LIS Interface Manual

Chemistry Analyzer

Foreword

For this Operator's Manual, the issued Date is 2014-12.

Before using the product, please read this operation manual thoroughly and understand it for relevant operation instructions.

Please keep this manual properly for convenient use.

Who Should Read This Manual

This manual is written for LIS (Laboratory Information Management System) developers and those who need to learn the HL7 interface or ASTM interface used by our company. Instructions are provided in this manual for LIS developers to guide them to develop LIS interface that enables their LIS to communicate with the analyzer of our company. The developers are expected to have knowledge of LIS, HL7 or ASTM standards, and capacity of network programming. The communication protocol is TCP/IP for network layer and HL7 version 2.3.1 or ASTM E1394-97 for application layer. LIS developers are recommended to develop the LIS interface using Visual C++, Visual Basic, etc. in the Windows operating system.

What Can You Find in This Manual

This manual introduces the HL7 interface and ASTM interface protocols used by our company. The manual is divided into two parts, the first is to introduce HL7 protocol, and the second part is to introduce ASTM protocol. Each part is divided into 3 sections. For the first part, the first section is a general description of the HL7 interface; the second section introduces Bidirectional Communication between the analyzer and LIS (sending test result and acquiring sample request information from LIS); the 3rd section introduces the communication process and gives some message samples. For the second part, the first section is a general description of the ASTM interface; the second section introduces Bidirectional Communication between the analyzer and LIS (sending test result and acquiring sample request information from LIS); the 3rd section introduces the communication process and gives some message samples.

Conventions Used in This Manual

This chart explains the symbols used in this manual.

When you see…	Description
⚠ NOTE	Read the statement following the symbol. The statement is alerting you to information that requires your attention.

Contents

1 *HL7 Interface*

1.1 HL7 Interface

HL7 interface is developed by our company for the Chemistry Analyzer to adapt to the prevailing Laboratory Information Management System (LIS). It provides a channel for IP-based networks. With TCP/IP, the LIS host can receive test results from chemistry analyzers, which also send patient information, sample information and test results to LIS in real-time or batch mode. Therefore, users can identify samples by both scanning sample bar code and downloading from LIS host. All data are transmitted in format of HL7 v2.3.1. This interface enables bidirectional communication between the chemistry analyzer and the LIS host

1.1.1   Messages Compatible with HL7 Interface

HL7, a transmission standard for electronic data and providing nurse for inpatients, was first defined by Americans and now has been applied by many countries. The HL7 interface is defined based upon HL7 v2.3.1. Refer to *HL7 Interface Standards Version 2.3.1* for details.

Only portion of the messages, segments and other data defined are used for the HL7 interface that needs only part of these data.

1.1.2   HL7 Lower Layer Protocol

TCP/IP is a byte stream protocol, which does not provide message border.HL7 is a higher layer protocol that is based upon messages but provides no message termination mechanism. To determine the message border, we have employed the minimal lower layer protocol. Refer to *HL7 Interface Standards Version 2.3.1* for details.

Communication Layer

The messages are transmitted in format of:

<SB> ddddd <EB><CR>

Where,

<SB> = Start Block character (1 byte)

ASCII <VT>, namely <0x0B>, must not be confused with the SOH or STX in ASCII.

ddddd = Data (variable number of bytes)

ddddd is an HL7 message, which only includes ISO 8859-1 characters (hexadecimal 20-FF) and <CR>, exclusive of other control characters and those that cannot be printed out.

<EB> = End Block character (1 byte)

ASCII <FS>, namely <0x1C >, must not be confused with the ETX or EOT in ASCII.

<CR> = Carriage Return (1 byte)

Enter character in ASCII is <0x0D>.

Minimal Lower Layer Protocol (MLLP)

The interface supports Minimal Lower Layer Protocol (MLLP) of HL7 and is a package mode of HL7 message. HL7 messages are encapsulated with a single character at the beginning and a dual character. The characters used by the HL7 interface are default in the HL7 standard.

Start character: Hexadecimal <0B>

End character: Hexadecimal <1C><0D>

1.2 Bidirectional Communication

Communication here concerns result sending and sample information downloading. The former means the analyzer transmits the measurement data to an external system (such as the LIS).There are two types of transmission: real-time and batch. Batch-mode transmission is not allowed in two conditions: 1) Real-time mode is enabled; 2) The system is in testing status. The latter means the analyzer downloads sample information from LIS in real-time or batch mode. Real-time mode can be achieved only if a sample bar code reader is equipped. Batch-mode downloading refers to retrieving samples in certain period of the day.

1.2.1 Introduction

This chapter introduces the message types (Ver. 2.3.1) used by the HL7 interface.

⚠ **NOTE**

HL7 supports many types of messages, but only 5 of them are employed on the HL7 interface.

The following sections introduce the common grammars in detail.

1.2.2 Message Grammar

This section introduces the general grammar of the HL7 interface.

⚠ **NOTE**

For complete and detailed descriptions of HL7 message grammar, refer to the HL7 standard written by the HL7 standard committee.

Each HL7 message is composed of segments that end with <CR>.

Each segment consists of a name (three characters) and fixed variable fields that are composed of components and subcomponents. The separators of each element are defined in the MSH segment in every message.

For instance,

MSH|^~\&|Manufacturer|analyzer|||20060427194802||ORU^R01|1|P|2.3.1||||0||ASCII|||

Where,

The five characters following MSH are defined as delimiters to separate the fields, components and subcomponents. The HL7 standard uses the following characters:

Character	Description
|	Field separator
^	Component separator
&	Subcomponent separator
~	Repetition separator
\	Escape character

The first field of MSH includes all the separators. MSH has the first field include all separators with most of the other fields empty that are optional and not used by the HL7 interface.

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Field 9	Includes message types (ORU, R01)
Field 10	Includes an unique text string to indicate message ID
Field 11	Includes processing ID (P refers to product)
Field 12	Defines the version of HL7 (2.3.1) for the message

The order of the segments following MSH in every message is specially specified. A segment is defined as optional or to be repeated by using the following grammar:

[ ] indicates the segment in it is optional.

{ } indicates the segment in it can be repeated for 0 or 1 time or more.

1.2.3   Compatible HL7 Messages

All messages used for HL7 interface include ORU, ACK, QRY, QCK and DSR.

Test results are transferred as follows:
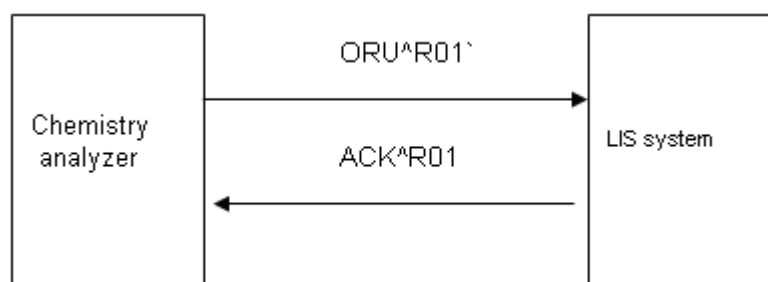
Sample information is downloaded from LIS as follows:
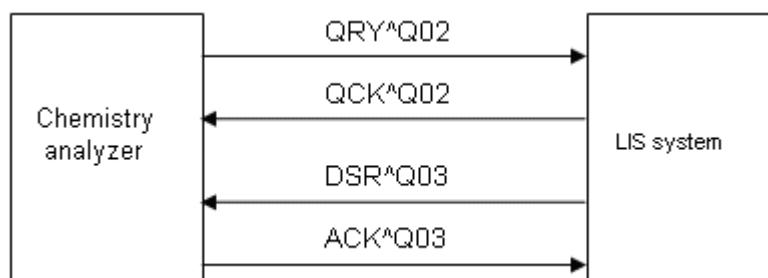
Details are explained in the following.

ORU/ACK: Observe result (unsolicited)/Acknowledgment

ORU^R01 is used to transmit test results (sample test, calibration test and QC test) to the LIS host.

An ORU^R01 message for sample test result includes:

- Patient information (patient name, sample ID, etc)

- Doctor's order (sample type, sender, tester, clinical diagnosis, etc)

- Test results

It is a group of messages. When the number of the samples is less or equal to 80 test results, one sample is corresponding to one message; but when the number of the samples is higher than80. The test result will be split to several messages to be sent.

The structure of an **ORU** message is as follows:

ORU	Observational Results (Unsolicited)	Description
MSH		Message Header
PID		Patient Identification
OBR		Observation report
{OBX}		Observation/Result

An ORU^R01 message for calibration test result includes:

- Test information (test No., test name)

- Calibration rule, calibration date

- Information related to calibrator (number, sequence No., name, lot No., expiration date, concentration, etc)

- Calibration result (response, number of calibration parameters, calibration parameters)

All calibration test results of a test can be transferred via one message. The LIS host is able to choose any of the information in the message as needed.

An ORU^R01 message for QC test result includes:

- Test information (test No., test name)

- Information related to control (number, sequence No., name, lot No., expiration date, mean concentration)

- Test date, test results (concentration)

All QC test results of a test can be transferred via one message. The LIS host is able to choose any of the information in the message as needed.

The calibration and QC test results are transferred as follows:

ORU	Observational Results (Unsolicited)	Description
MSH		Message Header
OBR		Observation report(calibration and QC)

ACK^R01 message is used to respond to the ORU message. The structure is as follows:

ACK	Acknowledgment	Description
MSH		Message Header
MSA		Message Acknowledgment

QRY/QCK: Query/Query acknowledgment

QRY^Q02 message is used for sample information query on LIS and has an event Q02.The structure of **QRY** message is as follows:

QRY	Query	Description MSH
		Message Header
QRD		Query Definition
QRF		Query Filter

QCK^Q02 message is used to respond to the QRY message. The structure is as follows:

QCK	Query Acknowledgment	Description
MSH		Message Header
MSA		Message Acknowledgment
ERR		Error
QAK		Query Acknowledgment

DSR/ACK: Display response/ Acknowledgment

DSR^Q03 message sends and displays searched results, i.e. send sample information from LIS to the analyzer. The structure of **DSR** message is as follows:

DSR	Display Response	Description
MSH		Message Header
MSA		Message Acknowledgment
ERR		Error
QAK		Query Acknowledgment
QRD		Query Definition
QRF		Query Filter
{DSP}		Display Data

DSC   Continuation Pointer

ACK^Q03 message is used to respond to the DSR message.

ACK   Acknowledgment   Description

MSH   Message Header

MSA   Message Acknowledgment

ERR   Error

1.2.4 Message Segment

This section describes the components of each segment:

- Field length

- Description

All fields used in message segment are listed in following tables. The numbers followed by a '#' symbol indicate the optional fields according to the HL7 protocol.

> **NOTE**
>
> All fields of the HL7 interface are provided for function extension in future although some of the fields are void.

MSH Message Header

All HL7 messages begin with MSH, which is the first segment of an HL7 message and always located at the beginning of the message. The MSH segment defines the intention, source, purpose and grammar of the message.

The MSH segment of the HL7 interface message uses the following fields:

No.	Field	Length	Description
1#	Field Separator	1	Includes the separator between segment ID and the first real field, and defines the field separators (|) of the remaining part of the message.
2#	Encoding Characters	4	Includes component, repetition, escape and subcomponent separators (^~\&).
3	Sending Application	180	Void and reserved. Sending application, set to our company.
4	Sending Facility	180	Void and reserved. Sending facility, set to machine type.
5	Receiving Application	180	Void and reserved. Receiving application.
6	Receiving Facility	180	Void and reserved. Receiving facility.
7	Date/Time Of	26	Time of the current message. Calling

No.	Field	Length	Description
	Message		the system time.
8	Security	40	Void and reserved. Security.
9#	Message Type	7	Type of the message, such as ORU^R01.
10#	Message Control ID	20	Message control ID. Indicates one message each and increases from 1 with message increasing.
11#	Processing ID	3	Processing ID. Always set to P (product).
12#	Version ID	60	Version ID. Version of HL7 protocol: 2.3.1.
13	Sequence Number	15	Void and reserved. Sequence number
14	Continuation Pointer	180	Void and reserved. Continuation pointer
15	Accept Acknowledgment Type	2	Type of accepted acknowledgment, only valid for DSR^Q03 message. The value is P, stating for the sample information sent by LIS. Other values state for sample information corresponded by LIS. It can be void.
16	Application Acknowledgment Type	2	Type of application response, used as result type.0-Sample result; 1-Calibration result; 2-QC result.
17	Country Code	2	Void and reserved. Country code
18	Character Set	10	Character set. ASCII is used.
19	Principal Language Of Message	60	Void and reserved. Principle language of the message
20	Alternate Character Set Handling Scheme	20	Void and reserved. Handling scheme of alternate character

Comments: MSH segment applies to all messages. Fields 3 and 4 are determined by LIS manufacturer; fields 5 and 6 are set to "Manufacturer" and machine type; fields 10 and 16 are integers; others are strings. When LIS sends sample request information to the chemistry analyzer, the 15 filed should be set to P.

MSA - message acknowledgment segment

The MSA segment of the HL7 interface message uses the following fields:

No.	Field	Length	Description
1#	Acknowledgment Code	2	Confirmation code, AA means "accept" ; AE means "error" ; AR means "refuse".
2#	Message Control ID	20	Message control ID, corresponding to MSH-10.

| 3 | Text Message | 80 | Text message, a description of error or reject event .Corresponding to field 6.

It can be written into error logs. |
4	Expected Sequence Number	15	Void and reserved. Expected sequence number.
5	Delayed Acknowledgment Type	1	Void and reserved. Delayed acknowledgment type.
6	Error Condition	100	Error condition (status code).

Note: Fields of MSA-6 are introduced as follows.

Status Code (MSA-6)	Status Text(MSA-3)	Description/Comment
Succeeded:		AA
0	Message accepted	Succeeded
Error code:		AE
100	Segment sequence error	Segment sequence is incorrect or required segment is missed.
101	Required field missing	Required field in a segment is missed.
102	Data type error	Data type of a field is incorrect.
103	Table value not found	Table value is not found, therefore not used temporarily.
Reject code:		AR
200	Unsupported message type	Message type is not supported.
201	Unsupported event code	Event code is not supported.
202	Unsupported processing id	Processing ID is not supported.
203	Unsupported version id	Version ID is not supported.
204	Unknown key identifier	Key identifier is unknown, such as inexistent patient information.
205	Duplicate key identifier	The key identifier already exists.
206	Application record locked	The transaction could not be performed at the application storage level, such as locked database.
207	Application internal error	Unknown application internal

Status Code (MSA-6)	Status Text(MSA-3)	Description/Comment
		error.

Comments: MSA segment applies to ACK^R01, QCK^Q02 and ACK^Q03 messages. Fields 4 and 6 are integers, while others are strings.

PID Patient Identification

PID segment is mainly used to construct the patient information. The HL7 interface message uses the following fields:

No.	Field	Length	Description
1	Set ID – PID	10	Identifies different patient fields
2	Patient ID	20	Patient ID
3#	Patient Identifier List	20	Void and reserved. MRN
4	Alternate Patient ID – PID	20	Void and reserved. Bed No.
5#	Patient Name	48	Name of patient
6	Mother's Maiden Name	48	Void and reserved. Patient Zone
7	Date/Time of Birth	26	Birth date of the patient (Format: hour, minute and second, such as 19830512000000).
8	Sex	1	Gender M for male F for female O for others U for unknown
9	Patient Alias	48	Void and reserved. Blood type (A for blood type A; B for blood type B; AB for blood type AB and O for blood type O). Others are defined by the customers themselves.
10	Race	80	Void and reserved. Race of patient
11	Patient Address	106	Address of patient

No.	Field	Length	Description
12	County Code	4	Void and reserved. County code of patient(postal code)
13	Phone Number - Home	40	Void and reserved. Phone number (home) of patient
14	Phone Number - Business	40	Void and reserved. Phone number (business) of patient
15	Primary Language	60	Void and reserved. Primary language of patient
16	Marital Status	80	Void and reserved. Marital status of patient
17	Religion	80	Void and reserved. Religion of patient
18	Patient Account Number	20	Void and reserved. Patient type
19	SSN Number -Patient	16	Void and reserved. Social security number of patient
20	Driver's License Number – Patient	25	Void and reserved. Payment type of patient
21	Mother's Identifier	20	Void and reserved. Mother's identifier
22	Ethnic Group	80	Void and reserved. Ethnic group the patient belongs to
23	Birth Place	60	Void and reserved. Birth place of patient
24	Multiple Birth Indicator	1	Void and reserved. Multiple birth indicator, Y(yes) or N(no).
25	Birth Order	2	Void and reserved. Birth order, an integer greater than 0
26	Citizenship	80	Common remark
27	Veterans Military Status	60	Void and reserved. Veterans military status of patient

No.	Field	Length	Description
28	Nationality	80	Void and reserved. Nationality of patient
29	Patient Death Date and Time	26	Void and reserved. Patient death date and time
30	Patient Death Indicator	1	Void and reserved. Patient death indicator, Y (yes) or N (no)

Comments: The PID segment only applies to the ORU^R01 messages. The 1st and 25th fields are integers, the 24th and 30th fields are Booleans, and others are strings.

OBR Observation Request

OBR segment is used to transfer the order information of test report. When the sample test result is transferred (MSH-16 is 0), the field used in the HL7 interface is shown in the following table.

No.	Field	Length	Description
1	Set ID – OBR	10	Identifies different OBR fields
2	Placer Order Number	22	Order number of placer, used as sample bar code
3	Filler Order Number	22	Order number of filler, used as sample ID
4#	Universal Service ID	200	Universal service ID (manufacturer^ machine type)
5	Priority	2	STAT. Y for yes and N for no.
6	Requested Date/time	26	Requesting date/time (sample collecting time)
7	Observation Date/Time	26	Observation date/time, used as testing date/time
8	Observation End Date/Time	26	Void and reserved. Observation end date/time
9	Collection Volume	20	Void and

No.	Field	Length	Description
			reserved. Collection Volume. Used for calculation manual dilution.
10	Collector Identifier	60	Collector Identifier. Used as sample position (sample disk No.^sample cup No.)
11	Specimen Action Code	1	Void and reserved. Specimen action code
12	Danger Code	60	Void and reserved. Danger code
13	Relevant Clinical Info.	300	Clinical diagnosis
14	Specimen Received Date/Time	26	Send D/T
15	Specimen Source	300	sample source, used as sample type. It varies among different product.
16	Ordering Provider	120	Order provider, used as sender
17	Order Callback Phone Number	40	Sending department
18	Placer Field 1	60	Void and reserved. Characteristic of sample (icterus, hemolysis and lipemia, others are named by the customer)
19	Placer Field 2	60	Void and reserved. Blood bag No.
20	Filler Field 1	60	Void and

No.	Field	Length	Description
			reserved. Attending doctor
21	Filler Field 2	60	Void and reserved. Treating department
22	Result Rpt/Status Change – Date/Time	26	Void and reserved. Result report/status change-date/time
23	Charge to Practice	40	Void and reserved. Charge to practice
24	Diagnostic Serv Sect ID	10	Void and reserved. Diagnosis ID
25	Result Status	1	Void and reserved. Status of result
26	Parent Result	200	Void and reserved. Parent result
27	Quantity/Timing	200	Void and reserved. Quantity/time
28	Result Copies To	150	Void and reserved. Result copies
29	Parent	150	Void and reserved. Parent order
30	Transportation Mode	20	Void and reserved. Transportation mode
31	Reason for Study	300	Void and reserved. Reason for study
32	Principal Result Interpreter	200	Void and reserved. Principal result interpreter

No.	Field	Length	Description
33	Assistant Result Interpreter	200	Void and reserved. Assistant result interpreter
34	Technician	200	Void and reserved. Technician
35	Transcriptionist	200	Void and reserved. Transcriptionist
36	Scheduled Date/Time	26	Void and reserved. Scheduled date/time
37	Number of Sample Containers	4	Void and reserved. Number of sample containers
38	Transport Logistics of Collected Sample	60	Void and reserved. Transport logistics of collected sample
39	Collector's Comment	200	Void and reserved. Collector's comment
40	Transport Arrangement Responsibility	60	Void and reserved. Transport arrangement responsibility
41	Transport Arranged	30	Void and reserved. Transport arranged
42	Escort Required	1	Void and reserved. Escort required
43	Planned Patient Transport Comment	200	Void and reserved. Planned patient transport comment
44	Ordering Facility Name	60	Void and reserved.

No.	Field	Length	Description
			Name of placer
45	Ordering Facility Address	106	Void and reserved. Address of placer
46	Ordering Facility Phone Number	48	Void and reserved. Phone number of placer
47	Ordering Provider Address	106	Void and reserved. Address of placer provider

Comments: The segment only applies to the ORU^R01 messages. The 1st, 3rd and 37th fields are integers, the 9th field is floating number, and others are strings.

When calibration test results are transferred (MSH-16 is 1), the applied fields include:

No.	Field	Length	Description
1	Set ID – OBR	10	Identifies different OBR fields
2	Placer Order Number	22	Order number of placer, used as test No.
3	Filler Order Number	22	Order number of filler, used as test name
4#	Universal Service ID	200	Universal Service ID (manufacturer^machine type)
5	Priority	2	Void and reserved. Priority
6	Requested Date/time	26	Void and reserved. Requesting date/time
7	Observation Date/Time	26	Observation date/time, used as calibration date/time
8	Observation End Date/Time	26	Void and reserved. Observation end date/time
9	Collection Volume	20	Used as calibration rule.0 - One-point linear; 1 – Two-point linear; 2 – Multi-point linear; 3 - Logistic-Log4P; 4 -

No.	Field	Length	Description
			Logistic-Log5P; 5 - Exponential 5P; 6 - Polynomial 5P; 7 – Parabola; 8 – Spline.
10	Collector Identifier	60	Void and reserved. Collector identifier
11	Specimen Action Code	1	Number of calibrators
12	Danger Code	60	Calibrator No.
13	Relevant Clinical Info.	300	Name of calibrator
14	Specimen Received Date/Time	26	Lot No. of calibrator
15	Specimen Source	300	Expiration date of calibrator
16	Ordering Provider	120	Standard concentration of calibrator
17	Order Callback Phone Number	40	Concentration level of calibrator. H for high; M for medium, L for low.
18	Placer Field 1	60	Response
19	Placer Field 2	60	Number of calibration parameters
20	Filler Field 1	60	Calibration parameter
21	Filler Field 2	60	Void and reserved.
22	Result Rpt/Status Change – Date/Time	26	Void and reserved. Result report/status change-date/time
23	Charge to Practice	40	Void and reserved. Charge to practice
24	Diagnostic Serv Sect ID	10	Void and reserved. Diagnosis ID
25	Result Status	1	Void and reserved. Status of result
26	Parent Result	200	Void and reserved. Parent result
27	Quantity/Timing	200	Void and reserved. Quantity/time
28	Result Copies To	150	Void and reserved. Result copies

No.	Field	Length	Description
29	Parent	150	Void and reserved. Parent order
30	Transportation Mode	20	Void and reserved. Transportation mode
31	Reason for Study	300	Void and reserved. Reason for study
32	Principal Result Interpreter	200	Void and reserved. Principal result interpreter
33	Assistant Result Interpreter	200	Void and reserved. Assistant result interpreter
34	Technician	200	Void and reserved. Technician
35	Transcriptionist	200	Void and reserved. Transcriptionist
36	Scheduled Date/Time	26	Void and reserved. Scheduled date/time
37	Number of Sample Containers	4	Void and reserved. Number of sample containers
38	Transport Logistics of Collected Sample	60	Void and reserved. Transport logistics of collected sample
39	Collector's Comment	200	Void and reserved. Collector's comment
40	Transport Arrangement Responsibility	60	Void and reserved. Transport arrangement responsibility
41	Transport Arranged	30	Void and reserved. Transport arranged
42	Escort Required	1	Void and reserved. Escort required
43	Planned Patient Transport Comment	200	Void and reserved. Planned patient transport comment
44	Ordering Facility Name	60	Void and reserved. Name of placer
45	Ordering Facility Address	106	Void and reserved. Address of placer
46	Ordering Facility Phone	48	Void and reserved. Phone number of

No.	Field	Length	Description
	Number		placer
47	Ordering Provider Address	106	Void and reserved. Address of placer provider

Comments: The PID segment only applies to the ORU^R01 messages. The 1st, 9th, 11th, 19th, and 37th fields are integers, the 10th field is floating number, and others are strings. Field 12-18 are respectively V1^V2^…Vi according to the number of calibrators. The different values of field 20 are separated by ^ according to the number of calibration parameters.

Different calibration rules have various parameters:

Linear (one-point, two-point and multi-point): K and R0;

Logit-Log4P: K, R0, a and b;

Logit-Log5P: K, R0, a, b and c;

Polynomial 5P: K, R0, a, b, c and d;

Parabola: R0, a and b;

Spline: 4*(n-1) parameters, which are R0i, ai, bi, ci. n is number of calibrators.

When QC test results are transferred (MSH-16 is 2), the applied fields include:

No.	Field	Length	Description
1	Set ID – OBR	10	Identifies different OBR fields
2	Placer Order Number	22	Order number of placer, used as test No.
3	Filler Order Number	22	Order number of filler, used as test name
4#	Universal Service ID	200	Universal Service ID (manufacturer^machine type)
5	Priority	2	Void and reserved. Priority
6	Requested Date/time	26	Void and reserved. Requesting date/time
7	Observation Date/Time	26	Observation date/time, used as QC date/time
8	Observation End Date/Time	26	Void and reserved. Observation end date/time
9	Collection Volume	20	Void and reserved.
10	Collector Identifier	60	Void and reserved.
11	Specimen Action Code	1	Number of controls
12	Danger Code	60	Control No.

No.	Field	Length	Description
13	Relevant Clinical Info.	300	Control name
14	Specimen Received Date/Time	26	Lot No. of control
15	Specimen Source	300	Expiration date of control
16	Ordering Provider	120	Void and reserved.
17	Order Callback Phone Number	40	Concentration level of control. H for high; M for medium, L for low.
18	Placer Field 1	60	Mean value (mean concentration)
19	Placer Field 2	60	Standard deviation of control
20	Filler Field 1	60	Test result (concentration)
21	Filler Field 2	60	Void and reserved.
22	Result Rpt/Status Change – Date/Time	26	Void and reserved. Result report/status change-date/time
23	Charge to Practice	40	Void and reserved. Charge to practice
24	Diagnostic Serv Sect ID	10	Void and reserved. Diagnosis ID
25	Result Status	1	Void and reserved. Status of result
26	Parent Result	200	Void and reserved. Parent result
27	Quantity/Timing	200	Void and reserved. Quantity/time
28	Result Copies To	150	Void and reserved. Result copies
29	Parent	150	Void and reserved. Parent order
30	Transportation Mode	20	Void and reserved. Transportation mode
31	Reason for Study	300	Void and reserved. Reason for study
32	Principal Result Interpreter	200	Void and reserved. Principal result interpreter
33	Assistant Result Interpreter	200	Void and reserved. Assistant result interpreter
34	Technician	200	Void and reserved. Technician
35	Transcriptionist	200	Void and reserved. Transcriptionist
36	Scheduled Date/Time	26	Void and reserved. Scheduled date/time
37	Number of Sample Containers	4	Void and reserved. Number of sample containers
38	Transport Logistics	60	Void and reserved. Transport

No.	Field	Length	Description
	of Collected Sample		logistics of collected sample
39	Collector's Comment	200	Void and reserved. Collector's comment
40	Transport Arrangement Responsibility	60	Void and reserved. Transport arrangement responsibility
41	Transport Arranged	30	Void and reserved. Transport arranged
42	Escort Required	1	Void and reserved. Escort required
43	Planned Patient Transport Comment	200	Void and reserved. Planned patient transport comment
44	Ordering Facility Name	60	Void and reserved. Name of placer
45	Ordering Facility Address	106	Void and reserved. Address of placer
46	Ordering Facility Phone Number	48	Void and reserved. Phone number of placer
47	Ordering Provider Address	106	Void and reserved. Address of placer provider

Comments: The segment only applies to the ORU^R01 messages. Fields 1, 11 and 37 are integers, while others are strings. Fields 12-15, and 17-20 are in the format of V1^V2^…Vi according to the number of controls. Please note that each day-to-day QC result is transferred via one message. However, multiple real-time and daily QC results for each test are transferred via a message. QC results of different batches are sent respectively.

OBX Observation

The OBX segment transmits the observations. If sample results are to be transmitted (MSH-16 is 0)—Each patient may have multiple test results, then more than one OBX segment will be used to transmit the results. On the analyzer, all test results of a patient are transmitted separately. The HL7 interface does not check the repeatability of the test results, which should be performed by the user system.

The OBX segment of the HL7 interface uses the following fields:

No.	Field	Length	Description
1	Set ID – OBX	10	Identifies different OBX segments.
2	Value Type	3	Value type, identifies the test result. **NM** (numeric), numeric value, for quantitative tests **ST** (string), for qualitative tests

No.	Field	Length	Description
3#	Observation Identifier	590	Observation identifier, used as test ID.
4	Observation Sub-ID	20	Observation Sub-ID, used as test name.
5	Observation Value	65536	Observation value, used as test result (concentration)
6	Units	90	Unit of test result.
7	References Range	90	Reference range for test result.
8	Abnormal Flags	5	Abnormity flag to indicate whether the test result is normal or not. L - Low H - High N - Normal
9	Probability	5	Probability; for qualitative result (Negative-, Positive+, weak positive+-)
10	Nature of Abnormal Test	2	Reason for abnormal test; used for reference.
11#	Observe Result Status	1	Status of observation result, set to F-final results.
12	Date Last Observe Normal Values	26	Void and reserved. Date of last normal observation value.
13	User Defined Access Checks	20	User-defined access check, used as original result.
14	Date/Time of the Observation	28	Observation date/time, used as testing date/time
15	Producer's ID	60	Void and reserved. Used for clinical department.
16	Responsible Observer	80	Responsible observer, used as tester.
17	Observation Method	60	Void and reserved. Observation method.

Comments: The OBX segment only applies to the ORU^R01 messages. Fields 1, 3 and 9 are integers; fields 5 and 13 are floating numbers; others are strings. Please note that fields 5 and 13 are in the format of Result1 ^ Result2 ^ Result3 when SI(serum index) test is run. Result 1 is turbidity(L), result 2 is hemolysis(H), and result 3 is icterus(I).

QRD - query definition segment

The QRD segment of the HL7 interface uses the following fields:

No.	Field	Length	Description
1#	Query Date/Time	26	Query date/time, i.e. system date/time.
2#	Query Format Code	1	Query format code, set to R (record-oriented format).
3#	Query Priority	1	Query priority, set to D (deferred).
4#	Query ID	10	Query ID, indicates different queries and increases from 1.
5	Deferred Response Type	1	Void and reserved. Deferred response type.
6	Deferred Response Date/Time	26	Void and reserved. Deferred response date/time.
7#	Quantity Limited Request	10	Quantity limited request, set to RD (records).
8#	Who Subject Filter	60	Subject filter, used as sample bar code.
9#	What Subject Filter	60	Subject filter. OTH for query
10#	What Department Data Code	60	Void and reserved. Department data code.
11	What Data Code Value Qual.	20	Void and reserved. Data code value qualifier.
12	Query Results Level	1	Void and reserved. Query results level. T for Full results

Comments: QRD segment may appear in QRY^Q02 and DSR^Q03 messages.
Field 8 is bar code for real-time downloading and null for group downloading;
Field 4 is an integer, while others are strings.

QRF - query filter segment

The QRF segment is used together with the QRD segment and uses the following fields:

No.	Field	Length	Description
1#	Where Subject Filter	20	Subject address filter, set to machine type.
2	When Data Start Date/Time	26	Data start date/time, used as start receipt date/time.
3	When Data End Date/Time	26	Data end date/time, used as end receipt date/time.
4	What User Qualifier	60	Void and reserved. User qualifier.
5	Other QRY Subject Filter	60	Void and reserved. Other QRY subject filter.
6	Which Date/Time	12	Object type. RCT(Specimen receipt date/time, receipt of

No.	Field	Length	Description
	Qualifier		specimen in filling ancillary (Lab))
7	Which Date/Time Status Qualifier	12	Object status. COR(Corrected only (no final with corrections))
8	Date/Time Selection Qualifier	12	Date/time selection qualifier. ALL(All values within the range)
9	When Quantity/Timing Qualifier	60	Void and reserved. Time interval.

Comments: QRF segment only applies to QRY^Q02 and DSR^Q03 messages.
Fields 3 and 4 are 0 o'clock and query time of the day, and used as search conditions. All fields are strings.

ERR - error segment

The ERR segment adds error description to acknowledgment message and uses the following fields:

No.	Field	Length	Description
1#	Error Code and Location	80	Error code and location.

Comments: ERR segment may appear in QCK^Q02, DSR^Q03 or ACK^Q03 message. The only field of this segment is an integer.

QAK - query acknowledgment segment

The QAK segment includes query response information and uses the following fields:

No.	Field	Length	Description
1	Query Tag	32	Query tag, set to SR (sample request information).
2	Query Response Status	2	Query response status: OK: Data found, no errors NF: No data found, no errors AE: Application error AR: Application reject

Comments: QRF segment only applies to QRY^Q02 message. All fields of this segment are strings.

DSP - display data segment

The DSP segment displays searched sample information and patient information and uses the following fields:

No.	Field	Length	Description
1	Set ID - DSP	4	Identifies different DSP segments.
2	Display Level	4	Display level.
3#	Data Line	300	Data line, i.e. searched contents.
4	Logical Break Point	2	Logical break point.
5	Result ID	20	Result ID.

Comments: The OBX segment only applies to the ORU^R01 messages. Field 1 is an integer, while others are strings.

The 3rd field is used to display the sample request information from LIS. The order of the sample request information is in the following table. The Bar Code and the Test ID are indispensable; others can be void. When the samples include more than one test, the field 29th will be added with the same format.

Sequence	What Can You Find in This Manual	Data Type and Value
1	Admission Number	String
2	Bed Number	String
3	Patient Name	String
4	Date of Birth	String. The format is YYYYMMDDHHmmSS, such as 20061122130540. All fields about time are of this format.
5	Sex	String. Male/M, Female/F, Other/O
6	Patient Alias	String, O, A, B, AB
7	Race	String, blank
8	Patient Address	String
9	County Code	String
10	Home Phone Number	String
11	Business Phone Number	String, sample position (sample disk No.^sample cup)

Sequence	What Can You Find in This Manual	Data Type and Value
12	Primary Language	String, sample collecting time
13	Marital Status	String, blank
14	Religion	String, blank
15	Patient Account Number	String. It includes Outpatient, inpatient, other.
16	Social Security Number	String
17	Driver License Number	String, It includes Own and Insurance.
18	Ethnic Group	String
19	Birth Place	String
20	Nationality	String
21	Bar Code	String
22	Sample ID	int
23	Sample Time	String. See item 4
24	STAT or not	String. It includes Y (yes), N (No) and void. N is default.
25	Collection Volume	Float, manual sample dilution ratio
26	Sample Type	String. It includes serum, plasma and urine. It can be set to defined sample type in dictionary.
27	Fetch Doctor	string
28	Fetch Department	string
29	Test ID^Test Name^Unit^Normal Range	String^string^string^string

The analyzer recognizes a test with its Test Number. For the same test, if the test number in the analyzer and that in the LIS server are not the same, you can open the ItemID.ini file in the folder where the executive file of operating software locates and configure the test number. The test settings on the analyzer are the same with that on the LIS by default.

DSC - Continuation pointer segment

The DSC segment indicates whether the data message is the last one.

No.	Field	Length	Description
1	Continuation pointer	180	Continuation pointer

Comments: DSC segment only applies to DSR^Q03 message. The only field of this segment is void when DSR^Q03 message responds to group query and not void in other conditions. This field is an integer.

1.3 Communication Process and Message Example

A message of HL7 protocol is the format of:

<SB> ddddd <EB><CR>

Where, <SB> means the start of the message and is <VT> in ASCII, that is 0x0B.

<EB> means the end of the message and is <FS> in ASCII, that is 0x1C.

<CR> acts as acknowledgement of message end and is used to separate different messages, that is, 0x0D.

ddddd means what to be transferred and includes multiple segments, each of which ends with <CR>, that is, 0x0D.

The following lines list multiple message examples of the HL7 protocol.

The chemistry analyzer sends test results to the LIS host by samples, that is, all tests of a sample are transferred via one message. The LIS host responses accordingly when receiving the message.
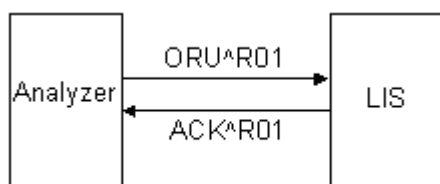
An ORU message may include the following segments: MSH, PID, OBR and OBX (multiple OBX segments may be contained if a sample has more than one test).MSH, standing for message header, is included in each message and in the format of: (The words in brackets are for explanation and not the segments)

MSH|^~\&|Manufacturer|analyzer(Device model)|||20070423101830(System date/time, yyyymmddhhMMss)||ORU^R01(Message type)|1(Control ID, used to identify the message and increases from 1)|P(Fixed value, means the product)|2.3.1(Version of HL7 protocol)||||0(0 for sample test result, 1 for calibration result, 2 for QC result, void for others)||ASCII(Character set)|||

Note: In all message examples, if the time segment is of 14 digits, it means YYYYMMDDHHMMSS; if the time segment is of 8 digits, it means YYYYMMDD.

There is a patient, who has the following information:

Field	Value
Name of patient	Mike
Gender	Male
Birth date	01.10.85
Sample bar code	12345678
Sample Type	Serum
Sample ID	10
STAT	Yes
Test No.	2, 5, 6
Test	TBil, ALT, AST
Test results	100, 98.2, 26.4
Unit	umol/L, umol/L, umol/L

The analyzer sends the test results to LIS via ORU^R01 message as follows:

When receiving the message, the LIS host first judges the legality and type of the message and then replies accordingly. The following is a standard reply by LIS.

`<SB>MSH|^~\&|||Company|Product|20070415110202||ACK^R01|1|P|2.3.1|||0||ASCII||| <CR>`

Message Type: Response of ORU

`MSA|AA|1|Message accepted|||0| <CR>`

Message Is received

Text information, which functions as notes.

Error code

If error is included in the ORU message, it can be returned in the MSA segment, and the analyzer will handle it properly and trigger alarms. When a reject error of 206 occurs on the LIS host, the ACK message for reply is as follows:

`<SB>MSH|^~\&|||Company|Product|20070415110202||ACK^R01|1|P|2.3.1|||0||ASCII||| <CR>`

Message Type: Response of ORU

`MSA|AR|1|Application record locked|||206| <CR>`

Message Is rejected

Text Information

Error code

`<EB><CR>`

The chemistry analyzer sends calibration results to the LIS host, that is, all calibration tests of a test are transferred via one ORU message.

The segments and their meanings in ORU message for calibration result transfer are significantly different from that for sample test result transfer. The former ORU message only includes two segments: MSH and OBR.

For example: A calibration test is requested as follows.

Field	Value
Test No.	6
Test	ASO
Rule	Spline
Calibrator No.	1, 2, 3
Name of calibrator	WATER, CALIB1, CALIB2
Lot No. of calibrator	1111, 2222, 3333
Expiration date of calibrator	January 1, 2030; January 1, 2030; January 1, 2030;
Standard concentration of calibrator	0, 2, 3
Concentration level of calibrator	Low(L), Low(L), Low(L)
Response	797.329332, 843.143762, 1073.672512
Calibration parameters (RO, a, b, c)	797.329332, 22.907215, -69.207178, 34.603589 和

Field	Value
	843.143762, 161.321571, 138.414356, -69.207178

The chemistry analyzer sends the test results to LIS via ORU^R01 message as follows:

<SB>MSH|^~\&|Company|Product|20070330143737||ORU^R01|1|P|2.3.1||||1||ASCII||| <CR>

Calib. Result

OBR|1|6|ASO|Company^ Product |||20070330120156||8|3|1^2^3|WATER^CALIB1^CALIB2

Test ID · Test Name · Calib. Time · Calib. Rule, 8 means Spline · Number of Calibrators · Calibrator Name · Calibrator No., which is separated from each other by '^' and respectively corresponds to the following fields.

|1111^2222^3333|20300101^20300101^20300101

Calibrator lot No. · Expiration date

|0.000000^2.000000^3.000000|L^L^L|797.329332^843.143762^1073.672512|8

Std. Conc. Of Calibrator · Conc. Level of Calibrator · Response · Number of Cali. Para

797.329332&22.907215&-69.207178&34.603589^843.143762&161.321571&138.414356&-69.207178

Cali. Value(R0&a&b&c)

|||||||||||||||||||||||||| <CR>

<EB><CR>

The LIS host replies as follows:

<SB> MSH|^~\&||| Company| Product |20070330143737||ACK^R01|1|P|2.3.1||||1||ASCII||| <CR>

MSA|AA|1|Message accepted|||0|<CR>

<EB><CR>

The chemistry analyzer sends QC test results to the LIS host. On the chemistry analyzer, each day-to-day QC test result is sent via one message, and multiple real-time and daily QC results of a test are sent via one message.

The ORU message for QC result transfer is similar to that for calibration result in segments and meanings.

For example: A QC test is requested as follows.

Field	Value
Test No.	7
Test	AST

Control No.	1, 2
Control name	QUAL1, QUAL2
Lot No. of control	1111, 2222
Expiration date of control	January 1, 2030; January 1, 2030
Concentration level of control	Low(L), High(H)
Mean value (mean concentration)	45, 55
Standard deviation of control	5, 5
Test result (concentration)	0.130291, 0.137470

The analyzer sends the test results to LIS via ORU^R01 message as follows:

The LIS host replies as follows:

The analyzer sends query request to the LIS host, and also downloads sample information, patient demographics and test information of specified bar code from LIS.
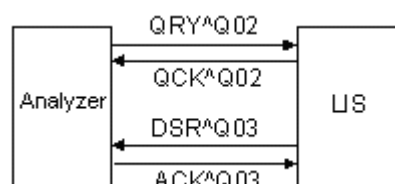
For example: To download a sample of 0019(bar code) from LIS, the analyzer sends a QRY^Q02 message as follows:

<SB> MSH|^~\&|Company|Product |||20070301193232||QRY^Q02|1|P|2.3.1|||||ASCII||| <CR>

Message type

QRD|20070301193232|R|D|1|||RD|0019|OTH|||T| <CR>

Qry. Time | Qry. Format Code | Qry. Priority | Quantity Limited Request | Sample Barcode | Query Results Level | What Subject Filter

QRF|Product |20070301193241|20070301193241|||RCT|COR|ALL|| <CR>

Which Date/Time Qualifier | Which Date/Time Status Qualifier | Date/Time Selection Qualifier

<EB><CR>

When receiving the message, the LIS returns the QCK^Q02 message and replies as follows if the sample of the bar code exists:

<SB>MSH|^~\&||| Company|Product |20070301193232||QCK^Q02|1|P|2.3.1|||||ASCII||| <CR>

Response Message Type

MSA|AA|1|Message accepted|||0|<CR>

ERR|0|<CR>

Error Code and Location

QAK|SR|OK|<CR>

Query Tag | Query Response Status

<EB><CR>

If the sample of the bar code does not exist, the LIS replies as follows:

<SB> MSH|^~\&||| Company|Product |20070301193232||QCK^Q02|1|P|2.3.1|||||ASCII||| <CR>

MSA|AA|1|Message accepted|||0| <CR>

ERR|0| <CR>

QAK|SR|NF| <CR>

No data found

<EB><CR>

When the sample of the specified bar code exists on LIS, the LIS returns the QCK^Q02 message and sends the data message DSR^Q03, which contains the patient demographics, sample and test information.

Name of patient	Tommy
Gender	Male

Name of patient	Tommy
Birth date	24.08.62
Blood type of patient	O
Patient type	Outpatient
Payment type of patient	Self-pay
Patient ID	1212
Bed No.	27
Sample bar code	0019
Sample ID	3
Sample receiving date/time	18:35 March 1, 2007
STAT	No
Sample Type	Serum
Sender	Mary
Sending department	Dept1
Test No.	1, 2, 5
Name of patient	Tommy

The DSR messages are as follows:

`<SB> MSH|^~\&|||Company|Product|20070301193232||DSR^Q03|1|P|2.3.1|||||ASCII||| <CR>`

Message Type(data)

```
MSA|AA|1|Message accepted|||0| <CR>
ERR|0| <CR>
QAK|SR|OK| <CR>
QRD|20070301193237|R|D|1||||RD|0019|OTH|||T| <CR>
QRF|Product|20070301193241|20070301193241||||RCT|COR|ALL|| <CR>
DSP|1||1212||| <CR>
```

Serial No.   Hospital No.

```
DSP|2||27||| <CR>
```

Bed No.

```
DSP|3||Tommy|||<CR>
```

Patient Name

```
DSP|4||19620824000000||| <CR>
```

Birthday

```
DSP|5||M||| <CR>
```

Gender

```
DSP|6||O||| <CR>
```

Blood Type

```
DSP|7||||| <CR>

DSP|8||||| <CR>
DSP|9||||| <CR>
DSP|10||||| <CR>
DSP|11||||| <CR>
DSP|12||||| <CR>
DSP|13||||| <CR>
DSP|14||||| <CR>
DSP|15||outpatient||| <CR>
```

Patient Type

```
DSP|16||||| <CR>

DSP|17||own||| <CR>
```

Pay Type

```
DSP|18||||| <CR>
DSP|19||||| <CR>
DSP|20||||| <CR>

DSP|21||0019||| <CR>
                    Sample
                    Barcode

DSP|22||3||| <CR>
                Sample ID

DSP|23||20070301183500||| <CR>
                            Sending Time

DSP|24||N||| <CR>
                Emergency


        DSP|25||||| <CR>
        DSP|26||serum||| <CR>
                        Sample Type

        DSP|27||Mary||| <CR>
                        Sender

        DSP|28||Dept1||| <CR>
                        Sending
                        Dept.

        DSP|29||1^^^||| <CR>
        DSP|30||2^^^||| <CR>

        DSP|31||5^^^||| <CR>
                        Test ID

        DSC||<CR>
<EB><CR>
```

No DSR message will be sent if a QCK^Q02 message has been sent indicating no corresponding sample on LIS.

When receiving the DSR message, the analyzer replies as follows:

```
<SB>MSH|^~\&| Company|Product |||20070301193242||ACK^Q03|1|P|2.3.1|||||ASCII||| <CR>

  MSA|AA|1|Message accepted|||0| <CR>
  ERR|0| <CR>

<EB><CR>
```

The analyzer sends group query request to LIS for downloading all or latest samples of the current day.

The two query modes are distinguished by the time period. See the table below.

Query Mode	Start Time	End Time
All samples of current day	0 o'clock of current day	System time when the query is sent
Latest samples of current day	End time of the latest query	System time when the query is sent

For example: A group query is sent to LIS at 15:00 on March 20, 2007 to download all samples of the current day. The query message is as follows:

```
<SB>MSH|^~\&| Company|Product  |||20070320170000||QRY^Q02|1|P|2.3.1||||||ASCII|||<CR>
     QRD|20070320170000|R|D|1|||RD||OTH|||T| <CR>
     QRF| Product |20070320000000|20070320170000|||RCT|COR|ALL|| <CR>
                     └Time interval    └Time interval
                      (start)           (end)
<EB><CR>
```

Similarly to single sample query, the LIS host replies accordingly if corresponding samples exist. If yes, the LIS host sends all qualified samples to the analyzer after returning the query reply. Each sample is transferred via a DSR message, and the DSC segment of the last DSR message is void, indicating the end of the group transfer. For example: 3 qualified samples are found on LIS and are as follows:

Name of patient	Jacky	Jessica	Anata
Gender	Male	Female	Female
Birth date	16.02.72	12.05.83	December 12, 1979
Sample bar code	1587120	1587121	1587125
Sample ID	2	3	9
Sample Type	Serum	Plasma	Urine
STAT	No	Yes	Yes
No. of included tests	1, 4	2, 3, 6	8
Name of patient	Jacky	Jessica	Anata

The DSR messages are as follows:

```
<SB> MSH|^~\&||| Company|Product |20070320170000||DSR^Q03|1|P|2.3.1|||||ASCII||| <CR>
        MSA|AA|1|Message accepted|||0| <CR>
        ERR|0| <CR>
        QAK|SR|OK| <CR>
        QRD|20070320170000|R|D|1|||RD||OTH|||T| <CR>
        QRF|Product |20070320000000|20070320170000|||RCT|COR|ALL||<CR>
        DSP|1||||| <CR>
        DSP|2||||| <CR>
        DSP|3||Jacky||| <CR>
        DSP|4||19720216000000||| <CR>
        DSP|5||M||| <CR>
        DSP|6||||| <CR>

        DSP|7||||| <CR>
        DSP|8||||| <CR>
        DSP|9||||| <CR>
        DSP|10||||| <CR>
        DSP|11||||| <CR>
        DSP|12||||| <CR>
        DSP|13||||| <CR>

        DSP|14||||| <CR>
        DSP|15||||| <CR>
        DSP|16||||| <CR>
        DSP|17||||| <CR>
        DSP|18||||| <CR>
        DSP|19||||| <CR>
        DSP|20||||| <CR>
        DSP|21||1587120|||<CR>
        DSP|22||2||| <CR>

            DSP|23||||| <CR>
            DSP|24||N||| <CR>
            DSP|25||||| <CR>
            DSP|26||serum||| <CR>
            DSP|27||||| <CR>

    DSP|28||||| <CR>
            DSP|29||1^^^||| <CR>
            DSP|30||4^^^||| <CR>
            DSC|1| <CR>
                        First DSR message
                        of the three

    <EB><CR>
```

```
<SB> MSH|^~\&||| Company|Product |20070320170000||DSR^Q03|2|P|2.3.1|||||ASCII||| <CR>
      MSA|AA|2|Message accepted|||0| <CR>
      ERR|0| <CR>
      QAK|SR|OK| <CR>
      QRD|20070320170000|R|D|2|||RD||OTH|||T| <CR>
      QRF|Product |20070320000000|20070320170000|||RCT|COR|ALL||<CR>
      DSP|1||||| <CR>
      DSP|2||||| <CR>
      DSP|3||Jessica||| <CR>
      DSP|4||19830512000000|||| <CR>
      DSP|5||F||| <CR>
      DSP|6||||| <CR>

      DSP|7||||| <CR>
      DSP|8||||| <CR>

      DSP|9||||| <CR>
      DSP|10||||| <CR>
      DSP|11||||| <CR>
      DSP|12||||| <CR>
      DSP|13||||| <CR>
      DSP|14||||| <CR>
      DSP|15||||| <CR>
      DSP|16||||| <CR>
      DSP|17||||| <CR>
      DSP|18||||| <CR>
      DSP|19||||| <CR>

      DSP|20||||| <CR>
      DSP|21||1587121||| <CR>
      DSP|22||3||| <CR>
      DSP|23||||| <CR>
      DSP|24||Y||| <CR>
      DSP|25||||| <CR>
      DSP|26||plasma||| <CR>
      DSP|27||||| <CR>
      DSP|28||||| <CR>
      DSP|29||2^^^||| <CR>

      DSP|30||3^^^||| <CR>

      DSP|31||6^^^||| <CR>
      DSC|2| <CR>
                 | Second DSR message
                 | of the three

<EB><CR>
```

42

```
<SB> MSH|^~\&|||  Company|Product |20070320170000||DSR^Q03|3|P|2.3.1||||||ASCII||| <CR>

MSA|AA|3|Message accepted|||0| <CR>
ERR|0| <CR>
QAK|SR|OK| <CR>
QRD|20070320170000|R|D|3|||RD||OTH|||T| <CR>
QRF| Product |20070320000000|20070320170000|||RCT|COR|ALL||<CR>
DSP|1||||| <CR>
DSP|2||||| <CR>
DSP|3||Anata||| <CR>
DSP|4||19791212000000||| <CR>
DSP|5||F||| <CR>
DSP|6||||| <CR>
DSP|7||||| <CR>
DSP|8||||| <CR>

DSP|9||||| <CR>
DSP|10||||| <CR>
DSP|11||||| <CR>
DSP|12||||| <CR>
DSP|13||||| <CR>
DSP|14||||| <CR>
DSP|15||||| <CR>
DSP|16||||| <CR>
DSP|17||||| <CR>
DSP|18||||| <CR>
DSP|19||||| <CR>
DSP|20||||| <CR>
DSP|21||1587125||| <CR>
DSP|22||9||| <CR>
DSP|23||||| <CR>
DSP|24||Y||| <CR>
DSP|25||||| <CR>
DSP|26||urine||| <CR>
DSP|27||||| <CR>
DSP|28||||| <CR>
DSP|29||8^^^||| <CR>

DSC|| <CR>
```

Third DSR message of the three. Void means the end of multiple-sample transferring

`<CR>`

The analyzer sends back an ACK message to LIS every time when receiving a DSR message. The ACK messages for the above-mentioned DSR messages are:

43

```
<SB> MSH|^~\&| Company|Product |||20070320170000||ACK^Q03|1|P|2.3.1||||||ASCII||| <CR>

    MSA|AA|1|Message accepted|||0| <CR>
    ERR|0| <CR>

<EB><CR>

<SB> MSH|^~\&| Company|Product |||20070320170000||ACK^Q03|2|P|2.3.1||||||ASCII||| <CR>

    MSA|AA|2|Message accepted|||0| <CR>
    ERR|0| <CR>

<EB><CR>

        <SB> MSH|^~\&| Company|Product |||20070320170000||ACK^Q03|3|P|2.3.1||||||ASCII||| <CR>

            MSA|AA|3|Message accepted|||0| <CR>
            ERR|0| <CR>

        <EB><CR>
```

If LIS system is to set sample request information, the 15th field of MSH should be set to P. If DSR^Q03 is to be set, the "patient", "sample", "test information" should be:

Field	Value
Name of patient	Tommy
Gender	Male
Birth date	24.08.62
Blood type of patient	O
Patient type	Outpatient
Payment type of patient	Self-pay
Patient ID	1212
Bed No.	27
Sample bar code	0019
Sample ID	3
Sample receiving date/time	18:35 March 1, 2007
STAT	No
Sample Type	Serum
Sender	Mary
Sending department	Dept1

Field	Value
Test No.	1, 2, 5

The DSR messages are as follows:

<SB> MSH|^~\&|||| Company|Product |20070301193232||DSR^Q03|1|P|2.3.1|||| P|||ASCII||| <CR>

Message type (data) — Send

MSA|AA|1|Message accepted|||0| <CR>

ERR|0| <CR>

QAK|SR|OK| <CR>

QRD|20070301193237|R|D|1|||RD|0019|OTH|||T| <CR>

QRF| Product |20070301193241|20070301193241|||RCT|COR|ALL|| <CR>

DSP|1||1212||| <CR>

Patient ID
serial number

DSP|2||27||| <CR>

Bed No.

DSP|3||Tommy||| <CR>

Patient name

DSP|4||19620824000000||| <CR>

Birth date

DSP|5||M||| <CR>

Gender

DSP|6||O||| <CR>

Blood type

DSP|7||||| <CR>

DSP|8||||| <CR>

DSP|9||||| <CR>
DSP|10||||| <CR>
DSP|11||||| <CR>
DSP|12||||| <CR>
DSP|13||||| <CR>
DSP|14||||| <CR>

DSP|15||outpatient||| <CR>
                       └Patient type

DSP|16||||| <CR>

DSP|17||own||| <CR>
                     └Pay type

DSP|18||||| <CR>
DSP|19||||| <CR>
DSP|20||||| <CR>

DSP|21||0019||| <CR>
                   └Sample bar code

DSP|22||3||| <CR>
               └Sample ID

DSP|23||20070301183500||| <CR>
                            └Send time

DSP|24||N||| <CR>
                └Stat

DSP|25||||| <CR>

DSP|26||serum||| <CR>
                   └Sample type

DSP|27||Mary||| <CR>
                └Send doctor

DSP|28||Dept1||| <CR>
                └Send department

DSP|29||1^^^||| <CR>

DSP|30||2^^^||| <CR>

```
DSP|31||5^^^||| <CR>
                  Test ID

      DSC|| <CR>

<EB><CR>
```

When receiving the DSR message, the analyzer replies as follows:

```
<SB>MSH|^~\&| Company|Product |||20070301193242||ACK^Q03|1|P|2.3.1||||||ASCII||| <CR>

    MSA|AA|1|Message accepted|||0| <CR>
    ERR|0| <CR>

<EB><CR>
```

⚠ **NOTE**

The <CR> in the sample above is only for reading convenience and is not included in the real message.

---

2 *ASTM Interface*

2.1 ASTM Interface

ASTM interface is developed by our company for the Chemistry Analyzer to adapt to the prevailing Laboratory Information Management System (LIS). It provides a channel for the analyzer and other IP-based networks. With TCP/IP, the LIS host can receive test results from chemistry analyzers, which also send patient information, sample information and test results to LIS in real-time or batch mode. Therefore, users can identify samples by both scanning sample bar code and downloading from LIS host. All data are transmitted in format of ASTM E1394-97. This interface enables bidirectional communication between the analyzer and the LIS host.

2.1.1 ASTM Protocol

ASTM is standard for transferring information between the instrument and the PC in clinical laboratory. It is set by American Society for Testing and Material (communication protocol). The standard has multiple versions. The version mentioned in the text is E1394-97, the version mentioned in the following text is ASTM E1394-97, which is set in 1997.

Only portion of the messages, segments and other data defined are used for ASTM interface that needs only part of these data.

2.1.2 The Sending and Receiving Procedure of the Protocol

ASTM protocol is a uni-directional mode which means the data transmission should be at only one direction at a specific time. When the instrument is sending data, the PC can only receive data; when the PC is receiving data, the instrument can only wait for response.

In ASTM protocol, when the sender is to send data, first it sends <ENQ> control character to the target receiver; if the receiver has resources, it will respond with

<ACK>; otherwise, it will respond with <NAK>. If the sender receives the <ACK>, the data frame will be sent. When the sending is completed, the <EOT>will be sent to the receiver which ends the whole process. The workflow is shown below:
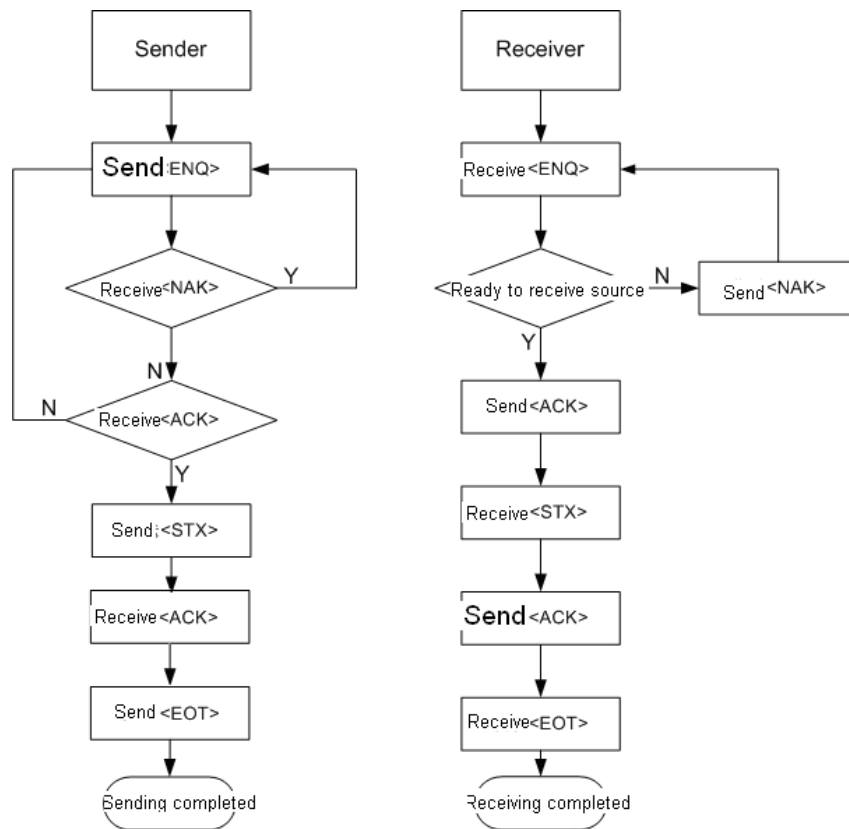
<ENQ>, <ACK>, <EOT>, <NAK> and <STX> are standard ASCII code control characters.

Control Character	ASCII Code Hexadecimal
<ENQ>	0x05
<ACK>	0x06
<EOT>	0x04
<NAK>	0x15
<STX>	0x02
<LF>	0x0A
<CR>	0x0D
<ETB>	0x17
<ETX>	0x03

2.1.3 ASTM Protocol Communication Mode

In ASTM protocol, three statuses are defined: main mode, subordinate mode and neutral mode. The main mode is data sending side. The subordinate mode is the data receiving side, receiving the data and responding with control command. The neutral mode is a waiting mode, which means no data receiving and sending occurs. When either of the instrument or the LIS is in main mode, the other should be in subordinate mode. The two can be in neutral mode simultaneously, but either side should be in one mode at a specific time.

When both of the instrument and the LIS system have no data to be sent, both sides will be in neutral mode. If one side has data to be sent (eg, instrument needs to inquire sample information from LIS system), the instrument first sends <ENQ> control character to LIS system. When the sending is completed, the instrument will not process any command or data, except for <ACK>, <NAK> and <ENQ>. When the LIS system receives <ENQ>, it will respond with <ACK> control character. If the response is completed, the LIS system will be in subordinate mode, ready to receive data. At this time the instrument will be in main mode, asking for data sending. When the sending is completed, the instrument will send control character to the LIS system, announcing the completion of the LIS system data. The instrument will be in neutral mode. After the LIS receives <EOT>, it will be in neutral mode.

The Communication Procedure of Sending Test Result

The following figure is a workflow to send test result.

.
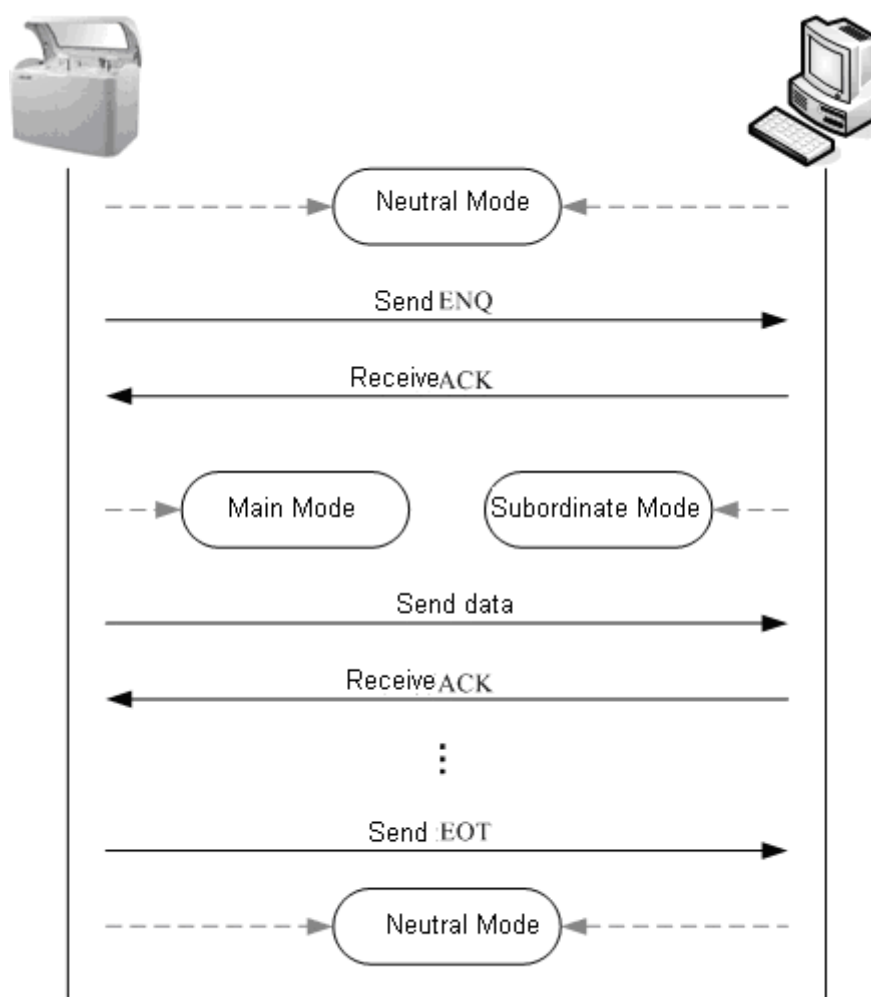
When both of the instrument and LIS system are in bidirectional communication status, both sides can be sender and receiver, so both sides might have data to send to each other at the same time, thus both sides will send <ENQ> to each other simultaneously to enter main mode. But ASTM protocol is a unidirectional protocol, the sending and receiving are simultaneously. If both sides are sending, conflict might occur. The ASTM protocol has two rules to avoid the conflict.

When the instrument receives control command character <ENQ> after sending it, it will send <NAK>,   waiting for the ACK from LIS.

When the LIS system receives <ENQ> control command character after sending it, it should stop any data send trial and be ready to receive data. When it receives the next <ENQ> control command character, it will return <ACK> and <NAK> to confirm.

The Procedure to Avoid Sending and Requesting Conflict

According to the rule, when conflict occurs, the instrument will be in main mode first. Only when the data sending on the instrument side is completed and enters neutral mode, can the LIS system enter main mode.

The following figure illustrate how to deal with conflict.
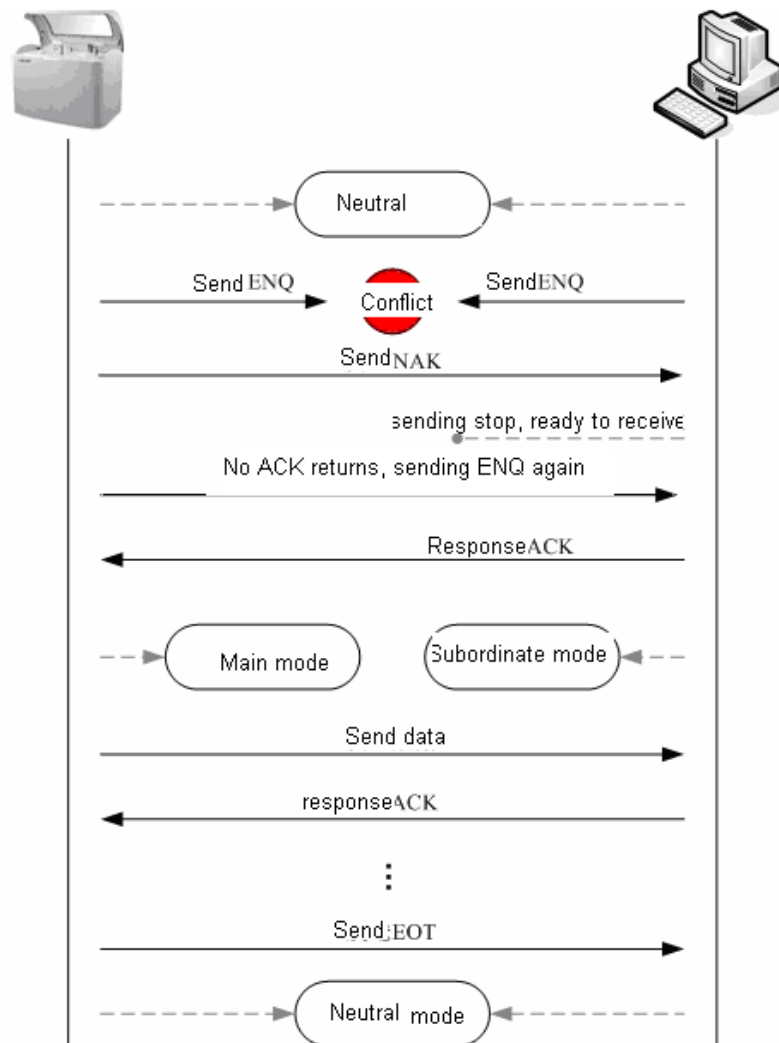
The Communication Procedure to Inquire and Download Sample

The procedure to inquire sample is as follows:
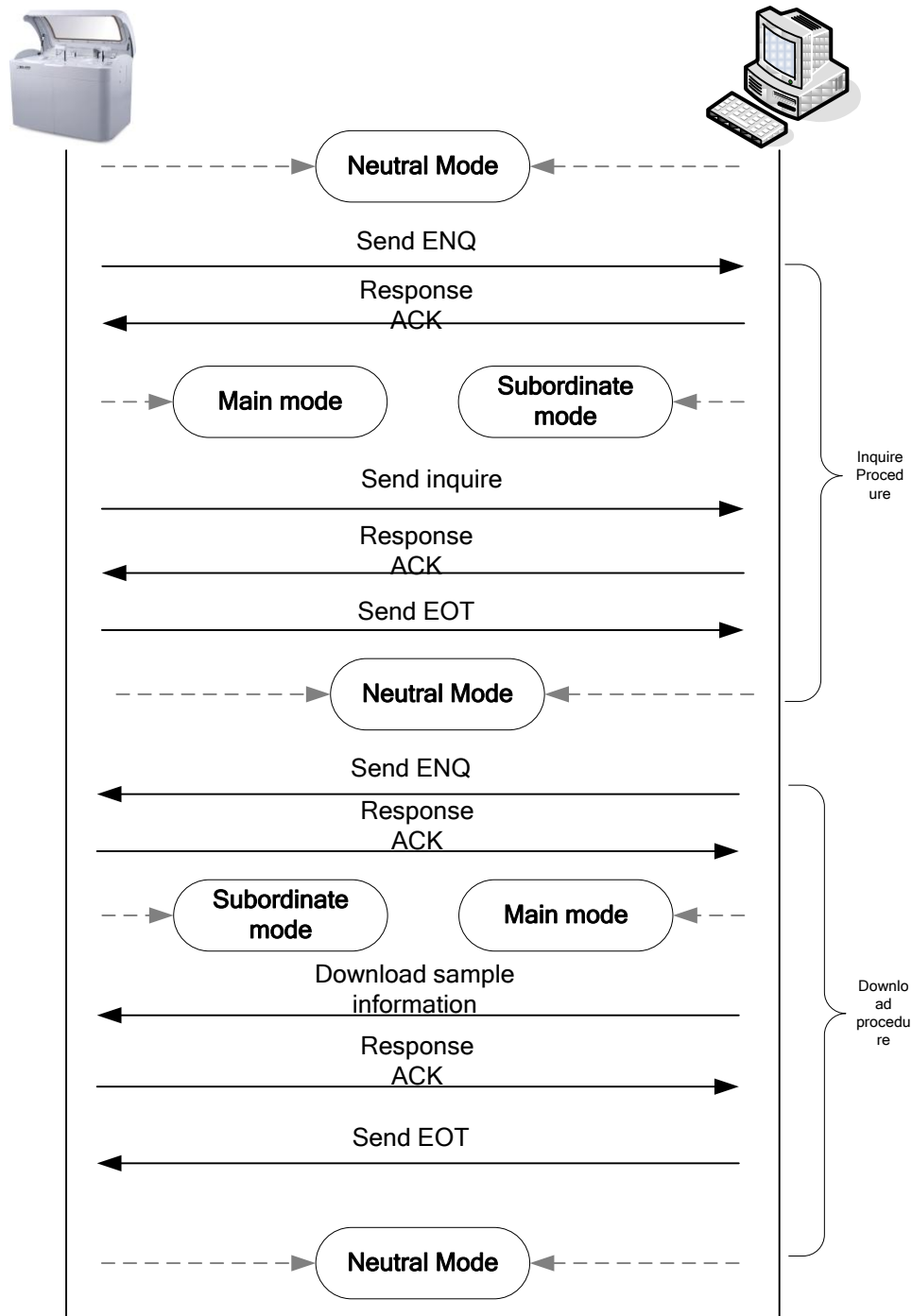
The workflow above is composed of two workflows: inquire procedure and download procedure. When the LIS system download sample information, only the downloading procedure is necessary.

2.2 ASTM Communication

It includes the transfer of the test result and the acquisition of the sample request information. The transfer of the test result is to transfer test data to external system (such as LIS). The transferring modes include real time transfer and batch transfer of the historical result. The acquisition of the sample request information is to acquire sample request information from LIS.

The acquisition includes real time acquisition and batch acquisition.

2.2.1 The Introduction to ASTM Protocol

The following sections introduce the common grammars in detail.

The ASTM protocol defines 7 message records:

Message Header Record

Patient Information Record

Test Order Record

Result Record

Comment Record

Request Information Record

Message Terminator Record

The sent data will include part or all of the 7 message record mentioned above.

For instance,

The ASTM protocol data frame of a complete sample test result is shown as follows:

Message Header Record

Patient Information Record

Test Order Record

Result Record

Comment Record (optional)

Result Record

Comment Record (optional)

Patient Information Record

Test Order Record

Result Record

Comment Record (optional)

…

Message Terminator Record

Each ASTM message is composed of segments that end with <CR>.

The record is composed of the record name of 1 character and some fields. The fields is composed of the components. H record defines the separator of the units.

For instance,

H|\^&|||Product
Model^01.03.07.03^123456|||||||PR|1394-97|20090910102501<CR>

Where,

The four characters following H are defined as delimiters to separate the fields, replicate degree and component. The following characters are used in the ASTM interface.

Character	Description
|	Field separator
\	Repetition separator
^	Component separator
&	Escape character

When the field content include the characters above, transferred meaning characters is needed. In the ASTM standard, " |" is transferred to " &|".

2.2.2　ASTM Data Frame Format

ASTM Data Record Format

The data sending of all ASTM data is as follows:

<STX> FN <FRAME> <CR> <ETB> or <ETX> <CS><CR><LF>

Where,

<STX>: Start frame header (0x02)

FN　　: Frame Number (0-7)

<FRAME> : Frame Data (The field separator is |)

<CR> : 　Frame data end character 　(0x0D)

<ETB> : Frame end character-when the requested data is too big, it is separated by frame end character (0x17)

<ETX>   : Frame end character (0x03)

<CS> : check sum-Cumulative sum of ASCII code from FN to <ETB> or <ETX> (the <STX> <CS> and the end of <CR><LF> are not involve in the calculation).

<CR> : ASCII enter (0x0D).

<LF> : ASCII new line (0x0A).

There are two types of ASTM protocol message frames: medium frame and end frame. The medium from is not a must, only used to separate the frame when the message is too big. The end frame is indispensable.

Medium frame format: **<STX>** FN <FRAME> **<ETB>** <CS> **<CR><LF>**

End frame format: **<STX>** FN <FRAME> **<ETX>**<CS> **<CR><LF>**

ASTM Message Record Code

Record type	Record description
H	Header Record
P	Patient Record
O	Order Record
R	Result Record
C	Comment Record
Q	Request Information Record (Host query)
L	Terminator Record

2.2.3 The Introduction of the ASTM Record Type

The following introduces the 7 records of ASTM.

The table lists all the fields used in the message record. The numbers followed by a '#' symbol indicate the optional fields according to the ASTM protocol.

> ⚠ **NOTE**
>
> In the ASTM interface, we not omit any field in the message record. If the field has no value, it is set to void.

Header Record- "H"

H is the header of all messages. The separator should be in the second field of the H message.

ASTM Field	Field Name	Field Contents	Max Length	Field Description
1#	Record Type ID	H	1	Record type ID
2#	Delimiter Definition	| \ ^ &	4	Field separator Repetition separator Element separator Code change separator
3	Message Control ID		-	Void and reserved.
4	Password		-	Void and reserved.
5	Sender Name or ID	String	40	Instrument name
	Software Version	String and number	20	Software Ver.:
	Sequence number	String and number	20	Instrument sequence number
6	Sender Street Address		-	Void and reserved.
7	Reserved field		-	Void and reserved.
8	Sender Telephone Number		-	Void and reserved.
9	Characteristics of sender		-	Void and reserved.
10	Receiver ID		-	Void and reserved.
11	Comment or Special Instructions		-	Void and reserved.

ASTM Field	Field Name	Field Contents	Max Length	Field Description
12#	Processing ID	PR (patient test result) QR (QC test result) CR (calibration result) RQ (request query) QA (query response) SA (sample request information)	2	Message type

Example:

Sending message header and ending record (Instrument => Host）

H|\^&|||Product
Model^01.03.07.03^123456|||||||PR|1394-97|20090910102501<CR>

L|1|N<CR>

Patient Record – "P"

The patient information is indispensable when acquiring or downloading sample information or sending sample test result.

ASTM Field	Field Name	Field Contents	Max Length	Field Description
1#	Record Type ID	P	1	Record type ID
2	Sequence Number		3	Sequence number
3	Practice Assigned Patient ID		-	Void and reserved.
4	Patient ID	String and number	25	Patient ID
5	Patient ID #3		-	Void and reserved.
6#	Patient Name			Name of patient Last^First^Middle Initial
	Last Name	String	20	First name
	First Name	String	20	Family name
	Middle Initial	String	1	

ASTM Field	Field Name	Field Contents	Max Length	Field Description
7	Reserved field		-	Void and reserved.
8	Birth date	String	8	Birth date 10012009
	Age	Number	6	Age
	Age Unit	Y = year M = Month W = week D = Days H = hours If empty =Year	1	Age
9	Patient Sex	M(Male) F(Female) U(unknown)	1	Patient gender
10	Patient Race	String	20	Void and reserved. Ethnic group the patient belongs to
11	Patient Address	String	50	Sending department
12	Reserved Field	A B O AB Others are defined by the customers themselves	20	Void and reserved. Blood type
13	Patient Telephone	String	13	Void and reserved. Contact information
14	Attending Physician Name			Void and reserved. Attending doctor
	Last Name	String	20	First name
	First Name	String	20	Family name
	Middle Initial	String	1	
15	Special field 1	icterus Hemolysis lipemia	30	Void and reserved. Sample type. When icterus is used, pay attention to that it is

ASTM Field	Field Name	Field Contents	Max Length	Field Description
				case sensitive.
16	Body Surface Area (M2)	String	20	Void and reserved. MRN
17	Patient Height		-	Void and reserved.
	Patient Height Unit		-	Void and reserved.
18	Patient Weight		-	Void and reserved.
	Patient Weight Unit		8	Void and reserved.
19	Patient Diagnosis	String	50	Clinical diagnosis
20	Patient Medications	String	20	Void and reserved. patient type
21	Patient Diet	String	20	Void and reserved. blood bag number
22	Practice Field #1		-	Void and reserved.
23	Practice Field #2		-	Void and reserved.
24	Admission and discharge dates		-	Void and reserved.
25	Admission Status		-	Void and reserved.
26	Location	String	10	Void and reserved. patient zone
27	Nature of alt. Diag. Code and Class.	String	10	Void and reserved. bed
28	Alt. Diag. Code and Class		-	Void and reserved.
29	Patient Religion		-	Void and reserved.
30	Marital Status		-	Void and reserved.
31	Isolation Status		-	Void and reserved.
32	Language		-	Void and reserved.
33	Hospital Service		-	Void and reserved.
34	Hospital Institution		-	Void and reserved.
35	Dosage Category		-	Void and reserved.

The user can enter the last name for the P-6 patient name.

Example:

Send patient message record (Host => Instrument)

H|\^&||| Product Model
^01.03.07.03^123456|||||||SA|1394-97|20090910102501<CR>

P|1||PATIENT111||Smith^Tom^J||19600315|M|||A||Dr.Bean|icteru|100012546|||
Diagnosis information||0001|||||A1|002||||||||<CR>

L|1|N<CR>

Test Order Record – "O"

ASTM Field	Field Name	Field Contents	Max Length	Field Description
1#	Record Type ID	O	1	Record type ID
2	Sequence Number	Number	3	Sequence number
3	Sample ID	String and number	20	Sample ID
	Sample Tray No.	Number	2	Sample disk No.
	Sample Pos	Number	2	Sample cup position
4	Instrument Specimen ID	String	29	Sample bar code
5	Assay No.	String	12	Test No.
	Assay Name	String	20	Test
	Dilution Rate	Number	4	Void and reserved. Dilution Ratio (Edit box on right side)
	Repeat Num	Number	2	Void and reserved. Replicate
6	Priority	R(routine)S (STAT test)	1	STAT
7	Requested Date and Time (Sample program creation date)	String	14	Sample request time 20090910121532
8	Specimen Collection Date and Time	String	14	Sample collection time 20090910121532
9	Collection end Time			Void and reserved.

ASTM Field	Field Name	Field Contents	Max Length	Field Description
10	Collection Volume	0-99999.0 Max = 99999.0	7	Void and reserved. Collection volume
11	Collected by (ID or Name)	String	18	Void and reserved. Collector
12	Action Code	String	-	Void and reserved.
13	Danger Code	String	-	Void and reserved.
14	Relevant Clinical Information	String	-	Void and reserved.
15	Date/Time Specimen Received in the Lab.	String	14	Send D/T 20090910121532
16	Specimen type (This field is not translated to local languages)	serum urine CSF plasma timed other blood amniotic urethral saliva cervical synovial	10	Sample type, case sensitive. The default sample type is set to the defined value at the left side which varies among different products. The customer can modify to their needs.
17	Ordering Physician			sender
	Last Name	String	20	First name
	First Name	String	20	Family name
	Middle Initial	String	1	
18	Physician Phone number	String	30	Sending department
19	Offline Dilution factor	number	4	Void and reserved. Dilution factor
20	User Field #2			sender
	Last Name	String	20	first name
	First Name	String	20	family name

ASTM Field	Field Name	Field Contents	Max Length	Field Description
	Middle Initial	String	1	
21	Laboratory field #1		-	Void and reserved.
22	Laboratory field #2		-	Void and reserved.
23	Date/Time Results Reported/Mod		-	Void and reserved.
24	Instrument Charge to computer system		-	Void and reserved.
25	Instrument Section ID		-	Void and reserved.
26#	Report Type	O (request from) Q (query response) F (final result)	1	Report type
27	Reserved Field		-	Void and reserved.
28	Location Specimen Collected		-	Void and reserved.
29	Nosocomial Infection flag		-	Void and reserved.
30	Specimen Service		-	Void and reserved.
31	Specimen Institution		-	Void and reserved.

The test code of the 5th field can be recognized by both sides. When the instrument sends test result to the LIS system. The ReportType of the 26th field is set to F. When the LIS system sends inquiry to the instrument, the ReportType of the 26th is set to Q. the ReportType of the 26th field is set to O, when LIS send sample information to the instrument.

Example:

Send sample request information (Host => Instrument)

H|\^&||| Product Model ^01.03.07.03^123456|||||||**SA**|1394-97|20090910102501<CR>

P|1||PATIENT111||Smith^Tom^J||19600315|M|||A|||icteru||||||01|||||A1|002|||||||||<CR>

O|1|1^1^1|SAMPLE123|1^Test1^2^1\2^Test2^2^1\3^Test3^2^1\4^Test4^2^1|R|20090910135300|20090910125300|||John||||||Urine|Dr.Who|Department1|1|Dr.Tom||||||O|||||<CR>

L|1|N<CR>

When QC result is to be transferred, the following fields are used.

ASTM Field	Field Name	Field Contents	Max Length	Field Description
1#	Record Type ID	O	1	Record type ID
2	Sequence Number	Number	3	Sequence number
3	Sample ID	String and number	20	Void and reserved.
	Sample Tray No.	Number	2	Void and reserved.
	Sample Pos	Number	2	Void and reserved.
4	Instrument Specimen ID	String	29	Void and reserved.
5	Assay No.	String	12	Code
	Assay Name	String	20	Test
	Dilution Rate	Number	4	Void and reserved.
	Repeat Num	Number	2	Void and reserved.
6	Priority	R(routine)S (STAT test)	1	Void and reserved.
7	Requested Date and Time (Sample program creation date)	String	14	QC time 20090910121532
8	Specimen Collection Date and Time	String	14	Void and reserved.
9	Collection end Time			Void and reserved.
10	Collection Volume	0-99999.0 Max = 99999.0	7	Void and reserved.
11	Collected by (ID or Name)	String	18	Void and reserved.
12	No.	String	10	Control No.
	Name	String	10	Control name
	Batch No.	String	20	Lot No. of control
	period of validity	String	8	Expiration date of control
	Average Concentration	Number	9	Control average
	Level	H for high; M for medium, L for low.	1	Concentration level of control.

ASTM Field	Field Name	Field Contents	Max Length	Field Description
	Standard Diff.	Number	9	Standard deviation of control
	Concentration	Number	9	Test result (concentration)
13	Danger Code	String	-	Void and reserved.
14	Relevant Clinical Information	String	-	Void and reserved.
15	Date/Time Specimen Received in the Lab.	String	14	Void and reserved.
16	Specimen type (This field is not translated to local languages)	Serum Urine CSF Plasma Timed Other Blood Amniotic Urethral Saliva Cervical Synovial	10	Void and reserved.
17	Ordering Physician			Void and reserved.
	Last Name	String	20	Void and reserved.
	First Name	String	20	Void and reserved.
	Middle Initial	String	1	Void and reserved.
18	Physician Phone number	String	30	Void and reserved.
19	Offline Dilution factor	Number	4	Void and reserved.
20	User Field #2			Void and reserved.
	Last Name	String	20	Void and reserved.
	First Name	String	20	Void and reserved.
	Middle Initial	String	1	Void and reserved.
21	Laboratory field #1		-	Void and reserved.

ASTM Field	Field Name	Field Contents	Max Length	Field Description
22	Laboratory field #2		-	Void and reserved.
23	Date/Time Results Reported/Mod		-	Void and reserved.
24	Instrument Charge to computer system		-	Void and reserved.
25	Instrument Section ID		-	Void and reserved.
26	Report Type	O (request from) Q (query response) F (final result) X (sample rejected)	1	Report type
27	Reserved Field		-	Void and reserved.
28	Location Specimen Collected		-	Void and reserved.
29	Nosocomial Infection flag		-	Void and reserved.
30	Specimen Service		-	Void and reserved.
31	Specimen Institution		-	Void and reserved.

Example:

Send QC record (Instrument   =>   Host)

H|\^&||| Product   Model ^01.03.07.03^123456|||||||**QR**|1394-97|20090910102501<CR>

P|1||||||||||||||||||||||||||||||||||||<CR>

O|1|||||20090910121532|||||1^QC1^1111^20100910^10^L^5^10.28\2^QC2^2222^20100910^20^M^10^20.48\3^QC3^3333^20100910^30^H^15^30.25|||||||||||||||F|||||<CR>

L|1|N<CR>

ASTM Field	Field Name	Field Contents	Max Length	Field Description
1#	Record Type ID	O	1	Record type ID
2	Sequence Number	Number	3	Sequence number
3	Sample ID	Number	20	Void and reserved.
	Sample Tray No.	R(routine)S (STAT	2	Void and reserved.

ASTM Field	Field Name	Field Contents	Max Length	Field Description
		test)		
	Sample Pos	String	2	Void and reserved.
4	Instrument Specimen ID	String	29	Void and reserved.
5	Assay No.		12	Code
	Assay Name	0-99999.0 Max = 99999.0	20	Test
	Dilution Rate	String	4	Void and reserved.
	Repeat Num	String	2	Void and reserved.
6	Priority	String	1	Void and reserved.
7	Requested Date and Time (Sample program creation date)	String	14	Calibration time 20090910121532
8	Specimen Collection Date and Time	String	14	Void and reserved.
9	Collection end Time	String		Void and reserved.
10	Collection Volume	Number	7	Void and reserved.
11	Collected by (ID or Name)	H for high; M for medium, L for low.	18	Void and reserved.
12	Action Code	Number	-	Void and reserved.
13	No.	Number	10	Calibrator No.
	Name	Number	10	Name of calibrator
	Batch No.	R(routine)S (STAT test)	20	Lot No. of calibrator
	Period of validity	String	8	Expiration date of calibrator 20090910
	Concentration	String	9	Standard concentration of calibrator
	Level		1	Concentration level of calibrator.
	Response	0-99999.0 Max = 99999.0	9	Calibration response
14	Calibrate Rule	0-single point	1	Used as calibration

ASTM Field	Field Name	Field Contents	Max Length	Field Description
		linear, 1- two point linear, 2-Multiple point linear, 3-Logistic-Log4P, 4-Logistic-Log5P, 5-Exponential 5P, 6-Polynomial 5P, 7-Parabola, 8-Spline.		rule.
	K	number	9	K parameter
	R0	number	9	R0 parameter
	a	number	9	a parameter
	b	number	9	b parameter
	c	number	9	c parameter
	d	number	9	d parameter
15	Date/Time Specimen Received in the Lab.	String	14	Void and reserved.
16	Specimen type (This field is not translated to local languages)	Serum Urine CSF Plasma Timed Other Blood Amniotic Urethral Saliva Cervical Synovial	10	Void and reserved.
17	Ordering Physician			Void and reserved.
	Last Name	String	20	Void and reserved.
	First Name	String	20	Void and reserved.
	Middle Initial	String	1	Void and reserved.
18	Physician Phone	String	30	Void and reserved.

ASTM Field	Field Name	Field Contents	Max Length	Field Description
	number			
19	Offline Dilution factor	number	4	Void and reserved.
20	User Field #2			Void and reserved.
	Last Name	String	20	Void and reserved.
	First Name	String	20	Void and reserved.
	Middle Initial	String	1	Void and reserved.
21	Laboratory field #1		-	Void and reserved.
22	Laboratory field #2		-	Void and reserved.
23	Date/Time Results Reported/Mod		-	Void and reserved.
24	Instrument Charge to computer system		-	Void and reserved.
25	Instrument Section ID		-	Void and reserved.
26	Report Type	O (request from) Q (query response) F (final result) X (sample rejected)	1	Report type
27	Reserved Field		-	Void and reserved.
28	Location Specimen Collected		-	Void and reserved.
29	Nosocomial Infection flag		-	Void and reserved.
30	Specimen Service		-	Void and reserved.
31	Specimen Institution		-	Void and reserved.

Different calibration rules have various parameters:

Linear (one-point, two-point and multi-point): K and R0;

Logit-Log4P: K, R0, a and b;

Logit-Log5P: K, R0, a, b and c;

Polynomial 5P: K, R0, a, b, c and d;

Parabola: R0, a and b;

Spline: R0i, ai, bi, ci. There are multiple groups of parameters for Spline.

8^^12.5^0.58^0.9871^2.447^\^187.5^150.58^220.9871^72.447^\^82.5^98.58^4.98
71^9.447^\^2.5^9.58^7.9871^9.447^

Example:

Send calibration record (Instrument => Host)

H|\^&||| Product Model
^01.03.07.03^123456|||||||**CR**|1394-97|20090910102501<CR>

P|1|||||||||||||||||||||||||||||||||||<CR>

O|1|||||20090910121532||||||1^Cal1^1111^20100910^10^L^11\2^Cal2^2222^20100
910^20^M^22\3^Cal3^3333^20100910^30^H^33|5^^1.25^25.1^36.48^10.78^98.41
|||||||||||||F|||||<CR>

L|1|N<CR>

Result Record- "R"

The result record includes one test and one test result, which means one test result is corresponding to one result record.

ASTM Field	Field Name	Field Contents	Max Length	Field Description
1#	Record Identifier	R	1	Record type ID
2	Sequence Number	1-n	3	Sequence number
3#	Assay No.#	String	12	Test No.
	Assay Name	String	20	Test
	Replicate number	Number	2	Void and reserved. Result replicate
	Result Type	I: Qualitative result value F: Qualitative result value	1	Result type
4	Measurement Value	Number (quantitative)	14	Quantitative final test result. Valid only when test type is F
	Interpretation	String (Negative(-), Positive(+), Weak positive(+-)etc)	15	Qualitative final test result. Valid only when test type is I

ASTM Field	Field Name	Field Contents	Max Length	Field Description
	SI L Value	turbidity （L）	14	Void and reserved. Serum index final result L
	SI H Value	hemolysis （H）	14	Void and reserved. Serum index final result H
	SI I Value	icterus （I）	14	Void and reserved. Serum index final result I
5	Units	String	12	Unit
6	Measurement Range Upper Limit	Number	12	Reference range high
	Measurement Range Lower Limit	Number	12	Reference range low
7	Result Abnormal flag	L (result< reference range) H (result> reference range) N - Normal	1	Abnormal result flag
8	Nature of Abnormality Testing	String	15	Qualitative reference value. Valid when the result type is I.
9#	Result Status	F(final result)	1	Status of result
10	Measurement Value	Number (quantitative)	14	Quantitative original test result, valid only when result type is F)
	Interpretation	String (Negative-, Positive+, weak Positive +-, etc)	15	Qualitative original test result, valid only when result type is I)
	SI L Value	turbidity （L）	14	Void and reserved. Original result of serum index L
	SI H Value	hemolysis （H）	14	Void and

ASTM Field	Field Name	Field Contents	Max Length	Field Description
				reserved.
				Original result of serum index H
	SI I Value	icterus (I)	14	Void and reserved. Original result of serum index I
11	Operator Identification		-	Void and reserved.
12	Date/time test started	String	14	Test start time
13	Date/Time test Completed	String	14	Void and reserved. Test end time
14	Instrument Identification (Sender Name)	String Such as LIS or Product Model	16	sender
	Device ID	number	10	Void and reserved. Instrument ID

Example:

Send sample test result (Instrument => Host）

H|\^&||| Product Model ^01.03.07.03^123456|||||||**PR**|1394-97|20090910102501<CR>

P|1||PATIENT111||Smith^Tom^J||19600315|M|||A|||icteru||||||01|||||A1|002|||||||||<CR>

O|1|1^1^1|SAMPLE123|1^Test1^2^1\2^Test2^2^1\3^Test3^2^1\4^Test4^2^1|R|20090910135300|20090910125300|||John|||||Urine|Dr.Who|Department1|1|Dr.Tom|||||F|||||<CR>

R|1|1^Test1^1^F|14.5^|Mg/ml||5.6^99.9|N||F|||20090910134300|20090910135300| Product Model^123<CR>

R|2|2^Test2^1^F|3.5^|Mg/ml||5.6^50.9|L||F|||20090910134300|20020316135301| Product Model^123<CR>

R|3|3^Test3^1^F|24.5^|Mg/ml||1.1^20.9|H||F|||20090910134300|20020316135302|

Product Model ^123<CR>

R|4|4^Test4^1^I|^Negative|Mg/ml|||||Positive|F|||20090910134300|20020316135303| Product Model ^123<CR>

L|1|N<CR>

Comment Record – "C"

Only the result comment of Comment Record is used currently to describe the test result.

ASTM Field	Field Name	Field Contents	Max Length	Field Description
1#	Record Identifier	C	1	Record type ID
2	Sequence Number	1-n	3	Sequence number
3	Comment Source	I	1	Comment source, fixed value
4	Comment Text	String	90	Comment text
5	Comment Type	G(result comment) I (abnormal string)	1	Comment type

Example:

Send comment record (Instrument => Host）

H|\^&||| Product Model ^01.03.07.03^123456|||||||**PR**|1394-97|20090910102501<CR>

P|1||PATIENT111||Smith^Tom^J||19600315|M|||A|||icteru||||||01|||||A1|002||||||||<CR>

O|1|1^1^1|SAMPLE123|1^Test1^2^1|R|20090910135300|20090910125300|||John|||||Urine|Dr.Who|Department1|1|Dr.Tom||||||F|||||<CR>

R|1|1^Test1^1^F|14.5^|Mg/ml||5.6^99.9|N||F|||20090910134300|20090910135300|Product Model ^123<CR>

C|1|I||Result Description|I<CR>

L|1|N<CR>

Request Record- "Q"

Request Record is used to send inquiring sample request info5rmation to LIS server. The message includes patient ID, sample ID, time range and etc. If the LIS server does not return information in specified time, the instrument can cancel inquiry.

ASTM Field	Field Name	Field Contents	Max Length	Field Description
1#	Record Identifier	Q	1	Record type ID

ASTM Field	Field Name	Field Contents	Max Length	Field Description
2	Sequence Number	1-n	3	Sequence number
3	Patient ID	String	20	Patient ID
	Specimen ID	String	29	Sample ID (bar code)
4	Ending Range ID		-	Void and reserved.
5	Universal Test Id		-	Void and reserved.
6	Nature of Request Time Limits		-	Void and reserved.
7	Beginning Request results date/time.	String	14	Inquire start time
8	Ending Request results date/time	String	14	Inquire end time
9	Requesting Physician name		-	Void and reserved.
10	Requesting Physician Telephone		-	Void and reserved.
11	User field # 1		-	Void and reserved.
12	User field # 2		-	Void and reserved.
13#	Request Information status Codes	O : Request sample inquire A : Cancel current inquire	1	Inquire order code

Example:

Send and cancel request record (Instrument => Host)

H|\^&||| Product   Model
^01.03.07.03^123456|||||||RQ|1394-97|20090910102501<CR>

Q|1|^SAMPLE123|||||||||||O<CR>

L|1|N<CR>

Send and cancel inquired record (Instrument => Host)

H|\^&||| Product Model ^01.03.07.03^123456|||||||RQ|1394-97|20090910102501<CR>

Q|1|^SAMPLE123|||||||||||A<CR>

L|1|N<CR>

Send termination record, the unfound sample information will be indicated by I .

 (Host => Instrument)

H|\^&||| Product Model ^01.03.07.03^123456|||||||QA|1394-97|20090910102501<CR>

L|1|I<CR>

Return inquired sample information record (Host => Instrument) H|\^&||| Product Model ^01.03.07.03^123456|||||||SA|1394-97|20090910102501<CR>

P|1||PATIENT111||Smith^Tom^J||19600315|M|||A|||icteru||||||01|||||A1|002||||||||<CR>

O|1|SAMPLE123^1^1||1^Test1^2^1\2^Test2^2^1\3^Test3^2^1\4^Test4^2^1|R|20090910135300|20090910125300|||John|||||Urine|Dr.Who|Department1|1|Dr.Tom||||||Q|||||<CR>

L|1|N<CR>

Terminator Record- "L"

The Terminator record will be at the end of the message indicating the termination of the message.

ASTM Field	Field Name	Field Contents	Max Length	Field Description
1#	Record Identifier	C	1	Record type ID
2	Sequence Number	1-n	3	Sequence number
3#	Terminator code	**N**=normal termination **I**=No information available from the last query. **Q**=Error for in last request for information	1	Termination code

Example:

Send termination record (Instrument   =>   Host)

H|\^&||| Product Model ^01.03.07.03^123456|||||||PR|1394-97|20090910102501<CR>

L|1|N<CR>

2.3 Communication Process and Message Example

ASTM protocol supports serial port sending, so the information in one message should not be too big, otherwise the message will be sent separately. So the following will illustrate on respectively. The check digit <CS> will be replaced by check sum.

2.3.1 Send Sample Test Result

It will be sent as a whole: all data will be sent in one data package.

INSTRUMENT:	<ENQ>
HOST:	<ACK>
INSTRUMENT:	<STX>1H|\^&||| Product Model ^01.03.07.03^123456|||||||PR|1394-97|20090910102501<CR> P|1||PATIENT111||Smith^Tom^J||19600315|M|||A|||icteru||||||01|||||A1|002|||||||||<CR> O|1|1^1^1|SAMPLE123|1^Test1^2^1\2^Test2^2^1\3^Test3^2^

<table>

	1\4^Test4^2^1|R|20090910135300|20090910125300|||John|||||Urine|Dr.Who|Department1|1|Dr.Tom||||||F|||||<CR>
	R|1|1^Test1^1^F|14.5^|Mg/ml||5.6^99.9|N||F|||20090910134300|20090910135300| Product Model ^123<CR>
	R|2|2^Test2^1^F|3.5^|Mg/ml||5.6^50.9|L||F|||20090910134300|20020316135301| Product Model ^123<CR>
	R|3|3^Test3^1^F|24.5^|Mg/ml||1.1^20.9|H||F|||20090910134300|20020316135302| Product Model ^123<CR>
	R|4|4^Test4^1^I|^Negative|Mg/ml||||Positive|F|||20090910134300|20020316135303| Product Model ^123<CR>
	L|1|N<CR><ETX><CS><CR><LF>
HOST:	<ACK>
INSTRUMENT:	<EOT>

</table>

It will be sent separately, split on the basis of the record.

<table>

INSTRUMENT:	<ENQ>
HOST:	<ACK>
INSTRUMENT:	<STX>1**H**|\^&||| Product Model ^01.03.07.03^123456|||||||PR|1394-97|20090910102501<CR><ETX><CS><CR><LF>
HOST:	<ACK>
INSTRUMENT:	<STX>2**P**|1||PATIENT111||Smith^Tom^J||19600315|M|||A|||icteru||||||01|||||A1|002|||||||||<CR><ETX><CS><CR><LF>
HOST:	<ACK>
INSTRUMENT:	<STX>3**O**|1|1^1^1|SAMPLE123|1^Test1^2^1\2^Test2^2^1\3^Test3^2^1\4^Test4^2^1|R|20090910135300|20090910125300|||John|||||Urine|Dr.Who|Department1|1|Dr.Tom||||||F|||||<CR><ETX><CS><CR><LF>
HOST:	<ACK>
INSTRUMENT:	<STX>4**R**|1|1^Test1^1^F|14.5^|Mg/ml||5.6^99.9|N||F|||20090910134300|20090910135300| Product Model ^123<CR><ETX><CS><CR><LF>
HOST:	<ACK>
INSTRUMENT:	<STX>5**R**|2|2^Test2^1^F|3.5^|Mg/ml||5.6^50.9|L||F|||20090910134300|20020316135301| Product Model ^123<CR><ETX><CS><CR><LF>
HOST:	<ACK>
INSTRUM	<STX>6**R**|3|3^Test3^1^F|24.5^|Mg/ml||1.1^20.9|H||F|||200909

</table>

ENT:	10134300|20020316135302| Product Model ^123<CR><ETX><CS><CR><LF>
HOST:	<ACK>
INSTRUM ENT:	<STX>7**R**|4|4^Test4^1^I|^Negative|Mg/ml||||Positive|F|||20090 910134300|20020316135303| Product Model ^123<CR><ETX><CS><CR><LF>
HOST:	<ACK>
INSTRUM ENT:	<STX>0**L**|1|N<CR><ETX><CS><CR><LF>
HOST:	<ACK>
INSTRUM ENT:	<EOT>

2.3.2 Sending Sample Inquiry

It will be sent as a whole

INSTRUM ENT:	<ENQ>
HOST:	<ACK>
INSTRUM ENT:	<STX>1H|\^&||| Product Model ^01.03.07.03^123456|||||||RQ|1394-97|20090910102501<CR> Q|1|^SAMPLE123||||||||||O<CR> L|1|N<CR><ETX><CS><CR><LF>
HOST:	<ACK>
INSTRUM ENT:	<EOT>

It will be sent separately.

INSTRUM ENT:	<ENQ>
HOST:	<ACK>
INSTRUM ENT:	<STX>1**H**|\^&||| Product Model ^01.03.07.03^123456|||||||RQ|1394-97|20090910102501<CR> <ETX><CS><CR><LF>
HOST:	<ACK>
INSTRUM ENT:	<STX>2**Q**|1|^SAMPLE123||||||||||O<CR><ETX><CS><CR><LF>

HOST:	<ACK>
INSTRUMENT:	<STX>3**L**|1|N<CR><ETX><CS><CR><LF>
HOST:	<ACK>
INSTRUMENT:	<EOT>

2.3.3 Return inquired sample and downloaded sample

When the server transfers the sample in multiple samples, the number of P records in one transfer can not exceed 10. The format of the multiple samples is as follows:

Message Header Record

Patient Information Record

Test Order Record

Patient Information Record

Test Order Record

…

Message Terminator Record

The following is an example of the sample transmission.

It will be sent as a whole.

HOST:	<ENQ>
INSTRUMENT:	<ACK>
HOST:	<STX>1H|\^&||| Product Model ^01.03.07.03^123456|||||||SA|1394-97|20090910102501<CR>
	P|1||PATIENT111||Smith^Tom^J||19600315|M|||A|||icteru||||||01|||||A1|002||||||||<CR>
	O|1|1^1^1|SAMPLE123|1^Test1^2^1\2^Test2^2^1\3^Test3^2^1\4^Test4^2^1|R|20090910135300|20090910125300|||John|||||Urine|Dr.Who|Department1|1|Dr.Tom||||||Q|||||<CR>
	L|1|N<CR><ETX><CS><CR><LF>
INSTRUMENT:	<ACK>

HOST:	<EOT>

It will be sent separately.

HOST:	<ENQ>
INSTRUMENT:	<ACK>
HOST:	<STX>1**H**|\^&||| Product Model ^01.03.07.03^123456|||||||SA|1394-97|20090910102501<CR> <ETX><CS><CR><LF>
INSTRUMENT:	<ACK>
HOST:	<STX>2**P**|1||PATIENT111||Smith^Tom^J||19600315|M|||A|||icteru||||||01|||||A1|002|||||||||<CR><ETX><CS><CR><LF>
INSTRUMENT:	<ACK>
HOST:	<STX>3**O**|1|1^1^1|SAMPLE123|1^Test1^2^1\2^Test2^2^1\3^ Test3^2^1\4^Test4^2^1|R|20090910135300|20090910125300 |||John|||||Urine|Dr.Who|Department1|1|Dr.Tom||||||Q|||||<CR>< ETX><CS><CR><LF>
INSTRUMENT:	<ACK>
HOST:	<STX>4**L**|1|N<CR><ETX><CS><CR><LF>
INSTRUMENT:	<ACK>
HOST:	<EOT>

If LIS system returns inquired sample information, the 26th field of O record is set to Q; If LIS system send sample information to the chemistry analyzer, the 26th record of O record is set to O.