# Chemiluminescence Immunoassay Analyzer Host Interface Manual



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# **Foreword**

## 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 Mindray. Instructions are provided in this manual for LIS developers to guide them to develop LIS interface that enables their LIS to communicate with the chemiluminescence immunoassay analyzer of Mindray (CL2200i, CL2000i). 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 Mindray. The manual is divided into two parts, the first is to introduce HL7 protocol, 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 Mindray HL7 interface; the second section introduces Bidirectional Communication between the analyzer and LIS (sending test result and acquiring sample request information from LIS); the 3<sup>rd</sup> section introduces the communication process and gives some message samples. For the second part, the first section is a general description of Mindray ASTM interface; the second section introduces Bidirectional Communication between the analyzer and LIS (sending test result and acquiring sample request information from LIS); the 3<sup>rd</sup> 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
Ţ	NOTE	Read the statement following the symbol. The statement is alerting you to information that requires your attention.

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# **1** Mindray HL7 Interface

#### 1.1 Mindray HL7 Interface

HL7 interface is developed by Mindray for the chemiluminescence immunoassay 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 chemiluminescence immunoassay 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 chemiluminescence immunoassay 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.

Mindray 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 Mindray 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>

#### **ASCII Code Table:**

					1				ſ				1			
^@	0	00		NUL		32	20	١. ا		64	40	@ A		96	60	'
^A	1	01		SOH		33	21	!		65	41	A		97	61	a
^B	2	02		STX		34	22	" "		66	42	B		98	62	b
^C	3	03		ETX		35	23	#		67	43	C		99	63	c
^D	4	04		EOT		36	24	\$ %		68	44	D		100	64	d
^E	5	05		ENQ		37	25			69	45	E		101	65	e
^F	6	06		ACK		38	26	&		70	46	F		102	66	f
^G	7	07		BEL		39	27	<b>'</b> .		71	47	G		103	67	g
^H	8	08		BS		40	28	(		72	48	H		104	68	ĥ
^I	9	09		нт		41	29	)		73	49	I		105	69	i
^]	10	0A		LF		42	2A	*		74	4A	J		106	6A	j
^K	11	0B		VT		43	2B	+		75	4B	K		107	6B	k
^L	12	0C		FF		44	2C	١,		76	4C			108	6C	
^M	13	0D		CR		45	2D	-		77	4D	M		109	6D	m
^N	14	0E		so		46	2E	·		78	4E	N		110	6E	n
^0	15	0F		SI		47	2F	/		79	4F	0		111	6F	0
^P	16	10		DLE		48	30	0		80	50	P		112	70	p
^Q	17	11		DC1		49	31	1 2 3 4 5 6 7		81	51	Q R		113	71	q
^R	18	12		DC2		50	32	2		82	52	R		114	72	r
^S	19	13		DC3		51	33	3		83	53	S		115	73	s
^T	20	14		DC4		52	34	4		84	54			116	74	t
^U	21	15		NAK		53	35	5		85	55	U		117	75	u
^V	22	16		SYN		54	36	6		86	56	V		118	76	V
^W	23	17		ETB		55	37	7		87	57	W		119	77	w
^X	24	18		CAN		56	38	8		88	58	X		120	78	X
^Υ	25	19		EM		57	39	9		89	59	Y		121	79	y
^Z	26	1A		SUB		58	3A	:		90	5A	Z [		122	7A	lz I
]^	27	1B		ESC		59	3B	;		91	5B			123	7B	{
^\	28	1C		FS		60	3C	<		92	5C	\		124	7C	
^]	29	1D		GS		61	3D	=		93	5D	]		125	7D	}
^^	30	1E	▲	RS		62	3E	>		94	5E	^		126	7E	~
^-	31	1F	▼	US		63	3F	?		95	5F	-		127	7F	Δ

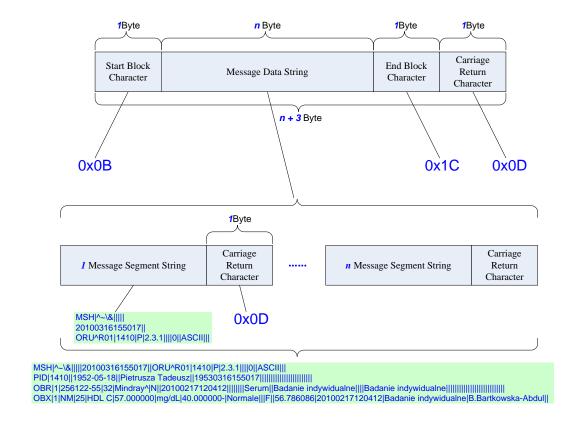
### 1.1.3 Minimal Lower Layer Protocol (MLLP)

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 in the end. The characters used by the HL7 interface are default in the HL7 standard.

Start character: Hexadecimal <0B>

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

The detailed data format is shown in the figure below:



#### 1.2 Bidirectional Communication

Communication here concerns result sending and sample information downloading. The former means the chemiluminescence immunoassay 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 Mindray HL7 interface.



#### **NOTE**

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

The following sections introduce the common grammars in detail.

#### 1.2.2 Message Grammar

This section introduces the general grammar of Mindray 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|^~\&| |||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. Mindray HL7 standard uses the following characters:

Character	Description
1	Field separator
۸	Component separator
&	Subcomponent separator
~	Repetition separator
\	Escape character

The first field of MSH include 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 Mindray HL7 interface.

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:

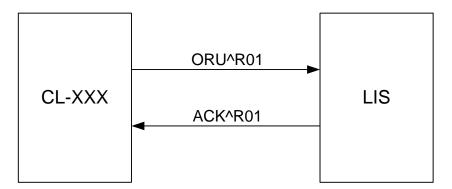
[] indicates the segment in it is optional.

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

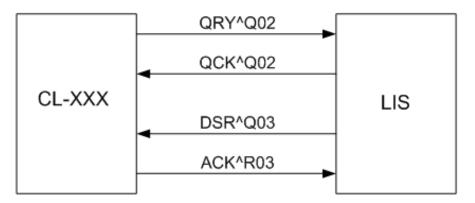
#### 1.2.3 Compatible HL7 Messages

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^R01**: result of patient sample (including control sample) / ressponse.

The chemiluminescence immunoassay analyzer sends test results to the LIS host through an ORU^R01 message. When receiving test results successfully, the LIS host shall send an ACK^R01 message to the analyzer; otherwise the analyzer may deem the results not received and will send them again for at most 3 times with alarm.

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 than 80. 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 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 QC test results are transferred as follows:

ORU	Observational Results (Unsolicited)	Description
MSH		Message Header
OBR	Observation rep	oort(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 r	message i	is used to res	pond to the DSR message.
ACK	Acknowl	edgment	Description
MSH			Message Header

#### 1.2.4 Message Segment

This section describes the components of each segment:

- Field length

MSA

**ERR** 

- 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 Mindray HL7 interface are provided for function extension in future although some of the fields are void.

Message Acknowledgment

Error

#### **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 Mindray 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,.
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 Message	26	Time of the current message. Calling 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; 2-QC result.
17	Country Code	2	Void and reserved. Country code
18	Character Set	10	Character set. ASCII is used.
19	Principal Language	60	Void and reserved. Principle language

No.	Field	Length	Description
	Of Message		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 10 and 16 are integers; others are strings. When LIS sends sample request information to the chemiluminescence immunoassay analyzer, the 15 filed should be set to P.

#### **MSA - Message Acknowledgment Segment**

The MSA segment of Mindray 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".
			It should be noted that if the LIS host responses to the analyzer's result sending with an ACK^R01 message containing AE or AR, the analyzer may deem that the LIS host may not process the results and will send them again for at most 2 times. It is recommended that the LIS host use AA instead of AE or AR.
2#	Message Control ID	20	Message control ID, same with that of MSH message and 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

Status Code (MSA-6)	Status Text(MSA-3)	Description/Comment
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 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. Mindray HL7 interface message uses the following fields:

No.	Field	Length	Description
1	Set ID – PID	10	Identifies different patient fields
2	Patient ID	20	ID number of the patient
3#	Patient Identifier List	20	Void and reserved. MRN

No.	Field	Length	Description
4	Alternate Patient ID – PID	20	Void and reserved. Bed No.
5#	Patient Name	40	Name of patient
6	Mother's Maiden Name	20	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
9	Patient Alias	20	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	20	Ordering Department
12	County Code	10	Void and reserved. County code of patient(postal code)
13	Phone Number - Home	20	Void and reserved. Phone number (home) of patient
14	Phone Number - Business	10	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	20	Void and reserved. Social security number of patient

No.	Field	Length	Description
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	20	Void and reserved. Ethnic group the patient belongs to
23	Birth Place	20	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	40	Common remark about the patient
27	Veterans Military Status	60	Void and reserved. Veterans military status of patient
28	Nationality	20	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  $1^{st}$  and  $25^{th}$  fields are integers, the  $24^{th}$  and  $30^{th}$  fields are Booleans, and others are strings.

#### **OBR - Observation Request**

OBR segment is used to transfer the order information of test report.

#### Test results of patient sample

When the sample test result is transferred (MSH-16 is 0), the field used in Mindray 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	27	Order number of placer, used as sample bar code
3	Filler Order Number	10	Order number of filler, used as sample ID

No.	Field	Length	Description
4#	Universal Service ID	200	Void and reserved. 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 (Test request time)
7	Observation Date/Time	26	Observation date/time, used as testing date/time
8	Observation End Date/Time	26	Observation end date/time used as sample collecting time
9	Collection Volume	20	Void and reserved. Collection Volume. Used for calculation manual dilution.
10	Collector Identifier	60	Fixed: 1^1 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	20	sample source, used as sample type. and defined as sample type on the operating software.
16	Ordering Provider	40	Order provider, used as attending doctor
17	Order Callback Phone Number	20	treating department
18	Placer Field 1	20	Void and reserved. Characteristic of sample (icterus, hemolysis and lipemia, others are named by the customer)
19	Placer Field 2	20	Void and reserved. Blood bag No.
20	Filler Field 1	40	Void and reserved. Attending doctor
21	Filler Field 2	20	Void and reserved. Treating department
22	Result Rpt/Status Change – Date/Time	26	Void and reserved. Result report/status change-date/time

No.	Field	Length	Description
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. 0:unknown 1:requested 2:running 3:completed 4: incomplete 5 rerun 6 sampling finished
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 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	200	Void and reserved. Planned

No.	Field	Length	Description
	Comment		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. The  $1^{st}$ , and  $37^{th}$  fields are integers, the  $9^{th}$  field is floating number, and others are strings.

#### QC test results

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

No.	Field	Length	Description
	1 1010		•
1	Set ID – OBR	10	Identifies different OBR fields
2	Placer Order Number	10	Order number of placer, used as test channel no
3	Filler Order Number	15	Order number of filler, used as shortened test name
4#	Universal Service ID	200	Fixed ^and reserved. Universal Service ID (manufacturer^machine type)
5	Priority	2	Priority used as sample type.0:serum 1: plasma 2:urine 4:other 35:whole blood 36 amniotic fluid
6	Requested Date/time	26	Requesting date/time used as the start time of QC test
7	Observation Date/Time	26	Observation date/time, used as QC requesting date/time
8	Observation End Date/Time	26	Observation end date/time test finish 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 3		Control No.
13	Relevant Clinical Info.	15	Control name

No.	Field	Length	Description	
14	Specimen Received Date/Time	18	Lot No. of control	
15	Specimen Source	26	Expiration date of control Format: yyyymmdd	
16	Ordering Provider	1	Fixed as 0	
17	Order Callback Phone Number	1	Fixed as M.Concentration level of control. H for high; M for medium, L for low.	
18	Placer Field 1	8	Mean value (mean concentration)	
19	Placer Field 2	8	Standard deviation of control	
20	Filler Field 1	25	Test result (concentration)	
21	Filler Field 2	20	Result unit	
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	1	Transportation mode. Used as module no. For special calculation, it is Void; for immunoassay chemistry, it is 1.	
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 26 Date/Time		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	

No.	Field	Length	Description	
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.

#### **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 Mindray 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	
3#	Observation Identifier	10	Channel number of test.  This field is used to match tests of results sent from the analyzer.	
4	Observation Sub-ID	50	Test name(full name)	
5	Observation Value	25	Observation value, used as test result	

No.	Field	Length	Description	
			(concentration) -0x0fffffff means invalid value	
6	Units	20	Unit of test result.	
7	References Range	90	Fixed and reserved. Reference range for test result.	
8	Abnormal Flags	5	Fixed as N and reserved. Abnormity flag to indicate whether the test result is normal or not.	
9	Probability	5	Probability; for qualitative result (Negative-, Positive+, weak positive+-) or optimized result. If they coexist, it stands for qualitative result.	
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	25	User-defined access check, used as original result0x0fffffff means invalid value	
14	Date/Time of the Observation	28	Observation date/time, used as test finish 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	Flag of rerun result	
	ivietriou		1 – Rerun result	
			0 – Not rerun result	

Comments: The OBX segment only applies to the ORU^R01 messages. Fields 1,and 9 are integers; fields 5 and 13 are floating numbers; others are strings.

Field No.17 is used to identify rerun result.

If the fifth field is invalid value, please refer to ninth field for the result.

#### **QRD - Query Definition Segment**

The QRD segment of Mindray 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 respons date/time.	
7#	Quantity Limited Request	10	Quantity limited request, set to RD (records).	
8#	Who Subject Filter	27	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 or downloading by sample ID; 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	Void and reserved. 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	10	Start sample ID. String
5	Other QRY Subject Filter	10	End sample ID. String. It is same as the start ID when a single sample is queried.
6	Which Date/Time Qualifier	12	Object type. RCT(Specimen receipt date/time, receipt of specimen in filling ancillary (Lab))

No.	Field	Length	Description	
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 2 and 3 are 0 o'clock and query time of the day, and used as search conditions. All fields are strings. Fields 4 and 5 are start sample ID and end sample ID for query and can be used for querying samples within an ID range. When field 4 is blank, the query is performed by time; otherwise, it is performed by sample ID.

#### **ERR - Error Segment**

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

No.	Field			Length	Description
1#	Error Location	Code	and	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  $3^{rd}$  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  $29^{th}$  will be added with the same format.

No.	Content	Туре	Value
1	Patient ID	String	Maximum of 20 characters
2	Bed Number	String	Blank
3	Patient Name	String	Maximum of 40 characters
4	Date of Birth	String	Blank. The format is YYYYMMDDHHmmSS, such as 20061122130540.
5	Sex	String	Male = M
			Female = F
			Other = O
6	Blood type	String	O, A, B, and AB
7	Race	String	Blank
8	Patient Address	String	Blank
9	Postal Code	String	Blank
10	Home Phone Number	String	Blank
11	Sample position	String	Blank. Consisting of sample carousel number and sample tube number, such as: 1^30 (Position No.30 of No.1

No.	Content	Туре	Value
			sample carousel)
12	Sample collection time	String	The format is YYYYMMDDHHmmSS, such as 20061122130540.
13	Not used		Blank
14	Not used		Blank
15	Patient type	String	Blank. Outpatient, inpatient, and other
16	Social Security Number	String	Blank Maximum of 20 characters
17	Charge type	String	Blank. Own and insurance
18	Ethnic Group	String	Blank Maximum of 20 characters
19	Birth Place	String	Blank. Maximum of 20 characters
20	Nationality	String	Blank. Maximum of 20 characters
21#	Bar Code	String	Maximum of 27 characters
22#	Sample ID	Integer	Maximum of 10 characters. Can be number or number mixed with upper case letters.
23	Sending time	String	Blank. The format is YYYYMMDDHHmmSS, such as 20061122130540.
24#	STAT or not	String	It includes Y (yes), N (No) and void. N is default.
25	Not used	String	Blank
26#	Sample Type	String	It includes serum, plasma, urine, whole blood, amniotic fluid, and other.
27	Fetch Doctor	String	Maximum of 40 characters
28	Fetch Department	String	Maximum of 20 characters
29#	Test ID^Test Name^Unit^Normal Range	String	Channel No. ^ Test name ^ Unit ^ Reference range
			For example: 100^ALT^g/ml^10.1-20.5
			Other three options except channel No. can be left blank, such as: 100^^.
			For channel no., maximum of 10 characters are allowed.

(Note: Options with "#" are compulsive.)

The analyzer recognizes a test with its Channel Number. For the same test, if the channel number in the analyzer is 100, the same channel number, in the LIS server should be used to transfer the sample information. You can set up the test channel number of the analyzer via Utility-System Setup-LIS Setup.

#### **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.

For instance, the LIS host needs to send 5 samples:

First sample: DSC|1|

Second sample: DSC|2|

Thired sample: DSC|3|

Fourth sample: DSC|4|

Fifth sample: DSC|5|

#### 1.2.5 Adding and Rerunning Tests

When a request to rerun and add some tests is proposed on the analyzer, the LIS host must send only those requested.

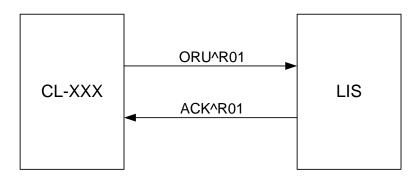
After finishing the added tests, the analyzer will only send their results rather than those that have been finished before to the LIS host.

After rerunning certain tests, the analyzer will send to the LIS host only the original results and all rerun results rather than those that have been finished before.

# 1.3 Communication Process and Message Example

#### 1.3.1 Example of Result Sending Message

The analyzer sends test results (of patient sample, calibrator and control) to the LIS host by samples, that is, all tests of a sample are transferred via one (ORU^R01) message. The LIS host must response accordingly when receiving the message.



An ORU message may includes 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)

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

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.

#### **Sending Results of Patient Sample**

There is a patient, who has the following information:

Field	Value
Name of patient	Mike
Gender	Male
Birth date	01.10.85
Ordering Department	Keshi(sending department)
Patient Comment	Beizhu(comment about the patient)
Sample bar code	12345678
Sample Type	Serum
Sample ID	10
Is sample ID or not	10
STAT	Yes
Test No.	2, 5 and 6
Test	TBil, ALT, AST
Test results	100, 98.2 and 26.4

Field	Value
Unit	umol/L, umol/L and umol/L

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

<\$B>M\$H|^~\&|||||20120508094822||**ORU^R01**|1|P|2.3.1||||0||A\$CII|||<CR>

PID|1|1001|||Mike||19851001095133|M|||keshi|||||||||beizhu|||||<CR>

OBX|1|NM|2|TBil|100| umol/L |-|N|||F||100|20120405194245||yishen|0|<CR>

OBX|2|NM|5|ALT|98.2| umol/L |-|N|||F||98.2|20120405194403||yishen|0|<CR>

OBX|3|NM|6|AST|26.4| umol/L |-|N|||F||26.4|||yishen||<CR>

<EB><CR>

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.

<\$B>M\$H|^~\&|||||20120508094823||**ACK^R01**|1|P|2.3.1||||0||A\$CII|||<CR>

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

<EB><CR>

If error is included in the ORU message, it can be returned in the MSA segment. For example, when an reject error of 206 occurs on the LIS host, the ACK message for reply is as follows:

<\$B>M\$H|^~\&||||20120508094823||**ACK^R01**|1|P|2.3.1||||0||A\$CII|||<CR>

MSA|AR|1|Application query error|||206|<CR>

<EB><CR>

#### Sending QC Results

For example: A QC test is requested as follows.

Field	Value
Test No.	7
Test	AST
Control No.	2

Field	Value
Control name	QUAL2
Lot No. of control	2222
Expiration date of control	January 1, 2030; January 1, 2030
Mean value (mean concentration)	55
Standard deviation of control	5
Test result (concentration)	0.137470

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

<\$B>M\$H|^~\&|||||20120508103014||\textbf{ORU^R01}|1|P|2.3.1||||2||A\$CII|||<CR>

<EB><CR>

The LIS host replies as follows:

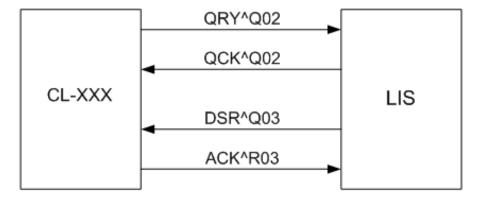
<\$B>M\$H|^~\&|||||20120508094823||**ACK^R01**|1|P|2.3.1||||2||A\$CII|||<CR>

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

<EB><CR>

#### 1.3.2 Example of Querying and Downloading Sample

The analyzer sends query request to the LIS host, which finds the relevant samples and send them to the analyzer. The HL7 messages used are as follows:



The analyzer provides three ways to download samples: by sample bar code, by specified sample ID range, and by test time.

Note: Please read the operator's manual of the analyzer for the downloading instructions.

#### **Downloading Sample of Specified Bar Code**

For example: To download a sample of 0019(bar code) from LIS, the analyzer sends a QRY^Q02 message as follows:

<\$B>M\$H|^~\&|||||20120508104700||QRY^Q02|4|P|2.3.1||||||A\$CII|||<CR>

QRD|20120508104700|R|D|1|||RD|0019|OTH|||T|<CR>

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

<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|^~\&||||20120508104700||QCK^Q02|4|P|2.3.1|||||ASCII|||<CR>

MSA|AA|4|Message accepted|||0|<CR>

ERR|0|<CR>

QAK|SR|OK|<CR>

<EB><CR>

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

<SB>MSH|^~\&||||20120508104700||QCK^Q02|4|P|2.3.1|||||ASCII|||<CR>

MSA|AA|4|Message accepted|||0|<CR>

ERR|0|<CR>

QAK|SR|NF|<CR>

<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.

Field Description	Value
Name of patient	Tommy
Gender	Male

Field Description	Value
Birth date	24.08.62
Blood type of patient	0
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:

<\$B>M\$H|^~\&|||||20120508110131||**D\$R^Q03**|4|P|2.3.1||||||A\$CII|||<CR>

MSA|AA|4|Message accepted|||0|<CR>

ERR|0|<CR>

QAK|SR|OK|<CR>

QRD|20120508110131|R|D|2|||RD||OTH|||T|<CR>

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

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

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

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

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

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

DSP|6||0|||<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|^~\&|||||20120508110131||ACK^Q03|4|P|2.3.1||||||ASCII|||<CR>
MSA|AA|4|Message accepted|||0|<CR>
ERR|0|<CR>

#### **Downloading Samples of Specified ID Range**

To download samples with ID between 1-9 from LIS, the analyzer sends a QRY^Q02 message as follows:

<SB>MSH|^~\&||||20120508115221||QRY^Q02|6|P|2.3.1|||||ASCII|||<CR>

QRD|20120508115221|R|D|3|||RD||OTH|||T|<CR>

QRF||||1|9|RCT|COR|ALL||<CR>

<EB><CR>

<EB><CR>

When receiving the message, the LIS returns the QCK^Q02 message and replies as follows if the samples whthin the ID range exist.

<\$B>M\$H|^~\&|||||20120508115221||**QCK^Q02**|6|P|2.3.1||||||A\$CII|||<CR>

MSA|AA|6|Message accepted|||0|<CR>

ERR|0|<CR>

QAK|SR|OK|<CR>

<EB><CR>

If samples within the ID range do not exist, the LIS replies as follows:

<\$B>M\$H|^~\&||||20120508104700||QCK^Q02|6|P|2.3.1|||||A\$CII|||<CR>

MSA|AA|6|Message accepted|||0|<CR>

ERR|0|<CR>

QAK|SR|NF|<CR>

<EB><CR>

When samples within the ID range exist 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.

Field Description	Sample 1	Sample 2
Name of patient	Tommy	Jack
Gender	Male	Male
Birth date	24.08.62	24.08.62
Blood type of patient	0	0
Patient type	Outpatient	Outpatient
Payment type of patient	Self-pay	Self-pay
Patient ID	1212	1212
Bed No.	27	27
Sample bar code	0019	0019
Sample ID	3	3
Sample receiving date/time	18:35 March 1, 2007	18:35 March 1, 2007
STAT	No	No
Sample Type	Serum	Serum
Sender	Mary	Mary
Sending department	Dept1	Dept1
Test No.	1, 2, 5	1, 2, 5

The DSR messages of sample 1 are as follows:

<\$B>M\$H|^~\&||||20120508110131||**D\$R^Q03**|4|P|2.3.1||||||A\$CII|||<CR>

MSA|AA|4|Message accepted|||0|<CR>

ERR|0|<CR>

QAK|SR|OK|<CR>

QRD|20120508110131|R|D|2|||RD||OTH|||T|<CR>

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

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

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

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

DSP|4||19620824000000|||<CR> DSP|5||M|||<CR> DSP|6||O|||<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||outpatient|||<CR> DSP|16|||||<CR> DSP|17||own|||<CR> DSP|18|||||<CR> DSP|19|||||<CR> DSP|20|||||<CR> DSP|21||0019|||<CR> DSP|22||3|||<CR> DSP|23||20070301183500|||<CR> DSP|24||N|||<CR> DSP|25||1|||<CR> DSP|26||serum|||<CR> DSP|27|||||<CR> DSP|28|||||<CR> DSP|29||1^^^|||<CR> DSP|30||2^^^|||<CR> DSP|31||5^^^|||<CR>

DSC|1|<CR>

# <EB><CR> When receiving the DSR message, the analyzer replies as follows: <\$B>M\$H|^~\&|||||20120508110131||**ACK^Q03**|4|P|2.3.1||||||A\$CII|||<CR> MSA|AA|4|Message accepted|||0|<CR> ERR|0|<CR> <EB><CR> The DSR messages of sample 2 are as follows: <\$B>M\$H|^~\&||||20120508110131||**D\$R^Q03**|5|P|2.3.1|||||A\$CII|||<CR> MSA|AA|5|Message accepted|||0|<CR> ERR|0|<CR> QAK|SR|OK|<CR> QRD|20120508110131|R|D|2|||RD||OTH|||T|<CR> QRF|||||RCT|COR|ALL||<CR> DSP|1||1213|||<CR> DSP|2||28|||<CR> DSP|3||Jack|||<CR> DSP|4||19620824000000|||<CR> DSP|5||M|||<CR> DSP|6||O|||<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||outpatient|||<CR>
DSP|16|||||<CR>
DSP|17||own|||<CR>
DSP|18|||||<CR>
DSP|19|||||<CR>
DSP|20|||||<CR>
DSP|21||0020|||<CR>
DSP|22||4|||<CR>
DSP|23||20070301183500|||<CR>
DSP|24||N|||<CR>
DSP|25||1|||<CR>
DSP|26||serum|||<CR>
DSP|27|||||<CR>
DSP|28|||||<CR>
DSP|29||1^^^|||<CR>
DSP|30||2^^^|||<CR>
DSP|31||5^^^|||<CR>
DSC||<CR>
<EB><CR>
 When receiving the DSR message, the analyzer replies as follows:
<$B>M$H|^~\&||||20120508110131||ACK^Q03|5|P|2.3.1|||||A$CII|||<CR>
MSA|AA|5|Message accepted|||0|<CR>
ERR|0|<CR>
<EB><CR>
```

# **Downloading Samples within Specified Time Range**

The chemiluminescence immunoassay analyzer sends group query request to LIS for downloading samples within specified time range.

For example, to download all samples from 10am to 3pm of the current day, the message should be:

<\$B>M\$H|^~\&||||20120508150259||QRY^Q02|7|P|2.3.1||||||A\$CII|||<CR>

QRD|20120508150259|R|D|4|||RD||OTH|||T|<CR>

QRF||20120508100000||20120508150000|||RCT|COR|ALL||<CR>

<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:

Field Description	Sample 1	Sample 2	Sample 3
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 of sample 1 are as follows:

<\$B>M\$H|^~\&|||||20120508110131||**D\$R^Q03**|5|P|2.3.1||||||A\$CII|||<CR>

MSA|AA|5|Message accepted|||0|<CR>

ERR|0|<CR>

QAK|SR|OK|<CR>

QRD|20120508110131|R|D|2|||RD||OTH|||T|<CR>

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

DSP|1|||||<CR>

DSP|2|||||<CR>

DSP|3||Jacky|||<CR>

DSP|4||19720216000000|||<CR>

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

DSP|6||O|||<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>
<EB><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:
<$B>M$H|^~\&|||||20120508110131||ACK^Q03|5|P|2.3.1||||||A$CII|||<CR>
MSA|AA|5|Message accepted|||0|<CR>
ERR|0|<CR>
<EB><CR>
The DSR messages of sample 2 are as follows:
<$B>M$H|^~\&|||||20120508110131||D$R^Q03|5|P|2.3.1||||||A$CII|||<CR>
MSA|AA|5|Message accepted|||0|<CR>
ERR|0|<CR>
QAK|SR|OK|<CR>
QRD|20120508110131|R|D|2|||RD||OTH|||T|<CR>
QRF|||||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||4^^^|||<CR> DSC|2|<CR> <EB><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: <\$B>M\$H|^~\&|||||20120508110131||ACK^Q03|5|P|2.3.1||||||A\$CII|||<CR>

The DSR messages of sample 3 are as follows:

MSA|AA|5|Message accepted|||0|<CR>

ERR|0|<CR>

MSA|AA|5|Message accepted|||0|<CR> ERR|0|<CR> QAK|SR|OK|<CR> QRD|20120508110131|R|D|2|||RD||OTH|||T|<CR> QRF|||||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>

<\$B>M\$H|^~\&|||||20120508110131||**D\$R^Q03**|5|P|2.3.1||||||A\$CII|||<CR>

DSP|24||Y|||<CR>

DSP|25|||||<CR>

DSP|26||urine|||<CR>

DSP|27|||||<CR>

DSP|28|||||<CR>

DSP|29||8^^^|||<CR>

DSC||<CR>

<EB><CR>

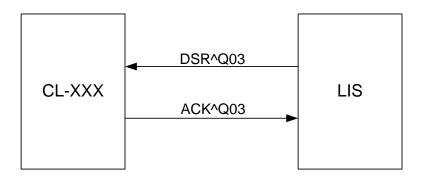
The analyzer sends back an ACK message to LIS every time when receiving a DSR message. The ACK messages for the above-mentioned DSR messages are:

<\$B>M\$H|^~\&|||||20120508110131||**ACK^Q03**|5|P|2.3.1||||||A\$CII|||<CR>

MSA|AA|5|Message accepted|||0|<CR>

ERR|0|<CR>

# 1.3.3 Example of Sending Samples to LIS



Note: Please read the operator's manual of the analyzer for instructions of sending samples to LIS host.

If LIS system is to set sample request information, the 15<sup>th</sup> 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

Field	Value
Blood type of patient	0
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

The DSR messages are as follows:

MSA|AA|4|Message accepted|||0|<CR>

ERR|0|<CR>

QAK|SR|OK|<CR>

QRD|20120508110131|R|D|2|||RD||OTH|||T|<CR>

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

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

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

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

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

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

DSP|6||O|||<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||outpatient|||<CR> DSP|16|||||<CR> DSP|17||own|||<CR> DSP|18|||||<CR> DSP|19|||||<CR> DSP|20|||||<CR> DSP|21||0019|||<CR> DSP|22||3|||<CR> DSP|23||20070301183500|||<CR> DSP|24||N|||<CR> DSP|25||1|||<CR> DSP|26||serum|||<CR> DSP|27|||||<CR> DSP|28|||||<CR> DSP|29||1^^^|||<CR> DSP|30||2^^^|||<CR> DSP|31||5^^^|||<CR> DSC||<CR> <EB><CR> When receiving the DSR message, the analyzer replies as follows: <\$B>M\$H|^~\&|||||20120508110131||**ACK^Q03**|4|P|2.3.1||||||A\$CII|||<CR>

MSA|AA|4|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 Mindray ASTM Interface

# 2.1 Mindray ASTM Interface

ASTM interface is developed by Mindray for the Chemiluminescence Immunoassay 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 chemiluminescence immunoassay 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 Mindray 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.

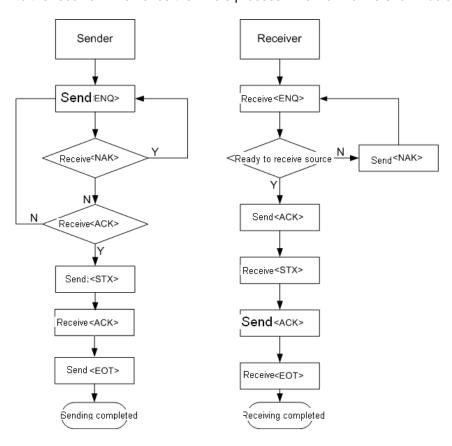
Only portion of the messages, segments and other data defined are used for ASTM interface that needs only part of these data.

# 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></enq>	0x05
<ack></ack>	0x06
<eot></eot>	0x04
<nak></nak>	0x15
<stx></stx>	0x02
<lf></lf>	0x0A
<cr></cr>	0x0D
<etb></etb>	0x17
<etx></etx>	0x03

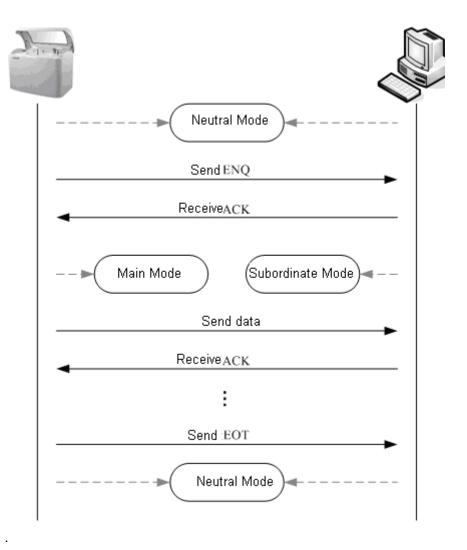
#### 2.1.3 ASTM Protocol Communication Mode

In ASTM protocol, three status 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.

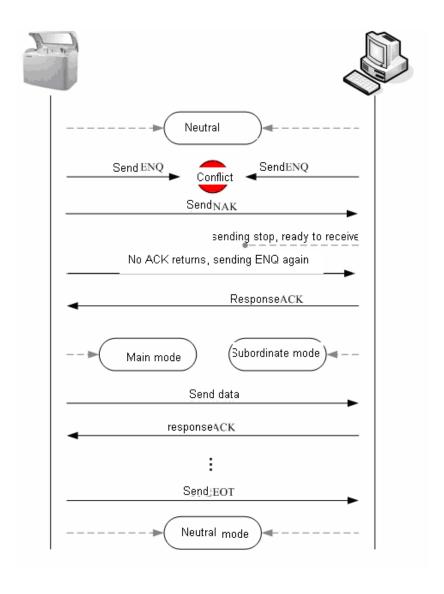
When the instrument receives control command character <ENQ> after sending it, it will send <NAK>, waiting for the ACK from LIS.

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

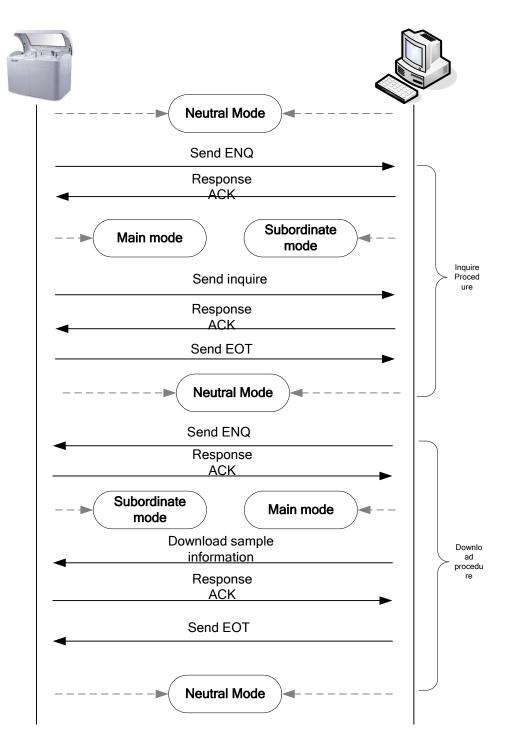
According to the rule, when conflict occurs, the instrument will be in main mode first. Only when the data sending on the instrument side is completed and enters neutral mode, can the LIS system enter main mode.

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.

# **Adding and Rerunning Tests**

When a request to rerun and add some tests is proposed on the analyzer, the LIS host must send only those requested.

After finishing the added tests, the analyzer will only send their results rather than those that have been finished before to the LIS host.

After rerunning certain tests, the analyzer will send to the LIS host only the original results and all rerun results rather than those that have been finished before.

## 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|\^&|||Mindray^\||||||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 Mindray ASTM interface.

Character	Description	
I	Field separator	
١	Repetition separator	
۸	Component separator	
&	Escape character	

When the field content include the characters above, transferred meaning characters is needed. In Mindray 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) starts from 1

<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) .

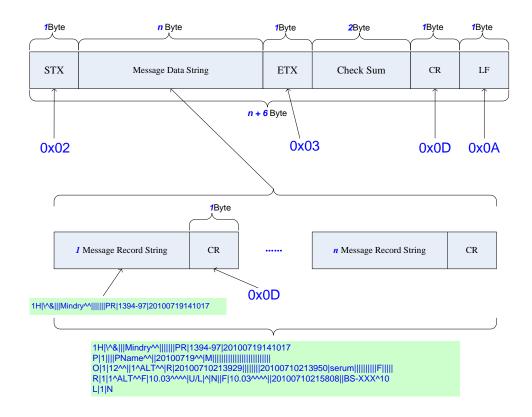
<LF> : ASCII new line (0x0A) .

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>

#### Lower Layer Data Structure of ASTM Message



2-9

## **ASTM Message Record Code**

Record type	Record description
Н	Header Record
Р	Patient Record
0	Order Record
R	Result Record
С	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 Mindray ASTM interface, we not omit any field in the message record. If the field has no value, it is set to void.

## HeaderRecord- "H"

 $\mbox{\ensuremath{\mathsf{H}}}$  is the header of all messages. The separator should be in the second field of the  $\mbox{\ensuremath{\mathsf{H}}}$  message.

ASTM Field	Field Name	Field Contents	Max Length	Field Description
1#	Record Type ID	Н	1	Record type ID
2#	Delimiter Definition	\ ^ &	4	Field separator Repetition separator Element separator Code change separator
3	Message Control ID		-	Void and reserved.

ASTM Field	Field Name	Field Contents	Max Length	Field Description
4	Password		-	Void and reserved.
5	Sender Name or ID	String	40	Fixed as Mindray Instrument name
	Software Version	String and number	20	Void and reserved. Software Ver.:
	Serial number	String and number	20	Void and reserved. Instrument serial 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.
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
13#	Version Number	String and Number	12	Version number of protocol, fixed as 1394-97
14	Date and Time	YYYYMMDDHHMMSS	14	Date and time when message is created

Example:

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

H|\^&|||Mindray^\||||||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	Р	1	Record type ID
2	Sequence Number		3	Sequence number
3	Practice Assigned Patient ID		-	Void and reserved.
4	Patient ID	String and number	30	Patient ID
5	Patient ID #3		-	Void and reserved.
	Patient Name			Name of patient
	1 auent Name			Last^First^Middle Initial
6#	Last Name	String	40	First name
	First Name	String	20	Family name
	Middle Initial	String	1	
7	Reserved field		-	Void and reserved.
	Birth date	String	8	Birth date, e.g. 20091001
	Age	Number	3	Age
		Y = year		
8	Age Unit	M = Month		
		W = Week	1	Age unit
		D = Days		Age unit
		H = Hours		
		If empty =Year		

ASTM Field	Field Name	Field Contents	Max Length	Field Description
9	Patient Sex	M(Male) F(Female) U(unknown)	1	Patient gender
10	Patient Race	String	20	Void and reserved. Patient race
11	Patient Address	String	20	Ordering Department
12	Reserved Field	A B O AB Others are defined by the customers	20	Void and reserved. Blood type
13	Patient Telephone	themselves String	20	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 Others defined by user	30	Void and reserved Sample type. When icterus is used, pay attention to that it is 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

ASTM Field	Field Name	Field Contents	Max Length	Field Description
22	Practice Field #1		-	Void and reserved.
23	Practice Field #2		-	Void and reserved.
24	Admission and dischargedates		-	Void and reserved.
25	Admission Status		-	Void and reserved.
26	Location	String	20	Void and reserved patient zone
27	Nature of alt. Diag. Code and Class.	String	20	Void and reserved. Bed No.
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|\^&|||Mindray^^|||||||SA|1394-97|20090910102501<CR>

Diagnosis

L|1|N<CR>

#### Test Order Record - "O"

The Test Order Record is used to transfer relevant information of test report.

When transferring patient sample results (PR/SA/QA for H-12), the following fields are used.

ASTM Field	Field Name	Field Contents	Max Length	Field Description
1#	Record Type ID	0	1	Record type ID
2	Sequence Number	Number	3	Sequence number
	Sample ID	String and number	10	Sample ID
3	Sample Tray No.	Number	2	Void and reserved
	Sample Pos	Number	2	Void and reserved
4	Instrument Specimen ID	String	27	Sample bar code
	Assay No.	String	10	Test channel No.
	Assay Name	String	50	Test Name(full name)
5	Dilution Rate	Number	4	Void and reserved Dilution Ratio
	Repeat Num	Number	2	Void and reserved Replicate
6	Priority	R(routine)S (STAT)	1	STAT
7	Requested Date and Time (Sample program creation date)	String	14	Sample request time 20090910121532
_	,		14	Sample collection
8	Specimen Collection  Date and Time	String		time 20090910121532
9	Collection end Time			Void and reserved.
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	Sending date and time 20090910121532

ASTM Field	Field Name	Field Contents	Max Length	Field Description
		serum	20	Sample type, case
		urine		sensitive. The default sample type
	Specimen type	plasma		is set to the defined
16	(This field is not	timed		value at the left side which varies
	translated to local	other		among different products. The
	languages)	blood		customer can
		amniotic		modify to their needs.
	Ordering Physician			sender
17	Last Name	String	40	First name
	First Name	String	20	Family name
	Middle Initial	String	1	
18	Physician Phone number	String	20	Sending department
19	Offline Dilution factor	number	4	Void and reserved Dilution factor
	User Field #2			Sender
20	Last Name	String	40	First name
20	First Name	String	20	Family name
	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#		O (request from)	1	
	Report Type	Q (query response)		Report type
		F (final result)		
27	Reserved Field		-	Void and reserved.
28	Location Specimen		-	Void and reserved.
28	Collected			void allu leselved.

ASTM Field	Field Name	Field Contents	Max Length	Field Description
29	Nosocomial Infection flag		-	Void and reserved.
30	Specimen Service		-	Void and reserved.
31	Specimen Institution		-	Void and reserved.

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

#### Example:

 $O|1|1^{\SAMPLE123}|1^{\Test1^{\2^{Test2^{\3^{Test3^{\4^{Test4^{\n}}}}}}|1/200909101353| \\ O|20090910125300|||||||20130715102431|Urine|Dr.Who|Department1||Dr.Tom|||||||F|||||<CR>$ 

#### L|1|N<CR>

When transferring QC results (QR for H-12), the following fields are used.

ASTM Field	Field Name	Field Contents	Max Length	Field Description
1#	Record Type ID	0	1	Record type ID
2	Sequence Number	Number	3	Sequence number
	Sample ID	String and number	20	Void and reserved.
3	Sample Tray No.	Number	2	Void and reserved.
	Sample Pos	Number	2	Void and reserved.
4	Instrument Specimen ID	String	29	Void and reserved.
	Assay No.	String	10	Test channel no.
5	Assay Name	String	15	Shortened Test Name
	Dilution Rate	Number	4	Void and reserved.
	Repeat Num	Number	2	Void and reserved.
6	Priority	R(routine)S (STAT)	1	Void and reserved. STAT or not

ASTM Field	Field Name	Field Contents	Max Length	Field Description
7	Requested Date and Time (Sample program creation date)	String	14	QC Request 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.
	No.	String	3	Control No.
	Name	String	15	Control name
	Batch No.	String	18	Lot No. of control
	Period of validity	String	8	Expiration date of control, e.g. 20090910
12	Average Concentration	Number	8	Control average
	Level	H for high; M for medium, L for low.	1	Concentration level of control.
	Standard Diff.	Number	8	Standard deviation of control
	Concentration	Number	25	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	10	Void and reserved.

ASTM Field	Field Name	Field Contents	Max Length	Field Description
		Blood		
		Amniotic		
		Urethral		
		Saliva		
		Cervical		
		Synovial		
	Ordering Physician			Void and reserved.
17	Last Name	String	20	Void and reserved.
17	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.
	User Field #2			Void and reserved.
20	Last Name	String	20	Void and reserved.
20	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.
		O (request from) Q (query	1	
26	Report Type	response) F (final result)		Report type
		X (sample rejected)		
27	Reserved Field		-	Void and reserved.
28	Location Specimen		-	Void and reserved.
20	Collected			void and reserved.

ASTM Field	Field Name	Field Contents	Max Length	Field Description
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|\^&|||Mindray^\||||||<mark>QR</mark>|1394-97|20090910102501<CR>

P|1||||||||||<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 Conter		Max Lengt h	Field Description	
1#	Record Identifier	R	1	Record type ID	
2	Sequence Number	1-n	3	Sequence number	
	Assay No.#	String	10	Test Channel No.	
	Assay Name	String	50	Full Test Name	
3#	Replicate number	Number	2	Void and reserved. Result replicate	
	Result Type	I: Qualitative result value	1	Result type	
	Tresum Type	F: Qualitative result value	'	result type	
4	Measurement Value	Number (quantitative)	25	Quantitative final test result. Valid only when test type is F0x0fffffff means invalid value	
	Interpretation	String	10	Qualitative final test	

ASTM Field	Field Name	Field Contents	Max Lengt h	Field Description
		(Negative(-), Positive(+), Weak positive(+-)etc)		result. or qualitative flag is used for quantitative test result or optimized result. If they coexist, it stands for qualitative flag.
	SI L Value	turbidity (L)	25	Void and reserved. Serum index final result L
	SI H Value	hemolysis (H)	25	Void and reserved. Serum index final result H
	SI I Value	icterus (I)	25	Void and reserved. Serum index final result I
	Units	String	12	Unit
	Measurement Range Upper Limit	Number	12	Blank. Reference range high
	Measurement Range Lower Limit	Number	12	Blank.Reference range low
7	Result Abnormal flag	L (result< reference range) H (result> reference range) N - Normal	1	Fixed as N. Abnormal result flag
8	Nature of Abnormality Testing	String	10	Qualitative reference value. Valid when the result type is I.
9#	Result Status	F( final result)	1	Status of result
	Measurement Value	Number (quantitative)	25	Quantitative original test result, valid only when result type is F) The value" -0x0fffffff" means invalid value.
10	Interpretation	String (Negative-, Positive+, weak Positive +-, etc)	10	Qualitative original test result, valid only when result type is I)
	SI L Value	turbidity (L)	25	Void and reserved. Original result of serum index L
	SI H Value	hemolysis (H)	25	Void and reserved.Original

ASTM Field	Field Name	Field Contents	Max Lengt h	Field Description
				result of serum index H
	SI I Value	icterus (I)	25	Void and reserved. Original result of serum index I
11	Operator Identification	Number 1 - Rerun result 0 - Not rerun result	1	Flag of rerun result.
12	Date/time test started	String	14	Test finish time
13	Date/Time test Completed	String	14	Void and reserved.Test finish time
14	Instrument Identification (Sender Name)	String Such as LIS or CLXXXX	16	Sender. Fixed as Mindray
	Device ID	number	10	Reserved and void. Instrument ID

#### Example:

Send sample test result (Instrument => Host)

H|\^&|||Mindray^^|||||||PR|1394-97|20090910102501<CR>

 $R|1|1^CA125^F|10000.000000^\\ |U/mL|^N||F|1074051.882311^\\ |0|20130715102938||Mindray^CR>$ 

 $R|2|2^TPSA^F|5547.808063^{\wedge \wedge \wedge}|ng/mL|^{|N||F|5547.808063^{\wedge \wedge \wedge}|0|2013071510302||Mindray^{<}CR>$ 

L|1|N<CR>

Note: Field No.11 is used to identify rerun result. If the result of the fourth field is invalid value, please refer to the result of the string.

#### 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 Lengt h	Field Description
1#	Record Identifier	С	1	Record type ID
2	Sequence Number	1-n	3	Sequence number
3	Comment Sourc	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|\^&|||Mindray^\|||||||PR||1394-97|20090910102501<CR>

 $O|1|1^{\SAMPLE123}|1^{\Test1^{\2^{Test2^{\3^{Test3^{\4^{Test4^{\n}}}}}}|1/200909101353} \\ O|20090910125300||||||20130715102431|Urine|Dr.Who|Department1||Dr.Tom|||||| F|||||<CR>$ 

 $R|1|1^CA125^F|10000.000000^{1/2}|U/mL|^N||F|1074051.882311^{1/2}|0|20130715102938||Mindray^CR>$ 

 $R|2|2^TPSA^F|5547.808063^{\circ}|ng/mL|^|N||F|5547.808063^{\circ}|0|20130715103002||Mindray^CR>$ 

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

L|1|N<CR>

# Request Record- "Q"

Request Record is used to send inquiring sample request information 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
2	Sequence Number	1-n	3	Sequence number
3	Patient ID	String	30	Void and reserved.Patient ID
	Specimen ID	String	27	Sample bar code
4	Ending Range ID		20	Start sample ID
5	Universal Test Id		20	End sample ID. It is same as the start ID when a single sample is queried.
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	1	Inquire order code

If field 3 is not blank, the query is performed based on sample bar code; if field 3 is blank while field 4 is not blank, the query is performed based on sample ID, with field 5 as the end sample ID. Query can be done for certain sample ID range. If both fields 3 and 4 are blank, query will be performed based on time range.

#### Example:

Send and cancel request record (Instrument => Host)

H|\^&|||Mindray\^||||||RQ|1394-97|20090910102501<CR>

```
Q|1|^SAMPLE123||||||||O<CR>
L|1|N<CR>
```

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

(Host => Instrument)

H|\^&|||Mindray^\||||||QA|1394-97|20090910102501<CR>

L|1|I<CR>

Return inquired sample information record (Host  $\Rightarrow$  Instrument) H\\^&\||Mindray^\\|||||SA|1394-97|20090910102501<CR>

 $P|1||PATIENT111||Smith^{\ }||19600315^{\ }45^{\ }Y|M||keshi|||||||zhenduan||01|||||A1|002|||||||||< CR>$ 

 $O|1|1^{SAMPLE123}|1^{Test1^{2}Test2^{3}Test3^{4}Test4^{R}|20090910135300|20090910125300||||||20130715102431|Urine|Dr.Who|Department1||Dr.Tom||||||Q|||||CR>$ 

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 Lengt h	Field Description
1#	Record Identifier	С	1	Record type ID
2	Sequence Number	1-n	3	Sequence number
	Terminator code	N=normal termination		Termination code
		I=No information	1	
		available from the		
3#		last query.		
		<b>Q</b> =Error for in		
		last request for		
		information		

Example:

Send termination record (Instrument => Host)

H|\^&|||Mindray^\||||||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.

INSTRUM ENT:	<enq></enq>
HOST:	<ack></ack>
INSTRUM ENT:	<stx>1H \^&amp;   Mindray^^      PR 1394-97 20090910102501&lt; CR&gt;</stx>
	P 1  PATIENT111  Smith^^  19600315^45^Y M  keshi       zhe nduan  01     A1 002         <cr></cr>
	O 1 1^\ SAMPLE123 1^CA125^\\2^CA126^\\3^TPSA^\4^HI V^\ R 20090910135300 20090910125300       201307151024 31 Urine Dr.Who Department1  Dr.Tom      F      <cr></cr>
	R 1 1^CA125^^F 10000.000000^^^^ U/mL ^ N  F 1074051.882 311^^^ 0 20130715102938  Mindray^ <cr></cr>
	R 2 2^CA126^F 10000.000000^^^ U/mL ^ N  F 1074051.882 311^^^ 0 20130715102938  Mindray^ <cr></cr>
	R 3 3^TPSA^^F 5547.808063^^^\ ng/mL ^ N  F 5547.808063^ ^^ 0 20130715103002  Mindray^ <cr></cr>
	R 4 4^HIV^^F 5547.808063^^^\ ng/mL ^ N  F 5547.808063^^^ ^ 0 20130715103002  Mindray^ <cr></cr>

	L 1 N <cr><etx><cs><cr><lf></lf></cr></cs></etx></cr>
HOST:	<ack></ack>
INSTRUM ENT:	<eot></eot>

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

INSTRUM ENT:	<enq></enq>
HOST:	<ack></ack>
INSTRUM ENT:	<stx>1H \^&amp;   Mindray^^      PR 1394-97 20090910102501<cr><etb>&lt; CS&gt;<cr><lf></lf></cr></etb></cr></stx>
HOST:	<ack></ack>
INSTRUM ENT:	<stx>2P 1  PATIENT111  Smith^^  19600315^45^Y M  keshi        zhendu an  01     A1 002        <cr><etb><cs><cr><lf></lf></cr></cs></etb></cr></stx>
HOST:	<ack></ack>
INSTRUM ENT:	<pre><stx>30 1 1^\SAMPLE123 1^CA125^\2^CA126^\3^TPSA^\4^HIV^\  R 20090910135300 20090910125300      20130715102431 Urine Dr.Who  Department1  Dr.Tom      F     <cr><etb><cs><cr><lf></lf></cr></cs></etb></cr></stx></pre>
HOST:	<ack></ack>
INSTRUM ENT:	<stx>4R 1 1^CA125^^F 10000.000000^^^^ U/mL ^ N  F 1074051.88231 1^^^ 0 20130715102938  Mindray^<cr><etb><cs><cr><lf></lf></cr></cs></etb></cr></stx>
HOST:	<ack></ack>
INSTRUM ENT:	<stx>5R 2 2^CA126^F 10000.000000^^^\U/mL ^ N  F 1074051.88231 1^^^\0 20130715102938  Mindray^<cr><etb><cs><cr><lf></lf></cr></cs></etb></cr></stx>
HOST:	<ack></ack>
INSTRUM ENT:	<stx>6R 3 3^TPSA^^F 5547.808063^^^\ ng/mL ^ N  F 5547.808063^^^\ 0 20130715103002  Mindray^<cr><etb><cs><cr><lf></lf></cr></cs></etb></cr></stx>
HOST:	<ack></ack>
INSTRUM ENT:	<stx>7R 4 4^HIV^^F 5547.808063^^^ ng/mL ^ N  F 5547.808063^^^ 0  20130715103002  Mindray^<cr><etb><cs><cr><lf></lf></cr></cs></etb></cr></stx>
HOST:	<ack></ack>
INSTRUM ENT:	<stx>8L 1 N<cr><etx><cs><cr><lf></lf></cr></cs></etx></cr></stx>
HOST:	<ack></ack>

INSTRUM	<eot></eot>		
ENT:			

# 2.3.2 Sending Sample Inquiry

It will be sent as a whole

INSTRUM ENT:	<enq></enq>
HOST:	<ack></ack>
INSTRUM ENT:	<stx>1H \^&amp;   Mindray^^      RQ 1394-97 20090910102501<cr> Q 1 ^SAMPLE123         O<cr> L 1 N<cr><etx><cs><cr><lf></lf></cr></cs></etx></cr></cr></cr></stx>
HOST:	<ack></ack>
INSTRUM ENT:	<eot></eot>

It will be sent separately.

INSTRUM ENT:	<enq></enq>
HOST:	<ack></ack>
INSTRUM ENT:	<stx>1H \^&amp;   Mindray^^      RQ 1394-97 20090910102501<cr><etb> <cs><cr><lf></lf></cr></cs></etb></cr></stx>
HOST:	<ack></ack>
INSTRUM ENT:	<stx>2Q 1 ^SAMPLE123         O<cr><etx><cs><cr><lf></lf></cr></cs></etx></cr></stx>
HOST:	<ack></ack>
INSTRUM ENT:	<stx>3L 1 N<cr><etx><cs><cr><lf></lf></cr></cs></etx></cr></stx>
HOST:	<ack></ack>
INSTRUM ENT:	<eot></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></enq>
INSTRUM ENT:	<ack></ack>
HOST:	<stx>1H \^&amp;   Mindray^^      SA 1394-97 20090910102501<cr></cr></stx>
	P 1  PATIENT111  Smith^^  19600315^45^Y M  keshi       zhenduan  01      A1 002         <cr></cr>
	O 1 1^\SAMPLE123 1^CA125^\\2^CA126^\\3^TPSA^\4^HIV^\ R 20090 910135300 20090910125300       20130715102431 Urine Dr.Who Depart ment1  Dr.Tom      F      <cr></cr>
	L 1 N <cr><etx><cs><cr><lf></lf></cr></cs></etx></cr>
INSTRUM ENT:	<ack></ack>
HOST:	<eot></eot>

It will be sent separately.

HOST:	<enq></enq>
INSTRUM ENT:	<ack></ack>
HOST:	<stx>1H \^&amp;   Mindray^^       SA 1394-97 20090910102501<cr><etb>&lt; CS&gt;<cr><lf></lf></cr></etb></cr></stx>

INSTRUM ENT:	<ack></ack>
HOST:	<stx>2 P 1  PATIENT111  Smith^^  19600315^45^Y M  keshi        zhenduan  01      A1 002        <cr></cr></stx>
	<etb><cs><cr><lf></lf></cr></cs></etb>
INSTRUM ENT:	<ack></ack>
HOST:	<pre><stx>30 1 1^\SAMPLE123 1^CA125^\2^CA126^\3^TPSA^\4^HIV^\  R 20090910135300 20090910125300      20130715102431 Urine Dr.Who  Department1  Dr.Tom      F     <cr><etb><cs><cr><lf></lf></cr></cs></etb></cr></stx></pre>
INSTRUM ENT:	<ack></ack>
HOST:	<stx>4L 1 N<cr><etx><cs><cr><lf></lf></cr></cs></etx></cr></stx>
INSTRUM ENT:	<ack></ack>
HOST:	<eot></eot>

If LIS system returns inquired sample information, the  $26^{th}$  field of O record is set to Q; If LIS system send sample information to the chemiluminescence immunoassay analyzer, the  $26^{th}$  record of O record is set to O.

P/N: 046-005640-00(2.0)