BA 400 LIS PROTOCOL SPECIFICATION

LIS2-A2 (ASTM) + HL7

TABLE OF CONTENTS

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

1 Introduction

1.1 Purpose

This document specifies the interface protocol that provides BA 400 system to a Laboratory Information Systems (LIS) software application. This interface forms the basis for the exchange of healthcare information between BA 400 instrument and outside LIS, e.g., receiving laboratory orders and generating laboratory results information.

This document is intended to be a guide for implementing the protocol to communicate to BA 400 instrument. In this guide, you will find detailed information of all the data that can be exchanged between BA 400 and a Laboratory Information System (LIS).

1.2 Overview

The BA 400 supports two different messaging workflows or protocols:

- **HL7 implementation based on the recommendation described on the IHE Technical Framework Laboratory Analytical Workflow Profile (IHE-LAW) v1.1.**[1] The implementation of the HL7 protocol is compliant with the rules defined for IHE regarding the LAW Profile version 1.1. In those cases where the Profile describes optional behaviour the one chosen by the implementation is described.
- **Traditional LIS2-A2 (formerly ASTM 1394) protocol.** The implementation of the LIS2-A2 protocol is compliant with the LIS2-A2 and LIS1-A2 communications standard.

This document intends to be descriptive enough for not requiring the reading of the IHE LAW specifications document or the LIS2-A2/LIS01-A2 specifications document.

1.3 Definitions and Acronyms

Acronym	Definition
ANSI	American National Standards Institute (www.ansi.org)
ASCII	American Standard Code for Information Interchange
ASTM	American Society for Testing and Materials (www.astm.org)
HL7	Health Level Seven (www.hl7.org)
IHE	Integrating the Healthcare Enterprise (www.ihe.net)
LAW	Laboratory Analytical Workflow
LIS	Laboratory Information System
LIS2-	Communication Protocol (High Level)

[1] For those LIS which they are not able to be fully IHE-LAW compliant, the instrument offers a relaxed version of the protocol

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

LIS1A	Communication Protocol (Low Level)
OSI	Open System Interconnection
QC	Quality Control
TBC	To be completed
TBD	To be defined
UTF	Unicode Transformation Format

1.4 References

[1]	NCCLS, NCCLS document LIS2-A2. Specification for Transferring Information Between Clinical Laboratory Instruments and Information Systems; Approved Standard - Second Edition, 2004.
[2]	CLSI, CLSI document LIS01-A2. Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory instruments and Computer Systems; Approved Standard-Second Edition, 2008.
[3]	IHE Laboratory Technical Committee, «IHE Laboratory Technical Supplement - Laboratory Analytical Workflow (LAW) v1.1,» March 9, 2012.

1.5 Background and Terminology

This document covers the exchange information between BA 400, acting as Analyzer, and an Analyzer Manager (typically a LIS). In this context data transmission from BA 400 to a LIS is called download and data transmission from BA 400 system to a LIS is called upload.

Since the HL7 implementation is based on IHE-LAW Profile, some concepts specific to this profile shall be noted:

- **AWOS**. **Analytical Work Order Step**. A Work Order Step in the LAW profile, representing a test or panel to be performed on a specimen by an Analyzer, producing observations.
- **Battery**. A set of one or more laboratory tests, identified by a single name and code, that can be ordered to a laboratory. Synonym: Panel.
- **Order**. A battery or test ordered by a ward and/or a physician to a laboratory, to be performed on one or more specimens collected from a patient.
- **Order Filler**. A system which manages orders on the laboratory side.
- **Order Group**. Also called the “Laboratory Request”: A set of orders placed together by a ward and/or a physician to one or more laboratories for a patient, to be performed on one or more specimens collected from this patient.
- **Order Placer**. A system that generates, places and manages orders.
- **Panel**. Synonym for Battery.
- **Work Order**. The testing of a battery or a test requested by the Order Filler to the Analyzer Manager.

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

- **WOS. Work Order Step**. A battery or test requested by the Analyzer Manager to the Analyzer.

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

2 Physical Layer

BA 400 interface is TCP/IP based. Depending on the protocol used, a different usage of the TCP/IP Sockets is performed.

2.1 LIS01-A2 (ASTM)

For LIS01-A2, a TCP/IP connection will be established during system start-up and maintained permanently as long as the system is up.

BA 400 supports two configurable modes of operation:

- TCP/IP-Server (LIS as Client).
- TCP/IP-Client (BA 400 as Client).

2.2 HL7

The HL7 2.5 standard does not define a network communications protocol. In this implementation the Minimal Lower Layer Protocol is required (See Section 3.2).

For compatibility with IHE-LAW profile and other HL7 implementations, two modes of operations are supported.

- A TCP/IP connection will be established during system start-up and maintained permanently as long as the system is up. BA 400 supports two configurable modes of operation:
  - TCP/IP (LIS as Client).
- TCP/IP-Transitory Connection. Two TCP/IP connections will be used:
  - When BA 400 wants to initiate a conversation, a network connection is initiated (a socket is opened to the LIS IP and port). The messages related to that conversation are sent and received through this socket. In the conversation ends the socket is closed by any of the peers.
  - When the LIS wants to initiate a conversation, a network connection is initiated (a socket is opened, a socket is opened from the LIS to BA 400 IP and port). The messages related to that conversation are sent and received through this socket. If the conversation ends the socket is closed by any of the peers.

Please refer to BA 400 configuration manual for information on how to configure either of the two modes.

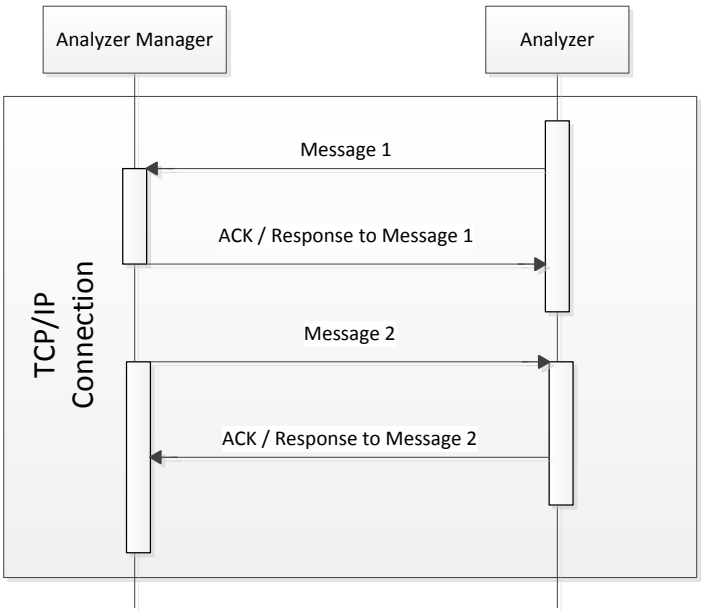
The two modes are illustrated in the following figure:

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

Single TCP/IP Connection:

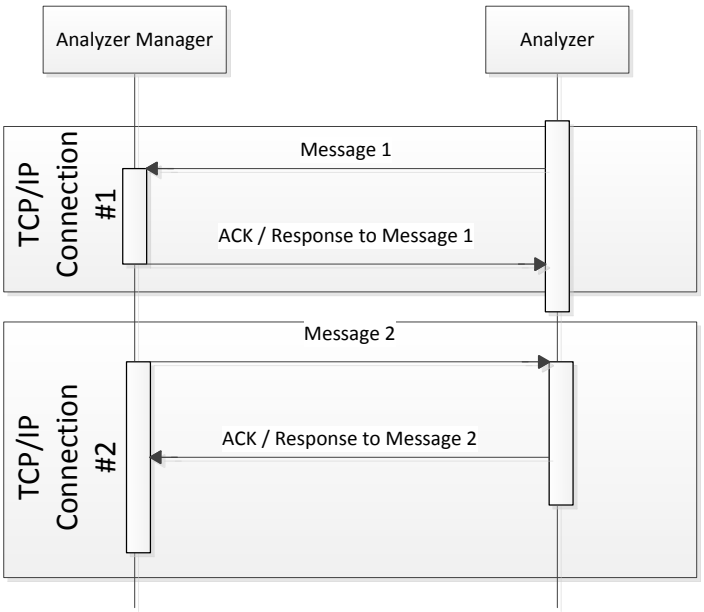


Where the connection is configured as follows:

- One actors will be the TCP/IP server and which one the TCP/IP client. This decision does not affect the message flow. In any case, the connection is open between the LIS and the Analyzer. The messages are sent from one to the other in sequence, using always the same connection. Usually this connection is open permanently as long as both systems are online.

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

Double TCP/IP Connection:



Where the connections are configured as follows:

- TCP/IP Connection #1. The LIS listens to a specific TCP port. The Analyzer connects to the LIS IP Address and port. The Analyzer opens the connection, sends the Message 1 and waits for the response. The LIS answers backs using the same connection. The connection is closed once the response message has been received by the Analyzer or in case of timeout waiting for the response message.
- TCP/IP Connection #2. The Analyzer listens to a specific TCP port. The LIS connects to the Analyzer IP Address and port. It follows the same flow as the previous one, except that in this case the initiator is the LIS and the receiver is the Analyzer.

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

3 Transport Layer

This is the Lower Layer Protocol used to communicate with the LIS. The following chapters are dedicated to explain the message structure and content.

3.1 Background

The data link layer has procedures for connection establishment and release, delimiting and synchronism, sequential control, error detection and error recovery. The application messages passed from the upper layer are framed and then transmitted. The frames received are packaged and then passed to the upper layer.

The Data Link Layer protocols supported by BA 400 are:

- Minimal Lower Layer Protocol (MLLP) when using HL7 protocol.
- LIS01-A2, when using LIS2-A2 as the high level protocol.

3.2 Minimal Lower Layer Protocol

The goal of the MLLP Message Transport protocol is to provide an interface between the Application and the transport protocol that uses minimal overhead. MLLP is based on a minimalistic OSI-session layer framing protocol. It is assumed that MLLP will be used only in a network environment. Most of the details of error detection and correction are handled by the lower levels of TCP/IP transport protocol and do not require any supplementation.

Message content is enclosed by special characters to form a Block. The Block format is as follows: *<SB>dddd<EB><CR>*

- **<SB>**: Start Block character (1 byte). ASCII <VT>: <0x0B>.
- **dddd**: Data (variable number of bytes). This is the data content of the Block. The data can contain any UTF-8 character values greater than 0x1F and the carriage return character, <CR>.
- **<EB>**: End Block character (1 byte). ASCII <FS>: <0x1C>.
- **<CR>**: Carriage Return (1 byte). ASCII <CR> character: <0x0D>.

In pseudo BNF-notation the Content Block Format is as follows: *Content-Block = SB, dddd, EB, CR.*

dddd = (printableChar | CR)-sequence.
printableChar = 0x20 | 0x21 | 0x22 | .. | 0xFF.
SB = 0x0B.
EB = 0x1C.
CR = 0x0D.

3.3 LIS01-A2

3.3.1 Overview

This standard uses a character-oriented protocol to send messages between directly connected systems. The coding is the ANSI X3.4-1986 and some restrictions are placed on the characters that can appear in the message content.

The data link mode of operation is a one-way transfer of information with alternate supervision. Information flows in one direction at a time. Replies occur after information is sent, never at the same time. It is a simple stop-and-wait protocol. The sender and receiver use timeouts to detect the loss of coordination between them and provide a method for recovery the communication.

The two systems operate actively to transfer information. The remainder of the time the data link is in a *Neutral State*. There are three phases involved in the transmission of message frames:

- **Establishment Phase** (or Link Connection). Determines the direction of information flow and prepares the receiver to accept information.
- **Transfer Phase** in which the sender transmits messages to the receiver using frames.
- **Termination Phase** in which the link is released and the sender notifies the receiver that all messages are sent.

3.3.2 Establishment Phase (Link Connection)

3.3.2.1 Operation

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

The system with information available, the sender, initiates the establishment phase to notify the receiver that information is available.

A system that does not have information to send monitors the data link to detect the *Establishment Phase*. It acts as a receiver, waiting for the other system.

The sequence is as follows:

1. The sender determines that the data line is in a *Neutral State*.
2. The sender sends the **<ENQ>** transmission control character to the receiver. Sender will ignore all responses other than **<ACK>**, **<NAK>** or **<ENQ>.**
3. At this point, there are two cases:
   a. If the receiver is prepared to receive data, it responds with the **<ACK>** character to the sender. The link connection is established, entering the *Transfer Phase*.
   b. If the receiver is not ready to receive data it responds with the **<NAK>** character. Upon receiving a **<NAK>,** the sender shall wait at least **10 seconds** before transmitting another **<ENQ>** transmission control character.

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

3.3.2.2 Contention

When the two systems simultaneously transmit **<ENQ>** the data link is in *contention*. In such cases, the device has priority.

So, when an **<ENQ>** is received in response to an **<ENQ>**, the situation is solved as follows:

- The system with priority waits at least **1 second** before sending another **<ENQ>**.
- The system without priority must stop trying to transmit and prepare to receive. When the next **<ENQ>** is received it replies with an **<ACK>** or **<NAK>** depending on its readiness to receive.

3.3.3 Transfer Phase

During the *Transfer Phase*, the sender shall transmit messages to the receiver until all messages are sent.

3.3.3.1 Frames

Messages are sent in frames, each frame contains a maximum of 64000 bytes (including frame overhead).

Messages longer than 64000 bytes are divided between two or more frames.

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

A frame is one of two types: the *Intermediate Frame* (IF) and the *End Frame* (EF). Their only difference relies on one transmission control character, but they are semantically different (see below for details).

Intermediate frame <STX> FN Text **<ETB>** C1 C2 <CR> <LF>
End frame <STX> FN Text **<ETX>** C1 C2 <CR> <LF>
The last frame of a message always is an *End Frame*. All previous frames are sent as *Intermediate Frames*.

A message containing 64000 bytes or less is sent in a single *End Frame*.

Longer messages are sent in intermediate frames with the last part of the message sent in an end frame.

A brief description for every part of a frame is given in the table below:

Frame Part	*Frame Part Description*
<STX>	Start of Text transmission control character
FN	Frame Number (single digit comprised in the range 0-7) – See details in section Frame Number
Text	Data content of Message
<ETB>	End of Transmission Block transmission control character
<ETX>	End of Text transmission control character
C1	Most significant character of checksum (belonging to {0-9, A-F}) –

BioSystems
Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

	See details in section Checksum
C2	Least significant character of checksum (belonging to {0-9, A-F}) – See details in section Checksum
<CR>	Carriage Return ASCII character
<LF>	Line Feed ASCII character

3.3.3.2 Frame number

The frame number (FN) permits the receiver to distinguish between new and retransmitted frames.

The frame number begins at 1 with the first frame of the Transfer phase (see below). The frame number is incremented by one for every new frame transmitted. After 7, the frame number rolls over to 0, and continues in this fashion.

3.3.3.3 Checksum

The checksum permits the receiver to detect a defective frame. The checksum is encoded as two characters.

The checksum is computed by adding the binary values of the characters, and keeping the least significant eight bits of the result. It is an addition module 256.

The checksum is initialized to zero with the <STX> character. The checksum computation uses the FN, all characters belonging to Text and <ETB> or <ETX>. The computation for the checksum does not include <STX>, the checksum characters, or the trailing <CR> and <LF>.

The checksum is an integer of eight bits, and can be considered as two groups of four bits. Both groups of four bits are converted to the ASCII characters of the hexadecimal representation, and transmitted as the message checksum.

Example: A checksum of 89 can be represented as 01011011 in binary or 5B in hexadecimal. The checksum is transmitted as the ASCII character 5 followed by the ASCII character B.

3.3.3.4 Acknowledgements

After a frame is sent, the sender stops transmitting until a reply is received (stop-and-wait protocol). The receiver can reply to each frame in three ways:

- A reply of <ACK> means the last frame was successfully received and the receiver is ready to receive the next one. The sender must send a new frame or terminate.
- A reply of <NAK> signifies the last frame was not successfully received and the receiver is prepared to receive the frame again.
- A reply of <EOT> means the last frame was successfully received, but the receiver requests the sender to stop transmitting.

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

This reply must be transmitted within the timeout period specified in the timeouts section.

3.3.3.5 Receiver Interrupts

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

If the sender chooses to ignore the <EOT>, the receiver must re-request the interrupt for the request to remain valid.

If the sender chooses to honor the <EOT>, it must first enter the termination phase to return the data link to the neutral state. The original sender must not enter the establishment phase for at least 15 seconds or until the receiver has sent a message and returned the data link to the neutral state.

BA 400 usage: BA 400 shall ignore the interrupt request. The instrument system ignores the <EOT> until the message transmission is completed. If the instrument system receives and <EOT> as an answer to the last frame, it waits 15 seconds until it goes to the establishment phase.

3.3.4 Termination Phase (link release)

The *Termination Phase* returns the data link to the neutral state. The sender initiates the *Termination Phase* by transmitting the **<EOT>** character and then regards the line to be in the *Neutral State*. After receiving the **<EOT>** the receiver also regards the line to be in the neutral state.

3.3.5 Error Recovery

3.3.5.1 Defective frames

A receiver checks every frame to guarantee it is valid. A reply of <NAK> is transmitted for invalid frames. Upon receiving the <NAK>, the sender retransmits the last frame with the same frame number.

A frame should be rejected because take place some of the following situations:

- Any character errors are detected (parity errors, framing error…).
- The frame checksum does not match the checksum computed on the received frame.
- The frame number is not the same as the last accepted frame or one number higher (modulo 8).
- There are invalid characters in the message body.

Any characters occurring before <STX> or <EOT>, or after the end of the block characters (<ETB> or <ETX>), are ignored by the receiver when checking for frame validity.

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

Every time the sender tries to transmit a particular frame, and receives a <NAK> or any other character different from <ACK> or <EOT> (a <NAK> condition), a retransmission counter for the given frame is increased. If this counter shows a single frame was sent and not accepted six times, the sender must abort this message by proceeding to the termination phase.

3.3.5.2 Timeouts

The sender and the receiver use timers to detect loss of coordination between them:

- During the establishment phase, the sender sets a timer when transmitting the <ENQ>. A timeout occurs if a reply of an <ACK>, <NAK> or <ENQ> is not received within 15 seconds. After a timeout, the sender enters the termination phase.
- During the establishment phase, if the system without priority detects contention, it sets a timer. If the subsequent <ENQ> is not received within **20 seconds**, it will regard the line to be in the neutral state.
- During the transfer phase, the sender sets a timer when transmitting the last character of a frame. If the reply is not received within **15 seconds**, a timeout occurs. After a timeout, the sender aborts the message transfer by proceeding to the termination phase.
- During the transfer phase, the receiver sets a timer when first entering the transfer phase or when replying to a frame. If a frame or an <EOT> is not received within 30 seconds, a timeout occurs. After a timeout, the receiver discards the last incomplete message and regards the line to be in the neutral state.
- A receiver must reply to a frame within **15 seconds** or the sender will timeout.

3.3.6 Valid Characters in the Text part

The data link protocol is designed for sending character based message text. There are restrictions on which characters may appear in the message text. These restrictions make it simpler to recognize frames, replies and avoid interfering with software controls for devices.

The restricted characters are: **<SOH>, <STX>, <ETX>, <EOT>, <ENQ>, <ACK>, <DLE>, <NAK>, <SYN>, <ETB>, <LF>, <DC1>, <DC2>, <DC3>** and **<DC4>.**

3.3.6.1 Checking channel status

To test the connection, the BA400 transmits the ASCII <ENQ> transmission control character, decimal value 5. If the receiving system responds within fifteen seconds with one of the following:

- The ASCII <ACK> transmission control character, decimal value 6,
- The ASCII <NAK> transmission control character, decimal value 21, or
- <ENQ>.

The instrument system enters the Termination phase and the result of the connection test is success. If the instrument system does not receive one of the above responses within 15 seconds, the instrument system enters the Termination phase and the result of the connection test is failure.

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

4 Message Layer

Messages consist of a hierarchy of records of various types. A record can be defined as an aggregate of fields describing one aspect of the complete message. A field can be seen as a specific attribute of a record, which may contain aggregates of data elements further refining the basic attribute.

4.1 Notation

Each message is defined in special notation that lists the record (for LIS2-A2) / segment (for HL7) in the order they would appear in the message.

Braces, { . . . }, indicate one or more repetitions of the enclosed group of segments. Of course, the group may contain only a single segment.

Brackets, [. . .], show that the enclosed group of segments is optional. If a group of segments is optional and may repeat it should be enclosed in brackets and braces, [{...}]

4.2 Message length

The standard does not impose a maximum record length. Outgoing messages can be of any size.

4.3 Records/Segments

Both LIS2-A2 and HL7 protocols organize the information in records or segments. Each of them is responsible of carrying some type of information within the message

4.3.1 LIS2-A2 Records

In LIS2-A2 the records have a hierarchical relationship. The hierarchy of records is composed by several levels. The record types allowed in each hierarchy level, and the hierarchical dependencies between record types, are showed below.

Level 0 records	*Level 1 records*	*Level 2 records*	*Level 3 records*	*Level 4 records*
Message Header (H)				
	Comment (C)			
	Request Information (Q)			
		Comment(C)		
	Patient Information (P)			
		Comment (C)		
		Test Order (O)		
		Comment (C)		
			Result (R)	
				Comment (C)
Message Terminator (L)				

Due to the use of this hierarchical structure, some rules have been established:

- A message shall be always headed by a message header record (H), and finished by a message terminator record (L).
- An order record (O) may never appear without a preceding patient information record (P).
- A result record (R) may never appear without a preceding order record (O).
- Comment records (C) may be inserted at any level in the hierarchy (except after a Message Terminator), and it refers to the prior higher-level record.

An example of a message structure and content, according to the records hierarchy described before, is the following:

```
(Level 0)       MESSAGE HEADER
(Level 1)               PATIENT_1
(Level 2)                       COMMENT_1
(Level 2)                       ORDER_1
(Level 3)                               COMMENT_1
(Level 3)                               RESULT_1
(Level 3)                               RESULT_2
(Level 4)                                       COMMENT_1
(Level 4)                                       COMMENT_2
                                        .
                                        .
(Level 3)                               RESULT_N
(Level 2)                       ORDER_2
(Level 3)                               RESULT_1
(Level 3)                               RESULT_2
                                        .
                                        .
(Level 3)                               RESULT_N
                                .
                                .
(Level 2)                       ORDER_N
```


Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

(Level 3)		RESULT_1
		.
		.
(Level 1)	PATIENT_2	
	.	
	.	
(Level 1)	PATIENT_N	
(Level 0)	MESSAGE TERMINATOR	

A sequence of patient information records, order records, or result records at one level, is terminated by the appearance of a record type of the same or higher level.

4.3.2 HL7 Segments

A message is the atomic unit of data transferred between systems. It is comprised of a group of segments in a defined sequence. Each message has a message type that defines its purpose. A three-character code contained within each message identifies its type.

The real-world event that initiates an exchange of messages is called a trigger event. These events (a three letter code) represent values such as 'A patient is admitted' or 'An order event occurred'. There is a one-to-many relationship between message types and trigger event codes. The same trigger event code may not be associated with more than one message type; however a message type may be associated with more than one trigger event.

A segment is a logical grouping of data fields. Segments of a message may be required or optional. They may occur only once in a message or they may be allowed to repeat. Each segment is given a name. For example, the ADT message may contain the following segments: Message Header (MSH), Event Type (EVN), Patient ID (PID), and Patient Visit (PV1). Each segment is identified by a unique three-character code known as the Segment ID.

4.4 Fields

4.4.1 Structure

A field can be seen as a specific attribute of a record, which may contain aggregates of data elements further refining the basic attribute. There are two kinds of aggregates within a message, the repeat field and the component field. HL7 specifications adds another level of detail, the subcomponent field

Repeat field – a single data element that expresses a duplication of the field definition. Each element of a repeat field is to be treated as having equal priority to associated repeat fields.

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

Component field – single data element or data elements that express a finer aggregate or extension of data elements, which precede it.

Subcomponent field (HL7 only) – an even finer aggregate or extension of data expressed in a component.

Example: A patient's name is recorded as last name, first name, and middle initial, each of which is separated by a component delimiter.

4.4.2 Lengths

The standard does not impose a maximum field length, and assumes that all fields are variables in length. The instrument system implementation restricts the maximum field length to a concrete value depending on the field, but never uses more characters than required by the given field value (according to the standard).

Example: For a ten characters length field, only ten characters space will be used in the message to allow the field content, delimiters space apart.

4.4.3 Character codes

All data is represented as eight bit values and single-byte as defined in ISO 8859-1:1987. The eight-bit values within the range from 0 to 127 of ISO 8859-1:1987 correspond to the ASCII standard character set (ANSI X3.4-1986). Values between 128 and 255 are undefined by this standard and are sent using the codepage specified in the instrument system configuration. The use of different codepages allows characters from different cultures to be exchanged without problems. Other characters not represented using the specified codepage are sent escaped using UTF-16 as described in 4.4.6.

Allowed characters in the message: **9, 13, 32-126, 128-254**

Disallowed characters in the message: **0-8, 10-12, 14-31, 127, 255**

The Latin-1 character 13 is reserved as the record terminator.

Although ISO 8859-1:1987 is the character set used by the standard to encode the message sets can be used. The message carry on the header record the character set used to encode the message.

4.4.4 Data Types

Data type is the basic building block used to restrict the contents of a data field. There are differences between LIS2-A2 and HL7 data types. In fact, HL7 types are much more restrictive than LIS2-A2 types. These are the data types in the messages used by the instrument system.

LIS2-A2 Data Types used		
Name	***Description***	***Default Length***
String	String. Can have a maximum length	
Numeric	Number coded as string. Can have a maximum and minimum value.	

LIS2-A2 Data Types used		
LIS2-A2 Date	Timestamp (Date and Time) YYYYMMDD[HHMMSS]	14

HL7 Data Types used		
Name	***Description***	***Default Length***
ST	String. Can have a maximum length	
NM	Numeric. Formatted with English	
HD	System identifier. Coded as string (can have several components)	
ID	Identifier. Coded as string with a limited number of valid values.	
TS	Timestamp (Date and Time) YYYYMMDD[HHMMSS]	14
SI	Sequence Integer. Positive integer.	4
MSG	Message Type. Composed by two or three strings that identifies a HL7 message	

4.4.5 Delimiters

4.4.5.1 Types

Delimiters are used to establish separate sections within a message. There are five different delimiters.

- Record delimiter: It signals the end of any of the defined record types. It is fixed to carriage return character Latin-1 (13) (ASCII 13).
- Field delimiter: It is used to separate adjacent fields. It is configurable, and is specified in the message header record. It shall be a single character excluding Latin-1 (13) (ASCII 13).
- Repeat delimiter: Used to separate variable number of descriptors for fields containing parts of equal members of the same set. It is configurable, and is specified in the message header record. It shall be a single character, excluding Latin-1 (13) (ASCII 13) and the value used by the field delimiter.
- Component delimiter: It is used to separate data elements of fields of a hierarchical or qualifier nature. It is configurable, and is specified in the message header record. It shall be a single character, excluding Latin-1 (13) (ASCII 13), the value used by the field delimiter and the value used by the repeat delimiter.
- Subcomponent delimiter (HL7 only): Separates adjacent subcomponents of data fields where allowed. If there are no subcomponents, this character may be omitted.
- Escape delimiter: Used within text fields to signify special case operations. It is configurable, and is specified in the message header record. It has a complex structure, but mainly use a single character. The chosen character shall be different from Latin-1 (13) (ASCII 13) and the field, repeat, and component delimiter values.

4.4.5.2 Considerations

Alphanumeric characters should not be used as delimiters, according to the standard. The instrument system implementation allows the use of the following characters as delimiters. (Boundary values are also included)

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

- Any value from ASCII (33) to ASCII (47)
- Any value from ASCII (58) to ASCII (64)
- Any value from ASCII (91) to ASCII (96)
- Any value from ASCII (12) to ASCII (126)
-

The instrument system default delimiters are the following set for ASTM:

• Field delimiter – vertical bar	(|) Latin-1 (124)	(ASCII 124)
• Repeat delimiter – backslash	(\ ) Latin-1 (92)	(ASCII 92)
• Component delimiter – caret	(^) Latin-1 (94)	(ASCII 94)
• Escape delimiter	(&) Latin-1 (38)	(ASCII 38)

The instrument system default delimiters are the following set for HL7:

• Field delimiter – vertical bar	(|) Latin-1 (124)	(ASCII 124)
• Component delimiter – caret	(^) Latin-1 (94)	(ASCII 94)
• Repeat delimiter – tilde	(~) Latin-1 (126)	(ASCII 126)
• Escape delimiter – backslash	(\ ) Latin-1 (92)	(ASCII 92)
• Subcomponent delimiter	(&) Latin-1 (38)	(ASCII 38)

Fields shall be identified by their position, obtained by counting field delimiters from the front of the record. This position-sensitive identification procedure requires that when the contents of the field are null, its corresponding field delimiter must be included in the record to ensure that the field can be found by counting (i-1) delimiters. Delimiters are not included for trailing null fields.

Ex:

For ASTM: |\^&

For HL7: |^~\&

The following escape sequences are pre-defined.

• \H\ (*)	start highlighting text
• \N\ (*)	normal text (end highlighting)
• \F\	embedded field delimiter character
• \S\	embedded component field delimiter character
• \R\	embedded repeat field delimiter character
• \E\	embedded escape delimiter character
• \T\	embedded subcomponent delimiter character (HL7 only)
• \Xhhhh\	hexadecimal data See §4.4.6 for more information
• \Zcccc\	Local defined escape sequences, used to send characters not represented in the configured codepage. See §4.4.7 for more information.

No escape sequence contains a nested escape sequence, according to the standard.

(*) The escape sequences marked above with an asterisk are ignored by the instrument system

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

4.4.6 Hexadecimal escaping

The escaping of LIS2-A2 or HL7 disallowed characters happens when the instrument system wants to send a character that is not allowed in LIS2-A2 or HL7. Characters that can be escaped are the ASCII characters 10, 13, 127, 255. In this case, the character will be escaped using the hexadecimal escaping. For example, if the instrument system wants to send the character 127 it will be escaped to \X7F\.

4.4.7 Local escape sequence

Local escape sequence is used to exchange characters not represented using the configured codepage. For example, if the instrument system wants to send a Japanese character (for example the Unicode character U+34C8) using the English codepage, the character would be lost in a normal transmission because it cannot be represented in that specific codepage.
To avoid losing any character, characters not represented in the selected codepage are escaped using the local escape sequence. In that case, the Japanese character will be sent in four hexadecimal digits as \Z34C8\. Also note, that many non-represented codepage characters can be added in the same escape sequence.

4.5 Acknowledge and error recovery

The acknowledge and error recovery is different in HL7 and LIS2-A2.

4.5.1 HL7

The Message Header Segment (MSH) contains several fields that control the later message flow. The sending application shall populate the MSH fields in the following manner:

- MSH.10 populated with a unique identifier for the message. Acknowledgements in response to this message shall refer to this ID.
- MSH.15 is set to 'ER', thus instructing the receiving application to send an 'Accept Acknowledgement' only in case of error at this level (e.g. syntactical error, communication error)
- MSH.16 is set to 'AL': The message requires an application acknowledgement.

Thus there shall be always one and only one acknowledgement message coming back to the sending application.

Upon receipt of the message the receiving application can make an initial determination as to whether or not the message can be accepted. If this acceptance validation fails the system shall reject the message with an 'accept acknowledgment' populating the acknowledgment code (MSA.1) with:

1. 'CR' Commit reject if the one of the values of message type (MSH.9), version ID (MSH.12) or processing ID (MSH.11) is not acceptable to the receiving application.
2. 'CE' Commit error if the message cannot be accepted for any other reason (e.g., required field is not present).

The 'Accept Acknowledgment' message shall populate fields MSH.15 and MSH.16 with an 'NE'.

BioSystems
Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

If the message is accepted the receiving application shall then process it. In case the header indicates it (MSH.16) the receiving application shall reply with an 'Application Acknowledgment'. The Acknowledgement Code (MSA.1) of the acknowledgment shall be one of the following:

1. 'AA' indicates the message has been processed successfully.
2. 'AE' indicates application error. The response message shall provide additional error information.
3. 'AR' indicates failure to process (reject) the message for reasons unrelated to its content or format (analyzer busy, system down, internal error, etc.).

In case of application error or reject, the message is not resent anymore.

4.5.2 LIS2-A2

In order to ensure proper error logging and error recovery, the next rule is followed according to the standard.

Storage Rule: Since data content is structured in hierarchical fashion, any decreasing change in the hierarchical level triggers storage of all data transmitted prior to said level change, and not previously saved.

An example of the prior rule application is the following.

Record #	**Record Type** **Storage action**	**Level**	**(level variation)**
1	Message Header	L0	(0)
2	Patient1	L1	(+1)
3	Order1	L2	(+1)
4	Result1	L3	(+1)
5	Order2	L2	(-1) {Save 1 – 4}
6	Order3	L2	(0)
7	Patient2	L1	(-1) {Save 5 – 6}
8	Order1	L2	(+1)
9	Comment1	L3	(+1)
10	Result1	L3	(0)
11	Comment1	L4	(+1)

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

12	Result2	L3	(-1)	{Save 7 – 11}
13	Order2	L2	(-1)	{Save 12}
14	Patient3	L1	(-1)	{Save 13}
15	Order1	L2	(+1)	
16	Result1	L3	(+1)	
17	Message Terminator	L0	(-3)	{Save 14 – 16}

Note: Record # 17 is assumed as saved by virtue of the record type function.

If a transmission failure occurs, transmission starts at the last record not presumed saved. In order to fulfil hierarchical record level requirements, all records necessary to reach the restart record point are repeated prior to transmitting the record where the line failure originally occurred.

An example of required retransmissions is showed below.

Line failure at	**Record Type of**	**Level (variation)**		**Storage action**	**Retransmission**
1	Message Header	L0	(0)		1
2	Patient1	L1	(+1)		1, 2
3	Order1	L2	(+1)		1, 2, 3
4	Result1	L3	(+1)		1, 2, 3, 4
5	Order2	L2	(-1)	{Save 1 – 4}	1, 2, 3, 4, 5
6	Order3	L2	(0)		1, 2, 5, 6
7	Patient2	L1	(-1)	{Save 5 – 6}	1, 2, 5, 6, 7
8	Order1	L2	(+1)		1, 7, 8
9	Comment1	L3	(+1)		1, 7, 8, 9
10	Result1	L3	(0)		1, 7, 8, 9, 10
11	Comment1	L4	(+1)		1, 7, 8, 9, 10, 11
12	Result2	L3	(-1)	{Save 7 – 11}	1, 7, 8, 9, 10, 11, 12

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

13	Order2	L2	(-1)	{Save 12}	1, 7, 8, 12, 13
14	Patient3	L1	(-1)	{Save 13}	1, 7, 13, 14
15	Order1	L2	(+1)		1, 14, 15
16	Result1	L3	(+1)		1, 14, 15, 16
17	Message Terminator 17	L0	(-3)	{Save 14 – 16}	1, 14, 15, 16,

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

5 Workflow Scenarios

5.1 AWOS transfer to the BA 400 before specimen arrival

In this use case the LIS sends to the BA 400 the scheduled list of AWOS prior to the specimen arriving at the BA 400. The delivery to the BA 400, solicited or unsolicited, will be described in the following two sub-cases.

Since the work list is transmitted before the specimen is present on the BA 400, in some cases it may not be known which device will receive the specimen. Laboratories may have multiple BA 400 with similar analytical capabilities for fault tolerance redundancy or to keep up with the workload. When an AWOS is scheduled on more than one BA 400, upon notification of AWOS completion by one of the BA 400 who transmits back the results, the LIS shall cancel the other redundant AWOS awaiting execution on the other BA 400.

5.1.1 AWOS broadcast by the LIS before specimen arrival

Initial part of the scenario:

1. The LIS sends the scheduled AWOS to the BA 400. Multiple AWOS may be grouped into a single work list provided to the BA 400. Each AWOS represents an analytical service requested on a specimen. In response to the AWOS broadcast, the BA 400 will notify the LIS that the AWOS has been accepted. This is done implicitly, only rejections are explicitly referenced in the message.
2. The BA 400 recognizes the specimen container (through barcode ID scanning or manual entry) and selects the set of AWOS related to that specimen from its memory.

Final part of the scenario:

1. The BA 400 performs the AWOS (one or more) on that specimen.
2. The BA 400 notifies the LIS of the completion of the AWOS (one or more). This notification message contains the results of the performed tests, fulfilling one or more AWOS, with their related properties.

Exceptions handling:

1. In the case where the AWOS has not been received when the specimen container is recognized, the BA 400 queries the LIS with the specimen container ID (transition to use case 5.1.1 step b).
2. In the time between receipt of the AWOS and the specimen recognition by the BA 400, the content of the Order Group, Order or Work Order may be modified (correcting patient data, suppressing some tests, adding some new tests, shifting to another target Analyzer) or even cancelled. Such events will require the cancellation of the original AWOS on the LIS. Therefore, the LIS shall notify the cancellation to all BA 400 that received the AWOS.
    a. The LIS notifies the BA 400 to cancel the AWOS.

b. Each BA 400 notifies the LIS if the AWOS cancel is accepted. BA 400 will evaluate the state of the AWOS and determine if cancellation is possible. If a BA 400 cannot cancel the AWOS, it will notify the LIS that it is unable to cancel. One of the following actions will occur:
    i. If processing on the AWOS has not started, the BA 400 will notify the LIS that the cancel was accepted and discard the AWOS.
    ii. If processing on the AWOS has started but the BA 400 cannot stop the processing, then the cancellation is rejected. The BA 400 will then transition to step b, "Final part of the scenario" of this use case.

5.1.2 AWOS query by the BA 400 for ALL specimens before specimen arrival

Initial part of the scenario:

1. The BA 400 queries the LIS for all the scheduled AWOS assigned to it.
2. The LIS responds by sending the complete AWOS work list assigned to the BA 400, and the BA 400 updates its local work list. In response to the AWOS receipt, the BA 400 will notify the LIS that the AWOS has been accepted or rejected. **The acceptance is done implicitly, only rejections are explicitly referenced in the message**
3. Continue with step b) of the Initial part of the scenario from use case 5.1.1.

Final part of the scenario:

Same as use case 5.1.1.

Exception handling:

Same as use case 5.1.1.

5.2 AWOS created at the BA 400

Initial part of the scenario:

1. The AWOS is created at the BA 400. The laboratory technical staff manually entering the AWOS on BA 400.
    a. By using information printed from the LIS.
    b. By using information: label on sample, information provided through a phone conversation (in emergency cases for example), etc. The BA 400 does not create an AWOS ID for the AWOS.
2. The BA 400 recognizes the specimen container (through barcode ID scanning, position identification on the carrier, or manual entry) and selects the set of AWOS related to that specimen from its memory.

Final part of the scenario:

1. The BA 400 performs the AWOS on that specimen.
2. The BA 400 notifies the LIS, with the status of the performed step. This notification message contains the results and status of the performed clinical tests.

BioSystems
Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

5.3 AWOS Query by the Analyzer at specimen arrival

Initial part of the scenario:

1. The LIS schedules the AWOS but does not send it to the BA 400.
2. In the case where the LIS receives a Work Order update or cancellation, it cancels the related AWOS appropriately, and creates a new one if needed.
3. The BA 400 system recognizes the specimen container (barcode scanning, location information, or manual entry); afterwards it queries the LIS with the specimen container ID or location information.
4. The LIS replies to the query with the AWOS to be performed.

Final part of the scenario:

Same as use case 5.1.1.

Exceptions handling:

1. The specimen may be placed on the BA 400, before the Work Order has been received by the LIS, and before the AWOS exist. In that case the query in step 3 is unsuccessful. The answer sent in step 4 will be “unknown specimen, no pending AWOS for it”. Two events may occur:
    a. The BA 400 suspends processing of the specimen and tries the query later.
    b. The AWOS is created at the Analyzer (transition to use case 5.2).
2. In this use case, the step to be performed on the BA 400 is sent by the LIS just in time, when the BA 400 is ready to perform it on the specimen. Thus, there is no need to cancel an AWOS that has been transferred to a BA 400.

5.4 Rerun

An AWOS usually needs one analytic run on the BA 400. In some circumstances the results obtained from this first run need to be controlled by subsequent runs or “reruns”.

The need for a rerun may be decided:

- Immediately after the first run on the BA 400, before uploading the results to the LIS.
- During the technical validation of the Analytical Work Order with the first run results, on the LIS application.
- During the clinical validation of the order with the first run results, on the Order Filler application.

Thus, three use cases to be considered:

5.4.1 Rerun decided on the BA 400 immediately after the first run

The rerun is decided automatically at the end of the first run or manually at any time during the working session. The reason may be:

- Results out of range, triggering a rerun with automatic dilution of the specimen.

Initial part of the scenario:

The initial part of the scenario can be from use case 5.1, 5.2 or 5.3.

Final part of the scenario:

1. The BA 400 performs the ordered step on that specimen (first run).
2. Based on the results obtained, the BA 400 schedules a second run.
3. After the appropriate fix (dilution, reagent refill, needle wash, calibration…) the BA 400 performs the second run.
4. The BA 400 notifies the LIS, with the results and status of the second run. The extra test results may be unexpected by the LIS, because more than one final test result is reported for the same test. The AWOS ID is included when reporting test results for a rerun, as the AWOS ID clearly identifies that the extra test results are associated with the original AWOS request. When rerun test results are reported, it is up to the LIS and operator to determine which test result (original or rerun) to report as the "clinically valid" test result.

5.4.2 Rerun decided during technical validation on the LIS

The control (rerun) is decided during the technical validation of the results of the first run, compared with normal ranges, patient's prior results, and other clinical information, or technical information such as drifting or out of range quality control detected. This decision is taken by the technical staff, or automatically by the LIS application.

Initial part of the scenario:

The initial part of the scenario can be from use case 5.1, 5.2 or 5.3.

Final part of the scenario:

1. The BA 400 performs the ordered step on that specimen (first run).
2. The BA 400 notifies the LIS, with the results and status of the first run for this AWOS.
3. The technical validation of the results is performed on the LIS, resulting in a new run requested with the same tests on the same specimen. This new run may be requested on the same BA 400 or on another one (to confirm the results obtained on the first one).

The rerun picks up the scenario appropriate to the working mode of the BA 400 chosen for the second run:

- The LIS may send a new AWOS to it, for the same specimen and the same tests. This starts a new 5.1.1 scenario.
- Or if the BA 400 is working in query mode, the LIS schedules the new AWOS and waits for the query from the BA 400. This starts a new 5.3 scenario.

5.4.3 Rerun decided during clinical validation on the Order Filler

The control (rerun) is decided during the clinical validation of the results of the whole order group, considering the clinical consistency of this whole set of results, together with normal

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

ranges, patient's prior results, and other clinical and technical information, or technical information such as drifting or out of range quality control detected. This decision is taken by the laboratory clinical expert, or by an automated expert system assisting the clinical expert.

In this situation, the final part of the first three scenarios ends normally. After the clinical validation the Order Filler generates a new Work Order for the same patient, same specimen, requesting the LIS to schedule the tests, on one of its Analyzers. This new Work Order may carry some additional tests ordered in the meantime. It may possibly require a new aliquot.

This kind of rerun is supported and described by the use case 5.1, 5.2 and 5.3.

5.5 Reflex [v2]

An AWOS usually needs one analytic run on the BA 400. In some circumstances the results obtained from this first run will trigger (manually) the need for one (or several) different test (i.e. a reflex test).

The need for a reflex may be decided:

- Either immediately after the initial test run on the BA 400, before uploading the results to the LIS.
- Or during the technical validation of the Analytical Work Order with the first run results, on the LIS application.
- Or later, during the clinical validation of the order with the first run results, on the Order Filler application.

Thus, three use cases are to be considered:

5.5.1 Reflex decided on the BA 400 immediately after the first run

The reflex is decided manually, at the end of the first run. The reason may be:

- Results in a particular range, triggering a reflex of a different test on the same specimen.

This reflex decision happens before the initial test results are uploaded to the LIS. The results of the first run may be sent either before the results from the reflex test or may be held and sent when the reflex test is complete.

The LIS may be notified of both the initial and reflex testing in order to track the BA 400 operations, and to register the reagent consumption.

Initial part of the scenario:

The initial part of the scenario can be from use case 5.1, 5.2 or 5.3.

Final part of the scenario:

1. The BA 400 performs the ordered step on that specimen (first run).

2. Considering the results obtained, a second run is scheduled. The BA 400 sends the results of the first test.
3. After the appropriate specimen is made available, the BA 400 performs the reflex test.
4. The BA 400 notifies the LIS, with the results and status of the first tests and reflex test with all known information (patient, specimen, container, test).

5.5.2 Reflex decided during clinical validation on the LIS

The reflex is decided during the technical validation of the results of the first run, compared with normal ranges, patient's prior results, and other clinical information, or technical information. This decision is taken by the technical staff, or automatically by the LIS application.

Initial part of the scenario:

The initial part of the scenario can be from use case 5.1, 5.2 or 5.3.

Final part of the scenario:

1. The BA 400 performs the ordered step on that specimen (first run).
2. The BA 400 notifies the LIS, with the results and status of the first run for this AWOS.
3. The technical validation of the results is performed on the LIS, resulting in a new run requested with different tests on the same specimen. This new run may be requested on the same analyzer or on another one.

The reflex picks up the scenario appropriate to the working mode of the BA 400 chosen for the second run:

- The LIS may send a new AWOS to it, for the same specimen and new tests. This starts a new 5.1.1 scenario.
- If the BA 400 is working in query mode, the LIS schedules the new AWOS and waits for the query from the BA 400. This starts a new 5.3 scenario

5.5.3 Reflex decided during clinical validation on the Order Filler

The reflex is decided during the clinical validation of the results of the whole order group, considering the clinical consistency of this whole set of results, together with normal ranges, patient's prior results, and other clinical and technical information. This decision is taken by the laboratory clinical expert, or by an automated expert system assisting the clinical expert.

In this situation, the final part of the first three scenarios ends normally. After the clinical validation the Order Filler generates a new Work Order for the same patient, same specimen, requesting the LIS to schedule the reflex tests on one of its BA 400. It may possibly require a new aliquot.

This kind of reflex is supported and described by the first three scenarios.

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

5.6 Retransmit results from BA 400

Usually at the completion of a run, the BA 400 notifies the LIS one time with the status and the test results of the performed AWOS. In some circumstances the AWOS results may be sent again by the BA 400 to the LIS. This decision to send the results again is generally made manually by the operator of the BA 400 in cases where the LIS was unable to receive and store the results of the initial transmission, or in the case when a manual send of the results is used for testing purposes of the connection between the BA 400 and the LIS.

In this situation, the LIS is responsible for determining if the results are the same as it has seen previously (same AWOS, same BA 400, same test, same results) and acting accordingly. It shall not reject the message from the BA 400 in the case of a retransmission, but shall either record the event or ignore the retransmission, depending on application design.

5.7 QC performed on an analyzer

This use case is a specialization of the following use cases:

- 5.1 AWOS transfer to the BA 400 before specimen arrival.
- 5.2 AWOS created at the BA 400.
- 5.3 AWOS Query by the BA 400 at specimen arrival.
- 5.6 Retransmit results from BA 400.

In all these use cases the specimen is a “QC specimen”.

5.8 Pooling of patient specimens [v2]

This use case is a specialization of the following use cases:

- 5.1 AWOS transfer to the BA 400 before specimen arrival.
- 5.2 AWOS created at the BA 400.
- 5.3 AWOS Query by the BA 400 at specimen arrival.
- 5.4 Rerun
- 5.5 Reflex [v2]
- 5.6 Retransmit results from BA 400.

In some cases (molecular biology for example), the sample transmitted to the BA 400 is mixture of several patient specimen.

- If the BA 400 return a negative result all the patient specimen of the pool are considered negative.
- If the BA 400 returns a positive result, all the patient specimen of the pool have to be tested individually.

The preceding uses cases, the following points have to be taken in account:

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

- The ordering of pooled specimens assumes the LIS managing the specimen pool (e.g., by connection to a pooling device) and the BA 400 responsible for measurement and calculation of the result of the pooled specimen.
- The Order send to the BA 400 should include the following information:
  a. It is a pooled specimen.
  b. The pool size, i.e., the number of specimens used for this specific sample. This information is used in the calculation of the result (the negative specimens generally "dilute" the result of positive specimens).
  c. Optional list of specimen IDs used in the pool (for informational purpose at the BA 400).

5.9 Reason for Rejection orders (BA400 sends a rejection message for related order)

5.9.1 Due to wrong syntax or unmapped values

Reason	Description	ASTM example
Missing mandatory field	Missing value in a field marked as REQUIRED in BA400 LIS Protocol Specification document	Specimen ID (O3 segment) not informed
Field with data type different than the expected	Field with data type different of the defined for it in BA400 LIS Protocol Specification	Patient DOB (P8 segment) does not contain a date
Field with length greater than the allowed	Field with length greater than the maximum value allowed for it in BA400 LIS Protocol Specification	Patient Last Name (P6.1 segment) contains a value with more than 30 characters
Field with incorrect format	Field with a format different than the defined for it in BA400 LIS Protocol Specification	Patient DOB (P8 segment) contains a valid date but expressed with a format different of YYYYMMDD
Field with incorrect value	Field with a value different of the list defined for it in BA400 LIS Protocol Specification	Priority (O6 segment) has a value different of R and S
Field with unknown value	Field with a value that is unknown for BA400 (bad mapped fields)	Sample Type (O16 segment) or Test ID (O5.4 segment) contain a value not mapped in BA400

5.9.2 Due to incorrect field content

Unknown Test/Sample Type	Both fields Test ID and Sample Type are known for BA400, but the Test has not programming defined for the Sample Type
Calculated Test that requires more than one Sample Type	Calculated Tests composed of Tests programmed with different Sample Types
Duplicate Specimen	The same Specimen ID is sent for several different Patients
Duplicate request	The same Test ID / Sample Type has been previously requested for the same Patient and the result has not been still uploaded to LIS
Internal QC for a wrong Test/Sample Type	• Internal QC for Calculated or External Tests • Internal QC for Standard or ISE Tests that have not Quality Control defined in BA400

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

5.9.3 Due to Reruns requests

Reruns requested by LIS are not allowed	Rerun working mode has been set to: Analyzer Only into LIS Configuration screen of BA400 Sw
LIS requests a rerun for an Internal QC	LIS requests for Rerun of Internal Controls are not allowed in BA400
LIS requests a rerun for a wrong Test/Sample Type	LIS requests for Rerun of Calculated and/or External Tests are not allowed in BA400
LIS requests a rerun for a different Specimen ID	LIS requests a Rerun after receiving the results of the previous request, but sends it for a different Specimen

5.9.4 Due to Cancellations requested by LIS (Cancel message sent by LIS)

Unknown Test/Sample Type for the Patient	The Test/Sample Type to cancel for a Patient does not exist in BA400
The Test/Sample Type to cancel is finished	Execution of the Test/Sample Type to cancel has finished (result has been already obtained for it)

5.9.5 Due to User's actions

User deletes accepted LIS orders that are pending of execution in BA400	• Required Specimen is not received • Lack of required Reagents • Other reasons

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

6 HL7 IHE-LAW Transaction LAB-27: Query for AWOS

6.1 Introduction

This transaction is used between a LIS and BA 400 working in query mode. It enables the LIS to issue a new AWOS to the BA 400. This is a two-part transaction that requires two message exchanges between the LIS and BA 400.

This transaction is used by the BA 400 to get the AWOS to perform for each specimen by querying the LIS after specimen container recognition. The transaction provides an initial message exchange of a query for one specimen or all specimens and the reply will carry the acknowledgement status of the request. The LIS will follow the query exchange with a second message exchange consisting of a LAB-28 AWOS Broadcast that provides the work to perform or an indication there is no work for that specimen.

The BA 400 can send multiple queries prior to receiving the AWOS Broadcast from the LIS. This allows the BA 400 to send a batch of queries, or asynchronous queries, without waiting for the AWOS Broadcast of the two-part message exchange.

6.2 Scope

This transaction supports the use cases:

- AWOS Query by the Analyzer for ALL specimens before specimen arrival.
- AWOS Query by the Analyzer at specimen arrival.

It is used by the LIS and the BA 400 in "Query Mode".

6.3 Use Case Roles

ACTOR	ROLE
LIS	Manages the Work Orders and AWOS. Responds with to a query from the Analyzer and sends the appropriate (positive acknowledgement, negative acknowledgment) response. When the acknowledgement response is positive, sends a LAB-28 AWOS Broadcast to the Analyzer.
Analyzer	Queries the LIS for a WOS related to the specimen, and receives the query response. Waits for the LAB-28 AWOS Broadcast when a positive query response is received. If no LAB-28 AWOS Broadcast for the queried specimen is received by an Analyzer-specific period of time, the Analyzer may notify the user that no AWOS was received.

6.4 Referenced Standard

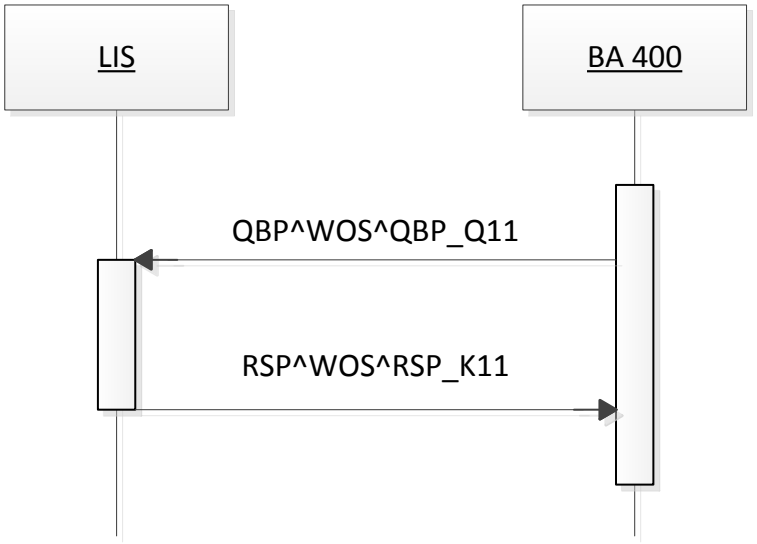
HL7 version 2.5.1:

- Chapter 5: “Query” → QBP and RSP messages.

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

- Chapter 5: "Query" → QPD, RCP and QAK segments.

6.5 Interaction Diagram



6.6 Message Static Definitions

After the BA 400 working in query mode recognizes one or more specimens, the Analyzer sends a "WOS Query Message" (QBP^WOS^QBP_Q11) for each specimen to the LIS.

The LIS replies with the response message (RSP^WOS^RSP_K11) containing the acknowledgement of specimen query. The LIS will then respond with a LAB-28 AWOS Broadcast containing the work for the specimen.

6.6.1 Trigger Events

- QBP (Q11): Query for the WOS sent by the BA 400.
- RSP (K11): Response including the WOS sent by the Automation Manager.

6.6.2 Message Semantics

6.6.2.1 QBP^WOS^QBP_Q11:

SEGMENT	MEANING	USAGE	CARD.	HL7 CHAPTER
MSH	Message Header	R	[1..1]	2
[{SFT}]	Software Segment	O[1]	[0..*]	2
QPD	Query Parameter Definition	R	[1..1]	5
RCP	Response Control Parameter	R	[1..1]	5

[1] For BA 400 'X'.

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

MSH.9: QBP^Q11^QBP_Q11.

MSH.21: LAB-27^IHE.

```
MSH|^~\&|BA400|Biosystems|Modulab|Systelab|20130416063226||QBP^Q11^QBP_Q1
1|822cc8b5-5f83-4f77-8173-66e3d942cb01|P|2.5.1|||ER|AL||UNICODE UTF-
8|||LAB-27^IHE
QPD|WOS^Work Order
Step^IHE_LABTF|822cc8b55f834f77817366e3d942cb01|001000003
```

6.6.2.2 *RCP|I||R<CR><FS><CR>RSP^WOS^RSP_K11:*

SEGMENT	MEANING	USAGE	CARD.	HL7 CHAPTER
MSH	Message Header	R	[1..1]	2
[{SFT}]	Software Segment	O[1]	[0..*]	2
MSA	Message Acknowledgement	R	[1..1]	2
[ERR]	Error	O	[0..1]	2
QAK	Query Acknowledgement	R	[1..1]	5
QPD	Query Parameter Definition	R	[1..1]	5

[1] Ignored by BA 400.

MSH.9: RSP^K11^RSP_K11.

MSH.21: LAB-27^IHE.

QPD shall be the same as the QPD sent in QBP^WOS^QBP_Q11.

```
MSH|^~\&|Modulab|Systelab|BA400|Biosystems|20130129102030||RSP^K11^RSP_K1
1|67F2746D24014F21AD7139756F64CAD8|P|2.5.1|||ER|NE||UNICODE UTF-8|||LAB-
27^IHE
MSA|AA|65F2746D24014F21AD7139756F64CAD8
QAK|65F2746D24014F21AD7139756F64CAD8|OK|WOS^Work Order Step^IHE_LABTF
QPD|WOS^Work Order Step^IHE_LABTF|67F2746D24014F21AD7139756F64CAD8|SPM01
```

6.6.3 Expected Actions

When specimen arrives on the BA 400 it sends a QBP message to the LIS to get the AWOS. This QBP message may be for one specimen or for all specimens.

The LIS receives the QBP message and returns the RSP message with the query acknowledgment status. The LIS prepares the AWOS by checking the container ID contained in the QBP message, and initiates the LAB-28 AWOS Broadcast. The BA 400 receives the AWOS(s) and performs processing for the specimen.

6.6.4 QPD Segment

SEQ	LEN	DT	USAGE	USAGE	CARD.	TBL#	NAME

			ANALYZER	ANALYZER MGR.			
1	60	CE	M	M	[1..1]		Message Query Name
2	32	ST	M	M	[1..1]		Query Tag
3	80	EI	C	C	[0..*]		SAC-3: Container Identifier

QPD.1 Message Query Name (CE), mandatory.

This field contains the value of the query for either a single sample or for all samples. The contents for each query type are described below.

Query for a single sample

SEQ	COMPONENT/SUB-COMPONENT	LEN	DT	USAGE	COMMENT
1.1	Identifier	3	ST	R	WOS
1.2	Text	15	ST	R	Work Order Step
1.3	Name of Coding System	9	ID	R	IHE_LABTF

Query for all samples samples

SEQ	COMPONENT/SUB-COMPONENT	LEN	DT	USAGE	COMMENT
1.1	Identifier	7	ST	R	WOS_ALL
1.2	Text	19	ST	R	Work Order Step All
1.3	Name of Coding System	9	ID	R	IHE_LABTF

QPD-2: Query Tag (ST), mandatory.

A unique identifier assigned to each query message instance.

QPD-3 Container Identifier (EI), conditional.

The Analyzer is querying for the container id field identifies the container. It is expected that the Container Identifier is the valued encoded on the container.

Predicate: When QPD.1.1 is 'WOS', QPD.3 must be populated if QPD.4 or QPD.6 is not populated. Usage is Not Supported when QPD.1.1 is 'WOS_ALL'.

SEQ	COMPONENT/SUB-COMPONENT	LEN	DT	USAGE	COMMENT
3.1	Entity Identifier	20	ST	R	

6.6.5 RCP Segment

SEQ	LEN	DT	USAGE ANALYZER	USAGE ANALYZER MGR.	CARD.	TBL#	NAME
1	1	ID	M	M	[0..1]	0091	Query Priority

3	60	CE	M	M	[0..1]	0394	Response Modality

RCP-1 Query Priority (ID), *mandatory.*

This field is always set to the value of 'I' for Immediate.

RCP-3 Response Modality (CE), *mandatory.*

This field is always set to the value of 'R' for Realtime.

SEQ	COMPONENT/SUB-COMPONENT	LEN	DT	USAGE	COMMENT
3.1	Identifier	1	ST	R	Always set to 'R'

6.6.6 QAK Segment

SEQ	LEN	DT	USAGE ANALYZER	USAGE ANALYZER MGR.	CARD.	TBL#	NAME
1	32	ST	M	M	[1..1]		Query Tag
2	2	ID	M	M	[1..1]	0208	Quantity Response Status
3	38	CE	M	M	[1..1]	0471	Message Query Name

QAK-1 Query Tag (ST), *mandatory.*

This field contains 'QPD.2 Query Tag' from the query message.

QAK-2 Query Response 2540 Status (ID), *mandatory.*

This field contains one of the following codes from the HL7 Table 0208.

VALUE	DESCRIPTION	COMMENTS
OK	Data found: no errors	
NF	No data found: no errors	
AE	Application Error	
AR	Application Rejects	

QAK-3 Message Query Name (CE), *mandatory.*

This field contains 'QPD.1 Message Query Name' from the query message.

SEQ	COMPONENT/SUB-COMPONENT	LEN	DT	USAGE	COMMENT
3.1	Identifier	20	ST	R	Contains value from QPD.1

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

7 HL7 IHE-LAW Transaction LAB-28: Analytical Work Order Step Broadcast

7.1 Scope

This transaction is used between a LIS and an Analyzer working in broadcast mode. It enables the LIS to issue a new AWOS to the Analyzer or cancel an existing AWOS previously sent to the Analyzer. Modification is achieved by combining cancellation and sending of a new AWOS.

7.2 Use Case Roles

ACTOR	ROLE
LIS	Translates a Work Order into a series of AWOS assigned to the Analyzers.
Analyzer	Performs the AWOS on the specimen.

7.3 Referenced Standard

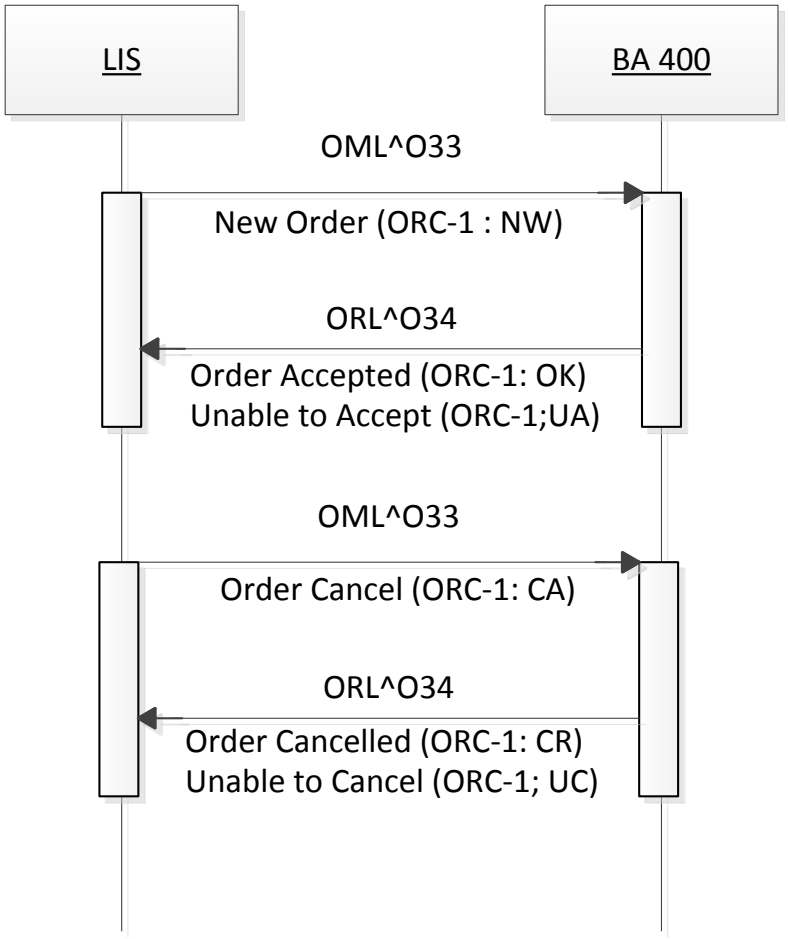
HL7 v2.5.1, Chapter 4 and Chapter 13:

- OML^O33 and ORL^R34 message and response.
- PID, PV1, SPM, SAC, ORC, TQ1, OBR, TCD, and NTE segments.

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

7.4 Interaction Diagram



7.5 Message Static Definitions

This transaction contains the messages used to broadcast an Analytical Work Order Step (AWOS) from the LIS to the Analyzer. It includes “new AWOS”, “cancel AWOS” and the related application acknowledgements.

The message contains zero or more AWOSs for one or more Specimens. The AWOSs are grouped by specimen.

7.5.1 Trigger Events

- OML (O33): AWOS sent by the LIS.
- ORL (O34): Acknowledgement sent by the Analyzer.

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

7.5.2 Message Semantics

7.5.2.1 OML^O33

SEGMENT	MEANING	USAGE	CARD.	HL7 CHAPTER
MSH	Message Header	R	[1..1]	2
[	--- PATIENT BEGIN	O	[0..1]	
PID	Patient Identification	R	[1..1]	3
[PV1]	Patient Visit	O	[0..1]	3
]	--- PATIENT end			
{	SPECIMEN begin	R	[1..*]	
SPM	Specimen	R	[1..1]	7
[{SAC}]	Specimen Container	R	[1..1]	13
{	--- ORDER begin	R	[1..*]	
ORC	Common Order (for one battery)	R	[1..1]	4
[{TQ1}]	Timing Quantity	RE	[0..1]	4
[	--- OBSERVATION REQUEST begin	RE	[0..1]	
OBR	Observation Request	R	[1..1]	4
[{TCD}]	Test Code Details	O	[0..1]	13
[{	--- PRIOR RESULT begin	O	[0..*]	
PV1	Patient Visit – previous result	R	[1..1]	3
{	--- ORDER PRIOR begin	R	[1..*]	
ORC	Common Order – prior result	R	[1..1]	4
OBR	Order detail – prior result	R	[1..1]	4
{	--- OBSERVATION PRIOR begin	R	[1..*]	
OBX	Observation/Result – prior result	R	[1..*]	
[{NTE}]	Comment of the result	C[1]	[0..*]	2
}	--- OBSERVATION PRIOR end			
}	--- ORDER PRIOR end			

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

SEGMENT	MEANING	USAGE	CARD.	HL7 CHAPTER
}]	--- PRIOR RESULT end			
]	--- OBSERVATION REQUEST end			
}	--- ORDER end			
}	--- SPECIMEN END			

[1] Ignored by BA 400.

MSH.9: OML^O33^OML_O33.

MSH.21: LAB-28^IHE.

SPM.11: 'Q' (Control specimen) in the case of a QC AWOS, 'P' (Patient) in the case of a patient AWOS, and 'L' (Pooled patient specimens) in the case of a pooled patient samples AWOS.

The OBSERVATION REQUEST group will not be present when ORC.1 = DC, which is "Discontinue Request". This indicates the message is in reply to a LAB-27 Query for AWOS and that there is no work to perform for the sample container.

The PRIOR RESULT segment group provides the prior results obtained for the same patient. Segment PID is not provided in this segment group because it is the same patient, and the laboratory is not concerned by the fact that this patient might have had a different identification when the prior results were produced.

Segment PV1, which is the first segment of the segment group PRIOR RESULT, is mandatory. The presence of this segment at this point in the message structure announces unambiguously a set of prior orders with related prior observations. The segment PV1 represents the patient visit (or encounter) during which these prior observations were produced. The only field mandatory in the segment PV1 is PV1.2 "Patient Class". The sender of this message SHALL set the value the field PV1.2 to 'U', which stands for "patient class unknown".

The ORC appearing in the PRIOR RESULT segment group is mandatory and SHALL have its first field "Order Control" populated with 'PR' (Prior results).

Some Analyzers need 'Observation OBX, TCD, and NTE segments'. Therefore, the message carries an optional OBSERVATION segment group to provide the analyzer with results related to the tests to be performed.

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

```
MSH|^~\&|Modulab|Systelab|BA400|Biosystems|20130129102030||OML^O33^OML_O3
3|69F2746D24014F21AD7139756F64CAD8|P|2.5.1|||ER|AL||UNICODE UTF-8|||LAB-
28^IHE
PID|||PID2||SURNAME^NAME2^^^^^L||19850819|M
SPM|1|SPECIMEN2||SER|||||||P||||||20130129092030|20130129112030
SAC|||||||||||||||||||||||||||||5
ORC|NW|||||||||20130129101530
TQ1|||||||||R
OBR||AWOS2||ALBUMIN^T1^BA400
ORC|NW|||||||||20130129101530
TQ1|||||||||R
OBR||AWOS2||Na+^T1^BA400
ORC|NW|||||||||20130129101530
TQ1|||||||||R
OBR||AWOS2||Li+^T1^BA400
ORC|NW|||||||||20130129101530
TQ1|||||||||R
OBR||AWOS2||CK^T1^BA400
ORC|NW|||||||||20130129101530
TQ1|||||||||R
OBR||AWOS2||CHOL HDL DIRECT^T1^BA400
ORC|NW|||||||||20130129101530
TQ1|||||||||R
OBR||AWOS2||CALCIUM ARSENAZO^T1^BA400
ORC|NW|||||||||20130129101530
TQ1|||||||||R
OBR||AWOS2||BILIRUBIN TOTAL^T1^BA400
ORC|NW|||||||||20130129101530
TQ1|||||||||R
OBR||AWOS2||BILIRUBIN DIRECT^T1^BA400
ORC|NW|||||||||20130129101530
TQ1|||||||||R
OBR||AWOS2||AMYLASE PANCREAT^T1^BA400
ORC|NW|||||||||20130129101530
TQ1|||||||||R
OBR||AWOS2||AMYLASE EPS^T1^BA400
ORC|NW|||||||||20130129101530
TQ1|||||||||R
OBR||AWOS2||AMYLASE DIRECT^T1^BA400
ORC|NW|||||||||20130129101530
TQ1|||||||||R
OBR||AWOS2||ALP-DEA^T1^BA400
ORC|NW|||||||||20130129101530
TQ1|||||||||R
OBR||AWOS2||ALP-AMP^T1^BA400
ORC|NW|||||||||20130129101530
TQ1|||||||||R
OBR||AWOS2||ACID GLYCOPROTEI^T1^BA400
```


Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

7.5.2.2 ORL^O34

SEGMENT	MEANING	USAGE	CARD.	HL7 CHAPTER
MSH	Message Header	R	[1..1]	2
MSA	Message Acknowledgement	R	[1..1]	2
[{ERR}]	Error	O	[0..*]	2
[	--- RESPONSE begin	O	[0..1]	
[	--- PATIENT begin	O	[0..1]	
PID	Patient Identification	O	[0..1]	3
{	--- SPECIMEN begin	R	[1..*]	
SPM	Specimen	R	[1..1]	7
[{SAC}]	Specimen Container	R	[1..1]	13
[{	--- ORDER begin	R	[1..*]	
ORC	Common Order (for one battery)	R	[1..1]	4
}]	--- ORDER end			
}	--- SPECIMEN end			
]	--- PATIENT end			
]	--- RESPONSE end			

MSH-9: ORL^O34ORL_O34.

MSH.21: LAB-28^IHE.

ORC.2, Placer Order Number, will be used to uniquely identify the AWOS to the LIS when the RESPONSE group is included.

The RESPONSE group may be used by the Analyzer to inform the LIS about the intent to perform an individual AWOS contained in the OML message:

- For accepted AWOS:
  - ORC.1: OK.
  - ORC.5: IP.
- For rejected AWOS:
  - ORC.1: UA.
  - ORC.5: CA.

The RESPONSE group will be used by the Analyzer to respond to a cancellation request from the LIS for each AWOS contained in the OML message:

- In case of successful cancellation:
  - ORC.1: CR.
  - ORC.5: CA.
- In case of not being able to cancel:
  - ORC.1: UC.
  - ORC.5: IP.

```
MSH|^~\&|BA400|Biosystems|Modulab|Systelab|20130416105615||ORL^O34^ORL_O3
4|af899d09-531c-4df7-9ff1-8aef1929b8eb|P|2.5.1|||ER|NE||UNICODE UTF-
8|||LAB-28^IHE
MSA|AA|69F2746D24014F21AD7139756F64CAD8
```

7.5.3 Expected Actions

The Analyzer receives the OML^O33 message from the LIS.

If the OML message contains the Order Control Code NW, the Analyzer will receive and register the order information. As part of the ORL^O34 response, it may transmit either “Notification or request accepted” or “Unable to accept order/service” for each AWOS contained in the OML message. See the ORC.1/ORC.5 discussion above for further details. The LIS will consider the absence of a response for an individual AWOS the same as receiving a “Notification or request accepted” for the AWOS from the Analyzer.

If the OML message contains the Order Control Code CA, the Analyzer will evaluate the cancel request. As part of the ORL^O34 response, the Analyzer will transmit either “Cancel as requested” or “Unable to cancel” for each AWOS contained in the OML message. See the ORC.1/ORC.5 discussion above for further details.

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

8 HL7 IHE-LAW Transaction LAB-29: AWOS Status Change

8.1 Scope

This transaction is used by the Analyzer to send test results to the LIS.

8.2 Use Case Roles

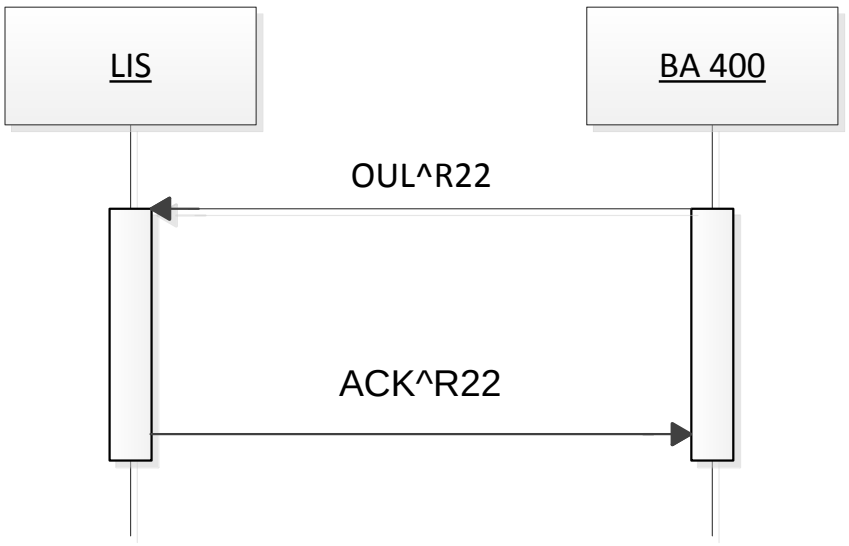
ACTOR	ROLE
LIS	Manages Analyzer in order to implement the AWOS. Receives the test results from Analyzer, performs technical validation, then sends the validated results to Order filler.
Analyzer	Analyzes the specimen and outputs the test results.

8.3 Referenced Standard

HL7 Version 2.5 Chapter 7 and Chapter 13:

- OUL^R22 message.
- PID, PV1, SPM, OBX, SAC, INV, OBR, ORD, TCD, SID, and NTE Segments.

8.4 Interaction Diagram



8.5 Message Static Definitions

This transaction contains the messages used by the Analyzer to send the tests results when the AWOS is complete. It also includes the related application acknowledgements from the LIS.

The message contains zero or more observations for one or more AWOSs for one or more specimens. The observations are grouped by AWOS, and the AWOSs are grouped by specimen.

8.5.1 Trigger Events

Analyzer sends test results. LIS returns acknowledgement.

8.5.2 Message Semantics

8.5.2.1 OUL^R22

SEGMENT	MEANING	USAGE	CARD.	HL7 CHAPTER
MSH	Message Header	R	[1..1]	2
[	--- PATIENT begin	O	[0..1]	
PID	Patient Identification	R	[1..1]	3
]	--- PATIENT end			
[	--- VISIT begin	O	[0..1]	
[PV1]	Patient Visit	R	[0..1]	3
]	--- PATIENT end			
{	SPECIMEN begin	R	[1..*]	
SPM	Specimen	R	[1..1]	7
[{OBX}]	Observation result (for specimen)	O	[0..*]	7
[{	--- CONTAINER begin	O	[0..1]	
SAC	Container information	R	[1..1]	13
[INV]	Detailed Substance information	O	[0..1]	13
}]	--- CONTAINER end			
{	--- ORDER begin	R	[1..*]	
OBR	Observation Order	R	[1..1]	7
[ORC]	Common Order	O	[0..1]	4
[{	--- Result begin	O	[0..*]	

SEGMENT	MEANING	USAGE	CARD.	HL7 CHAPTER
OBX	Observation Result	R	[1..1]	7
[TCD]	Test Code Detail	C	[0..1]	13
[{SID}]	Substance Identifier (e.g. reagent for testing)	C	[0..*]	13
[{NTE}]	Notes and comments	O	[0..*]	
}]	--- RESULT end			
}	--- ORDER end			
}	--- SPECIMEN end			

MSH.9: OUL^R22^OUL_R22.

MSH.21: LAB-29^IHE.

SPM.11: 'Q' (Control specimen) in the case of a QC AWOS, 'P' (Patient) in the case of a patient AWOS, and 'L' (Pooled patient specimens) in the case of a pooled patient samples AWOS.

```
MSH|^~\&|BA400|Biosystems|Modulab|Systelab|20130416071828||OUL^R22^OUL_R2
2|80f1a9fe-cd54-41d4-87ca-4c30b059ac2b|P|2.5.1|||ER|AL||UNICODE UTF-
8|||LAB-29^IHE
SPM|1|#201304150002||SER|||||||P|||||||
OBR||""||UREA-BUN-UV^UREA-BUN-UV^A400|||||||||||||||||||||||||
ORC|OK||||CM||||20130416071828OBX|1|ST|UREA-BUN-UV^UREA-BUN-UV^A400||-
1.351948|mg/dL^mg/dL^A400||See Analyzer remarks for this LIS
order|||F|||||BIOSYSTEMS||A400^Biosystems~834000114^Biosystems|2013041514
5415
OBR||""||ALP-DEA^ALP-DEA^A400|||||||||||||||||||||||||
ORC|OK||||CM||||20130416071828
OBX|1|ST|ALP-DEA^ALP-DEA^A400||-0.8337101|U/L^U/L^A400||See Analyzer
remarks for this LIS
order|||F|||||BIOSYSTEMS||A400^Biosystems~834000114^Biosystems|2013041515
1412
OBR||""||BUN MOD^BUN MOD^A400|||||||||||||||||||||||||
ORC|OK||||CM||||20130416071828
OBX|1|ST|BUN MOD^BUN MOD^A400||-0.6317512|mg/dL^mg/dL^A400||See Analyzer
remarks for this LIS
order|||F|||||BIOSYSTEMS||A400^Biosystems~834000114^Biosystems|2013041607
1702
```

8.5.2.2 ACK^R22

SEGMENT	MEANING	USAGE	CARD.	HL7 CHAPTER
MSH	Message Header	R	[1..1]	2

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

MSA	Message Acknowledgement	R	[1..1]	
[ERR]	Error	O	[0..1]	3

MSH.9: ACK^R22^ACK.

MSH.21: LAB-29^IHE.

```
MSH|^~\&|Modulab|Systelab|BA400|Biosystems|20130129102030||ACK^R22^ACK|71
F2746D24014F21AD7139756F64CAD8|P|2.5.1|||ER|NE||UNICODE UTF-8|||LAB-
29^IHE
MSA|AA|88F2746D24014F21AD7139756F64CAD8
```

8.5.3 Expected Actions

The Analyzer notifies the LIS of the test results using the OUL^R22 message. The LIS accepts and registers information, and responds to the Analyzer with the ACK^R22 message.

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

8.6 Common HL7 Segments

8.6.1 ERR Segment

SEQ	LEN	DT	USAGE ANALYZER	USAGE ANALYZER MGR.	CARD.	TBL#	NAME
2	18	ERL	C (M/X)[1]	C (M/X)[2]	[1..*]		Error Location
3	705	CWE	M	M	[1..1]	0357	HL7 Error Code
4	2	ID	M	M	[1..1]	0516	Severity

[1] For BA 400 'X'.

[2] Ignored by BA 400.

ERR.3 HL7 Error Code (CWE), *mandatory.*

Identifies the HL7 (communications) error code. Only the first component (Identifier) is supported using codes from the following subset of codes in HL7 Table 0357.

SEQ	COMPONENT/SUB-COMPONENT	DT	USAGE	COMMENT
3.1	Identifier	ST	R	

VALUE	DESCRIPTION	COMMENTS
100	Segment sequence error	Error: The message segments were not in the proper order, or required segments are missing.
101	Required field missing	Error: A required field is missing from a segment
102	Data type error	Error: The field contained data of the wrong data type, e.g., an NM field contained "FOO".
103	Table value not found	Error: A field of data type ID or IS was compared against the corresponding table, and no match was found.
200	Unsupported message type	Rejection: The Message Type is not supported.
201	Unsupported event code	Rejection: The Event Code is not supported.
202	Unsupported processing id	Rejection: The Processing ID is not supported.
203	Unsupported version id	Rejection: The Version ID is not supported.
204	Unknown key identifier	Rejection: The ID of the patient, order, etc., was not found. Used for transactions other than additions, e.g. transfer of a non-existent patient.
205	Duplicate key identifier	Rejection: The ID of the patient, order, etc., already exists. Used in response to addition transactions (Admit, New Order, etc.).
206	Application record locked	Rejection: The transaction could not be performed at the application storage level, e.g.
207	Application internal error	Rejection: A catchall for internal errors not explicitly covered by other codes.

ERR.4 Severity (ID), *mandatory.*

This field identifies the severity of an application error. The value of this field will always be 'E' for Error.

8.6.2 INV Segment

SEQ	LEN	DT	USAGE ANALYZER	CARD.	TBL#	NAME
1	250	CE	M	[1..1]	0451	Substance Identifier
2	250	CE	M	[1..1]	0383	Substance Status
3	250	CE	M	[0..1]	0384	Substance Type
12	26	TS	O	[0..1]		Expiration Date/Time
16	200	ST	O	[0..1]		Manufacturer Lot Number

INV.1 Substance Identifier (CE), mandatory.

This is a manufacturer-specific unique identifier for the control material. If the control material is in a bar-coded tube, this is also what is encoded in the bar- code to identify the material.

SEQ	COMPONENT/SUB-COMPONENT	LEN	DT	USAGE	CONTENTS
1.1	Identifier	20	ST	R	Identifier of substance

INV.2 HL7 Substance Status (CE), mandatory.

This field contains a subset of values taken from HL7 Table 0383 as described below to identify the current status of the substance.

SEQ	COMPONENT/SUB-COMPONENT	LEN	DT	USAGE	CONTENTS
2.1	Identifier	2	ST	R	Substance status

The value of this field will always be 'OK' for OK Status.

INV.3 Substance Type (CE), mandatory.

This field contains a subset of values taken from HL7 Table 0384 to identify the material as control material.

SEQ	COMPONENT/SUB-COMPONENT	LEN	DT	USAGE	CONTENTS
3.1	Identifier	2	ST	R	Type of substance (e.g., Control, Reagent, Bulk Supply, Waste)

The value of this field will always be 'CO' for Quality Control Specimen.

INV.12 Expiration Date/Time (TS), optional.

This is the expiration date of the material. Precision supported is to the day.

SEQ	COMPONENT/SUB-COMPONENT	USAGE	COMMENT
12.1	YYYYMMDD	R	

INV.16 Manufacturer Lot Number

This is a manufacturer-specific lot number of the control material.

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

8.6.3 MSA Segment

SEQ	LEN	DT	USAGE ANALYZER	USAGE ANALYZER MGR.	CARD.	TBL#	NAME
1	2	ID	M	M	[1..1]	00008	Acknowledgement Code
2	50	ST	M	M	[1..1]		Message Control Id

MSA.1 Acknowledgement Code (ID), *mandatory.*

This element contains the acknowledgment code, per the HL7 message processing rules. The following subset of codes from HL7 Table 0008 is supported.

VALUE	DESCRIPTION	COMMENTS
AA	Original mode: Application Accept	Message processed and accepted
AE	Original mode: Application Error	Message processed and was rejected due to and error in either content of format
AR	Original mode: Application Reject	Message rejected due to MSH error(s)

Note: the accompanying ERR segment to the MSA segment in the acknowledgement message will indicate the location of the error.

MSA.2 Message Control Id (ST), *mandatory.*

This field contains the value in MSH-10 Message Control ID from the message being acknowledged.

8.6.4 MSH Segment

SEQ	LEN	DT	USAGE ANALYZER	USAGE ANALYZER MGR.	CARD.	TBL#	NAME
1	1	SI	M	M	[1..1]		Field Separator
2	4	ST	M	M	[1..1]		Encoding Characters
3	227	HD	M	M	[1..1]		Sending Application
4	227	HD	M	M	[1..1]		Sending Facility
5	227	HD	M	M	[1..1]		Receiving Application
6	227	HD	M	M	[1..1]		Receiving Facility
7	26	TS	M	M	[1..1]		Date/Time of Message
9	15	MSG	M	M	[1..1]		Message Type
10	50	ST	M	M	[1..1]		Message Control Id
11	3	PT	M	M	[1..1]		Processing Id
12	60	VID	M	M	[1..1]		Version Id
15	2	ID	M	M	[1..1]	0155	Accept Acknowledgement Type
16	2	ID	M	M	[1..1]	0155	Application Acknowledgement Type
18	16	ID	M	M	[1..1]	0211	Character Set
21	427	EI	M	M	[1..1]	01598	Message Profile Identifier

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

MSH.1 Field Separator (SI), mandatory.

This profile supports the HL7-recommended value; that is | (ASCII 124).

MSH.2 Encoding Characters (ST), mandatory.

This field must contain the four characters in the following 1625 order: the component separator, repetition separator, escape character, and subcomponent separator. This profile supports the HL7-recommended values ^~\& (ASCII 94, 126, 92, and 38, respectively).

MSH.3 Sending Application (HD), mandatory.

This field contains the name of the sending application.

SEQ	COMPONENT/SUB-COMPONENT	LEN	DT	USAGE	CONTENTS
3.1	Namespace Id	20	IS	R	Vendor specified value

MSH.4 Sending Facility (HD), mandatory.

This field contains the name of the sending facility.

SEQ	COMPONENT/SUB-COMPONENT	LEN	DT	USAGE	CONTENTS
4.1	Namespace Id	20	IS	R	Laboratory specified value

MSH.5 Receiving Application (HD), mandatory.

This field contains the name of the receiving application.

SEQ	COMPONENT/SUB-COMPONENT	LEN	DT	USAGE	CONTENTS
5.1	Namespace Id	20	IS	R	Laboratory specified value

MSH.6 Receiving Facility (HD), mandatory.

This field contains the name of the receiving facility.

SEQ	COMPONENT/SUB-COMPONENT	LEN	DT	USAGE	CONTENTS
6.1	Namespace Id	20	IS	RE	Laboratory specified value

MSH.7 Date/Time of Message (TS), mandatory.

This field contains the date/time that the sending system created the message. This element shall be reported to a precision of seconds. This is the only date/time field in the message mandating the time zone. All other time stamps in the message do not support a specific time zone and are assumed to be in the same time zone as specified in this MSH-7 element.

SEQ	COMPONENT/SUB-COMPONENT	LEN	USAGE	COMMENT
7.1	YYYYMMDDHHMMSS+/-ZZZZ	19	R	Time zone is used for all other time stamps in the message

MSH.9 Message Type (MSG), mandatory.

This field contains the message type, trigger event, and the message structure ID for the message.

SEQ	COMPONENT/SUB-COMPONENT	DT	USAGE	COMMENT
9.1	Message Code	ID	R	
9.2	Trigger Event	ID	R	
9.3	Message Structure	ID	R	

MSH.10 Message Control Id (ST), *mandatory.*

This field contains a number or other identifier that uniquely identifies the message. Each message should be given a unique identifier by the sending system. The receiving system will echo this ID back to the sending system in the Message Acknowledgment segment (MSA).

MSH.11 Processing Id (PT), *mandatory.*

This field indicates whether to process the message as defined in HL7 Application (level 7) Processing rules.

SEQ	COMPONENT/SUB-COMPONENT	DT	USAGE	COMMENT
11.1	Processing Id	ID	R	

The value of this field will always be 'P' for Production.

MSH.12 Version Id (VID), *mandatory.*

The version number sent and supported is '2.5.1'.

MSH.15 Accept Acknowledgement Type (ID), *mandatory.*

This field identifies the conditions under which accept acknowledgements are required to be returned in response to a message. The LAW profile uses Enhanced Acknowledgement mode to have the accept acknowledgement report errors. MSH.15 will contain the value 'ER'.

MSH.16 Application Acknowledgement Type (ID), *mandatory.*

This field identifies the conditions under which application acknowledgements are required to be returned in response to a message. Application acknowledgements are always required, so MSH.16 will contain the value 'AL'.

MSH.18 Character Set (ID), *mandatory.*

This field contains the character set for the entire message. The value of this field will always be 'UNICODE UTF-8', UCS Transformation Format, 8-bit form.

MSH.21 Message Profile Identifier (EI), *mandatory.*

The field contains one repetition with a value representing the IHE transaction identifier.

SEQ	COMPONENT/SUB-COMPONENT	DT	USAGE	COMMENT
21.1	Entity Identifier	ST	R	<domain>-<transaction number>
21.2	Namespace Id	IS	R	IHE

8.6.5 NTE Segment

SEQ	LEN	DT	USAGE	CARD.	TBL#	NAME

			ANALYZER			
1	4	SI	O[1]	[1..1]		Set ID
3	65536	FT	O[1]	[1..n]		Comment

[1] For BA 400 'M'.

NTE.1 Set ID (SI), optional.

This field may be used where multiple NTE segments are included in a message. Their numbering must be described in the application message definition.

NTE.3 Comment (FT), optional.

This field contains the result comment contained in the segment.

8.6.6 OBR Segment

SEQ	LEN	DT	USAGE ANALYZER	USAGE ANALYZER MGR.	CARD.	TBL#	NAME
2	50	EI	M[2]	M	[1..1]		Placer Order Number (AWOS ID)
3	50	EI	O[1]	X	[0..1]		Filler Order Number
4	250	CE	M	M	[1..1]		Universal Service Identifier
17	250	XTN	O[1]	RE[2]	[0..2]		Order Callback Phone
29	200	EIP	O	X	[0..1]		Parent

[1] For BA 400 'X'.

[2] Ignored by BA 400.

OBR.2 Placer Order Number (EI), mandatory.

Each ordered battery/test is assigned to a unique Order, identified by a unique AWOS ID. The Placer Order Number is generated by the LIS actor and should be unique across all OBR segments across all messages. For the Analyzer, if the AWOS ID is unknown, then the value should be "", which is the NULL value.

SEQ	COMPONENT/SUB-COMPONENT	LEN	DT	USAGE	COMMENT
2.1	Entity Identifier	50	ST	R[3]	AWOS ID

OBR.4 Universal Service Identifier (CE), mandatory.

This field contains one ordered battery or test. A battery is composed of one or more tests or one or more batteries.

SEQ	COMPONENT/SUB-COMPONENT	LEN	DT	USAGE	COMMENT
4.1	Identifier	20	ST	R	Test/Battery Identifier
4.2	Text	199	ST	R	Name for the test/battery
4.3	Name of Coding System	20	ID	R	Analyzer Model

[2] If instrument is configured to have a relaxed LAW compliant it will be optional

[3] If instrument is configured to have a relaxed IHE-LAW compliant it will be optional

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

OBR.29 Parent (EIP), optional (Analyzer).

This field relates a child AWOS to its parent AWOS when a parent/child relationship exists. In reflex test decided in the instrument, this can be used to contain the reference to an AWOS ID that was used as part of the evaluation that determined a reflex was necessary.

SEQ	COMPONENT/SUB-COMPONENT	DT	USAGE	COMMENT
29.1	Entity identifier	ST	R	AWOS ID of Parent

8.6.7 OBX Segment

SEQ	LEN	DT	USAGE ANALYZER	USAGE ANALYZER MGR.	CARD.	TBL#	NAME
1	4	SI	M	M	[1..1]		Set ID – OBX
2	2	ID	C(M/X)	C(M/X)[2]	[1..1]	0125	Value Type
3	250	CE	M	M	[1..1]		Observation Identifier
4	20	ST	C(M/RE)[1]	C(M/X)[2]	[0..1]		Observation Sub-ID
5	99999	Varies	C(M/X)	C(M/X)	[1..1]		Observation Value
6	250	CE	C(M/X)	C(M/X)	[0..1]		Units
7	70	ST	O	RE	[0..1]		Reference Range
8	5	ID	M	M	[1..*]		Abnormal Flags
11	1	ID	M	M	[1..1]	0085	Observation Result Status
14	26	TS	O[1]	RE[2]	[0..1]		Date/Time of the Observation
16	250	XCN	M	M	[1..1]		Responsible Observer
18	427	EI	M	M[2]	[1..n]		Equipment Instance Identifier
19	26	TS	M	M	[1...1]		Date/Time of the Analysis

[1] For BA 400 'X'.

[2] Ignored by BA 400.

OBX.1 Set ID (SI), mandatory.

If the segment occurs only one time within a message structure, then its value will be '1'. If the message structure (e.g., segment group) repeats, then the first occurrence of the segment in each segment group will be '1'.

OBX.2 Value Type (ID), optional.

This field contains the format of the observation value in OBX.

Predicate: Usage is Mandatory if OBX-5 (Observation Value) is populated. Otherwise, usage is Not Supported.

The profile supports the following subset of values from HL7 Table 0125.

VALUE	DESCRIPTION	COMMENTS
CE	Coded Entry	Used to report exception code (reason test failed to produce a final result yet)
ED	Encapsulated Data	Used to report graphs, plots, etc.

NM	Numeric	Numeric result value only
NA	Numerical Array	n-dimensional set of plot values
RP	Reference Pointer	Reference to a location of the observation
SN	Structured Numeric	Used when result is above or below dynamic range of assay. (> or <)
ST	String	Interpretation string result

OBX.3 Observation Identifier (CE), mandatory.

This field contains a unique identifier for the observation.

SEQ	COMPONENT/SUB-COMPONENT	LEN	DT	USAGE	COMMENT
3.1	Identifier	20	ST	R	Test Identifier
3.2	Text	199	ST	R	Name for the test
3.3	Name of Coding System	20	ID	R	Analyzer Model

OBX.5 Observation Value (varies), conditional.

The observation value shall be reported using one of the allowed value types as specified in OBX-2; contains the result value for the test result part identified in OBX-3 Observation Identifier.

Predicate: Usage is Mandatory when the value of OBX-11 Observation Result Status is not "D. Otherwise usage is Not Supported.

If the result type is for an exception result, then the CE data type is used to report the exception code as the reason the test failed to run. The following table defines how to use the CE components to report exception.

SEQ	COMPONENT/SUB-COMPONENT	LEN	DT	USAGE	COMMENT
5.1	Identifier	4	ST	R	4 digit exception/error code
5.2	Text	260	ST	R	Text message associated with exception
5.3	Name of Coding System	20	ID	R	Analyzer Model

OBX.6 Units (CE), conditional.

This field is populated with the unit of measure for the result. UCUM shall be used to define the unit of measure.

Predicate: Usage is Mandatory if OBX-2 is valued with either with “NM” or “SN”. Otherwise usage is Not Supported.

SEQ	COMPONENT/SUB-COMPONENT	LEN	DT	USAGE	COMMENT
6.1	Identifier	20	ST	R	Unit of measure
6.2	Text	199	ST	R	
6.3	Name of Coding System	20	ID	R	Analyzer Model

OBX.7 Reference Range (ST), required if available (LIS), optional (Analyzer).

For numeric values, the suggested format of reference ranges is lower limit-upper limit when both lower and upper limits are defined (e.g., 3.5 - 4.5).

OBX.8 Abnormal Flags (IS), mandatory.

The field contains analyzer defined result flags (if any) assigned to the result. The field is set to NONE if no flags apply. Multiple flags can be assigned to a result, thus this field can repeat.

This field is intended to convey a categorical assessment of OBX-5 Observation Value, such as "Normal", "Abnormal", “Positive”, “Negative”, etc. This field may also be used to convey an assessment of an observation where no legitimate result may be obtained. This includes laboratory assays that are rejected due to the presence of interfering substances, specimen toxicity or failure of quality control. In addition, it may also be used to convey an analysis warning, such as not enough sample volume to be confident of the result.

The required flags defined in HL7 defined BA400 cases are defined in the table below.

VALUE	DESCRIPTION
001	Abs > optical limit
002	Sample Abs < Blank Abs
003	Sample Abs > Blank Abs
004	Non Linear Kinetics
005	Absorbance < 0
006	Absorbance increase < 0
007	Substrate depletion
008	Possible prozone (it requires manual dilution and repetition)
009	Reactions rotor thermo warning
010	Possible clot in sample
011	Clot detected in sample
012	Sample arm fluidic system blocked
013	Completed with optical errors
014	Main Abs > Blank Abs limit
015	Main Abs < Blank Abs limit
016	Abs Work Reagent > Blank Abs limit
017	Abs Work Reagent < Blank Abs limit
018	Initial Blank Abs > Blank Abs limit
019	Initial Blank Abs < Blank Abs limit
020	Kinetic Blank > Kinetic Blank limit
021	(Abs T2 - Abs T1) * RT > Kinetic Blank limit
022	Incorrect calibration curve
023	Calculated factor out of limits
024	Calibration factor can't be calculated
025	Expired calibrator lot
026	Conc. not calculated
027	Conc. out of calibration curve (HIGH)
028	Conc. out of calibration curve (LOW)
029	Conc < 0
030	Conc > Linearity limit
031	Conc < Detection limit
032	Conc < Normality Min
033	Conc > Normality Max
034	Conc < Panic Min

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

VALUE	DESCRIPTION
035	Conc > Panic max
036	Some standard tests with remarks
037	Drift in calibrator A
038	Drift in calibrator A
039	Noise in measuring calibrator A
040	Noise in measuring calibrator B
041	Noise measuring calibrator B
042	Voltage out of limit measuring calibrator A
043	Drift out of limits
044	Voltage out of limit measuring calibrator B
045	Result out of range
NONE	No flags

OBX.11 Observation Result Status (ID), mandatory.

This field supports a subset of values taken from HL7 User-defined Table 0085 as described 1870 below:

VALUE	DESCRIPTION	COMMENTS
F	Final results	Primary result value for the test run – the quantitative result
X	Results cannot be obtained	Test Exception. The reason for failure is being reported.

OBX.16 Responsible Observer (XCN), mandatory.

This field contains the identity of the observer that causes the change of the observation result status. Only the first component (ID number) of this field is necessary. If the value is unknown, then a NULL value will be used for the ID number.

SEQ	COMPONENT/SUB-COMPONENT	LEN	DT	USAGE	COMMENT
16.1	ID number	20	ST	R	Locally defined identifier

OBX.18 Equipment Instance Identifier (EI), mandatory.

This field specifies the manufacturer, model, serial number/ID, and optional UID of the analyzer that performed the test. It may also contain additional manufacturer or site specific identifiers.

OBX-18 is repeatable in v2.5.1. The first instance is mandatory and will be used to carry the instrument model, manufacturer, and optional UDI information.

First Instance of Element: OBX-18 Equipment Instance Identifier:

SEQ	COMPONENT/SUB-COMPONENT	USAGE	COMMENT
18.1	Entity Identifier	R	Model
18.2	Namespace	R	Manufacturer

Second Instance of Element: OBX-18 Equipment Instance Identifier:

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

SEQ	COMPONENT/SUB-COMPONENT	USAGE	COMMENT
18.1	Entity Identifier	R	Serial Number
18.2	Namespace	R	Manufacturer

The optional third and subsequent instance of OBX-18 will be used to carry manufacturer or site specific information to allow for the identification of the hierarchical configuration of the equipment (cluster of modules, etc.) and site specific identification. BA 400 will not send this information, and will ignore it in case of receiving such information from the LIS.

OBX.19 Date/Time of the Analysis (TS), *required if available (LIS), optional (Analyzer).*
This field contains the date and time the test processing completed. Time zone indicator is not supported. Degree of precision component is not supported.

SEQ	COMPONENT/SUB-COMPONENT	USAGE	COMMENT
19.1	YYYYMMDDHHMMSS	R	

8.6.8 ORC Segment

SEQ	LEN	DT	USAGE ANALYZER	USAGE ANALYZER MGR.	CARD.	TBL#	NAME
1	2	ID	M	M	[1..1]		Order Control
2	50	EI	C(M/X)[1]	X	[0..1]		Placer Order Number
4	20	EI	O	RE	[0..1]		Placer Group Number
5	2	ID	M	X	[1..1]		Order Status
9	26	TS	M	M	[1..1]	0038	Date/Time of Transaction
21	250	XON	O	RE	[0..1]		Ordering Facility Name
27	26	TS	O[1]	X	[0..1]		Filler Expected Availability Date/Time

[1] For BA 400 'X'.

ORC.1 Order Control (ID), *mandatory.*
This field may be considered the "trigger event" identifier for orders. The IHE Laboratory Technical Framework allows only the following subset for the LAW profile:

VALUE	DESCRIPTION	COMMENTS
NW	New Order	
OK	Notification or request accepted	Event acknowledgement in ORL message
UA	Unable to accept order/service	Event acknowledgement in ORL message
CA	Cancel order/service request	Event request in OML.
CR	Cancelled as requested	Event acknowledgement in ORL message responding to OML (CA)
UC	Unable to cancel	Event acknowledgement in ORL message responding to OML (CA)
DC	Discontinue Request	Used to indicate a negative query response
PR	Prior Results	

BioSystems
Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

ORC.2 Placer Order Number (EI), not supported (LIS), conditional (Analyzer).

The field is used by the Analyzer to uniquely identify an AWOS when used as part of an ORL^O34 response to the LIS.

Predicate: Usage is Mandatory if MSH-9.1 (Message type) is populated with “ORL” and MSH-9.2 (Event type) is populated with “O34”. Otherwise, usage is Not Supported because the placer order number is only carried by field OBR-2 Placer Order Number.

ORC.4 Placer Group Number (EI), required if available (LIS), optional (Analyzer)

The Placer Group Number represents an identification of a set of closely related batteries and/or tests for one subject ordered together and for the same diagnostic purpose. This field contains the Work Order identifier that groups AWOS ordered together by the LIS and sent to one or more Analyzers. The Work Order can encompass more than one sample from the same patient. Only the LIS establishes a Work Order identifier, therefore only the first identifier of the EIP data type is supported.

In cases where AWOS are not grouped under a common Work Order, this field is empty.

ORC.5 Order Status (ID), mandatory (Analyzer)

The allowed values for this field within IHE Laboratory Technical Framework are a subset of 1935 HL7 table 0038 - Order Status as shown below:

VALUE	DESCRIPTION	COMMENTS
CA	Order was cancelled	
CM	Order is completed	
IP	In process, unspecified	

ORC.9 Date/Time of Transaction (TS), mandatory.

This field contains the date and time of the event that initiated the current transaction as reflected in ORC-1 Order Control Code. This field is not equivalent to MSH-7 Date and Time of Message that reflects the date/time of the creation of the physical message.

In OML messages "Status changed", this field contains the date/time of the last status change of the unit of work (ORC-5).

SEQ	COMPONENT/SUB-COMPONENT	USAGE	COMMENT
9.1	YYYYMMDD	R	

ORC.21 Ordering Facility Name (XON), required if available (LIS), optional (Analyzer).

This field contains the name of the facility placing the order.

SEQ	COMPONENT/SUB-COMPONENT	DT	USAGE	COMMENT
21.1	Organization Name	ST	R	

8.6.9 PID Segment

SEQ	LEN	DT	USAGE ANALYZER	USAGE ANALYZER MGR.	CARD.	TBL#	NAME
3	30	CE	M	M	[1..1]		Patient Identifier List
5	250	XPN	O	RE	[0..1]		Patient Name
6	250	XPN	O[1]	RE[2]	[0..1]		Mother's Maiden Name
7	26	TS	O	RE	[0..1]		Date/Time of Birth
8	1	IS	O	RE	[0..1]	0001	Administrative Sex

[1] For BA 400 'X'.

[2] Ignored by BA 400.

PID.3 Patient Identifier List (CX), *mandatory.*

This element supports the list of identifiers (one or more) used by the healthcare facility to uniquely identify a patient (e.g., medical record number, billing number, birth registry, national unique individual identifier, etc.). Additional characteristics of the identifier are not necessary because only the identifier value is required for the Analyzer to identify the patient. The Analyzer should not receive multiple identifiers for the same patient.

SEQ	COMPONENT/SUB-COMPONENT	DT	USAGE	COMMENT
3.1	Entity Identifier	ST	R	Locally defined

PID.5 Patient Name (XPN), *required if available (LIS), optional (Analyzer).*

This element contains the primary or legal name of the patient.

SEQ	COMPONENT/SUB-COMPONENT	LEN	DT	USAGE	COMMENT
5.1	Family Name		FN	RE	
5.1.1	Surname (a.k.a. last name)	30	ST	RE	
5.2	Given name (a.k.a. first name)	30	ST	RE	
5.7	Name type code	1	ID	R	Always 'L'

PID.7 Date/Time of Birth (TS), *required if available (LIS), optional (Analyzer).*

This field contains the patient's date and time of birth. Only the birth date is supported. Time of birth and time zone indicator are not supported. Degree of precision component is not supported.

SEQ	COMPONENT/SUB-COMPONENT	USAGE	COMMENT
7.1	YYYYMMDD	R	

PID.8 Administrative Sex (IS), *required if available (LIS), optional (Analyzer).*

This field contains the patient's sex. Can be blank or contain only a value from HL7 User-defined Table 0001.

VALUE	DESCRIPTION	COMMENTS
F	Female	
M	Male	
U	Unknown	

8.6.10 PV1 Segment

SEQ	LEN	DT	USAGE ANALYZER	USAGE ANALYZER MGR.	CARD.	TBL#	NAME
2	1	IS	M	M	[1..1]	0004	Patient Class
3	80	PL	O	M[1]	[0..1]		Assigned Patient Location

[1] When PV1 is in the PRIOR RESULT segment group, the only mandatory field is PV1.2 and its value should be 'U'.

PV1.2 Patient Class (IS), *mandatory.*

This field is used by systems to categorize patients by site. The field must contain a value taken from HL7 User-defined Table 0004 Patient Class.

VALUE	DESCRIPTION	COMMENTS
B	Obstetrics	
C	Commercial Account	
E	Emergency	
I	Inpatient	
N	Not Applicable	
O	Outpatient	
P	Preadmit	
R	Recurring Patient	
U	Unknown	

PV1.3 Assigned Patient Location (PL), *required if available (LIS), optional (Analyzer).*

This field contains the patient's initial assigned location or the location to which the patient is being moved. Only a single patient location element is supported.

SEQ	COMPONENT/SUB-COMPONENT	LEN	DT	USAGE	COMMENT
3.2	Room	20	IS	RE	

8.6.11 SAC Segment

SEQ	LEN	DT	USAGE ANALYZER	USAGE ANALYZER MGR.	CARD.	TBL#	NAME
3	30	EI	C (M/X)[1]	C (M/X)[1]	[0..1]		Container Identifier
29	20	SN	O[2]	RE[3]	[0..1]		Dilution Factor

[1] For BA 400 'M'.

[2] For BA 400 'X'.

[3] Ignored by BA 400.

SAC.3 Container Identifier (EI), *conditional.*

This field identifies the container. This field is the container's unique identifier assigned by the corresponding equipment. A container may contain the primary (original) specimen or an aliquot

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

(secondary sample) of that specimen. For primary sample this field contains Primary Container ID; for bar-coded aliquot samples this field contains Aliquot Container ID; for non-bar-coded aliquot samples (e.g., microtiter plate) this field is empty.

It is expected that the Container ID here is normally encoded as the ID (barcode, RFID) on the sample container.

Predicate: Either SAC-3 or SAC-4 or both must be populated.

SEQ	COMPONENT/SUB-COMPONENT	LEN	DT	USAGE	COMMENT
3.1	Entity Identifier	30	ST	R	

8.6.12 SPM Segment

SEQ	LEN	DT	USAGE ANALYZER	USAGE ANALYZER MGR.	CARD.	TBL#	NAME
1	4	SI	M	M	[1..1]		Set ID – SPM
2	30	EIP	O	RE	[0..1]		Specimen Id
3	80	EIP	C	C (M/X)	[0..*]		Specimen Parent Ids
4	250	CWE	O	M	[1..1]	0487	Specimen Type
11	250	CWE	M	M	[0..1]	0369	Specimen Role
13	6	NM	C	C (M/X)	[0..1]		Grouped Specimen Count
17	26	DR	C (O/X)	C (RE/X)	[0..1]		Specimen Collection Date/Time
18	26	TS	C (O/X)	C (RE/X)	[0..1]		Specimen Received Date/Time

SPM.1 Set ID (SI), *mandatory.*

This field contains the sequence number. This field is used to identify segment instances in message structures (e.g., segment group) where the segment repeats within that structure. For the first occurrence of the segment, the sequence number shall be one, for the second occurrence, the sequence number shall be two, etc.

If the segment occurs only one time within a message structure (e.g., segment group), then its value will be '1'. If the message structure (e.g., segment group) repeats, then the first occurrence of the segment in each segment group will be '1'.

SPM.2 Specimen Id (EIP), *required if available (LIS), optional (Analyzer).*

This field contains the specimen identifier. It may be the enterprise-wide unique specimen identifier.

SEQ	COMPONENT/SUB-COMPONENT	LEN	DT	USAGE	COMMENT
2.1	Placer Assigned Identifier		EI	R	
2.1.1	Entity Identifier	30	ST	R	

SPM.3 Specimen Parent ID (EIP), conditional.

This field contains the identifiers for the specimen or specimens that contributed to the specimen that is described by the segment instance. For pooled patient samples indicated by SPM-11 equal to "L", this field will contain the specimen identifiers of the specimens that were pooled.

Predicate: Usage is Mandatory if SPM-11 Specimen Role is "L". Otherwise usage is Not Supported.

SEQ	COMPONENT/SUB-COMPONENT	LEN	DT	USAGE	COMMENT
3.1	Placer Assigned Identifier		EI	R	
3.1.1	Entity Identifier	20	ST	R	

SPM.4 Specimen Type (CWE), mandatory (LIS), optional (Analyzer).

This field describes the precise nature of the entity that will be the source material for the observation. The values defined in HL7 Table 0487 – Specimen Type will be used. The Analyzer may define extensions to the table, and the Analyzer may identify a subset of specimen types that are supported.

This field is required if the Specimen Role (SPM-11) is Patient. It will be NULL if the Specimen Role (SPM-11) is QC.

Only the first component is used.

SEQ	COMPONENT/SUB-COMPONENT	DT	USAGE	COMMENT
4.1	Identifier	ST	R	Code from HL7 Table 0487 – Specimen Type.

SPM.11 Specimen Role (CWE), mandatory.

This identifies the role of the specimen to be a Patient, Pooled Patient, or QC specimen. Only the first component (i.e. Identifier) is supported.

VALUE	DESCRIPTION	COMMENTS
P	Patient	
Q	Control specimen	
L	Pooled patient specimens	Specimens from multiple patients, number of pooled specimens is provided in SPM-13

SPM.13 Grouped Specimen Count (NM), conditional.

This field identifies the number patient specimens that were pooled.

Predicate: Usage is Mandatory if SPM-11 Specimen Role is "L". Otherwise usage is Not Supported.

SPM.17 Specimen Collection Date/Time (DR), conditional.

The date and time when the specimen was acquired from the source. Only the start date/time component is supported (i.e. first component).

LIS Predicate: Usage is Required if Available when SPM-11 is "P". Otherwise usage is Not Supported.

Analyzer Predicate: Usage is Optional when SPM-11 is "P". Otherwise usage is Not Supported.

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

This element shall be reported to a precision of seconds. Indication of the time zone is not supported. The degree of precision component is not supported.

SEQ	COMPONENT/SUB-COMPONENT	USAGE	COMMENT
17.1	YYYYMMDDHHMMSS	R	

SPM.18 Specimen Collection Date/Time (DR), conditional.

The specimen received date/time is the time that the specimen is received at the diagnostic service. The actual time that is recorded is based on how specimen receipt is managed and may correspond to the time the sample is logged in. This is fundamentally different from SPM-17 Specimen Collection Date/Time. Only the start date/time component is supported (i.e. first component).

LIS Predicate: Usage is Required if Available when SPM-11 is "P". Otherwise usage is Not Supported.

Analyzer Predicate: Usage is Optional when SPM-11 is "P". Otherwise usage is Not Supported.

This element shall be reported to a precision of seconds. Indication of the time zone is not supported. The degree of precision component is not supported

SEQ	COMPONENT/SUB-COMPONENT	USAGE	COMMENT
18.1	YYYYMMDDHHMMSS	R	

8.6.13 TCD Segment

SEQ	LEN	DT	USAGE ANALYZER MGR.	CARD.	TBL#	NAME
1	250	CE	M[1]	[1..1]		Universal Service Identifier
2	20	SN	RE[1]	[0..1]		Auto-Dilution Factor
3	20	SN	RE[1]	[0..1]		Rerun Dilution Factor
4	20	SN	RE[1]	[0..1]		Pre-Dilution Factor
5	20	SN	RE[1]	[0..1]		Endogenous Content of Pre-Dilution Diluent
6	1	ID	RE	[0..1]	0136	Automatic Repeat Allowed
7	1	ID	RE	[0..1]	0136	Reflex Allowed
8	250	CE	RE[1]	[0..1]	0389	Analyte Repeat Status

[1] Ignored by BA 400.

TCD.6 Automatic Repeat Allowed (ID), required if available.

This field identifies whether or not automatic repeats are to be initiated for this particular specimen for this particular test code. Refer to HL7 Table 0136 -Yes/no indicator for valid values.

VALUE	DESCRIPTION	COMMENTS
Y	Yes	
N	No	

TCD.7 Reflex Allowed (ID), *required if available.*

Definition: This field identifies whether or not automatic or manual reflex testing is to be initiated for this particular specimen. Refer to HL7 Table 0136 -Yes/no indicator for valid values.

VALUE	DESCRIPTION	COMMENTS
Y	Yes	
N	No	

8.6.14 TQ1 Segment

SEQ	LEN	DT	USAGE ANALYZER MGR.	CARD.	TBL#	NAME
9	250	CWE	M	[1..1]	0485	Priority

TQ1.9 Priority (CWE), *mandatory.*

This field identifies the priority of the order. Only the first component (i.e. Identifier) is supported and it can contain only values taken from HL7 User-defined Table 0485 (see below).

SEQ	COMPONENT/SUB-COMPONENT	DT	USAGE	COMMENT
9.1	Identifier	ST	R	Code from HL7 User-defined Table 0485

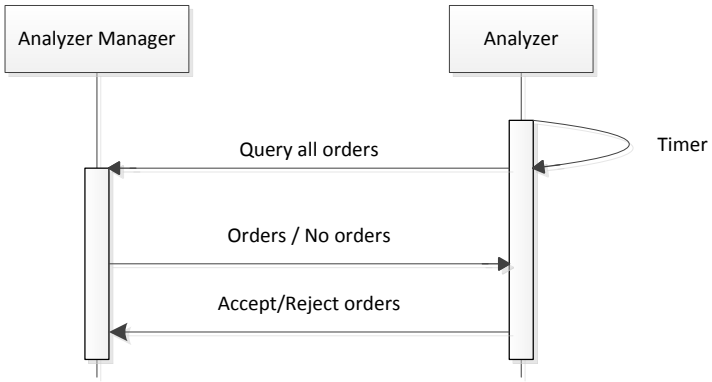
VALUE	DESCRIPTION	COMMENTS
R	Routine	
S	Stat	

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

9 LIS2-A2 Scenarios and Messages

9.1 AWOS query for all available orders.



9.1.1 Analyzer sends query message to the LIS

The message has the following structure

LEVEL 0	LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
H					
	Q				
L					

The Header record follows the structure described in Section 10.1 with the following details:

- H-5. Analyzer ID (BAx00).
- H-10. LIS ID (configurable at the Analyzer).

The Request record follows the structure described in Section 10.2 with the following details:

- Q-3. Contains the text 'ALL', only once.

The Termination record follows the structure described in Section 10.3 with the following details:

- L-3. 'N', normal termination.

```
H|\^&|64F2746D24014F21AD7139756F64CAD8||BA400|||||Modulab||P|LIS2A|201301
29102030
Q|1|ALL||O
L|1|N
```

9.1.2 LIS answers without orders

The message has the following structure

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

LEVEL 0	LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
H					
L					

The Header record follows the structure described in Section 10.1 with the following details:

- H-5. LIS ID.
- H-10. Analyzer ID.

The Termination record follows the structure described in Section 10.3 with the following details:

- L-3. 'I', no information available from last query.

```
H|\^&|69F2746D24014F21AD7139756F64CAD8||Modulab|||||BA400||P|LIS2A|201301
29102030
L|1|I
```

9.1.3 LIS answers with new orders or cancellation of orders

The message has the following structure. There can be one or more patients, one or more orders per patient and optionally, an order can contain one or more previous results.

LEVEL 0	LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
H					
{					
	P				
	{				
		O			
		[{			
			R		
			[		
				C	
			]		
		}]			
	}				
}					
L					

The Header record follows the structure described in Section 10.1 with the following details:

- H-5. LIS ID.
- H-10. Analyzer ID (BAx00).

The Patient record follows the structure described in Section 10.4.

The Order record follows the structure described in Section 10.5 with the following details:

- O-3. Specimen ID that is the subject of the test to perform.

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

- In case of actions (add/cancel orders) to perform on this specimen
  - O-5.4. Test or battery to perform, using the Analyzer coding system.
  - O-12. This field identifies the action to perform. Several options may be possible:
    - To program a new order on a patient sample, the value shall be 'A'.
    - To program a new order on a QC sample, the value shall be 'A' and 'Q' (the field is repeated).
    - To cancel an existing order on a patient sample, the value shall be 'C'.
    - To cancel an existing order on a QC sample, the value shall be 'C' and 'Q' (the field is repeated).
  - O-26. This field identifies the type of report. The values shall be 'O' and 'Q' (the field is repeated).
- In case no action has to be performed on this specimen
  - O-26. This field identifies the type of report. The values shall be 'Y' and 'Q' (the field is repeated).

The Result record follows the structure described in Section 10.6 with the following details:

- R-9. This field shall contain the value 'N' and also:
  - 'F' If the result sent to the analyzer is valid.
  - 'X' If the result sent to the analyzer was invalid.

The Comment record follows the structure defined in Section 10.7 with the following details:

- C-2 can only be '1', since only one record is allowed.
- C-3 shall be 'L', because the sender is the LIS.
- C-4.1 is the error code.
- C-4.2 is the error description.
- C-5 shall be 'I' because the provided information is an instrument code.

The Termination record follows the structure described in Section 10.3 with the following details:

- L-3. 'F', last request for information processed.

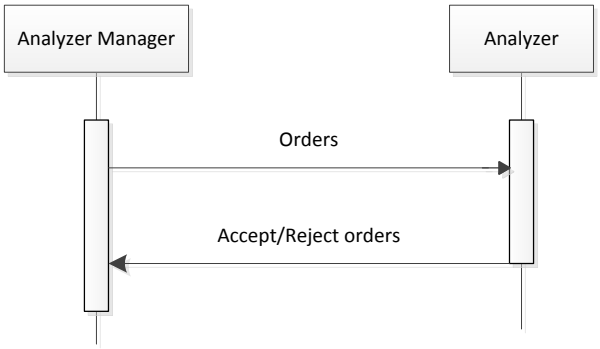
BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

```
H|\^&|69F2746D24014F21AD7139756F64CAD8||Modulab|||||BA400||P|LIS2A|201301
29102030
P|1||PID01||Campeny^Ricard||19850819|M
O|1|SPM01||^^^Test
1|R|20130129101530|20130129092030||||A||||HBLUD|||||^56|||||O\Q
O|2|SPM02||^^^|||20130129092530|||||||HBLUD|||||^57|||||Y\Q
L|1|F
```

9.2 AWOS broadcasted by the LIS



9.2.1 LIS answers with new orders or cancellation of orders

The message has the following structure. There can be one or more patients, one or more orders per patient and optionally, an order can contain one or more previous results. Each result can contain a Comment record to carry error information if any.

LEVEL 0	LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
H					
{					
	P				
	{				
		O			
		[{			
			R		
			[		
				C	
			]		
		}]			
	}				
}					
L					

The Header record follows the structure described in Section 10.1 with the following details:

- H-5. LIS ID.

- H-10. Analyzer ID (BAx00).

The Patient record follows the structure described in Section 10.4.

The Order record follows the structure described in Section 10.5 with the following details:

- O-3. Specimen ID that is the subject of the test to perform.
- O-5.4. Test or battery to perform, using the Analyzer coding system.
- O-12. This field identifies the action to perform. Several options may be possible:
  - To program a new order on a patient sample, the value shall be 'A'.
  - To program a new order on a QC sample, the value shall be 'A' and 'Q' (the field is repeated).
  - To cancel an existing order on a patient sample, the value shall be 'C'.
  - To cancel an existing order on a QC sample, the value shall be 'C' and 'Q' (the field is repeated).
- O-26. This field identifies the type of report. The values shall be only 'O'.

The Result record follows the structure described in Section 10.6 with the following details:

- R-9. This field shall contain the value 'N' and also:
  - 'F' If the result sent to the analyzer is valid.
  - 'X' If the result sent to the analyzer was invalid.

The Comment record follows the structure defined in Section 10.7 with the following details:

- C-2 can only be '1', since only one record is allowed.
- C-3 shall be 'L', because the sender is the LIS.
- C-4.1 is the error code.
- C-4.2 is the error description.
- C-5 shall be 'I' because the provided information is an instrument code.

The Termination record follows the structure described in Section 10.3 with the following details:

- L-3. 'N', last request for information processed.

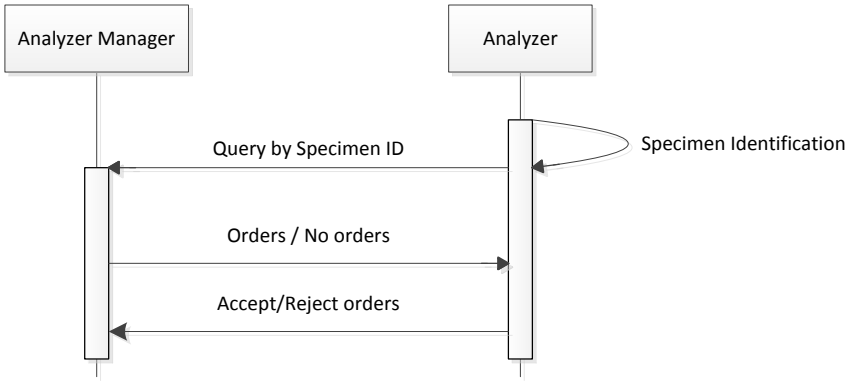
```
H|\^&|69F2746D24014F21AD7139756F64CAD8||Modulab|||||BA400||P|LIS2A|201301
29102030
P|1||PID01||Campeny^Ricard||19850819|M
O|1|SPM01||^^^Test
1|R|20130129101530|20130129092030||||A||||HBLUD|||||^56|||||O
O|2|SPM01||^^^Test
2|R|20130129101530|20130129092030||||A||||HBLUD|||||^56|||||O
O|3|SPM02||^^^Test
3|R|20130129101730|20130129092031||||A||||HBLUD|||||^57|||||O
L|1|N
```

9.3 AWOS queried by the Analyzer at specimen arrival

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es



9.3.1 Analyzer sends query message to the LIS

The message has the following structure.

LEVEL 0	LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
H					
	Q				
L					

The Header record follows the structure described in Section 10.1 with the following details:

- H-5. Analyzer ID (BAx00).
- H-10. LIS ID (configurable at the Analyzer).

The Request record follows the structure described in Section 10.2 with the following details:

- Q-3. Contains the Specimen ID, repeated for as many specimens are requested.

The Termination record follows the structure described in Section 10.3 with the following details:

- L-3. 'N', normal termination.

```
H|\^&|65F2746D24014F21AD7139756F64CAD8||BA400|||||Modulab||P|LIS2A|201301
29102030
Q|1|SPM01\SPM02||O
L|1|N
```

9.3.2 LIS answers without orders

The message has the following structure. There can be one or more patients, one or more orders per patient and optionally, an order can contain one or more previous results.

LEVEL 0	LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
H					
{					
	P				

	{				
		O			
	}				
}					
L					

The Header record follows the structure described in Section 10.1 with the following details:

- H-5. LIS ID.
- H-10. Analyzer ID (BAx00).

The Patient record follows the structure described in Section 10.4. All the fields except the second can be empty

The Order record follows the structure described in Section 10.5 with the following details:

- O-3. Specimen ID that is the subject of the original query.
- O-26. This field identifies the type of report. The values shall be 'Y' and 'Q' (the field is repeated).

The Termination record follows the structure described in Section 10.3 with the following details:

- L-3. 'F', last request for information processed.

9.3.3 LIS answers with new orders or cancellation of orders

This message is exactly the same as the one described in Section 9.1.3.

9.4 AWOS acceptance/rejection by the Analyzer

9.4.1 Analyzer accepts the actions proposed by the LIS

The message the following structure. The analyzer just reports to the LIS a message with the Header and Termination records.

LEVEL 0	LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
H					
L					

```
H|\^&|66F2746D24014F21AD7139756F64CAD8||BA400|||||Modulab||P|LIS2A|201301
29102030
L|1|N
```

9.4.2 Analyzer rejects the actions proposed by the LIS

The message has the following structure. The Analyzer reports to the LIS the outcome of the programming or cancellation of the orders. This message always follows to one of the messages described in sections 9.1.3 or 9.3.3.

LEVEL 0	LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
H					
{					
	P				
	{				
		O			
	}				
}					
L					

The Header record follows the structure described in Section 10.1 with the following details:

- H-5. Analyzer ID (BAx00).
- H-10. LIS ID.

The Patient record follows the structure described in Section 10.4.

The Order record follows the structure described in Section 10.5 with the following details:

- O-3. Specimen ID that is the subject of the test to perform.
- O-5.4. Test or battery to perform, using the Analyzer coding system.
- O-12 / O-26. These fields identify the action to perform and the report type. Several options may be possible:
    - If the action requested was to program a new order on a patient sample and
        - The action cannot be performed,
            - O-12 has the value ‘A’.
            - O-26 has the value ‘X’.
    - If the action requested was to program a new order on a QC sample and
        - The action was successful at the Analyzer,
            - O-12 has the value ‘A’ and ‘Q’ (the field is repeated).
            - O-26 has the value ‘X’.

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

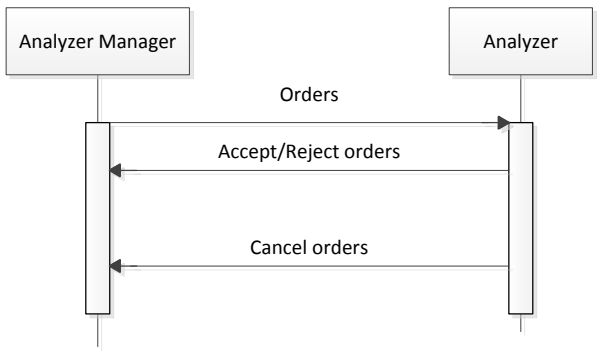
- If the action requested was to program a new order on a Pooled Patient sample and the action was successful at the Analyzer,
    - O-12 has the value 'A' and 'D' (the field is repeated).
    - O-26 has the value 'X'.
- If the action requested was to cancel an existing order on a patient sample and
    - The action cannot be performed,
        - O-12 has the value 'C'.
        - O-26 has the value 'I'.
- If the action requested was to cancel an existing order on a QC sample and
    - The action cannot be performed,
        - O-12 has the value 'C' and 'Q' (field is repeated).
        - O-26 has the value 'I'.
- If the action requested was to cancel an existing order on a Pooled Patient sample and the action cannot be performed,
    - O-12 has the value 'C' and 'D' (field is repeated).
    - O-26 has the value 'I'.

The Termination record follows the structure described in Section 10.3 with the following details:

- L-3. 'N', last request for information processed.

```
H|\^&|69F2746D24014F21AD7139756F64CAD8||Modulab|||||BA400||P|LIS2A|201301
29102030
P|1||PID01||Campeny^Ricard||19850819|M
O|1|SPM01||^^^Test
1|R|20130129101530|20130129092030||||C||||HBLUD|||||^56|||||O
L|1|N
```

9.5 Analyzer cancel orders already accepted



9.5.1 Analyzer cancel orders previously accepted

The message has the following structure. The Analyzer reports to the LIS the cancellation of the orders that previously have been accepted.

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

LEVEL 0	LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
H					
	P				
	{				
		O			
	}				
L					

The Header record follows the structure described in Section 10.1 with the following details:

- H-5. Analyzer ID (BAx00).
- H-10. LIS ID.

The Patient record follows the structure described in Section 10.4.

The Order record follows the structure described in Section 10.5 with the following details:

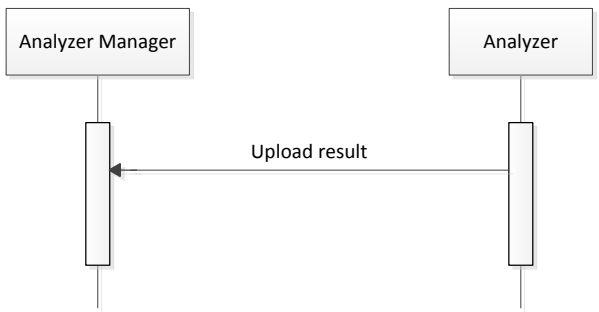
- O-3. Specimen ID that is the subject of the test to perform.
- O-5.4. Test or battery to perform, using the Analyzer coding system.
- O-12. In this case it must be empty
- O-26. These field identify the action to perform and the report type. In this case always has the value 'X' to cancel the order.

The Termination record follows the structure described in Section 10.3 with the following details:

- L-3. 'N', last request for information processed.

```
H|\^&|69F2746D24014F21AD7139756F64CAD8||Modulab|||||BA400||P|LIS2A|201301
29102030
P|1||PID01||Campeny^Ricard||19850819|M
O|1|SPM01||^^^Test 1|R||||||||||||||||||||X
L|1|N
```

9.6 Upload of results



Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

9.6.1 Analyzer upload results for the first time

The message has the following structure. The Analyzer reports to the LIS the outcome of the runs it has performed on some samples.

LEVEL 0	LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
H					
{					
	P				
	{				
		O			
		{[			
			R		
			{[		
				C	
			]}		
		]}			
	}				
}					
L					

The Header record follows the structure described in Section 10.1 with the following details:

- H-5. Analyzer ID (BAx00).
- H-10. LIS ID.

The Patient record follows the structure described in Section 10.4.

The Order record follows the structure described in Section 10.5 with the following details:

- O-3. Specimen ID that is the subject of the test to perform.
- O-5.4. Test or battery ordered, using the Analyzer coding system.
- O-12. Shall be empty if this is a patient sample, or has the value 'Q' if this is a QC sample.
- O-26. The allowed value is 'F'.

The Result record follows the structure described in Section 10.6 with the following details:

- R-3.4 . The test code of the analyte.
- R-9. This field may contains one of the following:
  - 'F' If the run was successful and there is a valid result.
  - 'X' If the run was unsuccessful and there were some error.

The Comment record follows the structure described in Section 10.7 with the following details:

- C-3. Always 'I'.
- If the comment is a general comment by the operator,
  - C-4.1. Contains the value 'COMMENT'.
  - C-4.2. Contains the comment text.

- C-5. The value is ‘G’.

- If the comment is the report of an error,
  - C-4.1. Contains the Error code.
  - C-4.2. Contains a description of the error.
  - C-5. The value is ‘I’.

The Termination record follows the structure described in Section 10.3 with the following details:

- L-3. ‘N’, last request for information processed.

```
H|\^&|69F2746D24014F21AD7139756F64CAD8||BA400|||||Modulab||P|LIS2A|201301
29102030
P|1||PID01||Campeny^Ricard||19850819|M
O|1|SPM01||^^^Test
1|R|20130129101530|20130129092030|||||||HBLUD|||||||20130129092031|||F
R|1|^^^Test 1|50|degree||||F||||20130129092031|BA400^SN-BA400-01
L|1|N
```

9.7 Rerun

The structure of this message is the same as the section above. The result values reported are the latest ones. This correction in the results is reported in the following field:

- R-9. The value shall be,
  - ‘F’ and ‘C’ if the analyzer successfully performed the run.
- ‘X’ and ‘C’ if the run was not successful for that analyte.

```
H|\^&|69F2746D24014F21AD7139756F64CAD8||BA400|||||Modulab||P|LIS2A|201301
29102030
P|1||PID01||Campeny^Ricard||19850819|M
O|1|SPM01||^^^Test
1|R|20130129101530|20130129092030|||||||HBLUD|||||||20130129092031|||F
R|1|^^^Test 1|50|degree||||F\C||||20130129092031|BA400^SN-BA400-01
L|1|N
```

9.8 Reflex

If there is a reflex test it is transmitted as a new result.

9.9 Retransmission

The message in case of retransmission is the same as the original one except for the following fields:

- H.3. The Message Control ID can be different than the original message.
- H.14. The date and time of the message is updated.

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

10 LIS2-A2 Segments

10.1 Header record

SEQ	LEN	DT	USAGE ANALYZER	USAGE ANALYZER MGR.	CARD.	NAME
1	1	ST	R	R	[1..1]	Record Type ID
2	5	ST	R	R	[1..1]	Delimiter Definition
3	50	ST	R	R	[1..1]	Message Control ID
5	227	ST	R	R	[1..1]	Sender ID
10	227	ST	R	R	[1..1]	Receiver ID
12	1	ST	R	R	[1..1]	Processing ID
13	10	ST	R	R	[1..1]	Version Number
14	14	DT	R	R	[1..1]	Date and Time of Message

10.1.1 Record Type ID

It must be valued to 'H'.

10.1.2 Delimiter Definition

The standard set of delimiters will be used: '|\^&|'.

10.1.3 Message Control ID

Unique identifier of the message.

10.1.4 Sender ID

Sender name, it is a site-configurable parameter at the analyzer.

10.1.5 Receiver ID

Receiver name, it is a site-configurable parameter at the analyzer.

10.1.6 Processing ID

The value of this field will be always 'P' for Production.

10.1.7 Version Number

The version number sent and supported is 'LIS2A'.

10.1.8 Date and Time of the Message

The date and time of the message if the LIS2-A2 date/time format: YYYYMMDDHHmmSS where,

- YYYY : year, four digits.
- MM: month, two digits, (01 = January).
- DD: day of the month, two digits (01-31).
- HH: hour of the day (24-hour format).
- mm: minutes of the hour (00-59).
- SS: seconds of the minute (00-59).

Milliseconds or timezones are not supported.

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

10.2 Request record

SEQ	LEN	DT	USAGE ANALYZER	USAGE ANALYZER MGR.	CARD.	NAME
1	1	ST	R	X	[1..1]	Record Type ID
2	1	ST	R	X	[1..1]	Sequence Number
3	100	ST	R	X	[1..*]	Starting Range ID Number
5	1	ST	R	X	[1..1]	Request Information Status Code

10.2.1 Record Type ID

The value of this field is set to 'Q'.

10.2.2 Sequence Number

This field represents the sequence number of all the requests records within this message.

10.2.3 Starting Range ID Number

This field contains the Specimen ID used for request. This field is repeatable.

10.2.4 Request Information Status Code

The value of this field is set to 'O' since the analyzer only requests for orders.

10.3 Termination record

SEQ	LEN	DT	USAGE ANALYZER	USAGE ANALYZER MGR.	CARD.	NAME
1	1	ST	R	R	[1..1]	Record Type ID
2	1	ST	R	R	[1..1]	Sequence Number
3	1	ST	R	R	[1..1]	Terminator code

10.3.1 Record Type ID

The value of this field is set to 'L'.

10.3.2 Sequence Number

This field represents the sequence number of all the termination records within this message.

10.3.3 Termination Code

This field provides an explanation of the end of the session.

Allowed values:

- N, normal termination.
- I, no information available from last query.
- F, last request for information processed.

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

10.4 Patient record

SEQ	LEN	DT	USAGE ANALYZER	USAGE ANALYZER MGR.	CARD.	NAME
1	1	ST	R	R	[1..1]	Record Type ID
2	1	ST	R	R	[1..1]	Sequence Number
4	30	ST	O	O	[0..1]	Laboratory-Assigned Patient ID
6.1	30	ST	O	O	[0..1]	Patient Last Name
6.2	30	ST	O	O	[0..1]	Patient First Name
8	8	DT	O	O	[0..1]	Patient Birth date
9	1	ST	O	O	[0..1]	Patient Sex
26	20	ST	O	O	[0..1]	Location

10.4.1 Record Type ID

The value of this field is set to 'P'.

10.4.2 Sequence Number

This field represents the sequence number of all the patient records within this message.

10.4.3 Laboratory-Assigned Patient ID

Patient identifier assigned by the laboratory. First time this value is received in BAx00, if additional demographic data is also received, it is added as new Patient. Once the patient has been added, each time the same identifier is received, its demographic data is updated with the last values received. Patient Identifiers should not be re-used.

10.4.4 Patient Name

The patient name is represented in two components:

- First component, last name.
- Second component, first name.

10.4.5 Birth date

Patient's birth date in the standard date format YYYYMMDD:

- YYYY: year, four digits.
- MM: month, two digits, (01 = January).
- DD: day of the month, two digits (01-31).

10.4.6 Patient Sex

The following values are supported:

- 'M', male.
- 'F', female.
- 'U', unknown.

10.4.7 Location

This field contains the description or identification of the clinic location, ward or bed of the patient.

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

10.5 Order record

SEQ	LEN	DT	USAGE ANALYZER	USAGE ANALYZER MGR.	CARD.	NAME
1	1	ST	R	R	[1..1]	Record Type ID
2	1	ST	R	R	[1..1]	Sequence Number
3	30	ST	R	R	[1..1]	Specimen ID
5.4	50	ST	O	O	[0..1]	Universal Test ID
5.5	50	ST	O	O	[0..1]	Order Group ID
6	1	ST	O	R	[0..1]	Priority
7	14	DT	X	O	[0..1]	Ordered Date and Time
8	14	DT	X	O	[0..1]	Specimen Collection Date and Time
12	1	ST	O	O	[0..*]	Action Code
16	50	ST	O	O	[0..1]	Specimen Descriptor
17	50	ST	X	O	[0..1]	Ordering Physician
19.1	80	ST	O	X	[0..1]	User Field #1: Quality Control ID
19.2	8	DT	O	X	[0..1]	User Field #1: QC Expiration Date
19.3	80	ST	O	X	[0..1]	User Field #1: QC Lot Number
21.1	80	ST	X	O	[0..1]	Lab. Field #1: Ordering Facility
21.2	80	ST	X	O	[0..1]	Lab. Field #1: Specimen dilution factor
21.3	1	ST	X	O	[0..1]	Automatic Rerun Allowed
21.4	1	ST	X	O	[0..1]	Automatic Reflex Allowed
22	30	ST	O	O	[0..*]	Parent Specimen ID
23	14	DT	O	X	[0..1]	Date/Time Results Reported
26	1	ST	R	R	[1..*]	Report Types

10.5.1 Record Type ID

The value of this field is set to 'O'.

10.5.2 Sequence Number

This field represents the sequence number of all the order records within this message.

10.5.3 Specimen ID

This field contains the Specimen ID used for the order.

10.5.4 Universal Test ID

This field identifies the test/profile in the message.

- The fourth component is the test code defined at the analyzer.
- The fifth component is an identifier to group all the orders that are closely related. For instance when doing a Creatinine Clearance test or a Glucose test, where more than one sample is involved.

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

10.5.5 Order Group ID

This field represents the identifier of the Work Order from the LIS. This is only provided when several tests are related with the same Work Order.

10.5.6 Priority

Test priority. Allowed values:

- 'S', for STAT.
- 'R', for routine samples.

10.5.7 Ordered Date and Time

This field represents the date and time when the test was ordered.

10.5.8 Specimen Collection Date and Time

This field records the date and time the specimen was collected.

10.5.9 Action Code

This field indicates the action to be taken with respect the specimens that are referenced in this order:

- 'C', cancel request for the battery or tests referenced.
- 'A', add the requested tests or batteries to the specimen referenced.
- 'Q' treat specimen as a QC test specimen.
- 'D' treat specimen as a Pooled Patient specimen[4].
- 'X', specimen or test already in process.
- 'P', pending specimen.

10.5.10 Specimen Descriptor

The first component of this field contains the specimen type. The set of sample codes is configurable at the BA 400.

10.5.11 Ordering Physician

This field contains the identifier of the ordering physician.

10.5.12 Date/Time Results Reported

This field is used to indicate the date and time of the reported results.

10.5.13 User Field #1, QC Identifier

This field contains the identifier of the control or substance used for Quality Controls. This field is only populated when the result to upload is a QC.

10.5.14 User Field #1, QC Expiration date

This field contains the expiration date of the control or substance used for Quality Controls. This field is only populated when the result to upload is a QC.

[4] O-22 field become mandatory if the specimen is pooled patient

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

10.5.15 User Field #1, QC Lot Number

This field contains the lot number of the control or substance used for Quality Controls. This field is only populated when the result to upload is a QC.

10.5.16 Lab. Field #1, Ordering Facility

This custom field is used to notify about the ordering facility.

10.5.17 Lab. Field #1, Specimen Dilution Factor

This custom field is used to notify about the dilution factor of the sample used at the analyzer.

10.5.18 Lab. Field #1, Automatic Rerun Allowed

- 'Y' to allow automatic rerun.
- 'N' to deny automatic rerun.

10.5.19 Lab. Field #1, Automatic Reflex Allowed

- 'Y' to allow automatic reflex.
- 'N' to deny automatic reflex.

10.5.20 Lab. Field #1, Parent Specimen ID

This field contains the parent specimen ID used for the specimen under test. This field is repeatable. If the sample is no pooled, this field is empty.

10.5.21 Date /Time Results Reported

If the message contains results, this date is the same as the execution date of the results.

10.5.22 Report Types

The following codes may be used. This field is repeatable, so more than one option may be supported:

- 'O', request for tests.
- 'C', correction of previously transmitted results.
- 'F', final results.
- 'X', order cannot be done, cancelled.
- 'Q', response to query.
- 'Y', no order on record for this test
- 'I', in instrument pending

10.6 Result record

SEQ	LEN	DT	USAGE ANALYZER	USAGE ANALYZER MGR.	CARD.	NAME
1	1	ST	R	R	[1..1]	Record Type ID
2	1	ST	R	R	[1..1]	Sequence Number
3.4	50	ST	R	R	[0..1]	Universal Test ID
4	99999	ST	O	O	[0..1]	Data or Measurement Value

SEQ	LEN	DT	USAGE ANALYZER	USAGE ANALYZER MGR.	CARD.	NAME
5	50	ST	O	O	[0..1]	Units
6	70	ST	O	O	[0..1]	Reference Ranges
7	5	ST	O	O	[0..*]	Result Abnormal Flags
9	1	ST	R	R	[1..*]	Result Status
11	16	ST	O	X	[0..1]	Operator ID
13	14	DT	O	O	[0..1]	Date/Time test completed
14.1	50	ST	R	X	[0..1]	Instrument ID (Model)
14.2	50	ST	R	X	[0..1]	Instrument ID (Serial Number)

10.6.1 Record Type ID

The value of this field is set to 'R'.

10.6.2 Sequence Number

This field represents the sequence number of all the result records under the referenced order.

10.6.3 Universal Test ID

This field identifies the test in the message. The only component used is the fourth one: Manufacturer or local code.

10.6.4 Data or Measurement Value

This field contains the measurement of the test.

10.6.5 Units

Units of measure reported by the analyzer.

10.6.6 Reference Ranges

This field contains a representation of the reference ranges of the test in the following format: lower limit to upper limit.

Examples: '0.7 to 1.0'

'-1.0 to 1.0'

10.6.7 Result Abnormal Flags

This field indicates the normalcy status of the result. The list of flags supported by the analyzer is described at Section 11.2. This field is repeatable.

10.6.8 Result Status

The following codes are used:

- 'C', correction of previously transmitted results.
- 'F', final results.
- 'X', order cannot be done.
- 'N', this result record contains necessary information to run a new order. This value is the one used when the LIS transmits orders with previous results to the analyzer.

BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

10.6.9 Operator ID

This field contains the ID of the operator that performed the test.

10.6.10 Date/Time test completed

This value contains the date and time of the completed test.

10.6.11 Instrument ID

This field identifies the instrument using the model as the first component and the serial number as the second component.

10.7 Comment record

SEQ	LEN	DT	USAGE ANALYZER	USAGE ANALYZER MGR.	CARD.	NAME
1	1	ST	R	R	[1..1]	Record Type ID
2	1	ST	R	R	[1..1]	Sequence Number
3	1	ST	R	R	[1..1]	Comment Source
4.1	50	ST	R	R	[1..1]	Comment Text (Code)
4.2	500	ST	O	O	[0..1]	Comment Text (Description)
5	1	ST	R	R	[1..1]	Comment Type

10.7.1 Record Type ID

The value of this field is set to 'C'.

10.7.2 Sequence Number

This field represents the sequence number of all the comments records under the reference record.

10.7.3 Comment Source

This field identifies the source of the comment.

- 'I' (clinical instrument system).
- 'L' (laboratory information system).

10.7.4 Comment Text

This field contains the text of the comment. The field is structured in two components. The first one contains the comment code and the second the description.

10.7.5 Comment Type

Depending on the information contained in the comment the following types can be used:

- 'G', generic/free result comment.
- 'I', instrument flag(s) comment.

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

11 Appendix A. Code Tables

11.1 Error codes (To edit by Biosystems)

ID	DESCRIPTION
ERROR 1	
ERROR2	
ERROR3	

11.2 Flag codes [v2.1]

ID	DESCRIPTION
001	Abs > optical limit
002	Sample Abs < Blank Abs
003	Sample Abs > Blank Abs
004	Non Linear Kinetics
005	Absorbance < 0
006	Absorbance increase < 0
007	Substrate depletion
008	Possible prozone (it requires manual dilution and repetition)
009	Reactions rotor thermo warning
010	Possible clot in sample
011	Clot detected in sample
012	Sample arm fluidic system blocked
027	Conc. out of calibration curve (HIGH)
028	Conc. out of calibration curve (LOW)
029	Conc < 0
030	Conc > Linearity limit
031	Conc < Detection limit
032	Conc < Normality Min
033	Conc > Normality Max
034	Conc < Panic Min
035	Conc > Panic max
036	Calculated Test with some partial tests with remarks
037	Drift in calibrator A
038	Drift in calibrator A
039	Noise in measuring calibrator A
040	Noise in measuring calibrator B
041	Noise measuring calibrator B
042	Voltage out of limit measuring calibrator A
043	Drift out of limits
044	Voltage out of limit measuring calibrator B
045	Result out of range

Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

12 Appendix B. Example Traces

The following appendix collects traces from the instrument to a LIS in all the protocols described in this document.

The direction of the data is represented by the words “Send” and “Recv” from the BA400 point of view.

The non-printable characters are represented enclosed in less-than, greater-than signs. (e.g. <ENQ> is the character with the ASCII code number 6)

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

12.1 LIS2-A2 Query

```
Send: <ENQ>
Recv: <ACK>
Send: <STX>H|\^&|21ec6ea0-5c78-4818-96d2-
59dbdf84b1e2||BA400|||||Modulab||P|LIS2A|20130419064309<CR>
Q|1|0010079||O<CR>
L|1|N<CR><ETX>84<CR><LF>
Recv: <ACK>
Send: <EOT>
```

12.2 LIS2-A2 Positive Response – Patient (Orders send from LIS)

```
Recv: <ENQ>
Send: <ACK>
Recv: <STX>H|\^&|69F2746D24014F21AD7139756F64CAD8||Modulab|||||BA400||
P|LIS2A|20130129102030<CR>
P|1||PID01||Campeny^Ricard||19850819|M<CR>
O|1|0010079||^^^ASO|R|20130129101530|20130129092030||||A||||SER|||||^56||
|||O<CR>
L|1|N<CR><ETX>OB<CR><LF>
Send: <ACK>
Recv: <EOT>
```

12.3 LIS2-A2 Positive Response – External QC (Orders send from LIS)

```
Recv: <ENQ>
Send: <ACK>
Recv: <STX>H|\^&|69F2746D24014F21AD7139756F64CAD8||Modulab|||||BA400||
P|LIS2A|20130129102030<CR>
P|1<CR>
O|1|SPM01||^^^ASO|R|20130129101530|20130129092030||||A\Q||||SER|||||^56||
|||O<CR>
L|1|N<CR><ETX>OB<CR><LF>
Send: <ACK>
Recv: <EOT>
```

12.4 LIS2-A2 Positive Response – Internal QC (Orders send from LIS)

```
Recv: <ENQ>
Send: <ACK>
Recv: <STX>H|\^&|69F2746D24014F21AD7139756F64CAD8||Modulab|||||BA400||
P|LIS2A|20130129102030<CR>
P|1<CR>
O|1|CONTROL||^^^ALP-AMP|R|20130129101530|20130129092030||||A\Q||||SER|
|||||^56|||||O<CR>
L|1|N<CR><ETX>OB<CR><LF>
Send: <ACK>
Recv: <EOT>
```


Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

12.5 LIS2-A2 Negative Response to a Query All Message

```
Recv: <ENQ>
Send: <ACK>
Recv: <STX>H|\^&|69F2746D24014F21AD7139756F64CAD8||Modulab|||||BA400
||P|LIS2A|20130129102030<CR>
L|1|I<CR><ETX>CC<CR><LF>
Send: <ACK>
Recv: <EOT>
```

12.6 LIS2-A2 Negative Response to a Query by specimen (Host Query Message)

```
Recv: <ENQ>
Send: <ACK>
Recv: <STX>H|\^&|69F2746D24014F21AD7139756F64CAD8||Modulab|||||BA400|
|P|LIS2A|20130129102030<CR>
P|1<CR>
O|1|0010079|||R|||||||||||||||||||Y\Q<CR>
L|1|F<CR><ETX>35<CR><LF>
Send: <ACK>
Recv: <EOT>
```

12.7 LIS2-A2 Upload Result Patient (without Flags)

```
Send: <ENQ>
Recv: <ACK>
Send: <STX>H|\^&|29ab52fb-9862-4b4e-b3dd-
4576fac50cbf||BA400|||||Host||P|LIS2A|20130628143243<CR>
P|1||XB000|||||<CR>
O|1|2400007003||^^^ALBUMIN^|R|||||||||SER|||||||20130628155323|||F<CR>
R|1|^^^ALBUMIN-
MAU|97.61501|mg/L||||F||BIOSYSTEMS||20130214161251|A400^834000103<CR>
L|1|N<CR><ETX>74<CR><LF>
Recv: <ACK>
Send: <EOT>
```

12.8 LIS2-A2 Upload Result Patient (with Flags)

```
Send: <ENQ>
Recv: <ACK>
Send: <STX>H|\^&|4036d0d4-c106-4514-927d-
721dde639835||BA400|||||Host||P|LIS2A|20130711150902<CR>
P|1||AG001|||||<CR>
O|1|P016||^^^ALBUMIN|R|||||||||SER|||||||20130628114243|||F<CR>
R|1|^^^ALBUMIN|-3.33903837||1 to 2|002\029\032||F||BIOSYSTEMS||
20130628114243|A400^834000134<CR>
L|1|N<CR><ETX>74<CR><LF>
Recv: <ACK>
Send: <EOT>
```


Biosystems. S.A.
Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

12.9 LIS2-A2 Upload Result External QC

```
Send: <ENQ>
Recv: <ACK>
Send: <STX>H|\^&|1423283c-c842-4450-89bc-
2bf4f2a9fe6f||BA400|||||Host||P|LIS2A|20130628121144<CR>
P|1<CR>
O|1|SPM01||^^^ASO^|R||||||Q|||||||||||20130628115219|||F<CR>
R|1|^^^ASO|-0.104455717|IU/mL|-1 to -1|033||F||BIOSYSTEMS
||20130628115219|A400^834000815<CR>
L|1|N<CR><ETX>6B<CR><LF>
Recv: <ACK>
Send: <EOT>
```

12.10 LIS2-A2 Upload Result Internal QC

```
Send: <ENQ>
Recv: <ACK>
Send: <STX>H|\^&|9b815a8f-18c1-4aaf-bc4a-
3b86c3836e53||BA400|||||Host||P|LIS2A|20130628121601<CR>
P|1<CR>
O|1|C1||^^^ASO|R||||||Q|||||||C1^20130928^123||||20130628115107|||F<CR>
R|1|^^^ASO|2.80751252|IU/mL|1 to 2|029||F||BIOSYSTEMS
||20130628115107|A400^834000815<CR>
O|2|C2||^^^ASO|R||||||Q|||||||C2^20130928^321||||20130628115116|||F<CR>
R|1|^^^ASO|1.05881464|IU/mL|3 to 4|029||F||BIOSYSTEMS
||20130628115116|A400^834000815<CR>
L|1|N<CR><ETX>6B<CR><LF>
Recv: <ACK>
Send: <EOT>
```


Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

12.11 HL7 Query All

Send:

```
<VT>MSH|^~\&|BA400|Biosystems|Host|Host
provider|20130704121800||QBP^Q11^QBP_Q11|8706f33c-fbc2-4360-b5f3-
25438c445933|P|2.5.1|||ER|AL||UNICODE UTF-8|||LAB-27^IHE<CR>
QPD|WOS_ALL^Work Order Step
All^IHE_LABTF|8706f33cfbc24360b5f325438c445933<CR>
RCP|I||R<CR><FS><CR>
```

Recv: (No info example)

```
<VT>MSH|^~\&|MODULAB|MODULAB|BA400|BA400|20130704121801||OML^O33^OML_O33|
201307041218011|P|2.5.1|||ER|AL||UNICODE UTF-8|||LAB-28^IHE<CR>
SPM|1|""||""|||||||U^Unknown^1.3.6.1.4.1.21367.100.1|||||||+||Y||||||1<CR
>
SAC|||""<CR>
ORC|DC||||||||20130704121801<CR><FS><CR>
```

12.12 HL7 Host Query

Send:

```
<VT>MSH|^~\&|BA400|Biosystems|Host1|Host
provider|20130704124210||QBP^Q11^QBP_Q11|1553dee3-27de-4aef-a4a1-
cbb919c9b945|P|2.5.1|||ER|AL||UNICODE UTF-8|||LAB-27^IHE<CR>
QPD|WOS^Work Order
Step^IHE_LABTF|1553dee327de4aefa4a1cbb919c9b945|2400007004<CR>
RCP|I||R<CR><FS><CR>
```

Recv:

```
<VT>MSH|^~\&|Host|Host
provider|BA400|Biosystems|20130704124210||RSP^K11^RSP_K11|20130704124210|
P|2.5.1|||NE|NE||UNICODE UTF-8|||LAB-27^IHE<CR>
MSA|AA|1553dee3-27de-4aef-a4a1-cbb919c9b945<CR>
QAK|1553dee327de4aefa4a1cbb919c9b945|OK|WOS^Work Order Step^IHE_LABTF<CR>
QPD|WOS^Work Order
Step^IHE_LABTF|1553dee327de4aefa4a1cbb919c9b945|2400007004<CR><FS><CR>
```

12.13 HL7 Order Download

```
<VT>MSH|^~\&|MODULAB|MODULAB|BA400|BA400|20130703111604||OML^O33^OML_O33|
201307031116041|P|2.5.1|||ER|AL||UNICODE UTF-8|||LAB-28^IHE<CR>
PID|1||xb005||fulanito|flungencia|19770703|F||2106-3<CR>
SPM|1|4800007005|PSPM_A~PSPM_B~PSPM_C|URI^URI^2.16.840.1.113883.12.70||||
|||P||3||||20130703111604|20130703111605||Y||||||1|
SAC|||4800007005|||||||||||||||||||||||||^1^1^22<CR>
ORC|NW|||AWOSID05|IP||||20130703111604||||||||||||SERVICIO<CR>
I+D^^^^^^FI^^^1||||||20130703111605<CR>
TQ1|||||||||S<CR>
OBR|1|AWOSID05||K+^K+^1.3.6.1.4.1.21367.100.1||||||||||||123456^NOMBRE
DOCTOR<CR><FS><CR>
```


BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es

12.14 HL7 Upload Results (patient with flags)

```
<VT>MSH|^~\&|BA400|Biosystems|Host|Host
provider|20130705093914||OUL^R22^OUL_R22|b023f4e1-dd4b-4ef5-9181-
81babdd3eea3|P|2.5.1|||ER|AL||UNICODE UTF-8|||LAB-29^IHE<CR>
PID|||xb004||^^|||<CR>
SPM|1|2400007004||SER|||||||P|||||||<CR>
OBR||20130628083831163IDALRIME||CHOLESTEROL^CHOLESTEROL^A400|||||||||||||
||||||||||||<CR>
ORC|OK||||CM||||20130705093914<CR>
OBX|1|NM|CHOLESTEROL^CHOLESTEROL^A400||-
0.0191002265|mg/dL^mg/dL^A400||002~029|||F|||||BIOSYSTEMS||A400^Biosystem
s~834000815^Biosystems|20130628114722<CR>
OBR||20130628083831163IDA0RIME||CK^CK^A400|||||||||||||||||||||||||<CR>
ORC|OK||||CM||||20130705093914<CR>
OBX|1|NM|CK^CK^A400||4.2266469|U/L^U/L^A400||002~029|||F|||||BIOSYSTEMS||
A400^Biosystems~834000815^Biosystems|20130628115237<CR><FS><CR>
```

12.15 HL7 Upload Results (QC without flags)

```
<VT>MSH|^~\&|BA400|Biosystems|Host|Host
provider|20130705094755||OUL^R22^OUL_R22|1298f4ab-8435-4633-8020-
f6e7dbe0cd47|P|2.5.1|||ER|AL||UNICODE UTF-8|||LAB-29^IHE<CR>
SPM|1|C1||NULL|||||||Q|||||||<CR>
INV|C1|OK|CO|||||||||20130928102426||||123<CR>
OBR||""||ASO^ASO^A400|||||||||||||||||||||||||<CR>
ORC|OK||||CM||||20130705094755<CR>
OBX|1|NM|ASO^ASO^A400||2.80751252|IU/mL^IU/mL^A400|1 -
2|NONE|||F|||||BIOSYSTEMS||A400^Biosystems~834000815^Biosystems|201306281
15107<CR>
SPM|1|C2||NULL|||||||Q|||||||<CR>
INV|C2|OK|CO|||||||||20130928102437||||321<CR>
OBR||""||ASO^ASO^A400|||||||||||||||||||||||||<CR>
ORC|OK||||CM||||20130705094755<CR>
OBX|1|NM|ASO^ASO^A400||1.05881464|IU/mL^IU/mL^A400|3 -
4|NONE|||F|||||BIOSYSTEMS||A400^Biosystems~834000815^Biosystems|201306281
15116<CR><FS><CR>
```

12.16 HL7 Error message

Send:

```
<VT>MSH|^~\&|BA400|Biosystems|Host|Host
provider|20130708074756||NACK^NACK|80|P|2.5.1||||||UNICODE UTF-8||<CR>
MSA|AR|<CR>
ERR|||207|E|invalidMessage||Message rejected<CR><FS><CR>
```


BioSystems

Biosystems. S.A.

Costa Brava, 30 - 08030 Barcelona, Spain Tel. +34 933110000 www.biosystems.es