BD FACS™ Workflow Manager Software LIS Interface

Specification Guide

23-23076(01)
2021-09

Regulatory information

BD FACSDuet™, BD FACSLyric™, BD FACSVia™, BD Leucocount™, BD Multitest™, BD OneFlow™, BD Plasma Count, BD Tritest™, and BD Trucount™ are for In Vitro Diagnostic Use. CE marked in compliance with the European In Vitro Diagnostic Medical Device Directive 98/79/EC.

Laser safety information

BD FACSDuet™, BD FACSLyric™, and BD FACSVia™ are Class 1 Laser Products.

History

Revision	Date	Change made
23-23076(01)	2021-09	Initial release

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Introduction

This document contains the specifications that a Laboratory Information System (LIS) can use to interface with the FACS™ Workflow Manager using either the CLSI (commonly referred to as ASTM) protocol or HL7 protocol. This document should be used as a guideline in the development of an interface from an LIS to use either the CLSI or HL7 protocol in conjunction with the corresponding BD FACS™ Workflow Manager drivers for transmitting orders and receiving results.

This chapter covers the following topics:

Definitions, acronyms, and abbreviations

Abbreviation	Term
ASTM	American Society for Testing and Materials. Specified the ASTM E1381-95 and E1394-97 standards detailing the transfer of data between Clinical Laboratory Instrument and Computer Systems. These standards are now owned by CLSI and have been renamed as LIS01-A2 and LIS02-A2 respectively. Commonly used to refer to the implementation of ASTM E1381-95 and E1394-97 or LIS01-A2 and LIS02-A2 in the integration between Clinical Laboratory Instruments and LIS.
CLSI	Clinical & Laboratory Standards Institute
DOB	Date of Birth
HL7	Health Level Seven
MRN	Medical Record Number
MSA	Message Acknowledgement Segment
MSH	Message Header Segment
NTE	Notes and Comments Segment
OBR	Observation Request Segment
OBX	Observation Result Segment
ORC	Common Order Segment
PID	Patient Identification Segment
PV1	Patient Visit Segment
TCD	Test Code Detail

Scope

BD FACS™ Workflow Manager software is a middleware solution to provide communication between BD instruments and the LIS. This document defines CLSI and HL7 interfaces for BD FACS™ Workflow Manager for bi-directional communication with an LIS. The solution will allow for the following communications methods: RS-232 serial (CLSI), TCP/IP (CLSI and HL7).

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General information

This chapter covers the following topics:

File import

The BD FACS™ Workflow Manager does not support file transfer of messages from an LIS.

File export

PDF copies of Laboratory, Physician and Supplemental reports generated by connected instruments can be made available for import by the LIS during the upload of results. This functionality can be enabled or disabled in the FACS™ Workflow Manager settings. If enabled, the FACS™ Workflow Manager will include the file name(s) of the reports that has been exported in the Order Record of the results uploaded to the LIS.

Host query

The BD FACS™ Workflow Manager can generate request messages if an unknown Sample ID is scanned into a worklist. This functionality can be enabled as an optional feature. The BD FACS™ Workflow Manager will ignore all the request information records sent by the LIS.

Communication interface

The BD FACS™ Workflow Manager connection to the LIS can be configured to use either RS-232 serial or TCP/IP.

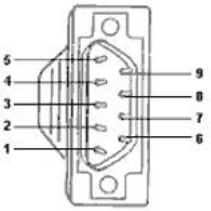
RS-232 Serial Communications for use with the CLSI protocol

The parameters for initialising the serial port are configurable by the user to allow proper communication. The configurable parameters include the following fields.

- Port Name – Acceptable values range from COM1 to COMx where x is the number of available serial ports on the computer.
- Baud Rate – Acceptable values include 300, 600, 1200, 2400, 4800, 9600, 19200, 38400, 57600, and 115200.
- Data Bits – Acceptable values include 7 and 8.
- Stop Bits – Acceptable values include 1 and 2.

- Parity – Acceptable values include ODD, EVEN, and NONE
- Pack Mode – Acceptable values are Packed and Unpacked

Pinout information for the serial connectors on the BD FACS™ Workflow Manager workstation:

Connector Type	Pin Out
9 PIN CONNECTOR (Male) 	2-Rx 3-Tx 5-SG

TCP/IP Connection Settings (CLSI and HL7)

The parameters for initialising TCP/IP communication are configurable by the user to allow for proper communication. The configurable parameters include the following fields.

- Local Port – Configure a unique TCP Port number starting from port 10000 up to 10099 if the FACS™ Workflow Manager will be the TCP Listener in the communication
- Remote Port – Configure the TCP Port number provided by the LIS if the FACS™ Workflow Manager will be the TCP Client in the communication
- Remote Host – Configure the IP Address provided by the LIS if the FACS™ Workflow Manager will be the TCP Client in the communication
- Operation Mode – Acceptable values are ASTM or HL7 and should be configured based on whether the CLSI or HL7 protocol will be used respectively in communicating with the LIS
- Secure – Configure as true if the communication between the FACS™ Workflow Manager and LIS will be encrypted or false if it is not configured
- Certificate – Provide the name of the encryption certificate to be used in encrypting the communication with the LIS

- Pack Mode – Acceptable values are Packed and Unpacked. Only needs to be configured if the FACS™ Workflow Manager and LIS will communicate using the CLSI protocol

Field mapping

There are several fields contained in the FACS™ Workflow Manager database that need to be exchanged with the LIS. BD has made every effort to properly map these fields, per the CLSI LIS02-A2 specification, and HL7 specifications, to a field position in an appropriate record. The field list indicates the descriptive name of the field. Fields not described in the list are accepted by the FACS™ Workflow Manager, but the value will not be used or displayed in FACS™ Workflow Manager.

Memory limitations

The CLSI LIS01-A2 and HL7 protocols do not place a limit on the total size of the message that can be received by the machine acting as the instrument. Since the FACS™ Workflow Manager is software resident on a standard PC, it does not have any significant restrictions on download message sizes. The FACS™ Workflow Manager expects to be able to handle any reasonably sized messages downloaded from the LIS. Should any download message exceed the maximum capacity of the FACS™ Workflow Manager, the message is rejected during transmission and an error notification is displayed to the user.

Mandatory fields

There are several mandatory field values which the FACS™ Workflow Manager requires in order to accept a request downloaded from the LIS. Without these mandatory values the message or part of the message will be rejected. If a message is rejected, the FACS™ Workflow Manager will generate an error that can be reviewed by the operator of the system. Fields that are mandatory for the acceptance of a message or record are indicated as “Required” in the protocol field lists for the CLSI and HL7 protocols described in this document.

Download only fields

Acting as an instrument, the FACS™ Workflow Manager does not assume the responsibility for updating fields that are downloaded to it. Specifically, field values for patient and order records are not changed in the FACS™ Workflow Manager and are always returned to the LIS as received. If field values, for example patient name, order

type and specimen type have to be modified, this modification has to be done on the LIS and the order has to be downloaded.

Field values

The BD FACS™ Workflow Manager accepts data in all textual fields up to 255 characters in length. This includes data fields and ID fields. The only exception to this is the Patient ID and Sample ID fields, which can accept a maximum of 50 characters. FACS™ Workflow Manager accepts data in all numerical fields up to 10 digits before the decimal separator, and up to 10 digits after the decimal separator. Certain result fields may be required to accommodate both numerical and textual results, and in these cases the fields will be defined as a textual field, with no limitation on the length of the value. The exact data type is determined by the FACS™ Workflow Manager result in question. For confirmation of a specific results' data type, contact a BD technical representative.

Results

The BD FACS™ Workflow Manager uploads results from several different types of tests. Each test carried out is defined by a configuration and this configuration determines the number and type of results that are returned to the LIS. Result records can also be received from the LIS containing data values that are used in further calculations within the FACS™ Workflow Manager.

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CLSI (ASTM) interface

This chapter covers the following topics:

Protocol specifications

Physical protocols

The BD FACS™ Workflow Manager interface implements the CLSI LIS01-A2 physical level protocol as outlined in the published specification except for the deviations described below.

Note: It is important to note that the FACS™ Workflow Manager operates as an instrument during LIS communication.

This should be kept in consideration when reading the CLSI specification, as the behaviour during communication (for example time-out durations) can differ between the instrument and computer system (LIS) view.

Packed/Unpacked frames

The FACS™ Workflow Manager interface is configurable to send logical CLSI records in either packed frames or unpacked frames. This is in response to two possible interpretations of the CLSI standard. An intermediate packed frame contains CLSI logical message data packed to 240 characters. Thus Header, Patient, Order, Result and Terminator records are added successively to the same transmission frame until the entire message is 240 characters, after which the next frame continues from the next character in the uncompleted record. Each intermediate frame does not need to contain a complete record. The final frame in a packed transmission may contain less than 240 characters in the frame. Unpacked mode is also supported in 64000 characters in a frame using TCP/IP protocol. An unpacked frame contains a single record per frame, i.e. Header, Patient, Order, Result and Terminator records all are sent in separate frames. This implies that most frames are less than 240 bytes in length. All these frames, except for the last frame are considered as intermediate frames. The frame transmission is structured accordingly, with each intermediate frame containing the **<STX>** and **<ETB>** character as defined in the CLSI low level standard (6.3.1). It is possible that a single logical record (Patient, Order or Result) could be longer than the 240-character limit for a frame. In this case a single logical record is sent in two or more consecutive intermediate frames. Each of these consecutive intermediate frames will contain the **<STX>** and **<ETB>** character as defined in the CLSI low level standard. All but the last frame is packed to 240 bytes and the last frame containing

that logical record is less than 240 bytes. This end frame will contain the **<STX>** and **<ETX>** character as defined in the LIS01-A2 standard (6.3.1).

Logical protocol

The BD FACS™ Workflow Manager interface implements the CLSI LIS02-A2 high level logical level protocol as outlined in the published specification except for the deviations described below.

Unprocessed records

The CLSI high level specification describes the use of Request Information, Scientific and Manufacturer records. FACS™ Workflow Manager does not accept these records in a download message. Messages generated by FACS™ Workflow Manager will include Request Information Records but will not include Manufacturer or Scientific records.

Communication errors

The CLSI LIS02-A2 protocol defines a hierarchical relationship to logical records. This protocol states that if a complete message is not successfully transmitted, then only the logical records that complete the hierarchical relationship must be resent. For example, if a message containing several patient records is not received by the instrument properly, then only the logical records from the latest Patient record must be resent in a new message.

The CLSI LIS01-A2 protocol, in section 6.5 states that if a message frame is not received properly, the complete frame is resent. However, should multiple failures to send at the physical level occur, resulting in the message being aborted, the specification indicates in section 6.5.2.3 that the entire logical message should be retained for retransmission to the FACS™ Workflow Manager.

Blanking fields

The BD FACS™ Workflow Manager does not support the “Blanking Fields” as per the CLSI LIS02-A2 specification. The FACS™ Workflow Manager will not accept the “” string as an indication that the value of a field should be blanked.

Configurable option

There are several aspects of the BD FACS™ Workflow Manager LIS interface that are configurable by the user. This allows the FACS™ Workflow Manager to tailor its connection to the local LIS.

Logical Protocol Settings

The CLSI LIS02-A2 protocol specifies four types of characters to be used as delimiters in a message. In FACS™ Workflow Manager these delimiters are defaulted to the ones used in the CLSI LIS02-A2 publication, 'l', '\', '^', and '&', indicating fields, repeats, components and escape characters respectively. The user is not able to configure which characters are used as delimiters. If Host Query is supported by the LIS, the option to transmit Host Query for unknown requests during the scanning of samples on an instrument can be enabled. A timeout setting for the reply to a Host Query can also be configured.

Message Content

The following sections describe which fields can be exchanged with the FACS™ Workflow Manager .

Field List

This section lists all the fields that the FACS™ Workflow Manager expects to exchange with the LIS. Each field is displayed with its default mapping in the CLSI LIS02-A2 records. This list indicates the record type (Header, Patient, Order, Result, and Terminator), a field delimiter counter and component delimiter counter. The record type appears in field 1. The fields are grouped according to the CLSI LIS02-A2 record type they appear in. Values placed between quotes '' in the "Allowed" column of the list are a sub-set of the allowed values defined in the CLSI LIS02-A2 specification. As not all allowed values for a field are implemented in FACS™ Workflow Manager, the FACS™ Workflow Manager will only react on or send those fixed values indicated. The last column is a reference to the relevant section in the CLSI LIS02-A2 specification. CLSI record types such as scientific records, not mentioned in the field list, are not supported by the FACS™ Workflow Manager and are ignored in a download message.

BD FACS™ Workflow Manager CLSI Field List						
Type	**Field Number**	**Component Number**	**Field Name**	**Allowed**	**Required**	**CLSI ref.**
Header Record						
H	1	1	Record Type	'H'	Y	6.1
H	2	1	Delimiter Definition	'|\^&'	Y	6.2
H	5	1	Sender Name	'FWM_Version_ 1.0'		6.5
H	13	1	Version Number			6.13
Patient Record						
P	1	1	Record Type	'P'	Y	7.1
P	2	1	Sequence Number	1 – Nx	Y	7.2
P	4	1	Patient ID		Y	7.4
P	5	1	Social Security umber			7.5
P	6	1	Patient Name (Last)		Y	7.6
P	6	2	Patient Name (First)		Y	7.6
P	8	1	Birth date			7.8
P	9	1	Sex	M, F, U		7.9
P	17	1	Patient Height			7.19

BD FACS™ Workflow Manager CLSI Field List						
Type	**Field Number**	**Component Number**	**Field Name**	**Allowed**	**Required**	**CLSI ref.**
P	18	1	Patient Weight			7.18
Order Record						
O	1	1	Record Type	'O'	Y	8.4.1
O	2	1	Sequence Number	1 – Nx	Y	8.4.2
O	3	1	Specimen ID		Y	8.4.3
O	5	4	Request ID		Y	8.4.5
O	5	5	Dilution			8.4.5
O	7	1	Requested/ Ordered Date and Time			8.4.7
O	8	1	Collection Date/Time			8.4.8
O	10	1	Collection Volume			8.4.10
O	12	1	Action Code			8.4.12
O	15	1	Received Date/Time			8.4.15
O	16	1	Specimen Type			8.4.16.1

BD FACS™ Workflow Manager CLSI Field List						
Type	**Field Number**	**Component Number**	**Field Name**	**Allowed**	**Required**	**CLSI ref.**
O	17	1	Ordering Physician			8.4.17
O	21	1	Laboratory Report Name			8.4.21
O	21	2	Physician Report Name			8.4.21
O	21	3	Supplemental Report Name			8.4.21
O	26	1	Report Types			8.4.26
Result Record						
R	1	1	Record Type	'R'	Y	9.1
R	2	1	Sequence Number	1 – Nx	Y	9.2
R	3	4	Result Parameter Code		Y	9.3
R	4	1	Result Value		Y	9.4
R	4	2	Interpretation			
R	5	1	Units			9.5
R	6	1	Reference Ranges			9.6
R	9	1	Result Status	'F' or "R"		9.9

BD FACS™ Workflow Manager CLSI Field List						
Type	**Field Number**	**Component Number**	**Field Name**	**Allowed**	**Required**	**CLSI ref.**
R	12	1	Date/Time Test Started			9.12
R	13	1	Date/Time Test Completed			9.13
R	14	1	Instrument Name			9.14
R	14	2	Instrument Serial Number			9.14
Comment Record						
C	1	1	Record Type	'H'		10.1
C	2	1	Sequence Number	1 – Nx		10.2
C	3	1	Comment Source	'I'		10.3
C	4	1	Comment Text – Record Type			10.4
C	5	1	Comment Type	'G'		10.5
Request for Information Record						
Q	1	1	Record Type	'Q'		11.1
Q	2	1	Sequence Number	1 – Nx		11.2

BD FACS™ Workflow Manager CLSI Field List						
Type	**Field Number**	**Component Number**	**Field Name**	**Allowed**	**Required**	**CLSI ref.**
Q	3	2	Sample ID			11.3
Q	13	1	Request Information Status Code	'O'		11.13
Terminator Record						
L	1	1	Record Type	'L'	Y	12.1
L	2	1	Sequence Number	'1'	Y	12.2
L	3	1	Termination Code	'N'	Y	12.3

Record field descriptions

This section provides detailed information on the CLSI fields used by FACS™ Workflow Manager. The convention used in identifying a field in the message is to provide the description of the field, followed in brackets by the record type, field delimiter position, repeat count and component count.

Header fields

The header record starts each logical CLSI message. An example record is provided below.

```
H|\^&|||FWM||||||FWM_Version|P|1|20190903094515|
```

Record Type (H, 1, 1, 1) –The character "H" identifies the record as a header record.

Delimiter Fields (H, 2, 1, 1) – These single characters can be used to process the remainder of the message. These characters denote the field, repeat, component and escape delimiters as described in the CLSI LIS02-A2 specification. These fields are defaulted to "|", "\", "^", and "&" respectively, as shown above.

Sender Name (H, 5, 1, 1) – Messages coming from the FWM have the value "FWM" in this field.

Version Number (H, 13, 1, 1) – This version number represents the version of the BD LIS interface used for communications.

Patient fields

A full patient record is shown below. The fields used in this example are referred to in the field explanations.

```
P|1||PX11|98011|Smith^John||19660711|M|||||Dr. Samuels|||180|85|
```

Record Type (P, 1, 1, 1) – The character "P" identifies the record as a patient record.

Sequence Number (P, 2, 1, 1) –For the first patient transmitted the value "1" shall be entered, for the second "2" and similarly for subsequent patients until the last as defined in section 6.6.7 of the CLSI LIS02-A2 specification.

Patient ID (P, 4, 1, 1) – Identifier that uniquely identifies a patient. In case LIS doesn't provide it, LIS will need to generate a unique key (ex.: Date + Time Stamp) This is a required field for patient demographic downloads. This field can be up to 16 characters long. (E.g. IDL001)

Patient Name (P, 6, 1, 1-2) – Patient name is divided into 5 components in the CLSI LIS02-A2 specification. Only the first two components (surname and first name) are used by the FACS™ Workflow Manager. The FACS™ Workflow Manager stores these fields as separate strings in its database. The patient name can be up to 40 characters long. The patient name shown in the sample record is John Smith.

Patient Birthdate (P, 8, 1, 1) – Patient's date of birth. The date of birth should be presented in the standard CLSI date format (see *CLSI LIS02-A2 section 6.6.2*)

Patient Sex (P, 9, 1, 1) – Accepted values in this field is 'F', 'M' or 'U'.

Patient Height (P, 17, 1, 1) – Patient's height in centimeter. This information is not included in the result message.

Patient Weight (P, 18, 1, 1) – Patient's weight in kilogram. This information is not included in the result message.

Order fields

A full order record is shown below to provide examples for the content of each field. For examples of Order records used in the context of a message, please refer to *Appendix A*.

```
O|1|HX130||^^^6CTBNK^1||20190903114246|20190903114246||100|||||201
90903114246|B|Dr. Samuels
```

Record Type (O, 1, 1, 1) -The character "O" identifies the record as an order record.

Sequence Number (O, 2, 1, 1) -For each order transmitted the value "1" shall be entered for the first order, for the second "2" and similarly for subsequent orders for that patient until the last, as defined in section 6.6.7 of the CLSI LIS02-A2 specification.

Specimen ID (O, 3, 1, 1) – A unique alphanumeric string that identifies a sample. This field can be up to 20 characters long. (E.g. AB760301) This is a required field for processing order and test information.

Request ID (O, 5, 1, 4) – The unique code used to represent a particular test. This is a coded field for the FACS™ Workflow Manager, determined by the configuration.

Dilution (O,5,1,5) - Dilution factor of the sample.

Requested / Ordered Date and Time (O, 7, 1, 1) – Date and time that the sample was ordered in the LIS or received in the laboratory.

Collection Date/Time (O, 8, 1, 1) – Date and time that the sample was collected from the patient, formatted as described in CLSI LIS02-A2 section 6.6.2. The date/time shown in the sample record is 12 August 2003 at 14:11.

Collection Volume (O,10,1,1) - Volume of the sample. The default unit of measure is milliliters. This information is not included in the result message.

Action Code (O,12,1,1) - this field shall indicate the action to be taken with respect to the specimens that accompany or precede this request. This field is defined in the CLSI LIS02-A2 specification.

Received On (O,15,1,1) - Date and time when the sample was recorded in the laboratory.

Specimen Type (O, 16, 1, 1) – The type of sample collected from the patient. This is not an LIS coded field. The textual description from the LIS is used (e.g. Peripheral Blood) .

Ordering Physician (O, 17, 1, 1) – The request physician's code.

Laboratory Report Name (O, 21, 1, 1) – The filename of the Laboratory Report exported from the FACS™ Workflow Manager. The file name will have an extension of ".pdf"

Physician Report Name (O, 21, 1, 2) – The filename of the Physician Report exported from the FACS™ Workflow Manager. The file name will have an extension of ".pdf".

Supplemental Report Name (O, 21, 1, 3) – The filename of the Supplemental Report exported from the FACS™ Workflow Manager. The file name will have an extension of ".pdf".

Report Type (O, 26, 1, 1) – This field is defined in the CLSI LIS02-A2 specification. When a cancelled order is sent back to the LIS, the report type is 'X'. For all other orders, the field is left empty. Note that FACS™ Workflow Manager V1.0 does not support cancellation of an order from the LIS. If the FACS™ Workflow Manager receives an "X" in this field position, it will be ignored, and treated as a new order.

Result fields

Below are examples of result records received from and sent to the LIS.

Result record received from the LIS with result value for import parameter.

```
R|1|^^^BC_abs|0.259|||||R
```

Result records sent to the LIS from FACS™ Workflow Manager.

```
R|1|^^^CD45C|875.00|cells/µl||||F|||||Lyric-1^123456
R|2|^^^CD3P|18.69|%||||F|||||Lyric-1^123456
R|3|^^^CD3C|163.00|cells/µl||||F|||||Lyric-1^123456
R|4|^^^CD4P|0.00|%||||F|||||Lyric-1^123456
```

Record Type (R, 1, 1, 1) –The character "R" identifies the record as a result record.

Sequence Number (O, 2, 1, 1) –For each result transmitted the value "1" shall be entered for the first record, for the second "2" and similarly for subsequent results for the associated order, until the last as defined in section 6.6.7 of the CLSI LIS02-A2 specification.

Result ID Code (R, 3, 1, 4) – This is a BD defined coded field that indicates the type of result being exchanged in the result record. The code is defined in the test configuration and can be modified to correspond with the code in the LIS.

Result Value (R, 4, 1, 1) – The field contains the quantitative value of the result. The significant digits and format of the result is determined by the test configuration

Interpretation (R,4,1,2) - Interpretation of the Result Value configured in FACS™ Workflow Manager.

Units (R,5,1,1) - The abbreviation of units for numeric results.

Reference Ranges (R,6,1,1) - Reference Ranges shall be reported in the following sample format: (minimum - maximum; i.e., 40.00 - 50.00).

Result Status (R, 9, 1, 1) – This field contains either an "R" or an "F" as defined in the CLSI LIS02-A2 specification. The value "R" indicates that the result was previously transmitted, therefore any values being sent from the LIS to FACS™ Workflow Manager must have the value "R" in this field. When FACS™ Workflow Manager reports results back to the LIS, all result records received from the LIS are sent back with the same value in this field as was originally received. The value "F" indicates a final result and is set for all results coming from the BD instrumentation via FACS™ Workflow Manager to the LIS.

Date/Time Test Started (R, 12, 1, 1) – The date and time at which the test was started. This date and time will correspond to the Acquisition date and time of the request on the connected instrument.

Date/Time Test Completed (R, 13, 1, 1) – The date and time at which the test was completed. Where available, this date and time will correspond to the Analysis date and time of the request on the connected instrument. If the Analysis date and time is not available, the Acquisition date and time may be reported.

Instrument Name (R,14,1,1) - Name of the instrument defined in FACS™ Workflow Manager.

Instrument Serial Number (R,14,1,2) - Serial number of the instrument defined in FACS™ Workflow Manager.

Comment fields

Comment records uploaded/downloaded between the LIS and FACS™ Workflow Manager.

```
C|1|I|Comment|G
```

Record Type (C, 1, 1, 1) – The character "C" identifies the records as a comment.

Sequence Number (C, 2, 1, 1) – This will be a numeric value starting at 1 for the first comment record and incrementing by one for each additional comment record as defined in section 5.6.7 of the CLSI LIS02-A2 specification.

Comment Source (C, 3, 1, 1) – This field will contain 'I' for "Clinical Instrument System" as defined in section 10.3 of the CLSI LIS02-A2 specification.

Comment Text (C, 4, 1, 1) – This field will contain comment text of Result set or Result.

Comment Type (C, 5, 1, 1) – This field will contain the code "G" for "Generic/Free Text Comments" as defined in section 10.5 of the CLSI LIS02-A2 specification.

Request for information fields

Query records uploaded from FACS™ Workflow Manager to the LIS.

```
Q|1|^SID12345^||||||||||O
```

Record Type (Q, 1, 1, 1) – The character "Q" identifies the records as a request for information.

Sequence Number (Q, 2, 1, 1) – This will be a numeric value starting at 1 for the first comment record and incrementing by one for each additional comment record as defined in section 6.6.7 of the CLSI LIS02-A2 specification.

Sample ID (Q, 3, 1, 2) – This field contains the Sample ID

Request Information Status Code (Q, 13, 1, 1) – This field will contain the code "O" for "Request Information Status Code" as defined in section 11.13 of the CLSI LIS02-A2 specification.

Termination fields

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

```
L|1|N
```

Record Type (L, 1, 1, 1) –The character "L" identifies the record as a terminator.

Sequence Number (L, 2, 1, 1) – The value of this field should always be 1.

Termination Code (L, 3, 1, 1) – Provides explanation of end of session. This should be set to “N” for normal message termination.

CLSI LIS02-A2 examples

These examples should assist in explaining the logical construction of an CLSI message and the BD FACS™ Workflow Manager implementation of the CLSI LIS02-A2 standard. These CLSI messages are not to be considered an exclusive set of allowable message formats, but are to be treated as a guideline for possible message constructions.

Simple order request

This example shows a order request sent from the LIS to FACS™ Workflow Manager containing only the required fields filled in. There is one patient and one order per message.

```
H|\^&|||LabSystem|||||||P|1
P|1||PIDX20123212||Mol^Eli||19760403|M
O|1|7480556||^^^THIV|||20031009155410|||||||Blood
L|1|N
```

Simple order response

This example shows the response to the order request sent from FACS™ Workflow Manager to LIS, containing the results for the testing. Only the required fields are filled in. There is one patient, one order and multiple results per message.

```
H|\^&|||BDFWM|||||LIS|FWM_Version_1.0|P|2.5.1|20190903153702
P|1||PIDX20123212||Mol^Eli||19760403|M
O|1|7480556||^^^THIV|||20031009155410|||||||Blood
R|1|^^^CD45C|875.00|cells/µl||||F|||||Lyric-1^123456
R|2|^^^CD3P|18.69|%||||F|||||Lyric-1^123456
R|3|^^^CD3C|163.00|cells/µl||||F|||||Lyric-1^123456
R|4|^^^CD4P|0.00|%||||F|||||Lyric-1^123456
L|1|N
```

Multiple order request for one patient in one message

This example shows multiple order requests in a single CLSI message, sent from the LIS to FACS™ Workflow Manager. These orders requests are all associated to the same patient. Only the required fields filled in.

```
H|\^&|||BDFWM|||||LIS|FWM_Version_1.0|P|2.5.1|20190903153702
P|1||PIDX20123212||Mol^Eli||19760403|M
O|1|7480636||^^^THIV|||20031009083754|||||||Blood
O|2|7480637||^^^HIVB|||20031009083754|||||||Blood
L|1|N
```

Multiple patient order request in one message

This example shows multiple order requests in a single CLSI message, sent from the LIS to FACS™ Workflow Manager. These orders are for more than one patient, with each patient record having only one order request associated with it. Only the required fields filled in.

```
H|\^&|||BDFWM|||||LIS|FWM_Version_1.0|P|2.5.1|20190903153702
P|1||PIDX20123212||Mol^Eli||19760403|M
O|1|7480618||^^^THIV|||20031009083754|||||||Blood
P|2||P8762915||Painter^Ryan
O|1|7480627||^^^THIV|||20031009083754|||||||Blood
L|1|N
```

Simple order request with result parameters

This example shows an order request sent from the LIS to FACS™ Workflow Manager containing only the mandatory fields filled in. In addition to the patient and order information, the LIS has sent a result record containing data for additional testing done external to the BD instrumentation. These results are used for calculations or simply for display in the FACS™ Workflow Manager. There is one patient, one order and one or more result records per message.

```
H|\^&|||BDFWM|||||LIS|FWM_Version_1.0|P|2.5.1|20190903153702
P|1||PIDX20123212||Mol^Eli||19760403|M
O|1|7480774||^^^THIV|||20031013154404|||||||Blood
R|1|^^^BC_abs|0.359|||||R
L|1|N
```

Simple order response with LIS result records

This example shows the response to an order request sent from FACS™ Workflow Manager to LIS, containing the original results received from the LIS, as well as the results from the BD Instruments. Only the required fields filled in. There is one patient, one order and multiple results per message. Note the first result records are the records originally received from the LIS.

```
H|\^&|||BDFWM|||||LIS|FWM_Version_1.0|P|2.5.1|20190903153702
P|1||PIDX20123212||Mol^Eli||19760403|M
O|1|7480774||^^^THIV|||20031013154404|||||||Blood
R|1|^^^BC_abs|0.359|||||R
R|2|^^^MC3|4.23628|||||F
R|3|^^^MC4|1.92799|||||F
R|4|^^^MC8|2.14541|||||F
L|1|N
```

Order Request with additional fields

This example shows a order request sent from the LIS to FACS™ Workflow Manager containing information in fields that are not used by the FACS™ Workflow Manager. In this case, the contents of these fields are saved for the response, but no action is carried out on them. There is one patient and one order per message.

```
H|\^&|||BDFWM|||||LIS|FWM_Version_1.0|P|2.5.1|20190903153702
P|1||PIDX20123212||Mol^Eli||19760403|M
O|1|7480987||^^^THIV|R||20031014090157||||N|20031014101500|
||Blood| |||||||||O
L|1|N
```

CLSI LIS01- A2 examples

These examples should assist in explaining the physical communication protocol when sending and receiving CLSI messages between FACS™ Workflow Manager and an LIS. The type of message seen below would be generated by a protocol analyser or line monitor between the FACS™ Workflow Manager and LIS systems. The explanation of the messages below indicates which system is the initiator of the communication. The letter “T” precedes messages from the initiator/transmitter, while the letter “R” precedes the response messages. For ease of reading, FACS™ Workflow Manager communications are displayed in bold font. Control characters appear in <brackets>. The logical CLSI LIS02-A2 message content appears in grey.

Simple Order Request - Packed

This example shows a order request message sent from the LIS to FACS™ Workflow Manager containing only the required fields filled in. There is one patient and one order per message.

```
T  <ENQ>
R  <ACK>
T <STX>1H|\^&|||LabSystem|||||||P|1<CR>P|1||K4651225||Keller^Brand
don<CR>O|1|7480556||^^^THIV|||20031009155410|||||||Blood<CR>L|1|N
<CR><ETX>CB<CR><LF>
R  <ACK>
T  <EOT>
```

Simple Order Request - Unpacked

This example shows a order request message sent from the LIS to FACS™ Workflow Manager containing only the required fields filled in. There is one patient and one order per message.

```
T  <ENQ>
R  <ACK>
T  <STX>1H|\^&|||LabSystem|||||||P|1<CR><ETX>4E<CR><LF>
R  <ACK>
T  <STX>2P|1||K4651225||Keller^Brandon<CR><ETX>64<CR><LF>
R  <ACK>
T  <STX>3O|1|7480556||^^^THIV|||20031009155410|||||||Blood<CR>
<ETX>7E<CR><LF>
R  <ACK>
T  <STX>4L|1|N<CR><ETX>3D<CR><LF>
R  <ACK>
```

Simple Order Response - Packed

This example shows the results for testing done for the order request sent from FACS™ Workflow Manager to LIS in packed mode. Only the required fields are filled in. There is one patient, one order and multiple results per message.

```
T  <ENQ>
R  <ACK>
T <STX>1H|\^&|||LabSystem|||||||P|1<CR>P|1||K4651225||Keller^Brand
don<CR>O|1|7480556||^^^THIV|||20031009155410|||||||Blood<CR>L|1|N
<CR><ETX>CB<CR><LF>
R  <ACK>
T  <EOT>
```

Simple Order Response - Packed (Longer message)

This example shows the results for a test sent from FACS™ Workflow Manager to LIS in packed mode, where the CLSI message is longer than 240 characters, resulting in the message being split over more than one CLSI LIS01-A2 frame. There is one patient, one order and multiple results per message. This example does not correspond to an earlier example request.

```
T  <ENQ>
R  <ACK>
T  <STX>1H|\^&|||MDMS|||||||V1.0|<CR>P|1||1001||Nicolson^Roger|||
|||  ||||||<CR>O|1|10001||^^^BD_TBNK|||20020617171131|||||||2002061
8171131|Peripheral
Blood|||||||20020618172420<CR>R|1|^^^%CD3|58.88|
||||F<CR>R|2|^^^%CD4|28.6|||||F<CR>R|3|^^^%CD8|24.05|||||F<CR>R|4|
^
^<ETB>04<CR><LF>
R  <ACK>
T  STX>2^%CD4+CD8|0.04|||||F<CR>R|5|^^^%CD19|17.86|||||F<CR>R|6|^^
^%CD16+56|14.54|||||F<CR>R|7|^^^CD3_abs|808.9|||||F<CR>R|8|^^^CD4_
abs|394.63|||||F<CR>R|9|^^^CD8_abs|331.93|||||F<CR>R|10|^^^CD4+CD8
_abs|0.53|||||F<CR>R|11|^^^CD19_abs|244.2|||||F<CR>R|12|^^^CD16+56
_abs|198<ETB>3C<CR><LF>
R  <ACK>
T  <STX>3.82|||||F<CR>R|13|^^^CD4/CD8|1.19|||||F<CR>L|1|N<CR><ETX>
D2 <CR><LF>
R  <ACK>
T  <EOT>
```

Simple Order Response - Unpacked

This example shows the results for testing done for the order request sent from FACS™ Workflow Manager to LIS in unpacked mode. Only the required fields are filled in. There is one patient, one order and multiple results per message.

```
R  <ENQ>
T  <ACK>
R  <STX>1H|\^&|||MDMS||||||||V1.0|<CR><ETX>CB<CR><LF>
T  <ACK>
R  <STX>2P|1||K4651225||Keller^Brandon<CR><ETX>64<CR><LF>
T  <ACK>
R  <STX>3O|1|7480556||^^^THIV|||20031009155410|||||||Blood
<CR><ETX>7E<CR><LF>
T  <ACK>
R  <STX>4R|1|^^^MC3|1.34846|||||F<CR><ETX>32<CR><LF>
T  <ACK>
R  <STX>5R|2|^^^MC4|0.28742|||||F<CR><ETX>32<CR><LF>
T  <ACK>
R  <STX>6R|3|^^^MC8|1.02447|||||F<CR><ETX>33<CR><LF>
T  <ACK>
R  <STX>7L|1|N<CR><ETX>FD<CR><LF>
T  <ACK>
R  <EOT>
```

Multiple Patient Order Request in one message - Packed

This example shows multiple order requests in a single CLSI message sent from the LIS to FACS™ Workflow Manager. These orders are for more than one patient, with each patient record having only one order request associated with it. Only the required fields are filled in.

```
T  <ENQ>
R  <ACK>
T  <STX>1H|\^&|||LabSystem|||||||P|1<CR>P|1||D4771689||Duzan^Carol
<CR>O|1|7480618||^^^THIV|||20031009083754|||||||Blood<CR>P|2||P87
62915||Painter^Ryan<CR>O|1|7480627||^^^THIV|||20031009083754||||||
||Blood<CR>L|1|N<CR><ETX>8D<CR><LF>
R  <ACK>
```

Multiple Patient Order Request in one message - Unpacked

This example shows multiple order requests in a single CLSI message, sent from the LIS to FACS™ Workflow Manager. These orders are for more than one patient, with each patient record having only one order request associated with it. Only the required fields are filled in.

```
T  <ENQ>
R  <ACK>
T  <STX>1H|\^&|||LabSystem|||||||P|1<CR><ETX>4E<CR><LF>
R  <ACK>
T  <STX>2P|1||D4771689||Duzan^Carol<CR><ETX>3E<CR><LF>
R  <ACK>
T  <STX>3O|1|7480618||^^^THIV|||20031009083754|||||||Blood
<CR><ETX>88<CR><LF>
R  <ACK>
T  <STX>4P|2||P8762915||Painter^Ryan<CR><ETX>C3<CR><LF>
R  <ACK>
T  <STX>5O|1|7480627||^^^THIV|||20031009083754|||||||Blood
<CR><ETX>8A<CR><LF>
R  <ACK>
T  <STX>6L|1|N<CR><ETX>3F<CR><LF>
R  <ACK>
T  <EOT>
```

4

HL7 interface

This chapter covers the following topics:

Description

Low-Level Protocol

To provide a streaming HL7 TCP/IP protocol, a Minimal Low-Level Protocol (MLLP) was chosen. The HL7 messages are enclosed by control characters to form a block. The format is: <sb>dddd<eb><cr>

- <sb> = Start Block character; ASCII 11_{dec}, the vertical tab character
- dddd = the transmitted data; a variable number of bytes
- <eb> = End Block character; ASCII 28_{dec}, it should not be confused with <etx> ASCII 3_{dec}, or <etb> ASCII 23_{dec}.
- <cr> = Carriage Return; ASCII 13_{dec}.

Delimiter Characters

HL7 default delimiters are characters used to separate fields within a segment and to separate components within fields. Below is a description of the delimiters and how they should be used:

Character	Delimiter
|	Field delimiter
^	Component delimiter
~	Repeat delimiter
\	Escape delimiter
&	Sub-component delimiter
CR	Segment delimiter

HL7 delimiters are defined by a string of five characters in left-to-right order: Field, Component, Repeat, Escape, and Sub-component delimiter characters on the first segment of the message, the Header segment.

Example:

```
MSH|^~\&|||||20131112170459||ORU^R01|23|P|2.5.1|||AL|NE<cr>
```

Sequence Numbers

HL7 segments are separated into levels, and when a segment is repeated within a level, its sequence number is incremented. These sequence numbers are reset upon returning to previous level.

Example:

```
MSH|^~\&|FWM_Version_1.0||LIS||20190903133524||ORU^R01|1021^563|P|2.5.1|||AL|NE|NULL
|8859/1|<cr>
PID|1||PIDX20123212||Doe^John||19760403|Male|<cr>
ORC|RE|SID15<cr>
OBR|1|SID15||||20190805061203|20190802122943|20190828100147|^|||||||||Lyric-
1^123456|||||||||||||||<cr>
OBX|1||CD45C|6CTBNK_TC||cells/µl|||||||20190828100147||||Lyric-1^123456|<cr>
OBX|2||CD3P|6CTBNK_TC||%|||||||20190828100147||||Lyric-1^123456|<cr>
OBX|3||CD3C|6CTBNK_TC||cells/µl|||||||20190828100147||||Lyric-1^123456|<cr>
```

Message hierarchy

For various information flows, various combinations of segments are relevant. Square brackets [ ] indicate segments that are optional; braces { } indicate the segments that can be repeated.

Note: There can be multiple Patient (PID) and Order (ORC) segments in an order message. However, only one of each will be returned with the result. Both orders and results can have multiple comment segments (NTE).

Laboratory Order Message

```
MSH              Message Header
{PID             Patient Identification
  [{NTE}]           Notes and Comments (for Detail)
  [PV1]             Patient Visit
  {
     ORC            Common Order
     OBR            Observation Request
        [{NTE}]     Notes and Comments (for Detail)
  }
}
```

Laboratory Result Message

```
MSH              Message Header
PID              Patient Identification
  [{NTE}]           Notes and Comments (for Detail)
  [PV1]          Patient Visit
     ORC             Common Order
     OBR             Observation Request
        [{NTE}]      Notes and Comments (for Detail)
     {OBX         Observation Results
        [{NTE}]      Notes and Comments (for Detail)
      }
```

Acknowledgment Message

```
MSH              Message Header
   MSA           Message Acknowledgment
```

New message segment structure

This section describes all the message segments used by the Standard HL7 interface. Only these segments can be used to communicate relevant data to the Standard HL7.

Note: The message segment numbers listed do not count the message types. The driver can be configured to support HL7 v2.2 or v2.4 or v2.5. This document assumes that the default configuration of v2.5 is being used.

Description of Segment Tables	
SEQ	Ordinal position of field/component within the segment. For example, if SEQ was "2", then the data would be in field 2, if SEQ was "4.1", then the data would be in field 4, component 1.

Description of Segment Tables	
REQUIRED	Optionality for Incoming and Outgoing Messages R: Required O:Optional -: Not Used, Ignored
ELEMENT NAME	Name of the field or component
USAGE	Description of possible contents

Laboratory Order Message

MSH Segment

SEQ	REQUIRED	ELEMENT NAME	USAGE
1	R	Field Separator	Vertical Pipe | ASCII 124
2	R	Encoding characters	Component delimiter, repeat delimiter, escape delimiter, sub-component delimiter; typically ^~\&
8	O	Security	
11	R	Processing ID	P for production D for debug/test This field must match the Processing ID configuration setting, or the order will be suppressed

Example:

```
MSH|^~\&|||||||ORM^O01|23|P|2.4<cr>
```

Patient Identification Segment (PID)

SEQ	REQUIRED	ELEMENT NAME	USAGE
1		Set ID	
3.1	R	Patient ID	Required and must be unique. In case LIS doesn't provide it, LIS will need to generate a unique key (ex.: Date + Time Stamp).
5.1	R	Patient Last Name	Will be sent to the instrument
5.2	R	Patient First Name	Will be sent to the instrument
7	O	Patient Date Of Birth	YYYYMMDD
8	O	Patient Sex	M – Male F – Female The incoming message must be M or F. Anything else will be suppressed.
19	O	Patient Social Security Number	

Example:

```
PID|1||PID12345||Doe^John^||19780211|M||||||||||001499991<
cr>
```

Patient Visit Segment (PV1)

SEQ	REQUIRED	ELEMENT NAME	USAGE
1		Set ID	

Example:

```
PV1|1|<cr>
```

Common Order Segment (ORC)

SEQ	REQUIRED	ELEMENT NAME	USAGE
1	R	Order Control	RE for outgoing results NW for new order CA to delete order
2	R	Specimen ID	Must be sent to the Instrument

Example:

`ORC|NW|01RBCTHEQ01L|<cr>`

Observation Request Segment (OBR)

SEQ	REQUIRED	ELEMENT NAME	USAGE
1	R	Set ID	Ignored on incoming messages
2	R	Specimen ID	
4	R	Orderable Test Panel	*See Instrument-Specific Orderable Panels and Result Test Codes for details*
6	O	Requested on	Format: YYYYMMDDHHMMSS
7	O	Specimen Collection Date/Time	Format: YYYYMMDDHHMMSS
9.1	O	Specimen Volume	
13.1	O	Patient Height	
13.2	O	Patient Weight	
14.1		Received On Date/Time	
15.1	O	Specimen Fluid Type	
16.1	O	Ordering Physician	

Example:

```
OBR|1|SID4090||6CTBNK||20201119084500|20201119080000||100||
||76^176|20201119083000|B|Dr.Yman<cr>
```

Observation Results Segment

SEQ	REQUIRED	ELEMENT NAME	USAGE
1	R	Set ID	This field contains the OBX segment index for the current specimen, 1 for the first OBX, 2 for the second, etc.
3	R	Test Code	See Instrument-Specific Orderable Panels and Result Test Codes (page 53) for details.
4	O	Orderable Test Panel	See Instrument-Specific Orderable Panels and Result Test Codes (page 53) for details.
5	O	Result Value	The result will be the value transmitted by LIS

Example:

```
OBX|1||CD3C|6CTBNK|440||
```

Test Code Details Segment (TCD)

SEQ	REQUIRED	ELEMENT NAME	USAGE
1	R	Set ID	
4	O	Pre-Dilution Factor	

Example:

```
TCD|1|||1<cr>
```

Notes and Comments Segment (NTE)

SEQ	REQUIRED	ELEMENT NAME	USAGE
1	O	Set ID	This field contains the NTE segment index, 1 for the first NTE, 2 for the second, etc.
2	O	Comment Type	L
3	O	• Test Comment • Specimen Comment	- NTE after the OBX segment - NTE after the OBR segment

Example:

```
NTE|1|L|These are comments<cr>
```

Laboratory Result Message

Message Header Segment (MSH)

SEQ	REQUIRED	ELEMENT NAME	USAGE
1	R	Field Separator	Vertical Pipe | ASCII 24
2	R	Encoding characters	Component delimiter, repeat delimiter, escape delimiter, sub-component delimiter; typically, ^~\&.
3	O	Sending Application	This field can be set up in the configuration.
5	O	Receiving Application	This field can be set up in the configuration.

SEQ	REQUIRED	ELEMENT NAME	USAGE
7	R	Date/Time of Message	Format: YYYYMMDDHHMMSS
9.1	R	Message Type	ORU for result messages
9.2	R	Event Code	R01 for result messages
10	R	Message Control ID	To be used as return ID in ACK message.
11	R	Processing ID	P for production D for debug/test For outgoing messages, this field can be toggled by setting the Processing ID configuration setting.
12	R	HL7 Version	2.2 or 2.4 or 2.5.1
15	R	Accept Acknowledgement Type	AL – always expect a low level ack
16	R	Application Acknowledgement Type	NE – never expect a high level ack on error

Example:

```
<vt>MSH|^~\&|FWM_Version_
1.0||LIS||20190903133524||ORU^R01|1021^563|P|2.5.1|||AL|NE|
<cr>
```

Patient Identification Segment (PID)

Note: All Patient Data sent down with the Order will be sent back with the Result message.

SEQ	REQUIRED	ELEMENT NAME	USAGE
1		Set ID	
3.1	R	Patient ID	

SEQ	REQUIRED	ELEMENT NAME	USAGE
5.1	R	Patient Last Name	
5.2	R	Patient First Name	
7	O	Patient Date Of Birth	YYYYMMDD
8	O	Patient Sex	M – Male F – Female
19	O	Patient Social Security Number	No dashes

Example:

```
PID|1||PID12345||Doe^John||19740921|M||||||||||001499991
<cr>
```

Patient Visit Segment (PV1)

SEQ	REQUIRED	ELEMENT NAME	USAGE
1		Set ID	

Example:

```
PV1|1|<cr>
```

Common Order Segment (ORC)

SEQ	REQUIRED	ELEMENT NAME	USAGE
1	R	Order Control	“RE”
2	R	Specimen ID	

Example:

```
ORC|RE|SID15<cr>
```

Observation Request Segment (OBR)

SEQ	REQUIRED	ELEMENT NAME	USAGE
1	R	Set ID	
2	R	Specimen ID	
4	R	Orderable test panel	
6	O	Requested On Date/Time	YYYYMMDDHHMMSS
7	O	Specimen Collection Date/Time	
8	O	Observation End Date/Time	
13.1	O	Patient Height	
13.2	O	Patient Weight	
15.1	O	Specimen Fluid Type	
16.1	O	Physician	
20.1	O	Laboratory Report Name	
20.2	O	Physician Report Name	
20.3	O	Supplemental Report Name	

Example:

```
OBR|1|SID4090||6CTBNK||20201119074500|20201119070000|202011
23113513||||||||||LYRIC-DESK1^123456||Worklist_004_6 Color
TBNK_SID4090_Lab Report.pdf^Worklist_004_6 Color TBNK_
SID4090_Physician Report.pdf^Worklist_004_6 Color TBNK_
SID4090_Supplemental Report.pdf~|
```

Observation Result Segment (OBX)

SEQ	REQUIRED	ELEMENT NAME	USAGE
1		Set ID	This field contains the OBX segment index for the current specimen, 1 for the first OBX, 2 for the second, etc.
3	R	Test Code	*See Instrument-specific orderable panels and result test codes (page 53)* for details.
4	O	Orderable Test Panel	*See Instrument-specific orderable panels and result test codes (page 53)* for details.
5.1	O	Result	
5.2	O	Interpretation	
6	O	Units	
7	O	Reference Range	
14	O	Result Started Date/time	If this value does not exist, this field will be populated with Observation Date/Time.
16.1	O	Intrument Operator	
18.1	O	Instrument Name	
18.2	O	Instrument Serial Number	

Example:

```
OBX|1||CD45C|6CTBNK|1500.00|cells/µl|||||||20201208174239|
|||Lyric-1^54321|<cr>
```

Notes and Comments Segment (NTE)

SEQ	REQUIRED	ELEMENT NAME	USAGE
1	O	Set ID	This field contains the NTE segment index, 1 for the first NTE, 2 for the second, etc...
2	R	Comment Type	L
3	O	• Test Comment • Specimen Comment	• NTE after the OBX segment • NTE after the OBR segment

Example:

```
NTE|1|L|These are comments<cr>
```

Acknowledgment Message

```
MSH Message Header
MSA Message Acknowledgment
```

Message Acknowledgment Segment (MSA)

SEQ	REQUIRED	ELEMENT NAME	USAGE
1	R	Acknowledgment Code	AA for Accept Acknowledgment AE for error
2	R	Message Control ID	Message Control ID of message being acknowledged
3	O	Text Message	If Acknowledgment Code is AE, this field can contain text describing the error condition.

When the driver acknowledges messages, it will always send an Acknowledgment Code of “AA”. When it receives acknowledgment messages it will accept Acknowledgment Codes of “AA”, “CA”, or “AE”.

Example :

```
MSH|^~\&|IM||||20200406102746||ACK^O01|0|P|2.5.1|<cr>
MSA|AA|e8820fe9|Success|<cr>
```

Communication examples

Definitions:

<vt> - ASCII 11

<cr> - ASCII 13

<fs> - ASCII 28

Laboratory Order Message

Order message sent from LIS to Standard HL7.

```
<vt> MSH|^~\&|||||||ORM|23|P|2.4<cr>
PID|1||PID12345|23|Doe^John^L||19780211|M||||||||||001499991<cr>
PV1|1|<cr>
ORC|NW|01RBCTHEQ01L|FillerOrder#|<cr>
OBR|1|01RBCTHEQ01L|FillerOrder#|LEUCO|||20000210022356|20000210025056|Volume^VolumeU
nits| || |||Fluid|1^Physician^Albert^Q|||||||Acc1|<cr>
NTE|1|L|These are comments<cr><fs><cr>
```

Laboratory Result Message

Result message sent from Standard HL7 to LIS.

```
<vt>MSH|^~\&|FWM_Version_1.0||LIS||20190903133524||ORU^R01|1021^563|P|2.5.1|||AL|N
NULL|8859/1|<CR>
PID|1||PIDX20123212||Doe^John||19760403|Male|<CR>
ORC|RE|SID15<CR>
OBR|1|SID15||||20190805061203|20190802122943|20190828100147|^|||||||||Lyric-
1^123456|||||||||||||||<CR>
OBX|1||CD45C|6CTBNK_TC||cells/µl|||||||20190828100147||||Lyric-1^123456|<CR>
OBX|2||CD3P|6CTBNK_TC||%|||||||20190828100147||||Lyric-1^123456|<CR>
OBX|3||CD3C|6CTBNK_TC||cells/µl|||||||20190828100147||||Lyric-1^123456|<CR>
OBX|4||CD4P|6CTBNK_TC||%|||||||20190828100147||||Lyric-1^123456|<CR>
OBX|5||CD4C|6CTBNK_TC||cells/µl|||||||20190828100147||||Lyric-1^123456|<CR>
OBX|6||CD4P_EDP|6CTBNK_TC||%|||||||20190828100147||||Lyric-1^123456|<CR>
OBX|7||CD4C_EDP|6CTBNK_TC||cells/µl|||||||20190828100147||||Lyric-1^123456|<CR>
OBX|8||CD8P|6CTBNK_TC||%|||||||20190828100147||||Lyric-1^123456|<CR>
OBX|9||CD8C|6CTBNK_TC||cells/µl|||||||20190828100147||||Lyric-1^123456|<CR>
OBX|10||CD8P_EDP|6CTBNK_TC||%|||||||20190828100147||||Lyric-1^123456|<CR>
OBX|11||CD8C_EDP|6CTBNK_TC||cells/µl|||||||20190828100147||||Lyric-1^123456|<CR>
OBX|12||CD4_8P|6CTBNK_TC||%|||||||20190828100147||||Lyric-1^123456|<CR>
OBX|13||CD4_8C|6CTBNK_TC||cells/µl|||||||20190828100147||||Lyric-1^123456|<CR>
OBX|14||CD4N_8NP|6CTBNK_TC||%|||||||20190828100147||||Lyric-1^123456|<CR>
OBX|15||CD4N_8NC|6CTBNK_TC||cells/µl|||||||20190828100147||||Lyric-1^123456|<CR>
OBX|16||CD19P|6CTBNK_TC||%|||||||20190828100147||||Lyric-1^123456|<CR>
OBX|17||CD19C|6CTBNK_TC||cells/µl|||||||20190828100147||||Lyric-1^123456|<CR>
OBX|18||CD16_56P|6CTBNK_TC||%|||||||20190828100147||||Lyric-1^123456|<CR>
OBX|19||CD16_56C|6CTBNK_TC||cells/µl|||||||20190828100147||||Lyric-1^123456|<CR>
OBX|20||CD4_8_R|6CTBNK_TC||ratio|||||||20190828100147||||Lyric-1^123456|<CR>
OBX|21||CD3_16_56P|6CTBNK_TC||%|||||||20190828100147||||Lyric-1^123456|<CR>
OBX|22||CD3_16_56C|6CTBNK_TC||cells/µl|||||||20190828100147||||Lyric-
1^123456|<cr><fs><cr>
```

5

Instrument-specific orderable panels and result test codes

There are several predefined Orderable Test Panels that can be ordered for each supported instrument. The order message from the LIS must contain one of the panels for that instrument. When the panel is complete, the instrument will generate multiple results based upon the ordered panel.

This chapter covers the following topics:

BD FACSVia™ instrument

The list of predefined BD FACSVia™ Orderable Test Panels that can be ordered, and the Test Code (results) that will be transmitted to the LIS are defined in the following table. In addition, several general test codes will be resulted for all panels. These are identified in the following table. Orders must be dynamically downloaded from the LIS to BD FACS™ Workflow Manager. Results will be dynamically uploaded to the LIS.

Predefined Orderable Test Panel and Result Test Codes for the BD FACSVia™ instrument

Request Code	Description	Test Code (result)	Description
3_4_45	TriTest 3/4/45	CD45C	CD45+ Lymph Abs Count
		CD3P	CD3+ Percent of Lymphs
		CD3C	CD3+ Abs Count
		CD4P	CD3+CD4+ Percent of Lymphs
		CD4C	CD3+CD4+ Abs Count
4_8_3	TriTest 4/8/3	CD3C	CD3+ T Cells Abs Count
		CD4P	CD3+CD4+CD8- Percent of T Cells
		CD4C	CD3+CD4+CD8- Abs Count
		CD8P	CD3+CD4-CD8+ Percent of T Cells
		CD8C	CD3+CD4-CD8+ Abs Count
		CD4_8P	CD3+CD4+CD8+ Percent of T Cells
		CD4_8C	CD3+CD4+CD8+ Abs Count
		CD4_8_R	4/8 Ratio Percent of T Cells

Request Code	Description	Test Code (result)	Description
3_8_45_4	MultiTest 3/8/45/4	CD45C	CD45+ Lymph Abs Count
		CD3P	CD3+ Percent of Lymphs
		CD3C	CD3+ Abs Count
		CD4P	CD3+CD4+ Percent of Lymphs
		CD4C	CD3+CD4+ Abs Count
		CD4_8P	CD3+CD4+CD8+ Percent of T Cells
		CD4_8C	CD3+CD4+CD8+ Abs Count
		CD4_8_R	4/8 Ratio Percent of T Cells
		CD8P	CD3+CD8+ Percent of Lymphs
		CD8C	CD3+CD8+ Abs Count
		TSUM	Percent T-Sum
TBNK	MultiTest 3/16+56/45/19	CD45C	CD45+ Lymph Abs Count
		CD3P	CD3+ Percent of Lymphs
		CD3C	CD3+ Abs Count
		CD16_56P	CD3-CD16&CD56+CD19- Percent of Lymphs
		CD16_56C	CD3-CD16&CD56+CD19- Abs Count
		CD19P	CD3-CD16&CD56-CD19+ Percent of Lymphs
		CD19C	CD3-CD16&CD56-CD19+ Abs Count
		LSUM	Lymphosum

Request Code	Description	Test Code (result)	Description
IMK	MultiTest IMK	CD4P	CD3+CD4+ Percent of Lymphs
		CD4C	CD3+CD4+ Abs Count
		CD4_8P	CD3+CD4+CD8+ Percent of T Cells
		CD4_8C	CD3+CD4+CD8+ Abs Count
		CD4_8P	CD3+CD4+CD8+ Percent of T Cells
		CD8C	CD3+CD4+CD8+ Abs Count
		CD4_8_R	4/8 Ratio Percent of T Cells
		CD8P	CD3+CD8+ Percent of Lymphs
		CD8C	CD3+CD8+ Abs Count
		TSUM	Percent T-Sum
		CD16_56P	CD3-CD16&CD56+CD19- Percent of Lymphs
		CD16_56C	CD3-CD16&CD56+CD19- Abs Count
		CD19P	CD3-CD16&CD56-CD19+ Percent of Lymphs
		CD19C	CD3-CD16&CD56-CD19+ Abs Count
		LSUM	Lymphosum
		CD4P	CD3+CD4+ Percent of Lymphs
		CD45C	CD45+ Abs Count Average
		CD3P	CD3+ Percent Lymphs Average
		CD3C	CD3+ Abs Count Average

Request Code	Description	Test Code (result)	Description
		CD3CD	CD3 Percent Difference
LEUCO	Leucocount	RWBC	Abs count of rWBCs per µL
		RWBC_PACK	Abs count of rWBCs per Pack
PLASMA	Plasma Count	RWBC	Abs count of rWBCs per µL
		RPLT	Abs count of rPLT per µL
		RRBC	Abs count of rRBC per µL

BD FACSLyric™ and BD FACSDuet™ instruments

The list of predefined BD FACSLyric™ and BD FACSDuet™ Orderable Test Panels that can be ordered, and the Test Code (results) of BD FACSLyric™ that will be transmitted to the LIS, are defined in the following table. These panels are available through the BD FACSuite™ Clinical application. User defined Test Panels are supported through the BD FACSuite™ application. Refer to the *BD FACSLyric™ Reference System* document for how to configure the “assay properties” that define the Orderable Test Panel and Result Test Codes for user defined panels. Orders must be dynamically downloaded from the LIS to BD FACS™ Workflow Manager. Results will be dynamically uploaded to the LIS.

Predefined Orderable Test Panel for BD FACSLyric™ and BD FACSDuet™ instruments and Result Test Codes for the BD FACSLyric™ instrument

Request Code	Description	Test Code (result)	Description
3_4_45 3_4_45_TC	TriTest 3/4/45 TriTest 3/4/45 with Trucount	CD45C	Lymphs Abs Count
		CD3P	CD3+ Percent of Lymphs
		CD3C	CD3+ Absolute Count
		CD4P	CD3+CD4+ Percent of Lymphs
		CD4C	CD3+CD4+ Absolute Count

Request Code	Description	Test Code (result)	Description
4_8_3	TriTest 4/8/3	CD3P	CD3+ Percent of Lymphs
		CD3C	CD3+ Absolute Count
		PCD4	CD3+CD4+ Percent of T Lymphs
		CD4C	CD3+CD4+ Absolute Count
		CD8P	CD3+CD8+ Percent of T Lymphs
		CD8C	CD3+CD8+ Absolute Count
		CD4_8P	CD3+CD4+CD8+ Percent of T Lymphs
		CD4_8C	CD3+CD4+CD8+ Absolute Count
		CD4N_8NP	CD3+CD4-CD8- Percent of T Lymphs
		CD4N_8NC	CD3+CD4-CD8- Absolute Count
		CD4P_EDP	CD3+CD4+ %T Lymphs (excluding dual positive.)
		CD4CS_EDP	CD3+CD4+ Abs Cnt (excluding dual positive)
		CD8P_EDP	CD3+CD8+ %T Lymphs (excluding dual positive)
		CD8C_EDP	CD3+CD8+ Abs Cnt (excluding dual positive)
		CD4_8_R	4/8 Ratio Percent of T Cells

Request Code	Description	Test Code (result)	Description
3_8_45_4 3_8_45_4_TC	MultiTest 3/8/45/4 MultiTest 3/8/45/4 with Trucount	CD45C	Lymphs Absolute Count
		CD3P	CD3+ %Lymphs
		CD3C	CD3+ Absolute Count
		CD4P	CD3+CD4+ %Lymphs
		CD4C	CD3+CD4+ Absolute Count
		CD8P	CD3+CD8+ %Lymphs
		CD8C	CD3+CD8+ Absolute Count
		CD4_8P	CD3+CD4+CD8+ %Lymphs
		CD4_8C	CD3+CD4+CD8+ Absolute Count
		CD4N_8NP	CD3+CD4-CD8- %Lymphs
		CD4N_8NC	CD3+CD4-CD8- Absolute Count
		CD4P_EDP	CD3+CD4+ %Lymphs (excluding dual positive)
		CD4C_EDP	CD3+CD4+ Abs Cnt (excluding dual positive)
		CD8P_EDP	CD3+CD8+ %Lymphs (excluding dual positive)
		CD8C_EDP	CD3+CD8+ Abs Cnt (excluding dual positive)
		CD4_8_R	4/8 Ratio

Request Code	Description	Test Code (result)	Description
TBNK	MultiTest 3/16+56/45/19	CD45C	Lymphs Absolute Count
		CD3P	CD3+ %Lymphs
		CD3C	CD3+ Absolute Count
		CD19P	CD19+ %Lymphs
		CD19C	CD19+ Absolute Count
		CD16_56P	CD3-CD16+CD56+ %Lymphs
		CD16_56C	CD3-CD16+CD56+ Absolute Count
		CD3_16_56P	CD3+CD16+CD56+ %Lymphs
		CD3_16_56C	CD3+CD16+CD56+ Absolute Count

Request Code	Description	Test Code (result)	Description
IMK IMK_TC	MultiTest IMK MultiTest IMK with Trucount	CD45C	Average Lymphs Absolute Count
		CD3P	Average CD3 %Lymphs
		CD3C	Average CD3 Absolute Count
		CD4P	CD3+CD4+ %Lymphs
		CD4C	CD3+CD4+ Absolute Count
		CD8P	CD3+CD8+ %Lymphs
		CD8C	CD3+CD8+ Absolute Count
		CD4_8P	CD3+CD4+CD8+ %Lymphs
		CD4_8C	CD3+CD4+CD8+ Absolute Count
		CD4N_8NP	CD3+CD4-CD8- %Lymphs
		CD4N_8NC	CD3+CD4-CD8- Absolute Count
		CD19P	CD19+ %Lymphs
		CD19C	CD19+ Absolute Count
		CD16_56P	CD3-CD16+CD56+ %Lymphs
		CD16_56C	CD3-CD16+CD56+ Absolute Count
		CD3_16_56P	CD3+CD16+CD56+ %Lymphs

Request Code	Description	Test Code (result)	Description
		CD3_16_56C	CD3+CD16+CD56+ Absolute Count
		CD4P_EDP	CD3+CD4+ %Lymphs (excluding dual positive)
		CD4C_EDP	CD3+CD4+ Abs Cnt (excluding dual positive)
		CD8P_EDP	CD3+CD8+ %Lymphs (excluding dual positive)
		CD8C_EDP	CD3+CD8+ Abs Cnt (excluding dual positive)
		CD4_8_R	4/8 Ratio

Request Code	Description	Test Code (result)	Description
6CTBNK 6CTBNK_TC	MultiTest 6-Color TBNK MultiTest 6-Color TBNK with Trucount	CD45C	Lymphs Absolute Count
		CD3P	CD3+ %Lymphs
		CD3C	CD3+ Absolute Count
		CD4P	CD3+CD4+ %Lymphs
		CD4C	CD3+CD4+ Absolute Count
		CD8P	CD3+CD8+ %Lymphs
		CD8C	CD3+CD8+ Absolute Count
		CD4_8P	CD3+CD4+CD8+ %Lymphs
		CD4_8C	CD3+CD4+CD8+ Absolute Count
		CD4N_8NP	CD3+CD4-CD8- %Lymphs
		CD4N_8NC	CD3+CD4-CD8- Absolute Count
		CD19P	CD19+ %Lymphs
		CD19C	CD19+ Absolute Count
		CD16_56P	CD3-CD16+CD56+ %Lymphs
		CD16_56C	CD3-CD16+CD56+ Absolute Count
		CD3_16_56P	CD3+CD16+CD56+ %Lymphs
		CD3_16_56C	CD3+CD16+CD56+ Absolute Count
		CD4P_EDP	CD3+CD4+ %Lymphs (excluding dual positive)
		CD4C_EDP	CD3+CD4+ Abs Cnt (excluding dual positive)
		CD8P_EDP	CD3+CD8+ %Lymphs (excluding dual positive)

Request Code	Description	Test Code (result)	Description
		CD8C_EDP	CD3+CD8+ Abs Cnt (excluding dual positive)
		CD4_8_R	4/8 Ratio

Predefined orderable test panel and result test codes for BD OneFlow™ assays on the BD FACSLyric™ instrument

Request Code	Description	Test Code (result)	Description
ALOT	OneFlow ALOT	ALLE	All Events # Events
		CELLE	Cells # Events
		CELLPP	Cells % Parent
		FSCSE	FSC Singlets # Events
		FSCSPP	FSC Singlets % Parent

Request Code	Description	Test Code (result)	Description
		FSCSPG	FSC Singlets % Grandparent
		SSCSE	SSC Singlets # Events
		SSCSPP	SSC Singlets % Parent
		SSCSPG	SSC Singlets % Grandparent
		LEUCOCE	Leucocytes # Events
		LEUKOPP	Leucocytes % Parent
		LEUKOPG	Leucocytes % Grandparent
		CD19E	CD19 # Events
		CD19PP	CD19 % Parent
		CD19PG	CD19 % Grandparent
		BCELLSE	B cells # Events
		BCELLSPP	B cells % Parent
		BCELLSPG	B cells % Grandparent
		CYCD3E	cyCD3+ # Events
		CYCD3PP	cyCD3+ % Parent
		CYCD3PG	cyCD3+ % Grandparent
		TCELLSE	T cells # Events
		TCELLPP	T cells % Parent
		TCELLSPG	T cells % Grandparent
		N19O3E	NOT CD19+ OR cyCD3+ # Events

Request Code	Description	Test Code (result)	Description
		N19O3PP	NOT CD19+ OR cyCD3+ % Parent
		N19O3PG	NOT CD19+ OR cyCD3+ % Grandparent
		NLYMPHE	Non-lymphoid # Events
		NLYMPHPP	Non-lymphoid % Parent
		NLYMPHPG	Non-lymphoid % Grandparent
		CYMPOE	cyMPO+ # Events
		CYMPOPP	cyMPO+ % Parent
		CYMPOPG	cyMPO+ % Grandparent
		CD45NDE	CD45 neg/dim # Events
		CD45NDPP	CD45 neg/dim % Parent
		CD45NDPG	CD45 neg/dim % Grandparent
		CD34E	CD34 # Events
		CD34PP	CD34 % Parent
		CD34PG	CD34 % Grandparent
		SOURCE	Sample Source
		COMMENTS	Comments

Request Code	Description	Test Code (result)	Description
BCLPDT1	OneFlow B-CLPD T1	ALLE	All Events # Events
		CELLE	Cells # Events
		CELLPP	Cells % Parent
		FSCSE	FSC Singlets # Events
		FSCSPP	FSC Singlets % Parent
		FSCSPG	FSC Singlets % Grandparent
		SSCSE	SSC Singlets # Events
		SSCSPP	SSC Singlets % Parent
		SSCSPG	SSC Singlets % Grandparent
		LEUKOE	Leucocytes # Events
		LEUKOPP	Leucocytes % Parent
		LEUKOPG	Leucocytes % Grandparent
		LYMPHE	Lymph # Events
		LYMPHPP	Lymph % Parent
		LYMPHPG	Lymph % Grandparent
		BCELLSE	B cells # Events
		BCELLSPP	B cells % Parent
		BCELLSPG	B cells % Grandparent
		SOURCE	Sample Source
		COMMENTS	Comments

Request Code	Description	Test Code (result)	Description
LST	OneFlow LST	ALLE	All Events # Events
		CELLE	Cells # Events
		CELLPP	Cells % Parent
		FSCSE	FSC Singlets # Events
		FSCSPP	FSC Singlets % Parent
		FSCSPG	FSC Singlets % Grandparent
		SSCSE	SSC Singlets # Events
		SSCSPP	SSC Singlets % Parent
		SSCSPG	SSC Singlets % Grandparent
		LEUKOE	Leucocytes # Events
		LEUKOPP	Leucocytes % Parent
		LEUKOPG	Leucocytes % Grandparent
		LYMPHOE	Lymph # Events
		LYMPHOPP	Lymph % Parent
		LYMPHOPG	Lymph % Grandparent
		BCELLSE	B cells # Events
		BCELLSPP	B cells % Parent
		BCELLSPG	B cells % Grandparent
		IGKAE	IgK # Events
		IGKAPP	IgK % Parent
		IGKAPG	IgK % Grandparent
		IGLAE	IgL # Events

Request Code	Description	Test Code (result)	Description
		IGLAPP	IgL # % Parent
		IGLAPG	IgL % Grandparent
		KL_R	B cell Ratio
		TCELLSE	T cells # Events
		TCELLSPP	T cells % Parent
		TCELLSPG	T cells % Grandparent
		TCRGDPE	TCRgd+ # Events
		TCRGDPPP	TCRgd+ % Parent
		TCRGDPPG	TCRgd+ % Grandparent
		TCRGDNE	TCRgd- # Events
		TCRGDNPP	TCRgd- % Parent
		TCRGDNPG	TCRgd- % Grandparent
		CD4_8NE	CD4+ CD8- # Events
		CD4_8NPP	CD4+ CD8- % Parent
		CD4_8NPG	CD4+ CD8- % Grandparent
		CD8_4NE	CD8+ CD4- # Events
		CD8_4NPP	CD8+ CD4- % Parent
		CD8_4NPG	CD8+ CD4- % Grandparent
		CD4_8E	CD4+ CD8+ # Events
		CD4_8PP	CD4+ CD8+ % Parent

Request Code	Description	Test Code (result)	Description
		CD4_8PG	CD4+ CD8+ % Grandparent
		CD4N_8NE	CD4- CD8- # Events
		CD4N_8NPP	CD4- CD8- % Parent
		CD4N_8NPG	CD4- CD8- % Grandparent
		CD4_8_R	T cell Ratio
		NB_NTE	NOT B cells OR T cells # Events
		NB_NTPP	NOT B cells OR T cells % Parent
		NB_NTPG	NOT B cells OR T cells % Grandparent
		CD16_56E	NK cells # Events
		CD16_56PP	NK cells % Parent
		CD16_56PG	NK cells % Grandparent
		LSUME	LymphoSum # Events
		LSUM	LymphoSum % Parent
		LSUMPG	LymphoSum % Grandparent
		SOURCE	Sample Source
		COMMENTS	Comments

Request Code	Description	Test Code (result)	Description
PCD	OneFlow PCD	ALLE	All Events # Events
		CELLE	Cells # Events
		CELLPP	Cells % Parent
		FSCSE	FSC Singlets # Events
		FSCSPP	FSC Singlets % Parent
		FSCSPG	FSC Singlets % Grandparent
		SSCSE	SSC Singlets # Events
		SSCSPP	SSC Singlets % Parent
		SSCSPG	SSC Singlets % Grandparent
		CD38E	CD38+ # Events
		CD38PP	CD38+ % Parent
		CD38PG	CD38+ % Grandparent
		PLASMAE	Plasma cells # Events
		PLASMAPP	Plasma cells % Parent
		PLASMAPG	Plasma cells % Grandparent
		BCELLSE	B cells # Events
		BCELLSPP	B cells % Parent
		BCELLSPG	B cells % Grandparent
		SOURCE	Sample Source
		COMMENTS	Comments

Request Code	Description	Test Code (result)	Description
PCST	OneFlow PCST	ALLE	All Events # Events
		CELLE	Cells # Events
		CELLPP	Cells % Parent
		FSCSE	FSC Singlets # Events
		FSCSPP	FSC Singlets % Parent
		FSCSPG	FSC Singlets % Grandparent
		SSCSE	SSC Singlets # Events
		SSCSPP	SSC Singlets % Parent
		SSCSPG	SSC Singlets % Grandparent
		CD38E	CD38+ # Events
		CD38PP	CD38+ % Parent
		CD38PG	CD38+ % Grandparent
		PLASMAE	Plasma cells # Events
		PLASMAPP	Plasma cells % Parent
		PLASMAPG	Plasma cells % Grandparent
		CYKAPE	cyIgK+ # Events
		CYKAPPP	cyIgK+ % Parent
		CYKAPPG	cyIgK+ % Grandparent
		CYLAME	cyIgL+ # Events
		CYLAMPP	cyIgL+ % Parent
		CYLAMPG	cyIgL+ % Grandparent

Request Code	Description	Test Code (result)	Description
		KL_R	cyIgK/cyIgL ratio
		BCELLSE	B cells # Events
		BCELLSPP	B cells % Parent
		BCELLSPG	B cells % Grandparent
		SOURCE	Sample Source
		COMMENTS	Comments

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