the operation of testing laboratories and/or ISO/IEC Guide 25: 1990 General Requirements for the Competence of Calibration and Testing Laboratories. Both these documents are currently being revised. A document for medical laboratories (ISO TC 212, ISO/IEC 17025) is currently at a draft stage. EN 45001 and ISO/IEC Guide 25 require the laboratory to keep records of certain data. This means, that for the support of the users in conforming to the standard, the instruments and LIS must be capable of handling (input, storage, validation, output) this data and also 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 must originally come from the instrument. ASTM E1394 does not explicitly handle

data required for quality management. In principle it is capable of doing so, but the required fields must be defined.

This European Prestandard includes provisions for using existing ASTM messages to meet European quality requirements.

Compatibility with ASTM E1394

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

1. SCOPE

1.1 Clinical Areas

This European Prestandard specifies general messages for bi-directional electronic information exchange between AIs and LISs within a clinical laboratory. It is intended to be applicable within the following specialties:

- Clinical Chemistry/Biochemistry
- Haematology
- Toxicology
- Microbiology
- Virology and Immunology

It is not intended to apply in the following specialty:

- Blood Transfusion and Blood Bank

1.2 Messages, Syntax and Transport

This European Prestandard is concerned only with the specification of messages used by communicating parties and the syntax in which they are communicated. It is not concerned with the transport mechanisms used for the message interchange.

1.3 Data Types

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

1.4 Domains

User Domain - This standard has been specifically created to provide common conventions for interfacing AIs and LISs in a clinical laboratory environment. It will also be applicable to the interfacing of AIs to computers in other clinical practice settings, such as physicians' offices, clinics, and satellite laboratories. The standard 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.

Interface Domain - This European Prestandard is intended for communication between communication parties where one party will assume the role of an AI and the other party will assume the role of an LIS. The standard is therefore also intended for communication involving independent workstations in the laboratory environment where these are capable of performing 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.

1.5 Validation

The provisions for this European Prestandard have been validated in the domains and for the purposes described above. However, messages conforming to this European Prestandard 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

??standards not referenced in the text will be transferred to a bibliography in the final version??

ISO 646	Information processing - ISO 7-bit coded character set for information interchange.
ISO 2022	Information Processing - ISO 7-bit and 8-bit coded character sets - with code extension techniques (1986).
ISO 2955-93	Information Processing-Representation of SI and Other Units in Systems with Limited Character Sets.
ISO 4873	Information processing - ISO 8-bit code for information interchange - Structure and rules for implementation.
ISO 5218	Information Interchange - Representation of Human Sexes.
ISO 8601	Data elements and interchange formats - Information interchange - Representation of dates and times.
ISO 8859-1	Information Processing - 8-bit single-byte coded graphic character sets- Part-1: Latin alphabet No. 1.
ENV 1613: 1995	Medical Informatics - Messages for exchange of laboratory information.
EN 45001: 1989	General criteria for the operation of testing laboratories.
ISO/IEC Guide 25: 1990	General Requirements for the Competence of Calibration and Testing Laboratories.
OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring, OECD 1992-1995 - Environment Monographs Nos. 45, 48, 49, 50, 73, 74, 110, 111, 115.	
ASTM E1381 - 90	Low-level Protocol to Transfer Messages between Clinical Laboratory Instruments and Computer Systems.
ASTM E1394 - 97	Standard Specification for Transferring Information between Clinical Instruments and Computer Systems.

3. TERMS AND DEFINITIONS

3.1
analyte
component indicated in the name of a measurable quantity

3.2
analytical instrument (AI)
named set of equipment, which provides implementations of laboratory services

NOTE In the ASTM E-1394 the term "Clinical Laboratory Instrument" or "Clinical Instrument" is used.

3.3
battery
group of analytical instrument investigations ordered together

NOTE this supplies a convention by which the user (the laboratory information system) can order multiple analytical instrument investigations by specifying a single name.

3.4
component field
single data element, or data elements which express a finer aggregate or extension of data elements which precede it

NOTE for example, parts of a field or repeat field entry. As an example, the patient's name is recorded as last name, first name, and middle initial, each of which is separated by a component delimiter. Components cannot contain repeat fields.

3.5
download
transmission of data from an LIS to an AI

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

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

NOTE in ASTM 1394 the term "Computer System" is used

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, pertaining to one or more specified systems

3.10
record
aggregate of fields describing one aspect of the complete message

3.11
repeat field
single data element that expresses a duplication of the field definition it is repeating

NOTE used for demographics, requests, orders and the like, where each element of a repeat field is to be treated as having equal priority or standing to associated repeat fields.

3.12
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

3.13
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

3.14
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

3.15
specimen
NOTE used in ASTM E1394 to denote **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

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

3.18
upload
transmission of data from an LIS to an AI

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

4. SYMBOLS AND ABBREVIATIONS

AI analytical instrument

ASTM American Society for Testing and Materials

LIS laboratory information system

5. NORMATIVE REQUIREMENTS

5.1 Messages for transmission of information between Analytical Instruments and Laboratory Information Systems, covered by this European Prestandard, shall use only the message types, records, fields and values specified in clause 6.

5.2 Messages conforming to this European Prestandard shall conform to only one of the Profiles defined in Clause 6.

5.3 When claiming conformance to this European Prestandard, implementations shall state which of the Profiles defined in clause 6 the messages conform to.

6. PROFILE TABLES

6.1 Introduction

This clause specifies the message profiles to which implementations must conform. For each message profile it specifies:

- The ASTM E1394 messages that must be supported
- The direction of communication in which the message must be supported
- The records allowed within each message
- The optionality of the fields within the message
- The values allowed within each field.

Table 1 specifies the messages included in each profile, the direction of message flow and the records included in each message. Table 2 specifies the optionality and allowed values.

6.2 Message Profiles

Table 1: Message Profiles

Message Profile	Description	Direction	Allowed Messages[a]	Records[b]
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	Bi-directional 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	Bi-directional query profile for the transfer of order queries from the AI to the LIS, result queries from the LIS to the AI, orders from the LIS to the AI, and results from the AI to the LIS. *??and results by query which is not entirely clear??*	AI → LIS	M5: Query for Order	H, L, Q
		LIS → AI	M6: Query for Results	H, L, Q
		LIS → AI	M4: Order	H, L, P, O
		AI → LIS	M1: Result	H, L, P, O, R, C
		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 the ASTM standard.	either/both	(no restrictions)	(no restrictions)

[a] The message identifiers correspond to the entries in Table 2.
[b] The record identifiers correspond to those used in the first column of Table 2.

6.3 Attribute Optionality and Allowed Values

Table 2: Attribute Optionality and Allowed Values

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 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	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		
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 lest 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			

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)
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)

243

Annex A
(informative)

Scenarios and Models

A.1 Introduction

This Annex shows the communications requirements supported by the use of message profiles specified in this European Prestandard. These requirements are identified in scenarios specified in this clause. These scenarios do not, however, form an exhaustive list of circumstances in which these message profiles are applicable.

The scenarios are specified in descriptive terms as text and as models using the Unified Modeling Language (UML).

In order to promote understanding, clause A.2, "User Friendly Scenarios", describes the scenarios in laboratory user terms. These are then stated formally as Use Case Descriptions in clause A.3. Clause A.4 shows Use Case Models in UML and the corresponding Sequence Diagrams.

A.2 User Friendly Scenarios

A.2.1 Introduction

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

A.2.2 Analytical Instrument with direct sample identification, bi-directional communication

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:

- The AI reads the bar code label and transmits a message to the LIS asking for test requests for this sample.
- LIS has to transmit the test orders for this sample to the AI within a given time window.
- 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.
- The bar code label of the next sample is read by the AI. This typically happens during the processing of the previous one.

A.2.3 Analytical Instrument with direct sample identification, bi-directional communication

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:

- The AI reads the carousel ID and sends a massage to LIS asking test orders for this carousel.
- LIS downloads all test orders for these samples to the AI.
- 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.
- When all the tests for this carousel have been performed, the AI reads the next carousel ID.

A.2.4 Batch Analytical Instrument, bi-directional 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 loadlist is printed out by the LIS to determine the sample positions. The samples are placed to their positions.
- The AI sends a message to the LIS indicating, which test will be done next.
- The LIS sends the position numbers of all samples having this test requested.
- 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 sample position number and test ID.
- When all orders have been processed, the AI will initiate the next test.

A.2.5 Manual workplace, uni-directional communication

- A single test is to be performed on a number of samples on a manual photometer workplace.
- A worklist is printed out on the LIS. This list defines the sequential order of the samples.
- After a test specific pre-treatment, the samples are measured on the photometer in the order of the workplace list.
- 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.

A.2.6 Haematology Analytical Instrument

Blood counts are to be done for series of samples on an automatic cell counter. For a part of the samples simple blood counts, for others differential blood counts are requested. The samples are identified by their position in a chain.

- LIS prints out a loadlist to determine the sample positions.
- On an operator command on the LIS, the orders indicating which cell count is to be done are downloaded to the counter.
- The counter performs the requested cell counts and transmits the results to the LIS.

A.2.7 Microbiology scenario

??To be added??

A.3 Use Case Descriptions

A.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 A.4.

The scenarios covered are:

- A.3.2.1 Scenario 1a: Uni-directional communication with sequential sample identification.
- A.3.2.2 Scenario 1b: Uni-directional communication with positive sample identification.
- A.3.3.1 Scenario 2a: Bi-directional communication, loadlisting a batch AI with sequential sample identification.
- A.3.4.2 Scenario 2b: Bi-directional communication, positive sample ID and general order download to the AI.
- A.3.4.1 Scenario 3a: Bi-directional communication with positive sample ID and specific order queries.
- A.3.4.2 Scenario 3b: Bi-directional communication, positive sample ID and patient demographic order queries.
- A.3.5.1 Scenario 4a: Bi-directional 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.

A.3.2 Unidirectional communication

A.3.2.1 Scenario 1a: Uni-directional 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 must be handled in such a way that the LIS can be able to identify the sample from the message information or the message sequence.

Workflow example

1. The operator prints a Worklist from the LIS.
2. The operator prepares the samples for analysis.
3. The samples are inserted into the AI and measurement is performed in the defined order.
4. 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.
5. 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 2)	Trigger Event
Sender	→	Receiver	M1. Result	Operator starts working.

Message examples:

```
H|\^&
P|1
O|1
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|||||||ENV-### 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
```

A.3.2.2 Scenario 1b: Uni-directional 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.

Workflow example

1. The operator prepares the samples for analysis.
2. The samples are inserted into the AI and measurement is performed.
3. When the test-result(s) are completed, the results are transmitted to the LIS, either spontaneously or in some way initiated by an operator.
4. 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 2)	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|||||||ENV-### 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
```

A.3.3 Simple Bi-directional communication

A.3.3.1 Scenario 2a: Bi-directional 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 capabilities 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 must be handled in such a way that the LIS and the AI will be able to correctly identify the sample by the message information.

Workflow example

1. The operator creates and prints a Loadlist from the LIS.
2. The operator prepares the samples for analysis and loads the sample carrier(s).

3. The sample carriers are inserted into the AI.
4. 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.
5. The AI performs measurements on the particular samples ordered.
6. When the test-result(s) are completed, the results are transmitted to the LIS, either spontaneously or in some way initiated by an operator.
7. 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 4 → 7 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 (6) as they are completed or when results for the whole sample are completed.

Dialogue:

AI	Direction	LIS	Message(see Table 2)	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
```

A.3.4.2 Scenario 2b: Bi-directional 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.

Workflow example:

1. The operator initiates a download of orders to the AI.
2. LIS will transmit the sample information and test orders for the samples to the AI.
3. The operator loads the AI with samples.
4. The AI reads a bar code label on the sample-tube.
5. The AI performs the ordered tests on the sample.
6. When test results are completed, the AI transmits the results to the LIS.
7. The LIS identifies the results in the message by the sample-ID and test ID.

Dialogue:

AI	Direction	LIS	Message (see Table 2)	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
```

A.3.4 Bi-directional communication with Order Query (P3)

A.3.4.1 Scenario 3a: Bi-directional 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.

Workflow example:

1. The operator loads the AI with samples.
2. The AI reads a bar code label on the sample tube.
3. The AI transmits a message to the LIS asking for sample information and test requests for this sample.

4. LIS will transmit the sample information and test orders for this sample to the AI (see note 1).
5. The AI starts performing the ordered tests on the sample.
6. When test results are completed, the AI transmits the results to the LIS (see note 2).
7. The LIS identifies the results in the message by the sample-ID and test ID.

NOTE 1: On several AI 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 2 → 5 and operations 6 → 7 may be strictly sequential or independent of each other. In the most powerful AIs the sample loading and request-query operations operate completely independent of the result transmissions.

Dialogue:

AI	Direction	LIS	Message (see Table 2)	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.
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|||||||ENV-### 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
```

A.3.4.2 Scenario 3b: Bi-directional 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.

Workflow example

1. The operator loads the AI with samples.
2. The AI reads a bar code label on the sample tube.
3. The AI transmits a message to the LIS asking for patient demographic information.
4. LIS transmits the information to the AI.

Dialogue

AI	Direction	LIS	Message (see Table 2)	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
```

A.3.5 Bi-directional communication with Order and Result Queries

A.3.5.1 Scenario 4a: Bi-directional communication, query for results.

An 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.

Workflow example

1. The AI is continuously running tests on samples loaded in the AI.
2. The LIS will periodically (or initiated by an operator) query for new results.
3. The AI transmits the queried results to the LIS.
4. The LIS identifies the results in the message by the sample-ID and test ID.

Dialogue

AI	Direction	LIS	Message (see Table 2)	Trigger Event
Receiver	←	Sender	M5. 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
```

A.4 Use Case and Sequence Diagrams

A.4.1 Introduction

The Use Case Diagrams in this clause are derived by a process of decomposition from the Use Case Descriptions given in clause A3. 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 1-to-1 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 paper, Sequence Diagrams are used to indicate the time order for the exchange of messages between an AI and an (LIS).

A.4.2 Organisation of Models

The use case diagrams have been ordered following the order of general topics of communication in the scenarios, i.e. order, result, query, and special data transmission. For readability, order transmission has been split into two diagrams.

Figure 1 below shows the interrelation and overlap between the particular Use Case Diagrams.

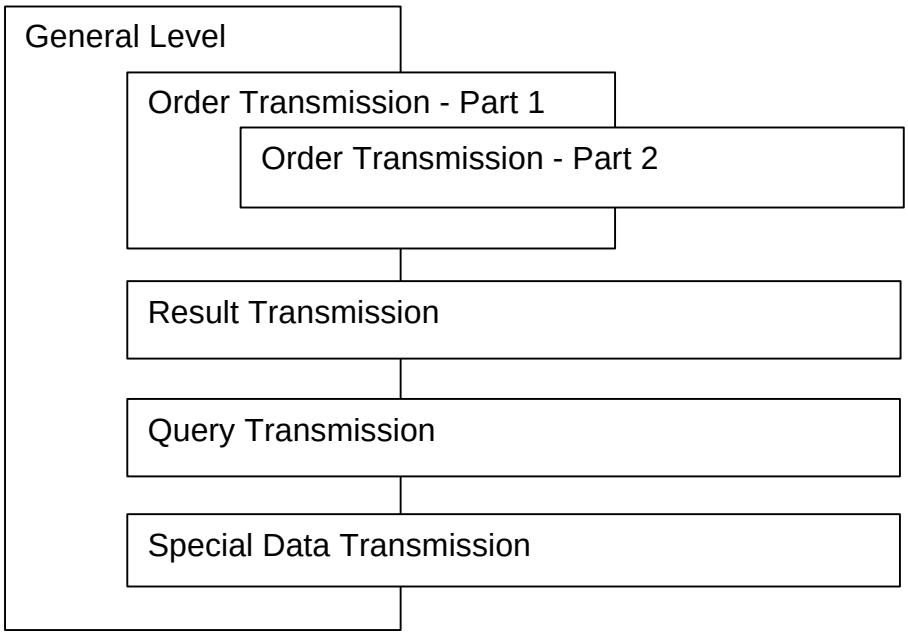
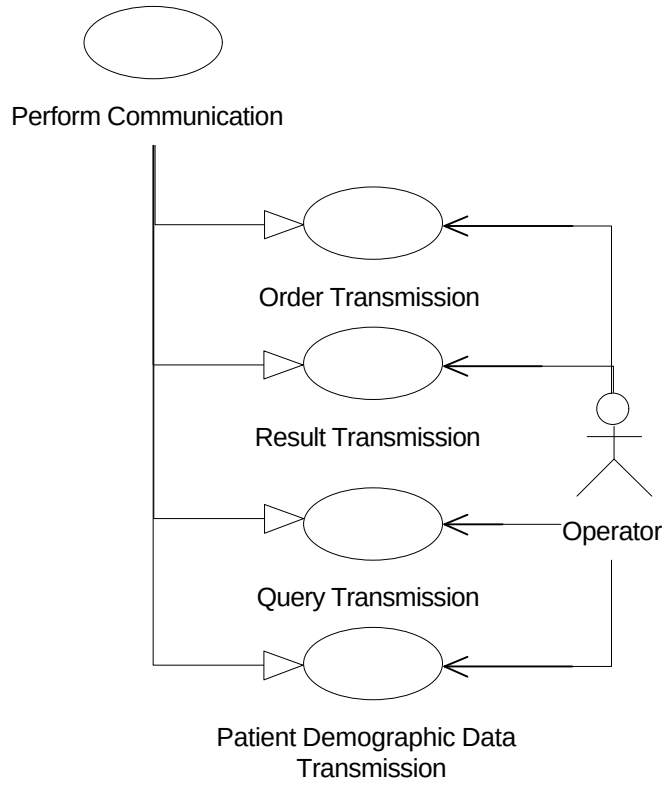
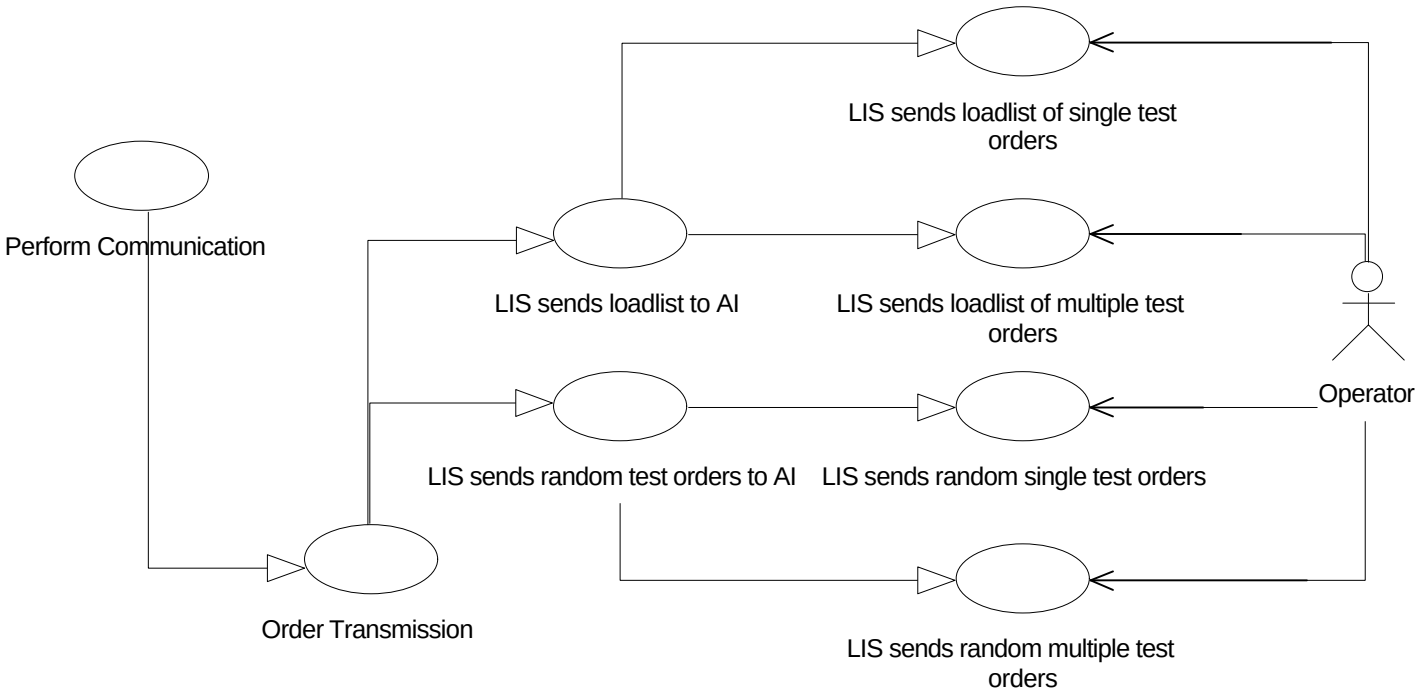


Figure 1: Organisation of Use Case Diagrams

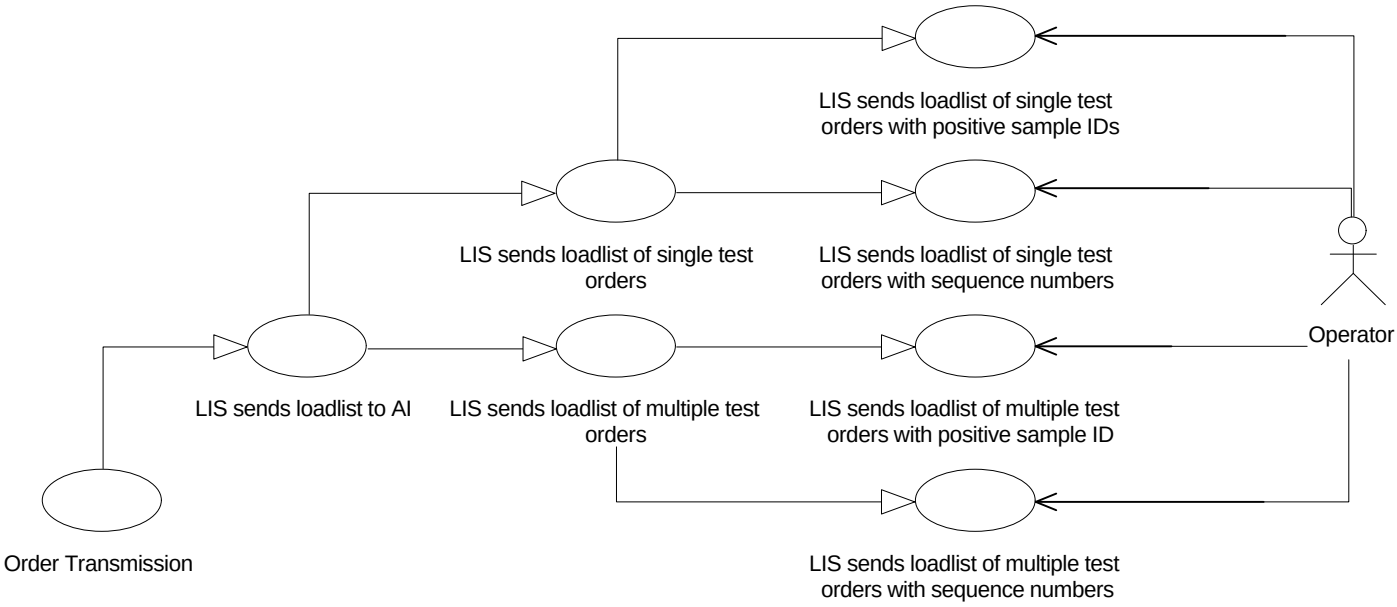
A.4.3 Use Cases: General Level



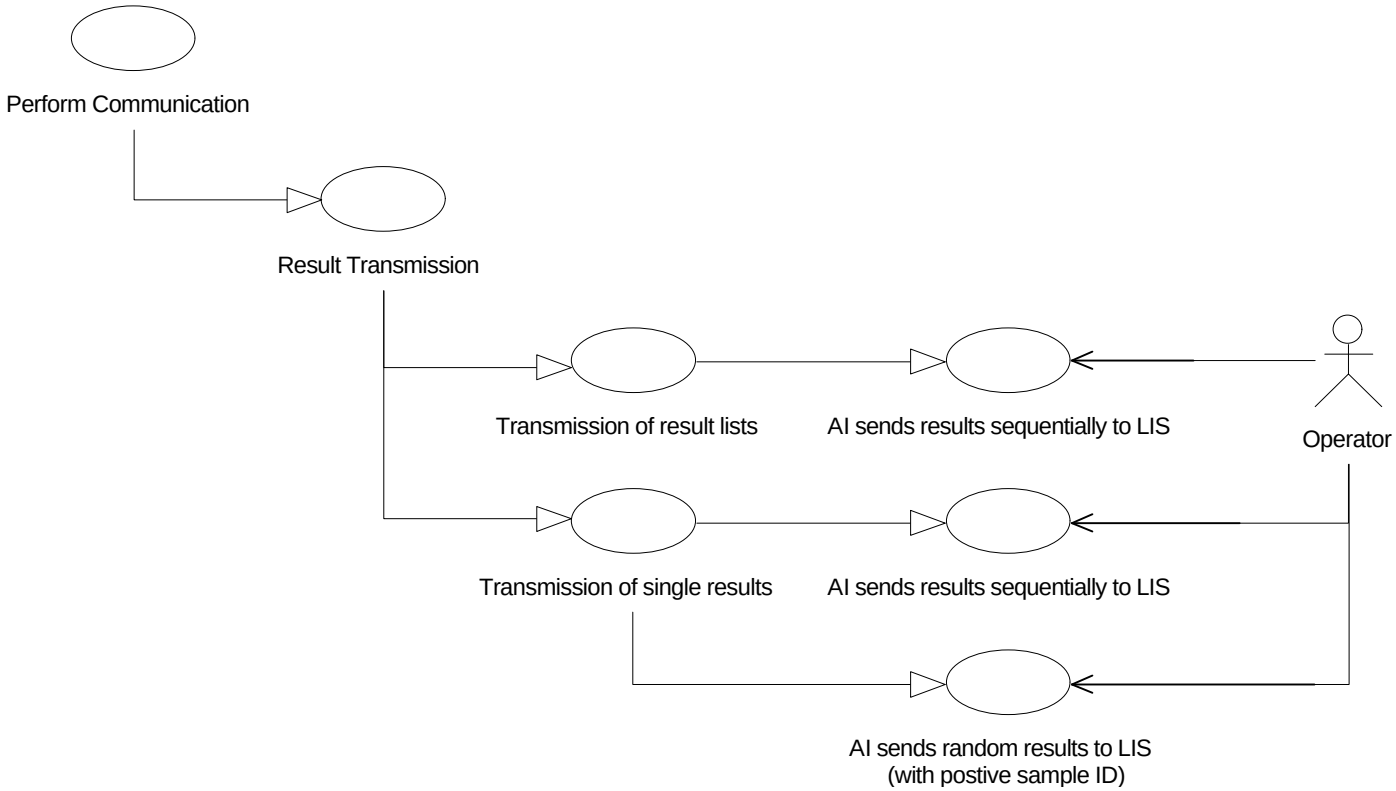
A.4.4 Use Cases: Order Transmission – Part 1



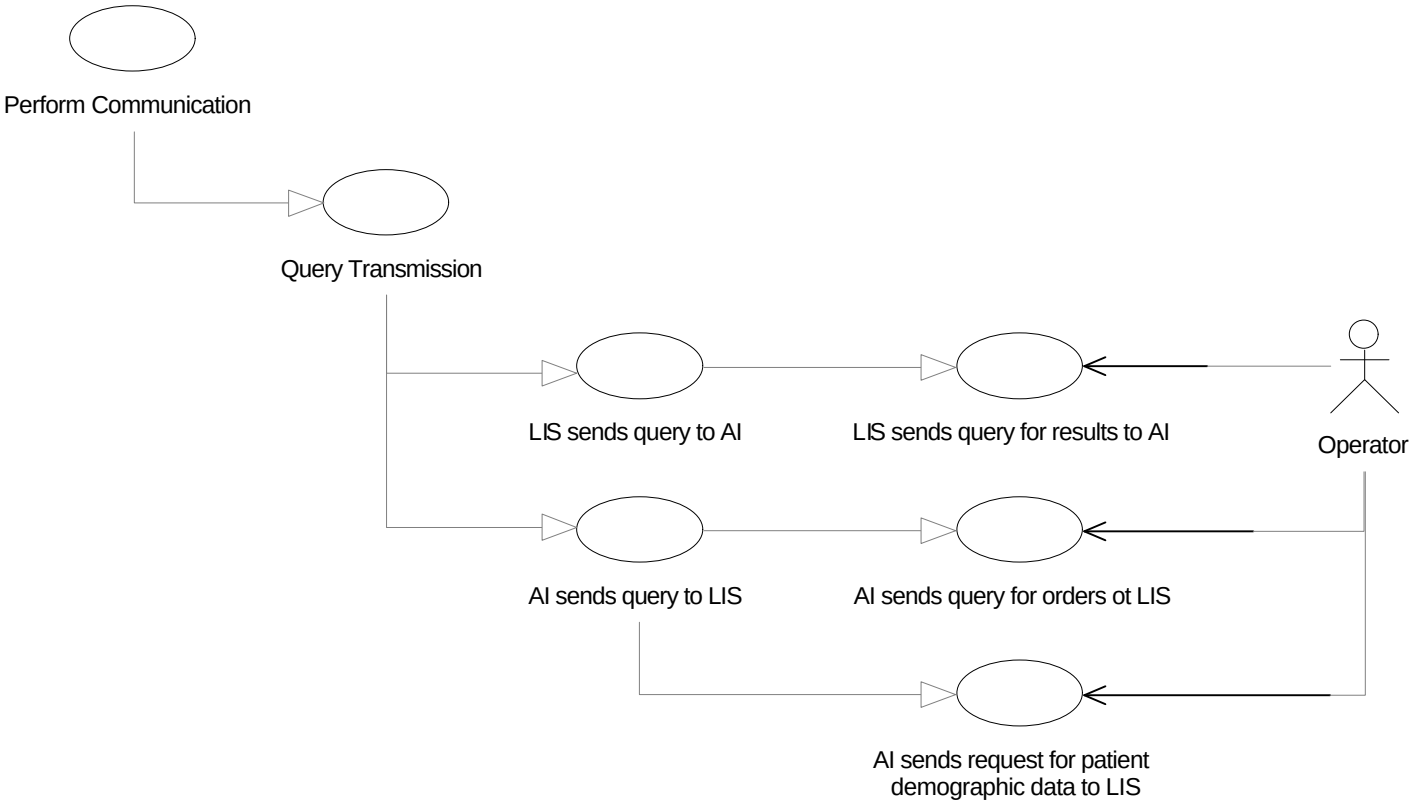
A.4.5 Use Cases: Order Transmission – Part 2



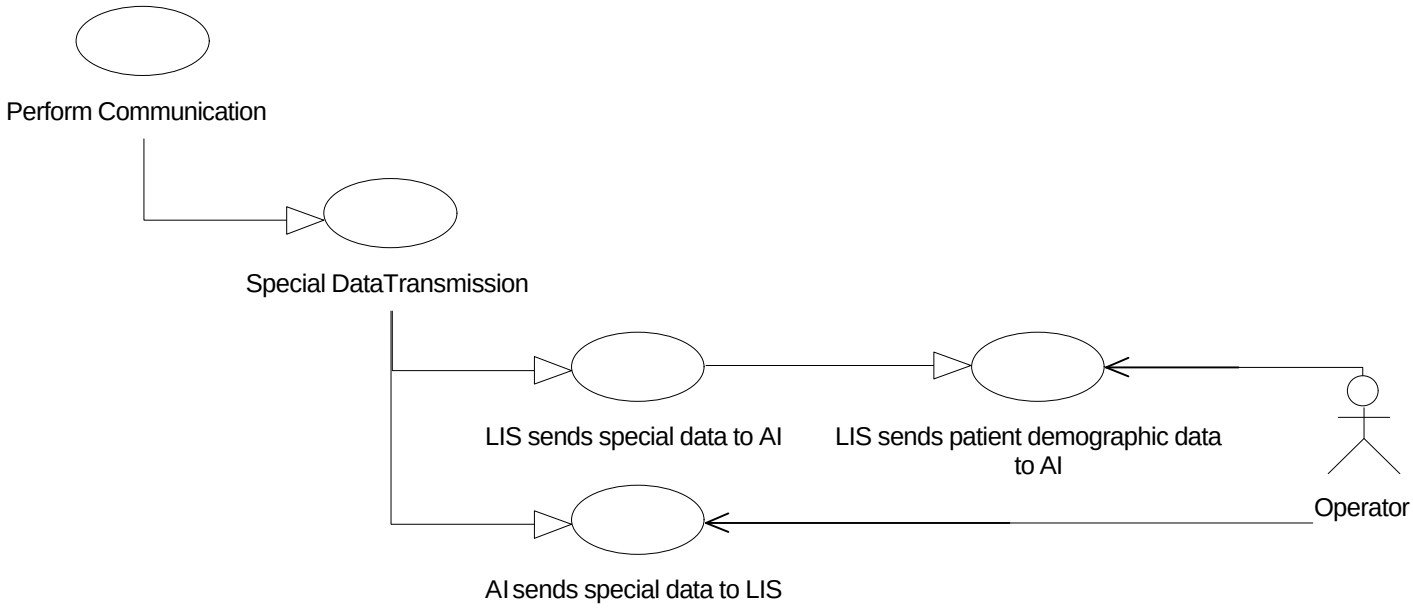
A.4.6 Use Cases: Result Transmission



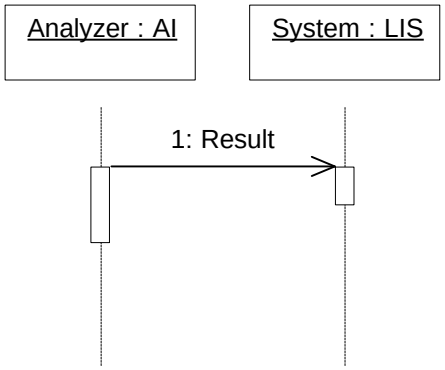
A.4.7 Use Cases: Query Transmission



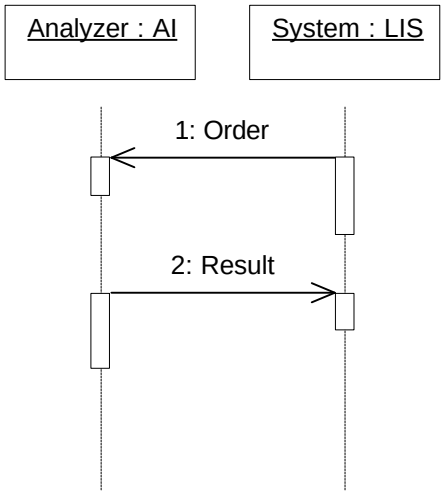
A.4.8 Use Cases: Special Data Transmission



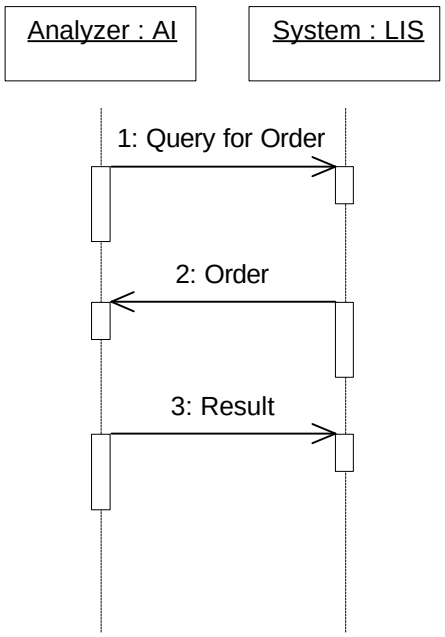
A.4.9 Sequence Diagram: Scenarios 1a/1b



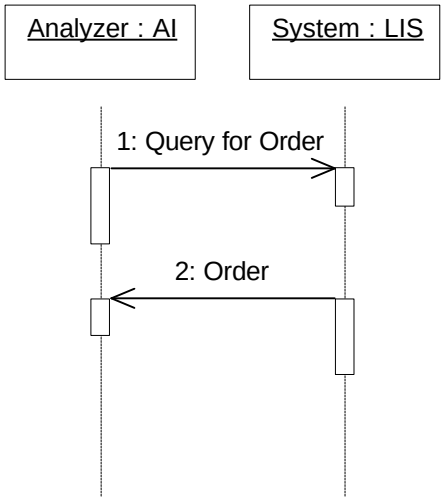
A.4.10 Sequence Diagram: Scenarios 2a/2b



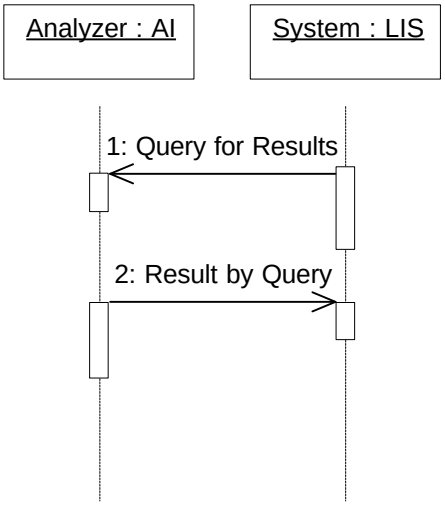
A.4.11 Sequence Diagram: Scenario 3a



A.4.12 Sequence Diagram: Scenario 3b



A.4.13 Sequence Diagram: Scenario 4



Blank page

Annex B
(informative)

Implementation guidelines

As discussed in the Introduction to this European Prestandard, different implementers interpret the same clauses of ASTM E1394 in different ways. Also, the vast choice of data items available gave 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 European Prestandard describes a number of profiles that improve this situation, but there are advantages in further explanation of the fields and records ASTM E1394. This Annex quotes all fields used in the standard and gives guidance, where appropriate on how they should be implemented.

Table 3 below deals with general considerations, e.g. common fields and formats. Table 4 to Table 12 list all ASTM records, including all fields, and give guidelines for each.

Each Table includes the following (where applicable):

ASTM ref	paragraph number in ASTM E1394
Field name	name of field in ASTM
ASTM text	text quoted from ASTM
Use type	Suggested limitations on use: mandatory (M), optional (O), deprecated (D)
Content	Suggested allowable values
Implementation Guideline	Guideline on how the field should be implemented so as to promote interworking

Table 3: Message Content - General Considerations

ASTM ref	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	

ASTM ref	Field Name	ASTM text	Implementation Guideline
		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.	

ASTM ref	Field Name	ASTM text	Implementation Guideline
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.	Use ISO 8601. Dates should be represented as YYYY-MM-DD. When times are required, these should be sent with the date as YYYY-MM-DDTHH:MM:SS. *??the use of "-" and ":" separators is not conformant with ASTM. Does this matter??*
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.	If this field is used, it should conform to the format used in Europe: Name^Street & Street No.^Postal Code^City ^Country
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	Maximum value should be limited to 32768.

ASTM ref	Field Name	ASTM text	Implementation Guideline
		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.	
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. NOTE T, P and N are covered by G and I.

733

734 **Table 4: Message Header Record**

ASTM ref	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	M	|\^&	Do not use delimiters other than |\^&. NOTE ASTM 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.

ASTM ref	Field name	ASTM text	Use Type	Content	Implementation Guideline
		second field contains the repeat, component and escape delimiters. Using the example delimiters, the first six characters in the header record would appear as follows: H | \ ^ & |.			
7.1.3	Message Control ID	This is a unique number or other ID that uniquely identifies the transmission for use in network systems that have defined 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.	O		NOTE 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.
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.	O		See 6.6.5.
7.1.7	Reserved Field	This field is currently unused but reserved for future use.	D		Do not use.
7.1.8	Sender Telephone Number	This field identifies a telephone number for voice communication with the sender as specified in 6.6.3.	O		As per ASTM. NOTE it should not be used for the telephone number of the AI manufacturer.
7.1.9	Characteristics of	This field contains any characteristics of the	D		Do not use.

ASTM ref	Field name	ASTM text	Use Type	Content	Implementation Guideline
	Sender	sender such as, parity, checksums, optional protocols, etc. necessary for establishing a communication link with the sender.			NOTE 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.
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. NOTE 1: If the field is empty or not present, P should be assumed. NOTE 2: If Q is used, all the following messages are QC-messages. NOTE 3: If T or D is used, the receiver should ignore the message. NOTE 4: See also 9.4.12.
7.1.13	Version No.	This value identifies the version level of the specification. This value is currently 1394-	O	E 1394-97	As ASTM.

ASTM ref	Field name	ASTM text	Use Type	Content	Implementation Guideline
		97			NOTE it is recommended that this field is 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 6.6.2.

735

736 **Table 5: Patient Information Record**

ASTM ref	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 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. NOTE 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.	O		As ASTM, 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. NOTE 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.	O		
8.1.6.1			O	Last Name	
8.1.6.2			O	First Name	
8.1.6.3			O	Middle Name or Initial.	

ASTM ref	Field name	ASTM text	Use Type	Content	Implementation Guideline
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. NOTE 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.	O	YYYY-MM-DD	Use ISO 8601. Age should not be used NOTE 1: see 6.6.2.
8.1.9	Patient Sex	This field shall be represented by M, F, or U.	O	M, F or U	Use ISO 5218 *??is this conformant with ASTM??*
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. NOTE 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. NOTE 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. NOTE 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	D		Do not use. NOTE 1: not necessary for the communication between the AI and LIS.

ASTM ref	Field name	ASTM text	Use Type	Content	Implementation Guideline
		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.			NOTE 2: Only ordering physician (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. NOTE no meaningful use. If there is additional information to transmit, then the standard must be changed.
8.1.16	Special Field 2	An optional text field for vendor use.	D		See 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.	O		NOTE In Europe use cm only.
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.	O		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. NOTE 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 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	D		Do not use (see 8.1.19).

ASTM ref	Field name	ASTM text	Use Type	Content	Implementation Guideline
		testing)			
8.1.22	Practice Field No. 1	A text field for use by the practice, the optional transmitted text will be returned with the results.	D		Do not use (see 8.1.19).
8.1.23	Practice Field No. 2	Same as section 8.1.22.	D		Do not use (see 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 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 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.	O		NOTE 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 8.1.19).
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	D		Do not use (see 8.1.27).

ASTM ref	Field name	ASTM text	Use Type	Content	Implementation Guideline
		separated by repeat delimiters. Individual codes can be followed by optional test descriptors (when the latter are present) and must be separated by component delimiters.			
8.1.29	Patient Religion	When needed, this value shall include the patient's religion. Codes or names may be sent as agreed upon between the sender and the receiver. Full names of religions may also be sent as required. A list of sample religious codes follows: P Protestant C Catholic M Church of the Latter Day Saints (Mormon) J Jewish L Lutheran H Hindu	D		Do not use (see.8.1.19). NOTE 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.8.1.19). NOTE 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.	D		Do not use. NOTE 1: in modern laboratory medicine, every sample should be handled like a ”dangerous” sample. If the sample is known to be a dangerous sample, then sample should be marked as such, not the data records. NOTE 2: see also 9.4.13.

ASTM ref	Field name	ASTM text	Use Type	Content	Implementation Guideline
		ARP antibiotic resistance precautions BP blood and needle precautions ENP enteric precautions NP precautions for neutropenic patient PWP precautions for pregnant women RI respiratory isolation SE secretion/excretion precautions SI strict isolation WSP wound and skin precautions			
8.1.32	Language	The value of this field indicates the patient's primary language. This may be needed when the patient is not fluent in the local language.	D		Do not use (see.8.1.19). NOTE 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 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 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	D		Do not use (see 8.1.19).

ASTM ref	Field name	ASTM text	Use Type	Content	Implementation Guideline
		to define dosage sub-groups.			

737

738 **Table 6: Test Order Record**

ASTM ref	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 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).	M		NOTE 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.	O		
9.4.5	Universal Test ID	This field shall use universal test ID as described in section 6.6.1	O		
9.4.6	Priority	Test priority codes are as follows: S - stat A - as soon as possible R - routine C - call-back	O	S or R	NOTE LISs normally only recognise two priorities. Therefore only the following should be used: S - stat (do now) R – routine.

ASTM ref	Field name	ASTM text	Use Type	Content	Implementation Guideline
		P - preoperative If more than one priority code applies, they must be separated by repeat delimiters			
9.4.7	Requested/ Ordered Date and Time	The contents of this field shall be represented as specified in 6.6.2 and will denote the date and time the test order should be considered ordered. Usually this will be the date and time the order was recorded. This is the date and time against which the priorities should be considered. If the ordering service wants the test performed at a specified time in the future, for example, a test to be drawn two days in the future at 8 pm, the future date and time should be recorded here. Note that the message header data and the future date and time should be recorded here. Further, note that the message header record date and time (see 7.1.14) indicates the time the order was transmitted to or from the instrument.	D		Do not use. NOTE 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.	O		See 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. NOTE 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	D		See 9.4.9.

ASTM ref	Field name	ASTM text	Use Type	Content	Implementation Guideline
		follow the conventions given in 6.6.4.			
9.4.11	Collector ID	This field shall identify the person and facility which collected the specimen. If there are questions relating to circumstances surrounding the specimen collection, this person will be contacted.	O		NOTE see also 9.4.17.
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.	M		If this test order is one QC order among non-QC orders then this field should b 'Q' AND field 7.1.12 should NOT be Q. If the message contains only QC orders then 7.1.12 AND 9.4.12 must be Q. Q should always be used as indicated by ASTM. 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.	O		As ASTM.
9.1.14	Relevant Clinical Information	Additional information about the specimen would be provided here and used to report information such as amount of inspired O2 for blood gasses, point in menstrual cycle for cervical pap tests or other conditions that influence test interpretations.	D		Do not use. NOTE use comment record instead

ASTM ref	Field name	ASTM text	Use Type	Content	Implementation Guideline
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. NOTE 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.	O		Note 1: Chemistry/ Haematology: Specimen ID should be specified in the universal test ID. Note 2: Microbiology: use as ASTM, 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.	O		
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).	O		
9.4.17	Ordering Physician	This field shall contain the name of the ordering physician in the format outlined in 6.6.6.	O		NOTE this should be used rather than attending Physician (8.1.14). Note 2: see also 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.	O		
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. NOTE use comment record instead.
9.4.20	Users Field No. 2	similar to 9.4.19.	D		See 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.

ASTM ref	Field name	ASTM text	Use Type	Content	Implementation Guideline
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		NOTE 1: Chemistry/ Haematology: do not use. NOTE 2: Microbiology: 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. NOTE 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. NOTE use 10.1.14 instead.
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	O		*??As ASTM??*

ASTM ref	Field name	ASTM text	Use Type	Content	Implementation Guideline
		I - in instrument pending Y - no order on record for this test (in response to query) Z - no record of this patient (in response to query) Q - response to query (this record is a response to a request-information query)			
9.4.27	Reserved Field		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. NOTE 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. NOTE 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. NOTE 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. NOTE not required by AI.

739

740 **Table 7: Result Record**

ASTM ref	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 6.6.7.

ASTM ref	Field name	ASTM text	Use Type	Content	Implementation Guideline
10.1.3	Universal Test ID		M		See 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		NOTE 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. NOTE 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	D		Do not use

ASTM ref	Field name	ASTM text	Use Type	Content	Implementation Guideline
		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.			
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 ">". NOTE other values have little or no meaning to most LISs.

ASTM ref	Field name	ASTM text	Use Type	Content	Implementation Guideline
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
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 5 - For example, when ordering a sensitivity, the computer system may download a result record containing the organism type, or species, identified in a previous test.	M		NOTE V, operator validation of result should not be done on the AI.

ASTM ref	Field name	ASTM text	Use Type	Content	Implementation Guideline
		Q - this result is a response to an outstanding query V - operator verified/approved result W - warning: validity is questionable			
10.1.10	Date of Change in Instrument Normative Values or Units	This field shall remain empty if there are no relevant normals or units. Otherwise, it shall be represented as in 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.	O		See 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		NOTE operator validation of result should not be done on the AI.
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.	O		See 6.6.2.
10.1.13	Date/Time Test Completed	Date and time the instrument completed the test results being reported. Date and times should be reported as specified in 6.6.2.	O		See 6.6.2.
10.1.14	Instrument identification	Identifies the instrument or section of instrument that performed this particular measurement	O		NOTE if this field is not used, the AI ID should be carried in 7.1.5.

741

742 **Table 8: Comment Record**

ASTM ref	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 6.6.7.
11.1.4	Comment Text	Where comment codes/mnemonics are	M	Free text or	Do not use more than two components. Repeats are not

ASTM ref	Field name	ASTM text	Use Type	Content	Implementation Guideline
		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.		code^text	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. NOTE T, P and N are covered by G and I.

743

744 **Table 9: Request Information Record**

ASTM ref	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 6.6.7.
12.1.3	Starting Range ID Number		M		
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	O		Use 12.1.3.1 or 12.1.3.2.

ASTM ref	Field name	ASTM text	Use Type	Content	Implementation Guideline
		to separate IDs.			
12.1.3.2		When ALL is entered, and the computer system is sending the request record, it is taken to mean all specimen results ordered by the inquiring system. If the instrument is generating the request record, then it is taken to mean all demographics and tests being ordered should be sent to the instrument at this time. The request is then interpreted for that identified subset of specimens as further modified by the test specifications and date ranges as described below.	O		Use 12.1.3.1 or 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 describes in 12.1.6 and 12.1.7	O		See 6.6.1. NOTE ALL means all tests.

ASTM ref	Field name	ASTM text	Use Type	Content	Implementation Guideline
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. NOTE not used by any known AI.
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.

ASTM ref	Field name	ASTM text	Use Type	Content	Implementation Guideline
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		"D" should not be used.

745

746 **Table 10: Message Terminator Record**

ASTM ref	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 6.6.7.
13.1.3	Termination Code	Provides explanation of end of session. Nil, N - normal termination T - sender aborted	M		N (normal) - use as ASTM T should not be used.

ASTM ref	Field name	ASTM text	Use Type	Content	Implementation Guideline
		R - receiver requested abort E - unknown system error Q - error in last request for information I - no information available from last query F - last request for information processed Note 7 - F, I, or Q will terminate a request and allow processing of a new request record.			

747

748 **Table 11: Scientific Record**

ASTM ref	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. NOTE Not necessary for AI-LIS communication and difficult to standardise, therefore should not be used in a standard interface.

749

750 **Table 12: Manufacturer Information Record**

ASTM ref	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. NOTE Not necessary for AI-LIS communication and difficult to standardise, therefore should not be used in a standard interface.

751