TRANSASIA BIO-MEDICALS LTD

XL-200(Clinical Chemistry Analyzer)

ASTM - Host Interface Document

Version: 2.0

VERSION CONTROL:

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This manual was created by the Transasia Bio-Medicals Ltd Research and Development Department.

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OVERVIEW:

Purpose:

This Document details the specifications for ASTM Host Interconnection and communication for Clinical Chemistry analyzer by Transasia Bio-Medicals Lid.

Scope:

Detailed information on operation of the system is beyond the scope of this document. The information offered here is strictly to aid programmers in grasping very basic operational features of the analyzer.

Conventions:

This document consists primarily of a series of examples that show the information needed to successfully interface to the system. The basic concept of data transfer in this interface is the exchange of data and control frames between the host system and the analyzer.

Primary Reference:

E1381 – 02

Low-Level Protocol to Transfer Messages between Clinical Laboratory Instruments and Computer Systems.

E1394 – 97

Transferring Information Between Clinical Instruments and Computer Systems.

INTERCONNECTION DIAGRAM:

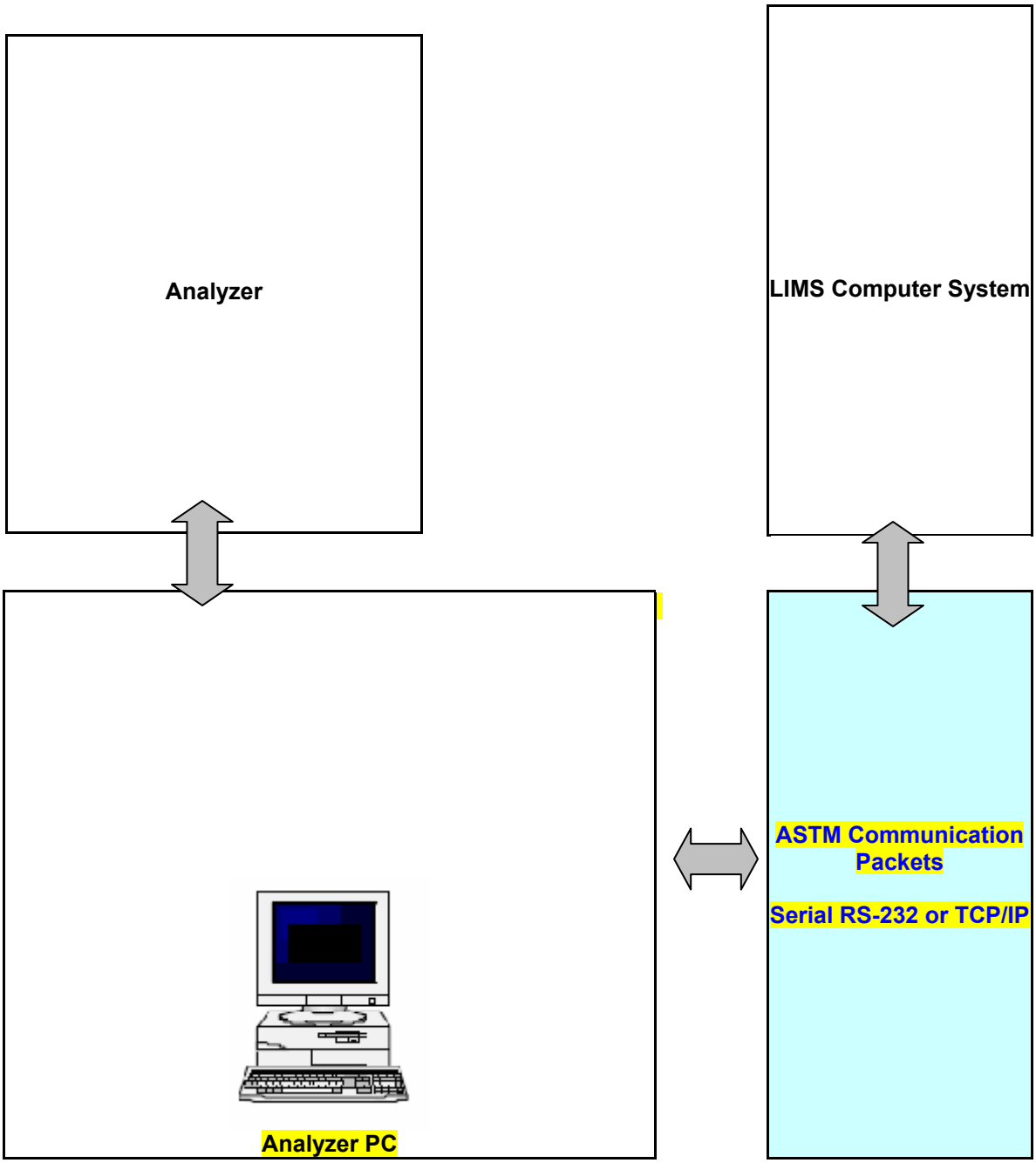


Fig (2.0) ASTM Interconnection with LIMS Computer System

OSI (Open System Interconnection) Layers:

Application Layer	**Application Software**
Presentation Layer	
Session Layer	
Transport Layer	MsComm (VBA Component) or TCP/IP (Win socket)
Network Layer	
DataLink Layer	ANSI X3.4-1986 standards. / IEEE 802.3 standards. **Frame Structure:** <STX> FN text <ETX> C1 C2 <CR><LF>: End Frame Or <STX> FN text <ETB> C1 C2 <CR><LF>: Intermediate frame. (For messages greater than 1024 characters) FN = Frame No.
Physical Layer	**RS232 / Fast Ethernet (TCP/IP)** Electrical Characteristics: EIA-232-D-1986 standards. Serial: 9600 BAUD, 8-bit, No Parity, 1 Stop Bit. TCP/IP: 10MBPs Connectors: DB9 / DB25 or RJ45.

PHYSICAL LAYER:

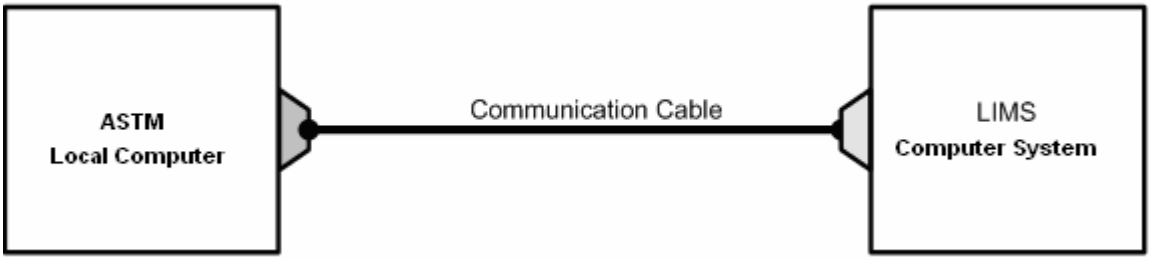
1. ASTM provides an option of RS232C : Serial Communication for the user to connect with LIMS Computer System.

RS232C (Serial Communication)

Communication Specifications:

Transmission Method	RS232C asynchronous, half duplex.
Transmission Rate	1200, 2400, 4800, 9600, 19200 bps
Transmission Code	ASCII
Data Length	7 bits, 8 bits
Parity	Even, Odd, None
Stop Bit	**1 bit**, 2 bit

Connections:



Connector:

D-SUB 9-Pin Connector (Male) on Standard PC
D-SUB 9-Pin Connector (Female): for Communication Cable.

Pin Assignment: Communication Cable

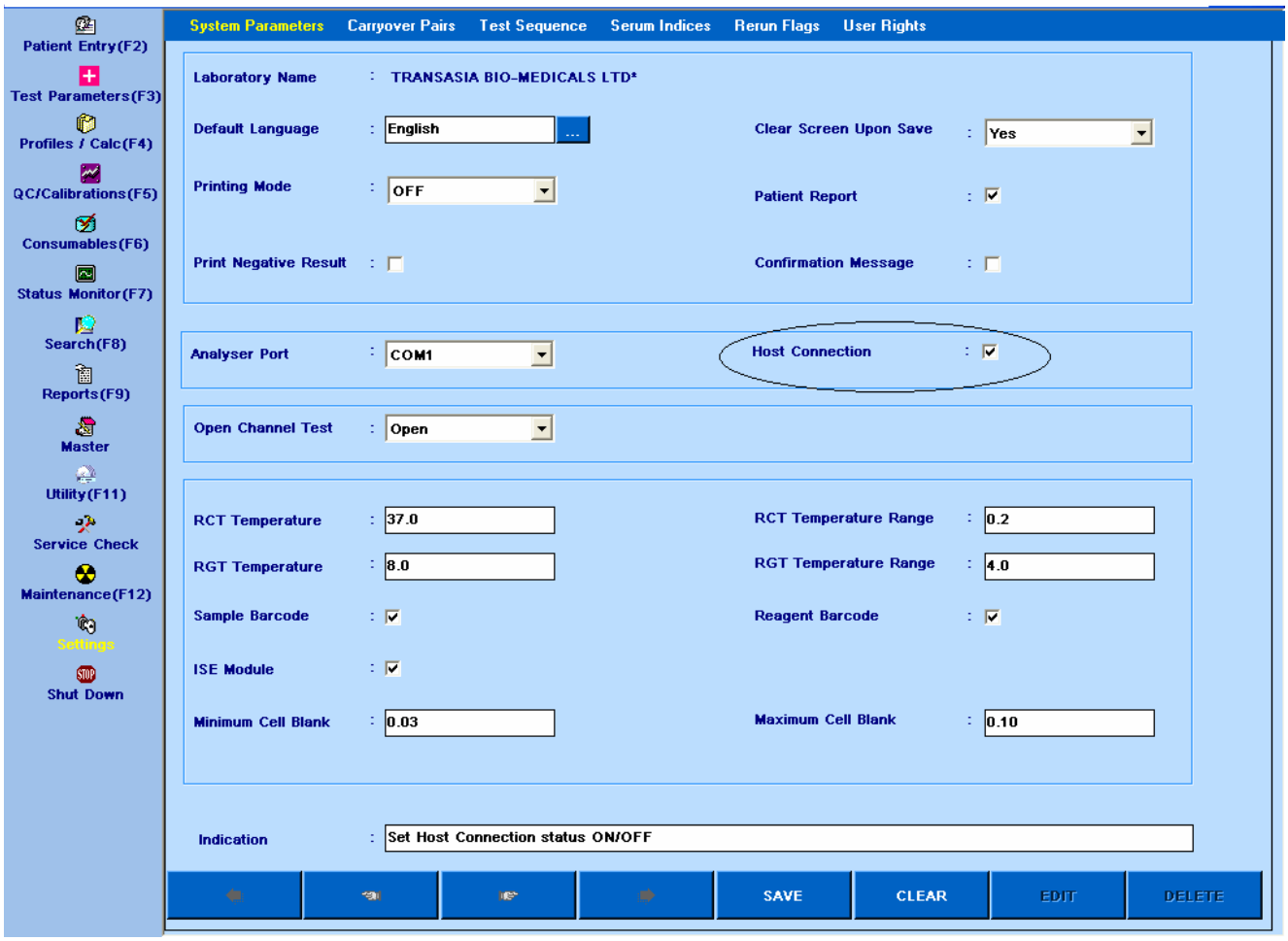
D-SUB 9-Pin			D-SUB 9-Pin	
Frame GND	1		1	Frame GND
Receive Data	2	⇐	3	Transmit Data
Transmit Data	3	⇒	2	Receive Data
Data Terminal Ready	4	⇐	6	Data Set Ready
Signal GND	5	⇔	5	Signal GND
Data Set Ready	6	⇒	4	Data Terminal Ready
Request to Send	7	⇒	8	Data Set Ready
Data Set Ready	8	⇐	7	Request to Send
NC	9		9	NC

NOTE: For 25-Pin Connector consider following Pin details:

Pin		Description
1		Frame GND
2	TXD	Transmit Data
3	RXD	Receive Data
4	RTS	Request to Send
5	CTS	Clear to Send
6	DSR	Data Set Ready
7	GND	Signal GND
20	DTR	Data Terminal Ready

MODIFYING HOST SETTINGS:

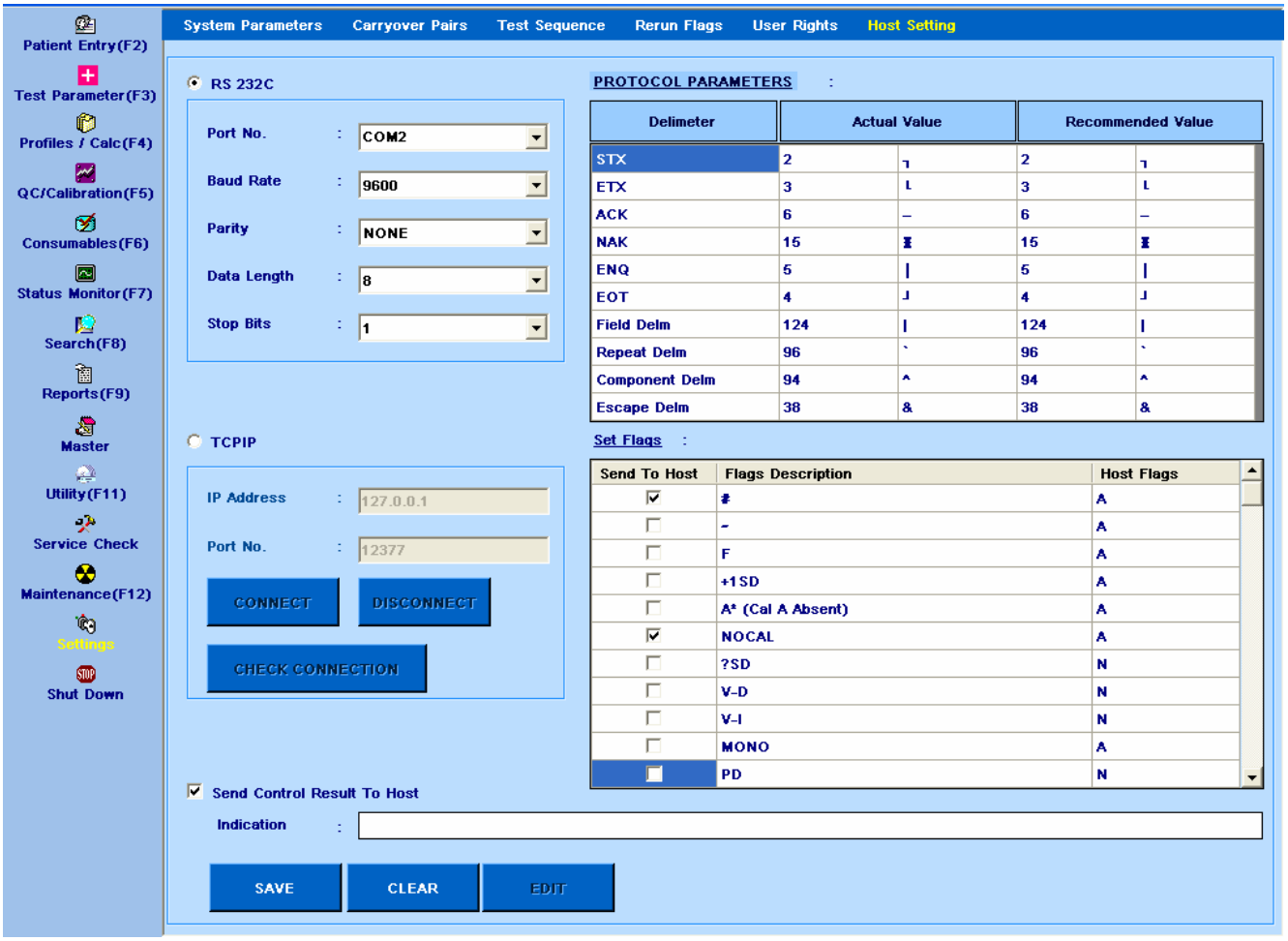
Go to Settings Window and select “Host Connection”



Go to Host Setting. If ‘Host Setting’ menu is not visible click on Settings again .
There are two modes of Communication

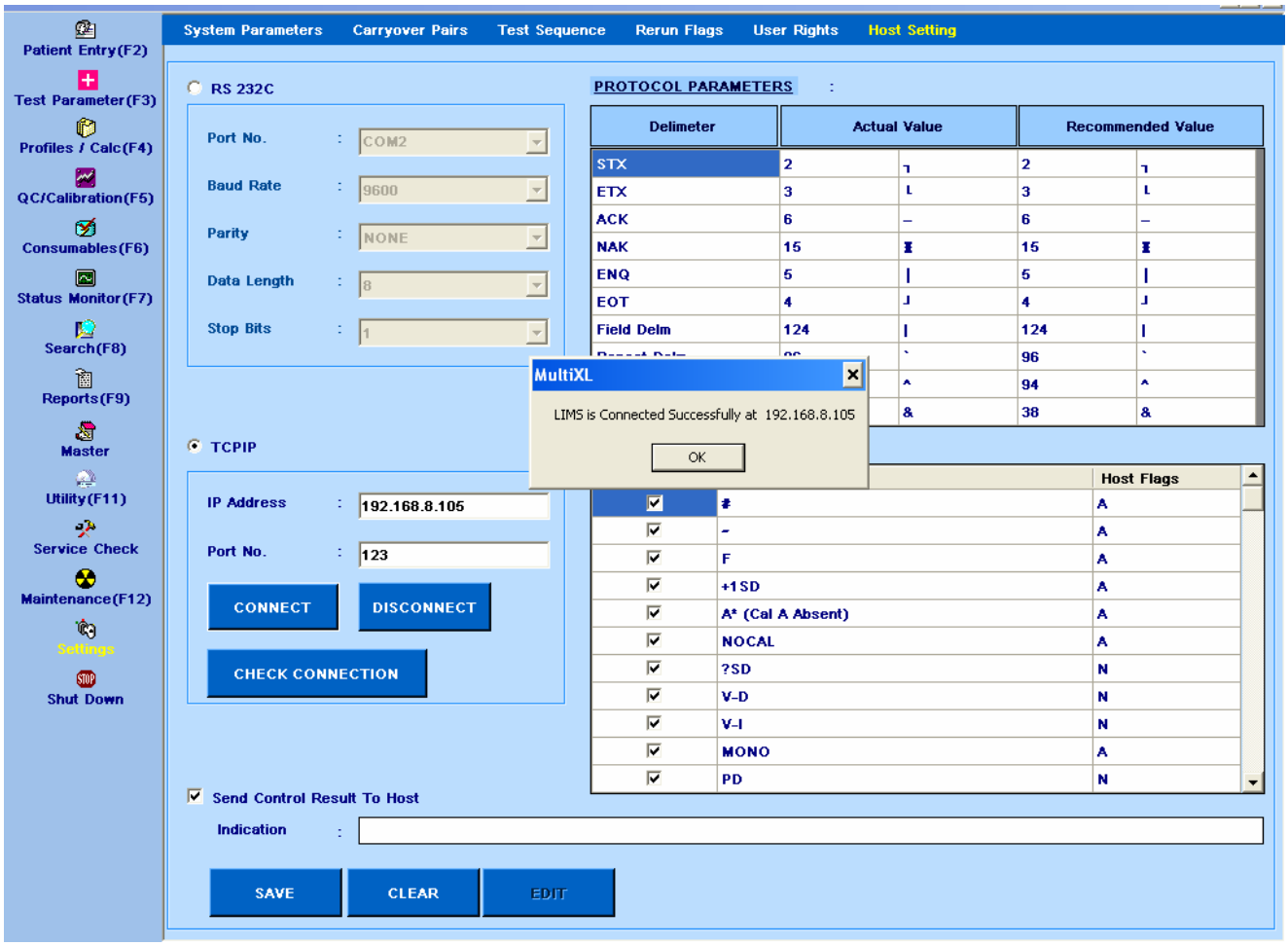
1. **RS232 for Serial Communication**

Select RS232 Option for Serial Communication. Select ‘Send Control Result To Host’
If want to send Control Result. Select ‘Send To Host’ option for sending result with selected flag.

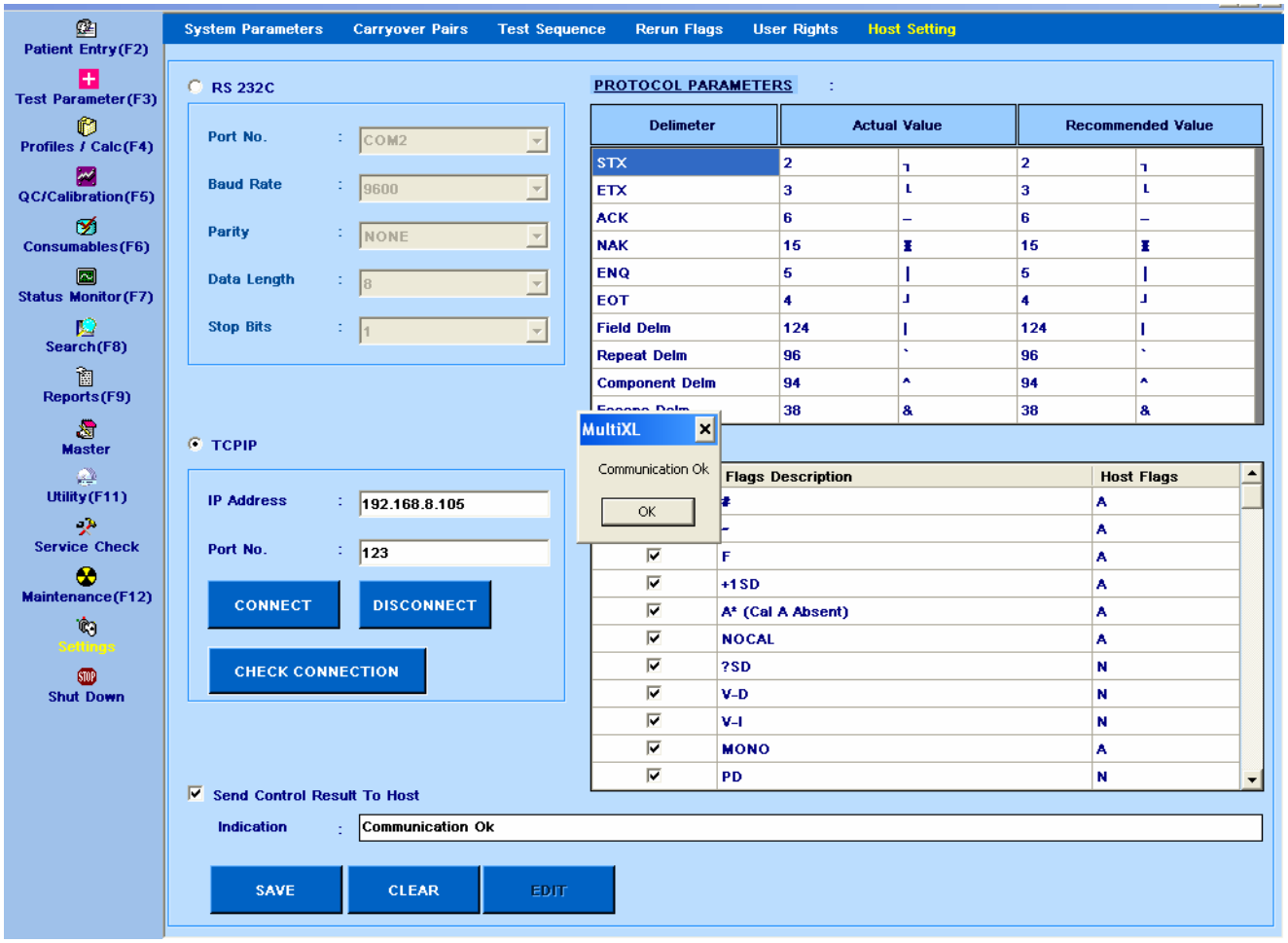


2. **TCP/IP**

Select TCPIP Option for TCP/IP Communication. Enter the IP address of the machine in which LIMS is running. After clicking on ‘ CONNECT’ LIMS Connected successfully message will come



If LIMS is not connected Successfully then click on ‘Check Connection’ and check the status of Communication.



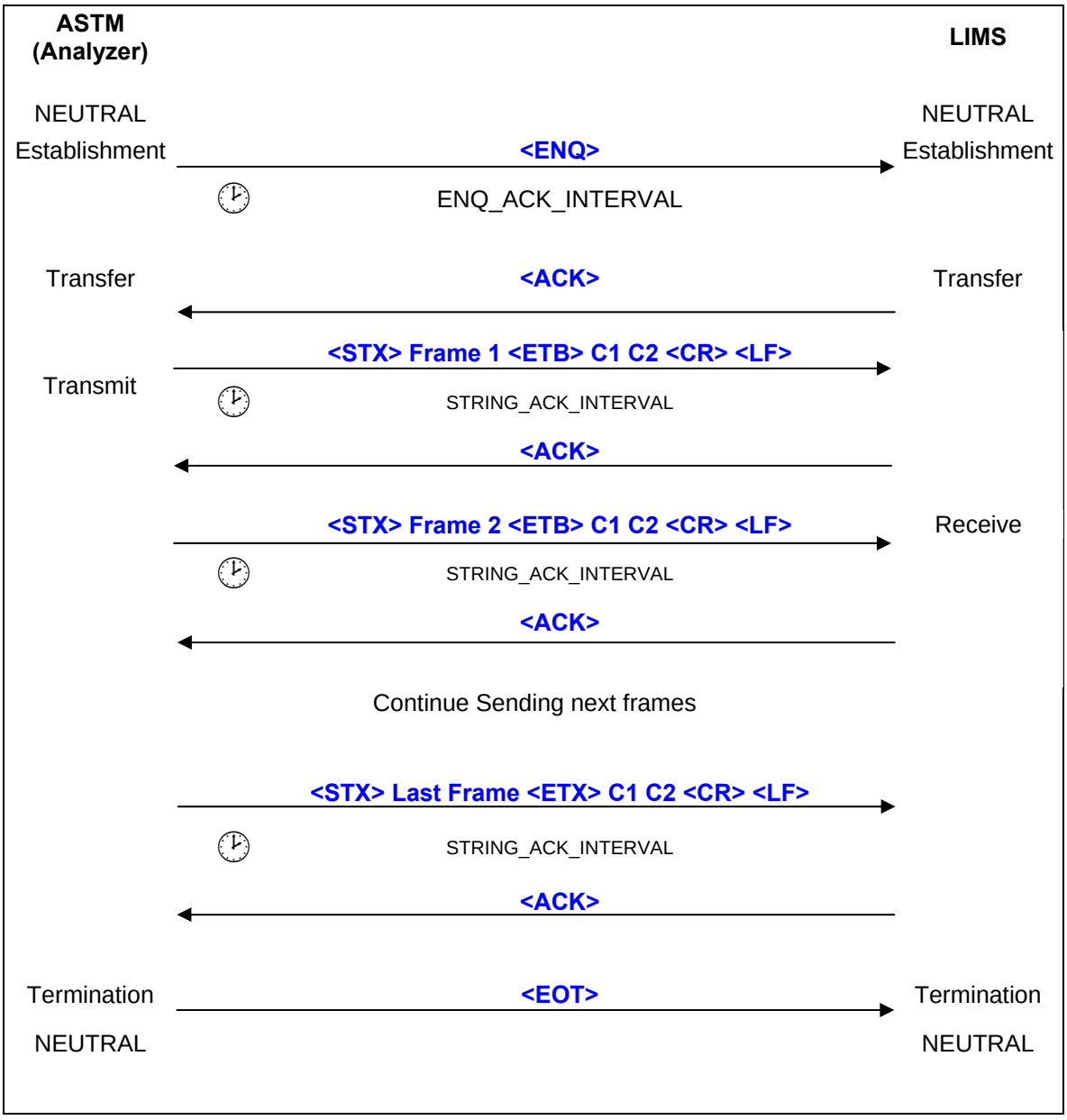
ASTM Lower Level Communication Methodology:

Item	Method	Explanation
Frame Configurations	For Middle Frame <STX> FN text <ETB> C1 C2 <CR><LF> For Last Frame <STX> FN text <ETX> C1 C2 <CR><LF>	Control character (characters enclosed in <>): <STX> is control character (HEX 02) <ETB> is control character (HEX 17) <CR> is control character (HEX 0D) <LF> is control character (HEX 0A) <ETX> is control character (HEX 03) FN: FN is a single ASCII number. FN indicates the sequence number for a frame (the frame number modulus 8). Frames of a single transmission phase are consecutively numbered beginning with 1, so FN runs from 1 to 7, then continues with 0, 1, and so on. Text: the data content of a frame (maximum 1024 characters). Records are sub-divided into intermediate (middle) frames with 1024 or fewer characters. Text is part of a split message. C1 and C2: When 1 byte resulting from adding each byte, FN to <ETB> for the middle frame and FN to <EXT> for the last frame, is expressed in hexadecimal, the upper character (161) is C1 and the lower character (160) is C2. Characters used are '0' to '9' or 'A' to 'F'
Frame Character Configuration of Text	Characters other than <SOH><STX><ETX> <EOT><ENQ><ACK> <DLE><NAK><SYN> <ETB><LF><DC1> <DC2><DC3><DC4>	<SOH> is control character (HEX 01) <EOT> is control character (HEX 04) <ENQ> is control character (HEX 05) <ACK> is control character (HEX 06) <DLE> is control character (HEX 10) <NAK> is control character (HEX 15) <SYN> is control character (HEX 16) <DC1> ~ <DC4> is control character (HEX 11 ~ 14)
Maximum Length of the Frame	1024 characters	For one frame, maximum of 1024 characters for text, 7 characters for frame control characters. Messages equal to or less than 1024 characters are transmitted as one final frame. Messages greater than 1024 characters are split into frames that have character lengths that fall within the 1024-character limit. The only or final remaining frame becomes the last frame and is indicated by <ETX>. All others are intermediate (middle) frames and are indicated by <ETB>.

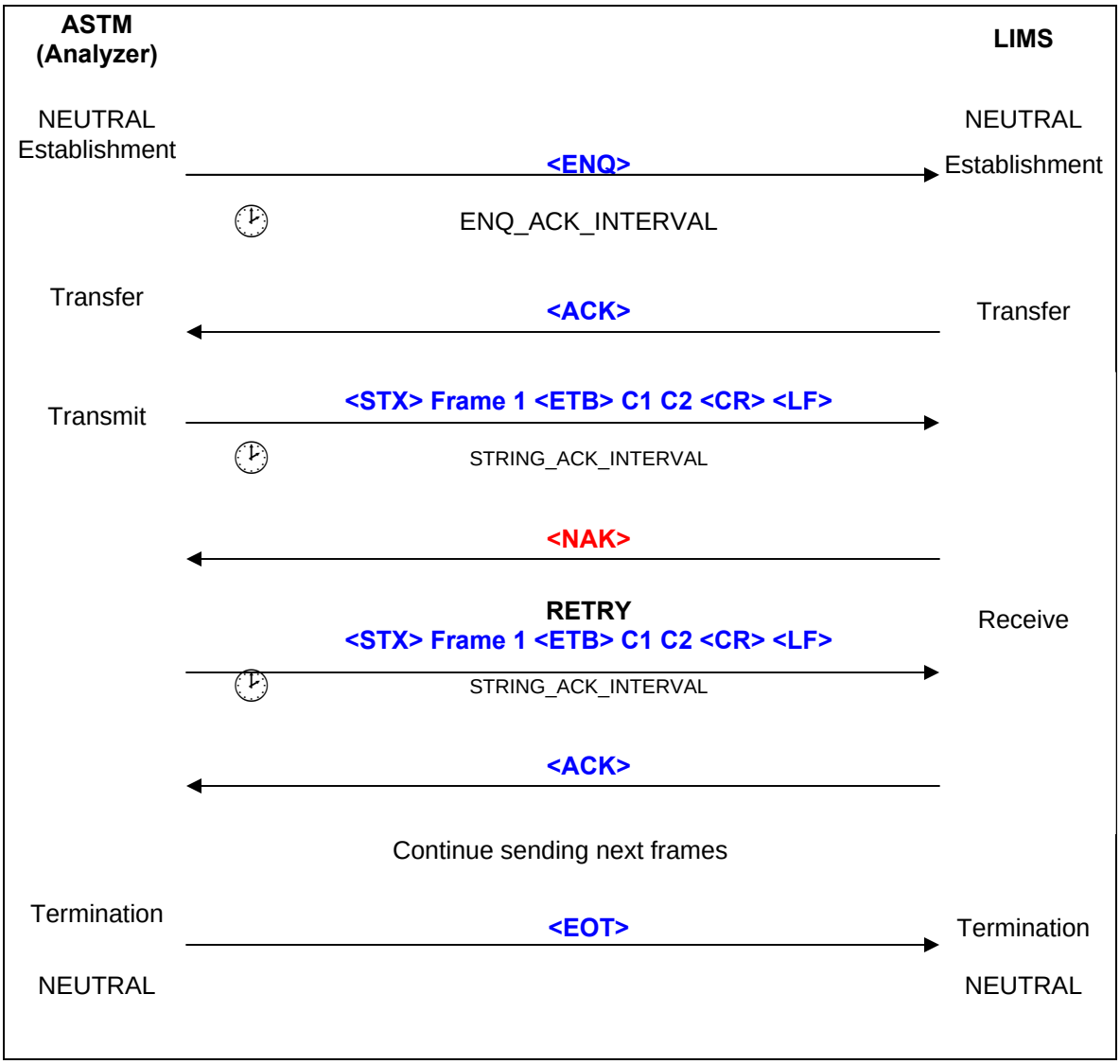
Data Flow Diagram:

Transmitting Message:

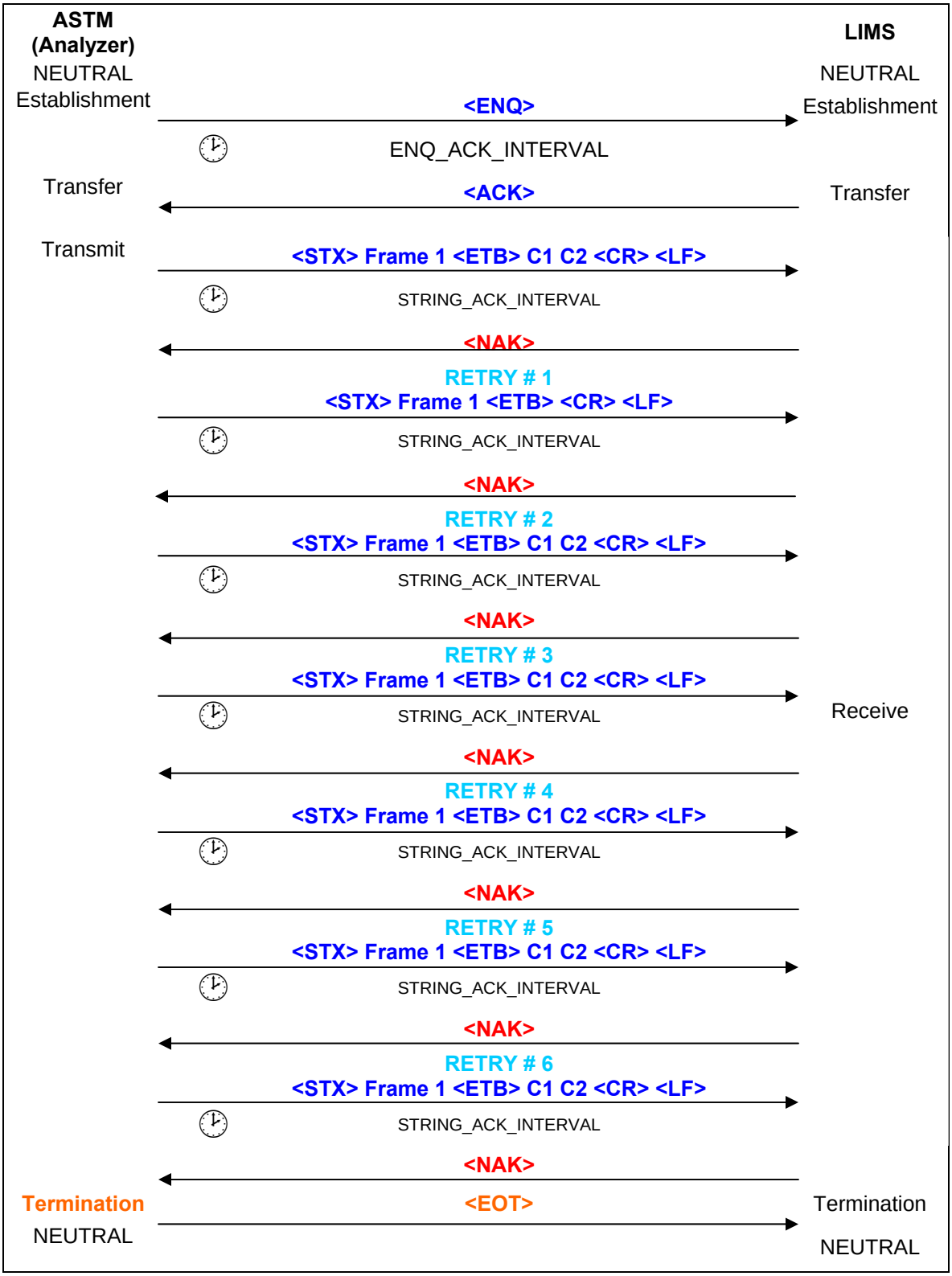
Case 1: Ideal Transmit Data.



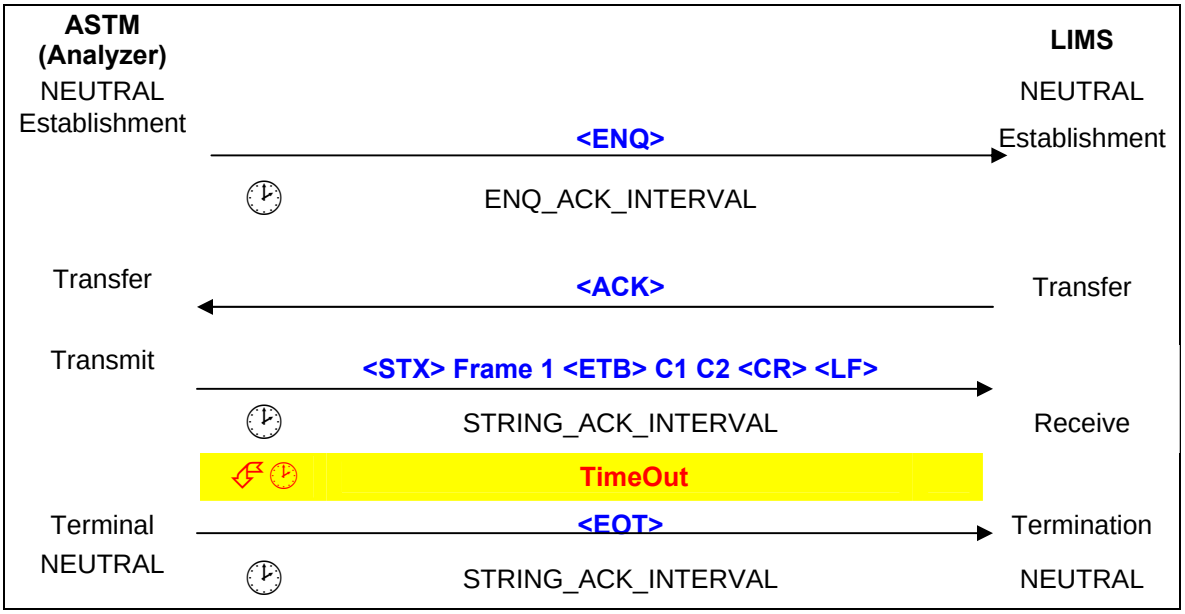
Case 2: <NAK> Received



Case 3: <NAK> Received for more than 6 times.

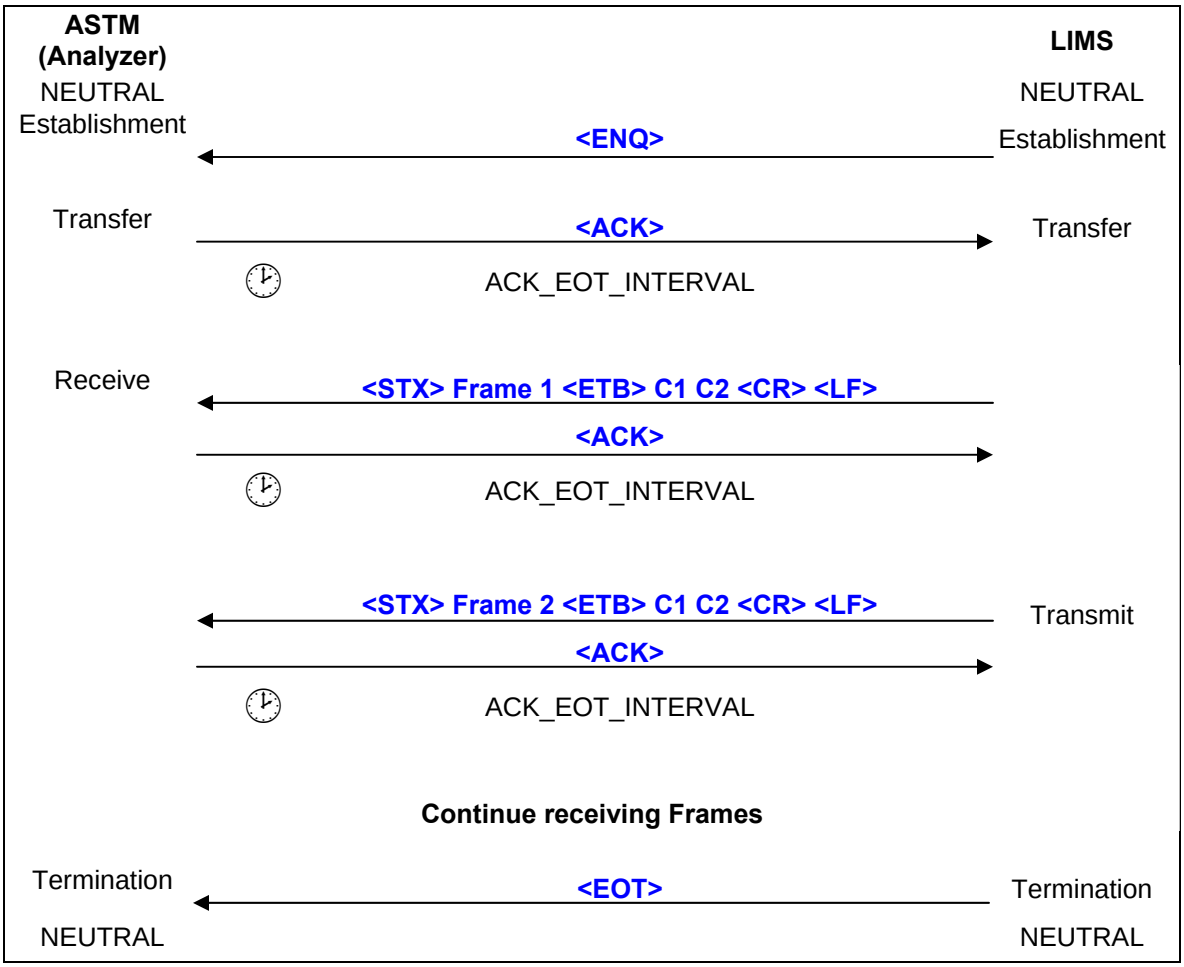


Case 4: Time out after sending frame.

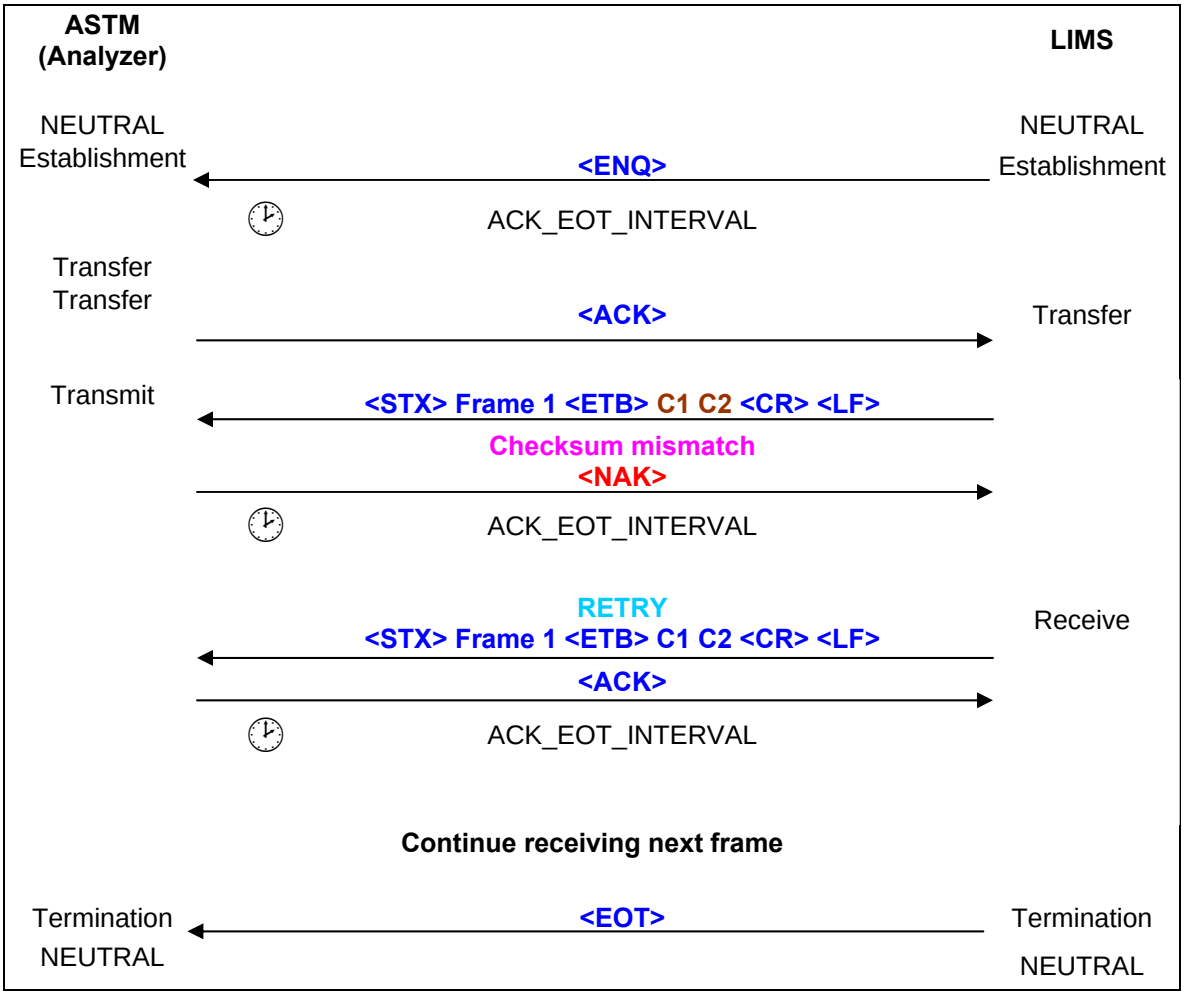


Receiving Message:

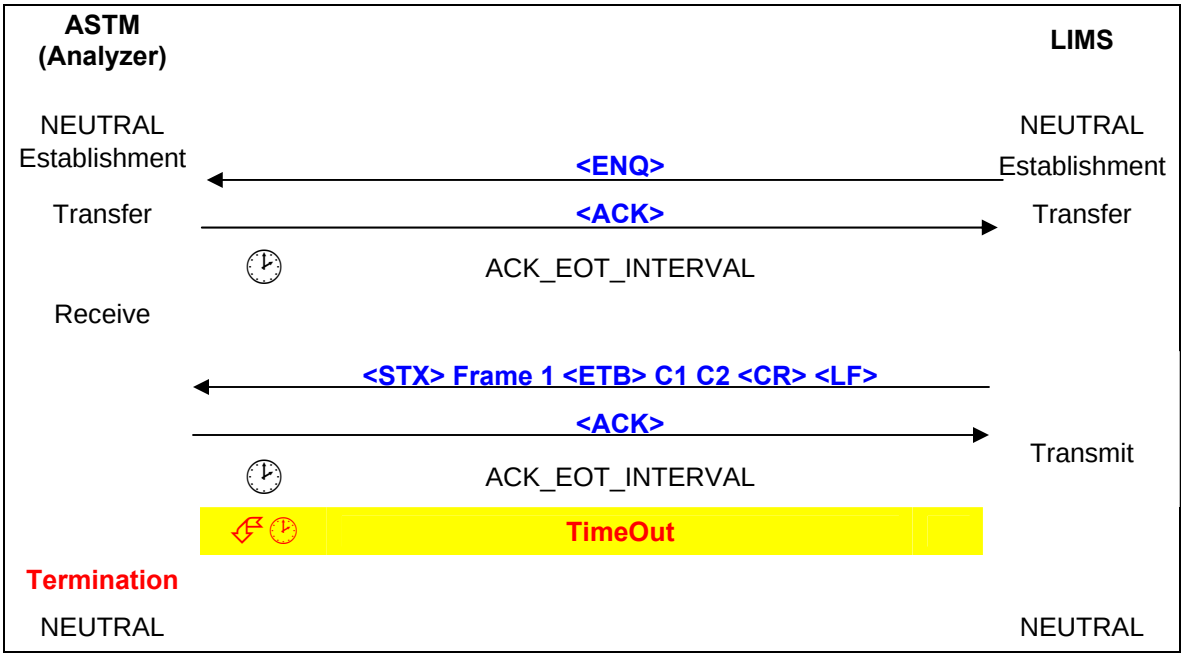
Case 1: Ideal Receive Data



Case 2: Checksum Mismatch



Case 3: Time Out after sending <ACK>



CHECKSUM CALCULATION:

Consider a message Frame to be transmitted:

<STX> FN Text Message <ETB> C1 C2 <CR> <LF>

Where:

- C1 & C2 Represents the high nibble (= most significant 4 bit) respectively, the low nibble (=least significant 4 bit) of the 8-bit checksum.
- C1 and C2 are represented as two digits of hex numbers.
- The checksum is the modulus 8 of the sum of ASCII values of the frame characters starting with and including 'FN' and completing with <ETX> respectively <ETB>.

Sample VB Code to calculate Checksum:

"strString" = FN Text Message <ETB>
strString consists of entire message string starting from Frame Number "FN" up till <ETB> or <ETB>.

```
For i = 1 To Len(strString)
   Checksum = Checksum + Asc(Mid$(strString, i, 1))
Next i

strCksm = Right$(Hex$(Checksum), 2)
If Len(strCksm) < 2 Then
   For i = Len(strCksm) To 1
      strCksm = "0" + strCksm
   Next i
End If
```

strCksm now holds the two byte checksum to be transmitted.

SPECIAL FUNCTION CHARACTER TABLE:

Decimal	Hex	Character
0	&H0	<NUL>
1	&H1	<SOH>
2	&H2	<STX>
3	&H 3	<ETX>
4	&H4	<EOT>
5	&H5	<ENQ>
6	&H6	<ACK>
7	&H7	<BEL>
8	&H8	<BS>
9	&H9	<TAB>
10	&HA	<LF>
11	&HB	<VT>
12	&HC	<FF>
13	&HD	<CR>
14	&HE	<SO>
15	&HF	<SI>
16	&H10	<DEL>
17	&H11	<DC1>
18	&H12	<DC2>
19	&H13	<DC3>
20	&H14	<DC4>
21	&H15	<NAK>
22	&H16	<SYN>
23	&H17	<ETB>
24	&H18	<CAN>
25	&H19	<EM>
26	&H1A	<SUB>
27	&H1B	<ESC>
28	&H1C	<FS>
29	&H1D	<GS>
30	&H1E	<RS>
31	&H1F	<US>

ASTM HIGHER LEVEL CONCEPT:

ASTM data is sent or received in terms of packets. Packet starts with the Header (H) and ends with the Terminator (L). Packet without header and terminator is treated as invalid and will be ignored.

ASTM Record Types :

Seq No.	Record Type	Convention	Used
1	Message Header Record	H	Y
2	Patient Information Record	P	Y
3	Test Order Record	O	Y
4	Result Record	R	Y
5	Comment Record	C	Y
6	Request Information Record	Q	Y
7	Scientific Record	S	N
8	Manufacturer Information Record	M	N
9	Message Terminator Record	L	Y

Example :

H|`^&||Password1|Micro1|||||LSI1||P|139-94|19890501074500<CR>
P|1||52483291<CR>
O|1|5762^01||^^^BC ^^POSCOMBO||||||||||BL|||||||||F<CR>
R|1|^^^ORG#|103^Group D Entero<CR>
R|2|^^^AM^MIC|>16<CR>
R|3|^^^AM^INTERP1|++<CR>
R|4|^^^AM^DOSAGE1|PO 250.500 mg Q6h<CR>
.
.
.
R|90|^^^BIOTYPE|102-34021<CR>
L|1<CR>

Each record type has predefined fields. If any field has no data, it should be separated with delimiter. All the delimiters are defined in header.

This message is then passed to ASTM Lower level to be further spitted in to frames of specified lengths and transmitted to LIMS.

ASTM RECORDS:

* Fields mentioned in bold are mandatory.

1	Message Header Record	
	Fields	**String format**
1	**Record Type ID**	H
2	**Delimiter Definition**	|`^&
3	Message Control ID	Unique Number
4	Access Password	******
5	Sender Name Or ID	Manufacturer^Instrument1^Software or firmware version`Instrument2
6	Sender Street Address	Street Address^City^State^Zip^Country Code
7	Reserved Field	
8	Sender Telephone Number	Phone1`Phone2`Phone3 (It may contain areacode ,countrycode,beeper number,hours to call) e.g. +912212345678`+912212345679
9	Characteristics of sender	Contains Parity,Chechsums,operational protocols
10	Receiver ID	The name or Id of receiver
11	Comment /Special Instructions	
12	Processing ID	P/T/D/Q (At a time only one , default P)
13	Version No.	ASTM version No. 1394-97
14	Date and Time of message	current datetime YYYYMMDDHHMMSS
15	Carriage Return	<CR> End of the string

H|`^&||PSWD|Harper Labs|2937 Southwestern Avenue^Buffalo^NY^73205||319 412-9722||||P|1394-97|19890314<CR>

About Processing ID :

P–Production: Treat message as an active message to be completed according to standard processing.
T–Training: Message is initiated by a trainer and should not have an effect on the system.
D–Debugging: Message is initiated for the purpose of a debugging program.
Q–Quality Control: Message is initiated for the purpose of transmitting quality control/quality assurance or regulatory data.

About Delimiters :

i) Default Delimiters in Header (Point 2)

|	Field Delimeter (Alt + 124)
`	Repeat Delimeter (Alt + 96)
^	Component Delimeter (Alt + 94)
&	Escape Delimeter (Alt + 38)
♪	<CR> (Alt + 13)

ii) Delimiters can be changed .
iii) Allowed characters for delimiters. Alt + (7,9,11,12,13,32-126,128-254)
iv) Disallowed characters for delimiters : 0 - 6 ,8,10, 14 - 31 , 127 ,255
v) 13 is reserved for a record terminator (CR) and can not be used for any other purpose.
vi) All delimiters should have different values.
viii) Alphanumeric characters should not be used as delimiters.

2	Patient Record	
	Fields	**String format**
1	**Patient Record Number**	P
2	**Sequence Number**	Frame Number (only 1 digit)
3	**Practice Assigned Patient ID**	Patient ID
4	Laboratory Assigned Patient Id	
5	PatId3	
6	Patient Name	Name of the Patient (Last Name^First Name^Middle Name^Title)
7	Mother's maiden Name	Required to distinguish between patients with same birthdate and last name. This will be represented only with mother's maiden's surname
8	BirthDate	YYYYMMDDHHMMSS
9	Patient Sex	M/F/U (Male/Femal/Other)
10	Patient Race - Ethnic Origin	W`B`O`NA`H
11	Patient Address	Street Address^City^State^Zip^Country Code
12	ReservedField	
13	Patient Telephone No.	Phone1`Phone2`Phone3 (It may contain areacode ,countrycode,beeper number,hours to call) e.g. +912212345678`+912212345679
14	Attending Physician ID	(Ordering Physician`Attending Physician`Referring Physician)
		Physician IDNumber^Code (401-0^Merchant^Darshak^V`401-0^Mehta^Kantilal^^Shri)
15	SpecialField1	
16	SpecialField2	
17	Height	Height/Weight and Unit are separated by component delimiter. 1.2^mtr (default unit is cms for ht and for wt kg). Unit (mtr/kg) is optional , if the value is in default unit.
18	Weight	
19	Patient's known or Suspected Diagnosis	Either ICD -9 code or free text. Multiple diagnoses are separated by repeat delimiter.
20	Patient's Active Medications	Generic name can be used.
21	Patient's Diet	Free text. Indicate conditions that affect results of testing.
22	Practice Field No. 1	
23	Practice Field No. 2	
24	Admission and Discharge dates	Separated by repeat delimiter
25	Admission Status	OP/PA/IP/ER (Only 1 is allowed)
26	Location	Clinic location /Nursing Unit /Ward /Bed
27	Nature of Alternative Diagnostic Code and Classifiers	Identifies the class code
28	Alternative Diagnostic Code and Classification	Separated by Repeat delimiter
29	Patient Religion	P/C/M/J/L/H (Only 1)
30	Marital Status	M/S/D/W/A (Only 1)
31	Isolation Status	ARP/BP/ENP/NP/PWP/RI/SE/SI/WSP (Only 1)

32	Language	Patient's primary language
33	HospitalService	Both Code and text seperated by component delimiter
34	HospitalInstitution	
35	DosageCategory	A/P1/P2 (Only 1)
36	**Carriage Return**	<CR>

P|1|2462|158|287-17-2791|POHL^ALLEN^M|Samules|9600401|M|W|4526 C street^Fresno^CA^92304 ||(402)782-342X242|542^Dr.Brown|||72^in|175^lb||Penicillin|||| 19890428 |IP|Ward1|||C|M|WSP||ERR|PC ^ Prompt Care<CR>

About Admission Status :

OP (outpatient)
PA (preadmit)
IP (inpatient)
ER (emergency room).

About Patient Origin :

W white
B black
O asian/pacific islander
NA native american/alaskan native
H Hispanic

About Patient Religion :

P Protestant
C Catholic
M Church of the Latter Day Saints (Mormon)
J Jewish
L Lutheran
H Hindu

About Marital Status :

M married
S single
D divorced
W widowed
A separated

About Isolation Status :

ARP antibiotic resistance precautions
BP Blood and needle precautions
ENP Enteric precautions
NP Precautions for neutropenic patient
PWP Precautions for pregnant women
RI Respiratory isolation
SE Secretion/excretion precautions
SI Strict isolation
WSP Wound and skin precautions

About Dosage Category :

A–ADULT
P1–PEDIATRIC (1–6 months)
P2–PEDIATRIC (6 months–3 years).

3	Test Order Record	
	Fields	**String format**
1	**Test Order Identifier**	O
2	**Sequence Number**	Frame No.
3	**Speciman ID**	Sample ID^Container No. (Samp1^01)
4	Instrument Speciman ID	Unique identifier assigned by the instrument
5	**Universal Test ID**	Test Name (^^^ALB`^^^ALP`^^^LIVER)
6	**Priority**	S`A`R`C`P
		S : Stat (Immediate)
		A : As soon as possible
		R : Routine
		C : Callback
		P : PreOperative
7	Requested/Ordered Date And Time	Denote the date and time , the test order should be considered ordered. Future time is recorded here. (YYYYMMDDHHMMSS)
8	**Speciman collection Date and Time**	Actual date and time , the sample was collected (YYYYMMDDHHMMSS)
9	Collection End Time	End date and time of a timed speciman collection (YYYYMMDDHHMMSS)
10	Collection Volume	Sample Volume^Unit (default in ml)
11	Collector ID	The person and facility which collected the speciman
12	**Action Code**	**C : Cancel request for the battery or tests named (Delete Test)**
		A : Add the requested tests or batteries to the existing sample
		N : New requests accompanying a new sample
		P : Pending sample (Add but don't schedule)
		L : Reserved (Not in use)
		X : Sample or test already in process
		Q : Treat a sample as a Q/C test sample
13	Danger Code	Represents by either test or code , indicating any special hazard associated with the sample
14	Relevant clinical information	Additional information about the sample
15	Date/ Time Speciman Received	Date and Time recorded by laboratory
16	**Speciman Descriptor**	Sample Type ^ Sample Source
		Sample Type : Blood , Urine , Serum
		Sample Source : Sample source body site (left arm ,left hand , right lung)
17	Ordering Physician	Physician IDNumber^Code (401-0 ^ Thomas ^ John^V`401-0^Mehta^Kantilal^^Shri)

18	Physician's Telephone Number	Phone1`Phone2`Phone3 (It may contain area code ,country code, beeper number, hours to call) e.g. +912212345678`+912212345679
19	User Field No.1	
20	User Field No.2	
21	Laboratory Field No.1	
22	Laboratory Field No.2	
23	Date/ Time Result reported or Last modified	
24	Instrument charge to computer system	Accounting reference by the instrument for the tests performed
25	Instrument Section ID	In the case where the multiple instruments are on a single line or a test was moved from one instrument to another , this field will show which instrument or section of an instrument performed the test
26	**Report Types**	**O : Order Record , User asking analysis be performed**
		C : Correction of previously transmitted results (When sending results from Result Reprint)
		P : Preliminary results (Before Rerun)
		F : Final Results
		X : Order Cancelled (When order can not be performed)
		I : In Instrument Pending
		Y : No order on Record for this test (in response to query)
		Z : No record of this patient (In response to query
		Q : Response to a request-information query
27	Reserved Field	
28	Location or Ward of Speciman Collection	Ward of sample collection
29	Nosocomial Infection Flag	Hospital acquired infection
30	Speciman Service	Specific service responsible for the sample collection
31	Speciman Institution	Institution of sample collection
32	**Carriage Return**	<CR>

O|1|5762^01||^^^BC^BloodCulture^POSCOMBO|R|19890501530|198905020700|||456^Famsworth|N|||198905021130|BL^Blood|123^Dr.Wirth|||||||Instrument#1|||ERR|N<CR>

4	Result Record	
	Fields	**String format**
1	**Result Record Identifier**	R
2	**Sequence Number**	Frame No.
3	**Universal Test ID**	Test Name (^^^ALB) or (^^^LIVER^ALB)
4	**Data or Measurement Value**	Result value
5	Units	ISO 2955
6	Reference Ranges	Lower limit to Upper limit
7	**Result Abnormal Flags**	L: Below Low Normal
		H: Above High Normal
		LL: Below Panic Normal
		HH: Above Panic High
		<:Below absolute low
		>:Above absolute high
		N: Normal
		A: AbNormal
		U: Significant Change Up
		D: Significant Change Down
		B: Better, Use when direction not relevant or not defined
		W: Worse, Use when direction not relevant or not defined
8	Nature of Abnormality Testing	A :Age based population
		S :Sex based population
		R :Race based population
		N :Generic Normal Range was applied to all patients
9	Result Status	**C : Correction of previously transmitted results (Patient Report)**
		P : Preliminary results (Before Rerun)
		F : Final Results
		X : Order Cancelled (When test can not be preformed)
		I : In Instrument Pending
		S : Partial Results
		M : MIC Level Results
		R : Result was previously transmitted
		N : This result contains necessary information to run a new order
		Q : Response to a request-information query
		V: Operator verified / approved result
		W: Validity is questionable
10	Date of change in instrument Normative Values or Units	

11	Operator Identification	1st Component : Instrument Operator who performed the test
		2nd Component : Verifier for the test
12	Date / Time Test Started	YYYYMMDDHHMMSS
13	**Date / Time Test Completed (**Result Date**)**	YYYYMMDDHHMMSS
14	Instrument Identification	Identifies instrument or section of instrument that performed the test
15	**Carriage Return**	<CR>

R|1|^^^ALB|2.3|mg/dl<CR>

5	Comment Record	
	Fields	**String format**
1	**Comment Record Identifier**	C
2	**Sequence Number**	Frame No.
3	**Comment Source**	Comment Origination Point
		P : Practice
		L : Computer System (LIS)
		I : Instrument (ASTM)
4	**Comment Text**	Code ^Comment Text
5	**Comment Type**	**G : Generic/Free text comment**
		T: Test Name comment
		P: Positive Test Comment
		N: Negative Test comment
		I: Instrument Flag Comment
6	**Carriage Return**	<CR>

C|1|L|Notify IDC if tests positive|G<CR>

6	Request Information Record	
	Fields	**String format**
1	**Request Record Identifier**	Q
2	**Sequence Number**	Frame No.
3	**Starting Range ID Number**	PatID^SampleID1`SampleID2^Manufacturer defined Battery No. OR ALL . Use Repeat delimiter for multiple samples
4	Ending Range ID Number	PatID^SampleID
5	Universal Test ID	^^^ALB`^^^ALP / ALL
6	Nature of Request Time Limits	S : Sample Collection Date
		R : Result Test Date
7	Beginning Request Results Date And Time	This field represent either a beginning date and time for which results are being requested or a single date and time.
		YYYYMMDDHHMMSS`YYYYMMDDHHMMSS`YYYYMMDDHHMMSS
8	Ending Request Results Date And Time	If not null, specifies the ending or latest date and time for which results are being requested. If beginning date consists of multiple dates , then ending date should be null. (YYYYMMDDHHMMSS)
9	Requesting Physician Name	Physician IDNumber^Code (401-0 ^ Merchant ^ Darshak^V`401-0^Mehta^Kantilal^^Shri)
10	Requesting Physician Telephone Number	Phone1`Phone2`Phone3 (It may contain area code ,country code, beeper number, hours to call) e.g. +912212345678`+912212345679
11	User Field No. 1	
12	User Field No. 2	
13	**Request Information Status Codes**	**C : Correction of Previously transmitted results (Patient Report)**
		P : Preliminary Results (PreRerun results , for tests gone for Rerun)
		F : Final Result
		X : Request can not be done , request cancelled
		I : Results pending in instrument
		S : Request Partial / UnFinalized results
		M : Result is a MIC Level
		R : This Result was previously transmitted
		A : Abort/cancel last request criteria (allows a new request to follow)
		N : requesting new or edited results only (Modified from patient report or online/offline results but not transmitted to LIMS)
		O : Requesting test orders and demographics only
		D : Requesting demographics only (Patient record)
15	**Carriage Return**	<CR>

Q|1|032989326||ALL<CR>

7	Message Terminator Record	
	Fields	**String format**
1	**Message Terminator Record Identifier**	L
2	**Sequence Number**	1
3	**Termination Code**	Nil
		N : Normal Termination
		T : Sender Aborted
		R : Receiver Requested Abort
		E : Unknown System Error
		Q : Error in Last request for information
		I : No Information available from last query
		F : Last request for information processed

L|1|N<CR>

Data transferred from ASTM to LIMS :

1) Result Record :

Only **photometric** and **ISE** tests for **patient sample** and **controls** will be sent to LIMS. Standard and Blank results will not be sent to LIMS.

In following cases results will be sent to LIMS

- Online : When Run is on.
- Offline : From Offline Entry module.
- Result Reprint : From Result Reprint module.
- Patient Report : Only modified results from Patient Report will be sent to LIMS.

2) Request Information Record :

After sample barcode scan, the sampleID will be checked in Application Software. If the sampleID is not available then, the request will be sent to LIMS.

3) Comment Record (Optional) :

This is free text, where user can write any extra information about the record, in his/her own language.

In following cases comment will be sent to LIMS

- Invalid Test : IF test sent from LIMS , is not available in Application Software, comment saying test name XXX not available in instrument, will be sent to LIMS.
- Invalid Result Flag : ASTM has some predefined flags. If Application software flag is not matched with ASTM flag, then the actual flag generated from Application software will be sent to LIMS

4) Patient and Test Order Record :

Normally this information comes from the LIMS. But there is provision in Application software, to make entry for patient and sample. This information will be sent from ASTM to LIMS.

Data transferred from LIMS to ASTM :

1) **Patient Record :**
   All the patient history.

2) **Test Order Record :**
   The sample information along with the tests schedules / not scheduled.

3) **Request Information Record :**
   i) Results
   ii) Patient and Test Order, for which, the entry is made in Application software.

4) **Comment Record (Optional) :**
   i) Patient Information
   ii) Any other information

Examples of each record type :

Example 1 : Patient Order Data

Header
- **Patient Information Record A**
  - **Comment Record for Patient A**
  - **Order Information Record A1**
  - **Order Information Record A2**
- **Patient Information Record B**
  - **Order Information Record B1**
  - **Order Information Record B2**
  - **Order Information Record B3**

Message Terminator

Example 2 : Result Data

Header
- **Patient Information Record A**
  - **Comment Record for Patient A**
  - **Order Information Record A1**
    - **Result Information Record A11**
      - **Comment Record For Result A11**
    - **Result Information Record A12**
    - **Result Information Record A13**
  - **Order Information Record A2**
    - **Result Information Record A21**
    - **Result Information Record A22**
- **Patient Information Record B**
  - **Order Information Record B1**
    - **Result Information Record B11**
    - **Result Information Record B12**
      - **Comment Record For Result B12**

Order Information Record B2
Result Information Record B21
Result Information Record B22
Order Information Record B3
Result Information Record B31
Message Terminator

Example 3 : Request Information Data
Header
Request Information Record A
Message Terminator

While Sending / Receiving the string…

1. Every packet should start with header (H) and end with terminator (L).
2. All delimiters should be defined in Header (H).
3. Each string in the packet should be max 1024* characters in length.
4. Each string should start with record type (H / P / O / Q / C / L) and terminate with <CR>.
5. The record type ID (H / P / O / Q / C / L) is case sensitive.
6. Each string should contain the Record Sequence Number.
7. There should not be <CR> in between the string.
8. Delimiters should not be included for trailing null fields.
   Example: **P|1|Pat1||||<CR>** should be written as **P|1|Pat1<CR>**
9. Fields should be arranged in the positional order specified.
10. The sending system can use null values to indicate no change. This null value should not overwrite existing data in the receiving system.
11. A field containing only a pair of double quotes (Alt + 34) should be treated as an instruction to the receiver that the existing contents pertaining to that field should be deleted.
12. All dates should be in the format of YYYYMMDDHHMMSS.
13. Measurement units should be expressed with ISO 2955.

*Handled by ASTM Lower Level.

Ref No.	Sr No.	Check in System Settings
6.1.1	1	Allowed characters (Delimiters) : 7,9,11,12,13,32-126,128-254
6.1.1	2	Disallowed characters (Delimiters) : 0 - 6 ,8,10, 14 - 31 , 127 ,255
6.1.1	3	13 is reserved for a record terminator.
6.2	4	All fields are variable in length .But clinical instrument can decide the max length of field.
6.4.1	5	Alphanumeric characters should not be used as delimiters.
	6	Any special characters should not be used in clinical instrument application.
6.4	7	All delimiters should have different values.
	8	System settings should be disabled , when communication is on. **(Set Flag when communication is on)**

Ref No.	Sr No.	Check while building the string
	1	Every packet should start with header (H) and end with terminator (L) .
6.4.7	2	All delimiters should be defined in Header (H)
	3	Each string in the packet should be max 64000 characters in length.
6.5	4	Each string should start with record type (H / P / O / Q / C / L) and terminate with <CR>
6.5	5	The record type ID is case sensitive

6.6.7	6	Each string should contain the Record Sequence Number.
	7	There should not be <Enter> pressed inbetween the string.
6.4.8	8	Delimiters are not included for trailing null fields.
6.4.9	9	Transmitted records may include more fields than are required by a receiving system. When processing a message , the receiving system may ignore any field it does not require.
6.4.9	10	Fields always be transmitted in the positional order specified.
6.4.10.1	11	**The sending system can use null values to indicate no change .This null value should not overwrite existing data in the receiving system.**
6.4.10.2		
6.4.10.3	12	**A field containing only a pair of double quotes (Alt + 34) should be treated as an instruction to the receiver that the existing contents pertaining to that field should be deleted.**
6.6.2	13	All dates should be in the format of YYYYMMDDHHMMSS
6.6.4	14	Measurement units should be expressed with ISO 2955 . **(Define 2D Array)**

ASTM and LIMS Communication :

Sr #	Instrument Software	ASTM	LIMS
1	Scan the Barcode.	Get the barcode detail from instrument and send to LIMS. ⇒	Receive the sample request from ASTM. ⇓
			⇓
	With the Patient entry option, view the same data.	Receive test order data from LIMS and send to instrument software.	Send the sample order data to ASTM. ⇐
2	Run the Sample.	Get the results from instrument application and send to LIMS.	Receive the result from the ASTM.
3	Send the results through Result Reprint option to ASTM		
4	Modify result through Patient Report and send to ASTM.		
5	Make offline entry		

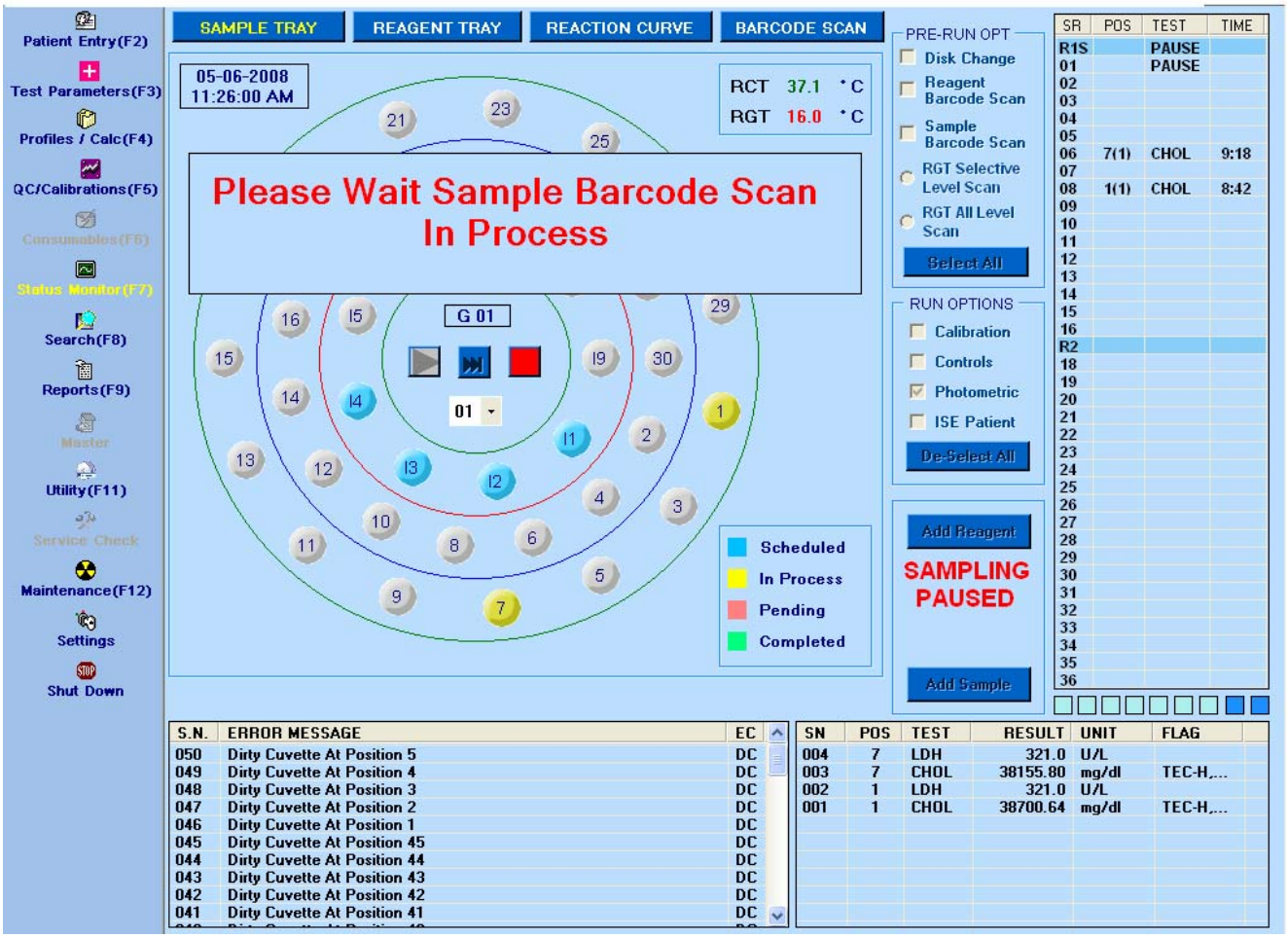
1) **Scan the barcode and send request to the LIMS**

i) Schedule the patient.

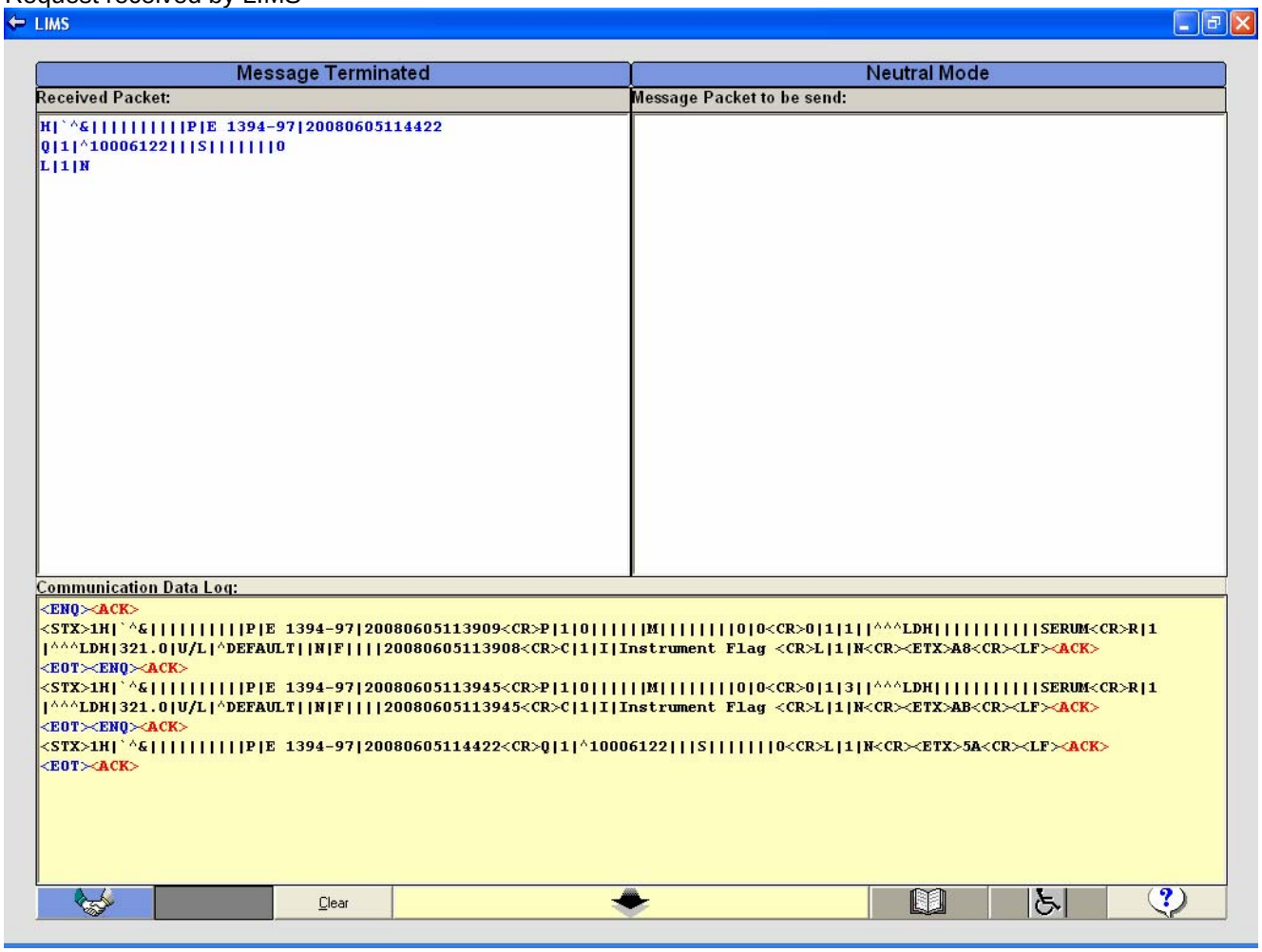
ii) Start the Run.

iii) Click on Sample Added button.

iv) Send request for new samples to LIMS in batch of 5.



Request received by LIMS

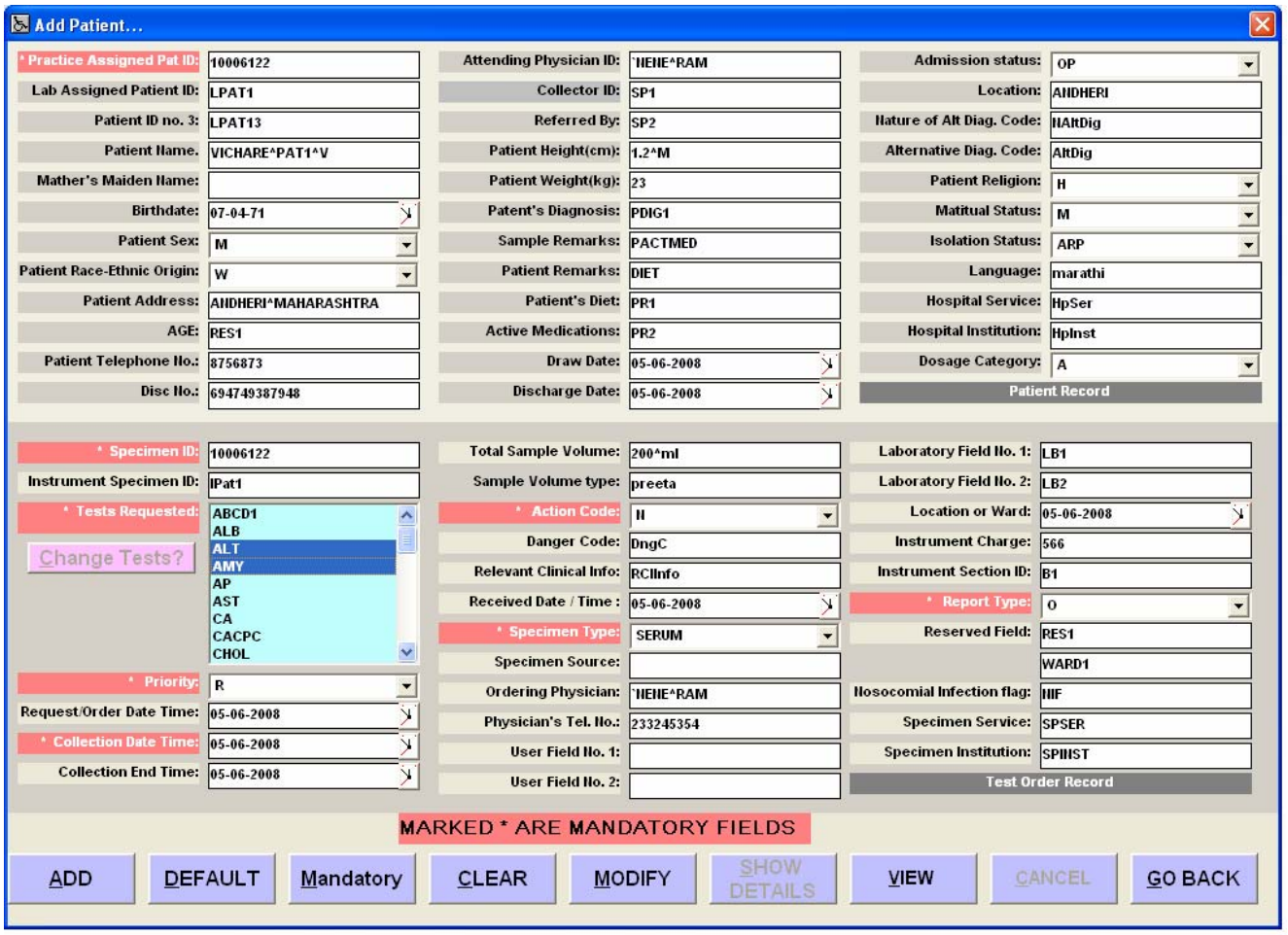


H|`^&|||||||||P|E 1394-97|20080605114422
Q|1|^10006122|||S|||||||O
L|1|N

v) In Response to this Query LIMS sends “Patient Information” and “Test Order” data for respective SampleID.

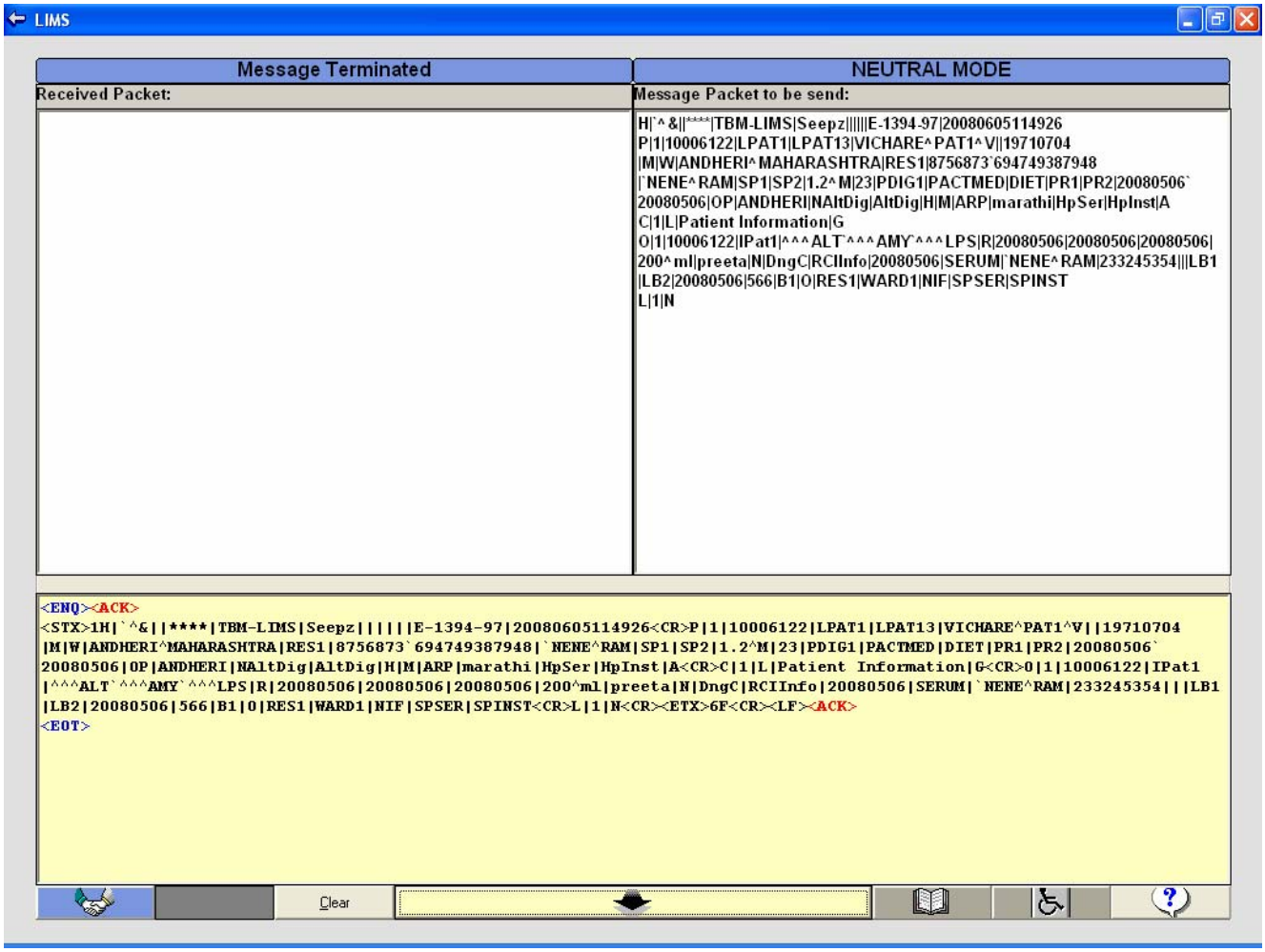
2) Patient and Order data sent from LIMS to ASTM.

i) Patient and Order data entered in LIMS, with new sampleID.

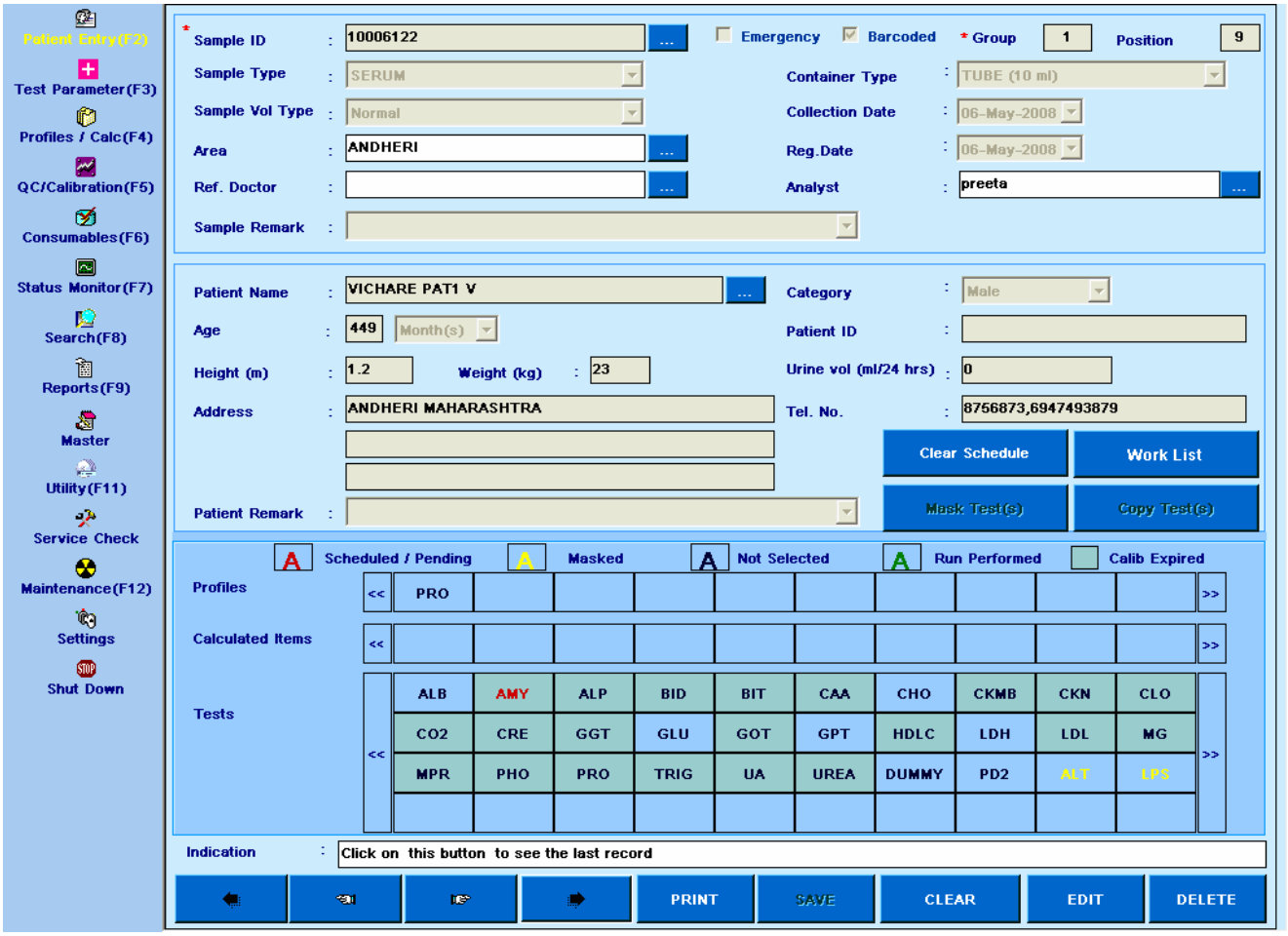


ii) String generated after clicking on (+) button.

<ENQ><ACK>
<STX>1H|`^&||****|TBM-LIMS|Seepz|||||E-1394-97|20080605114926<CR>P|1|10006122|LPAT1|LPAT13|VICHARE^PAT1^V||19710704|M|W|ANDHERI^MAHARASHTRA|RES1|8756873`694749387948|`NENE^RAM|SP1|SP2|1.2^M|23|PDIG1|PACTMED|DIET|PR1|PR2|20080506`20080506|OP|ANDHERI|NAltDig|AltDig|H|M|ARP|marathi|HpSer|HpInst|A<CR>C|1|L|Patient Information|G<CR>O|1|10006122|IPat1|^^^ALT`^^^AMY`^^^LPS|R|20080506|20080506|20080506|200^ml|preeta|N|DngC|RCIInfo|20080506|SERUM|`NENE^RAM|233245354|||LB1|LB2|20080506|566|B1|O|RES1|WARD1|NIF|SPSER|SPINST<CR>L|1|N<CR><ETX>6F<CR><LF><ACK>
<EOT>

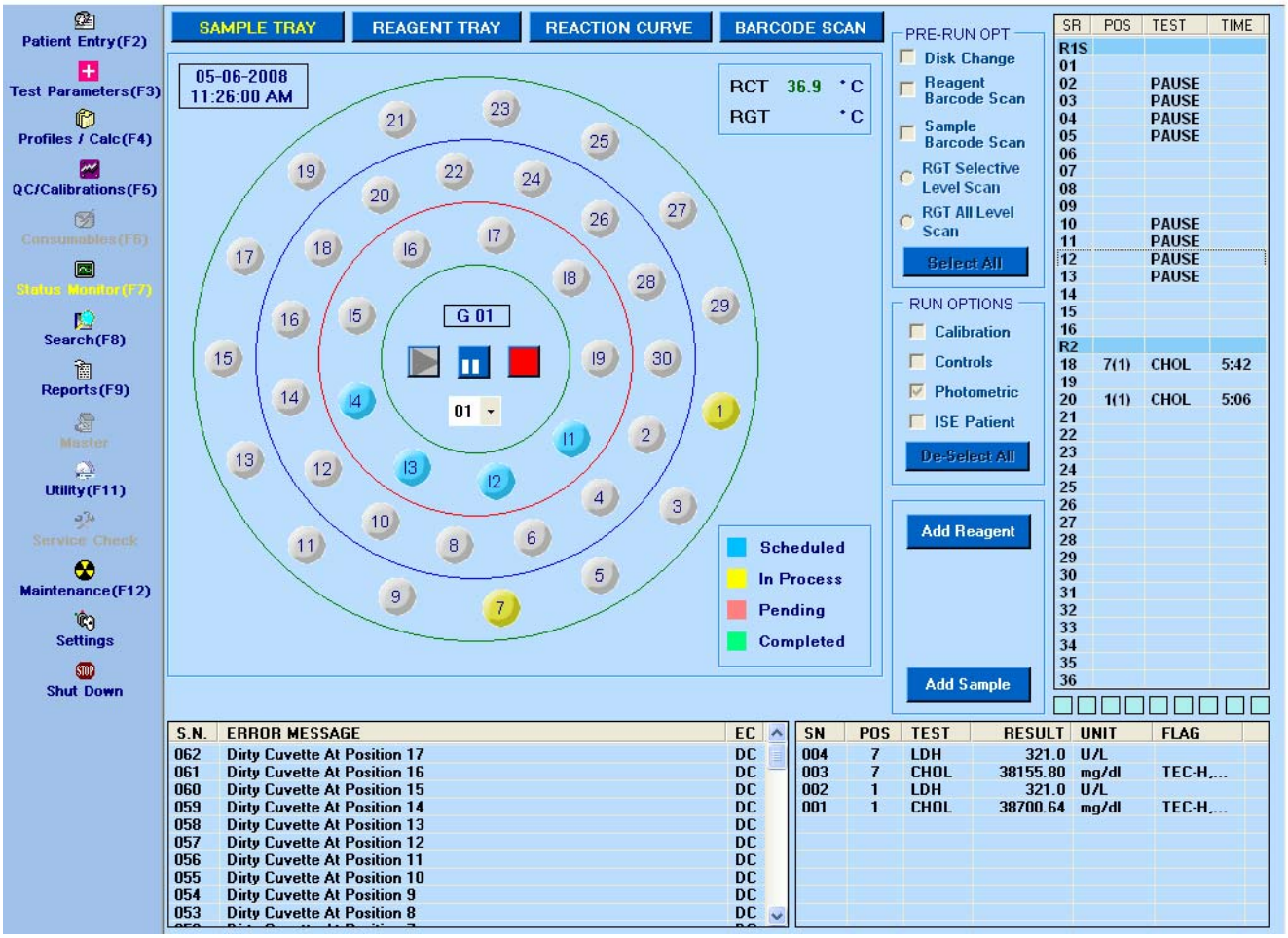

LIMS
Message Terminated
NEUTRAL MODE
Received Packet:
Message Packet to be send:
H|`^&||****|TBM-LIMS|Seepz|||||E-1394-97|20080605114926
P|1|10006122|LPAT1|LPAT13|VICHARE^PAT1^V||19710704
|M|W|ANDHERI^MAHARASHTRA|RES1|8756873`694749387948
|`NENE^RAM|SP1|SP2|1.2^M|23|PDIG1|PACTMED|DIET|PR1|PR2|20080506`
20080506|OP|ANDHERI|NAltDig|AltDig|H|M|ARP|marathi|HpSer|HpInst|A
C|1|L|Patient Information|G
O|1|10006122|IPat1|^^^ALT`^^^AMY`^^^LPS|R|20080506|20080506|20080506|
200^ml|preeta|N|DngC|RCIInfo|20080506|SERUM|`NENE^RAM|233245354|||LB1
|LB2|20080506|566|B1|O|RES1|WARD1|NIF|SPSER|SPINST
L|1|N
<ENQ><ACK>
<STX>1H|`^&||****|TBM-LIMS|Seepz|||||E-1394-97|20080605114926<CR>P|1|10006122|LPAT1|LPAT13|VICHARE^PAT1^V||19710704
|M|W|ANDHERI^MAHARASHTRA|RES1|8756873`694749387948|`NENE^RAM|SP1|SP2|1.2^M|23|PDIG1|PACTMED|DIET|PR1|PR2|20080506`
20080506|OP|ANDHERI|NAltDig|AltDig|H|M|ARP|marathi|HpSer|HpInst|A<CR>C|1|L|Patient Information|G<CR>O|1|10006122|IPat1
|^^^ALT`^^^AMY`^^^LPS|R|20080506|20080506|20080506|200^ml|preeta|N|DngC|RCIInfo|20080506|SERUM|`NENE^RAM|233245354|||LB1
|LB2|20080506|566|B1|O|RES1|WARD1|NIF|SPSER|SPINST<CR>L|1|N<CR><ETX>6F<CR><LF><ACK>
<EOT>
Clear

iii) String received by the ASTM and stored in the instrument software.

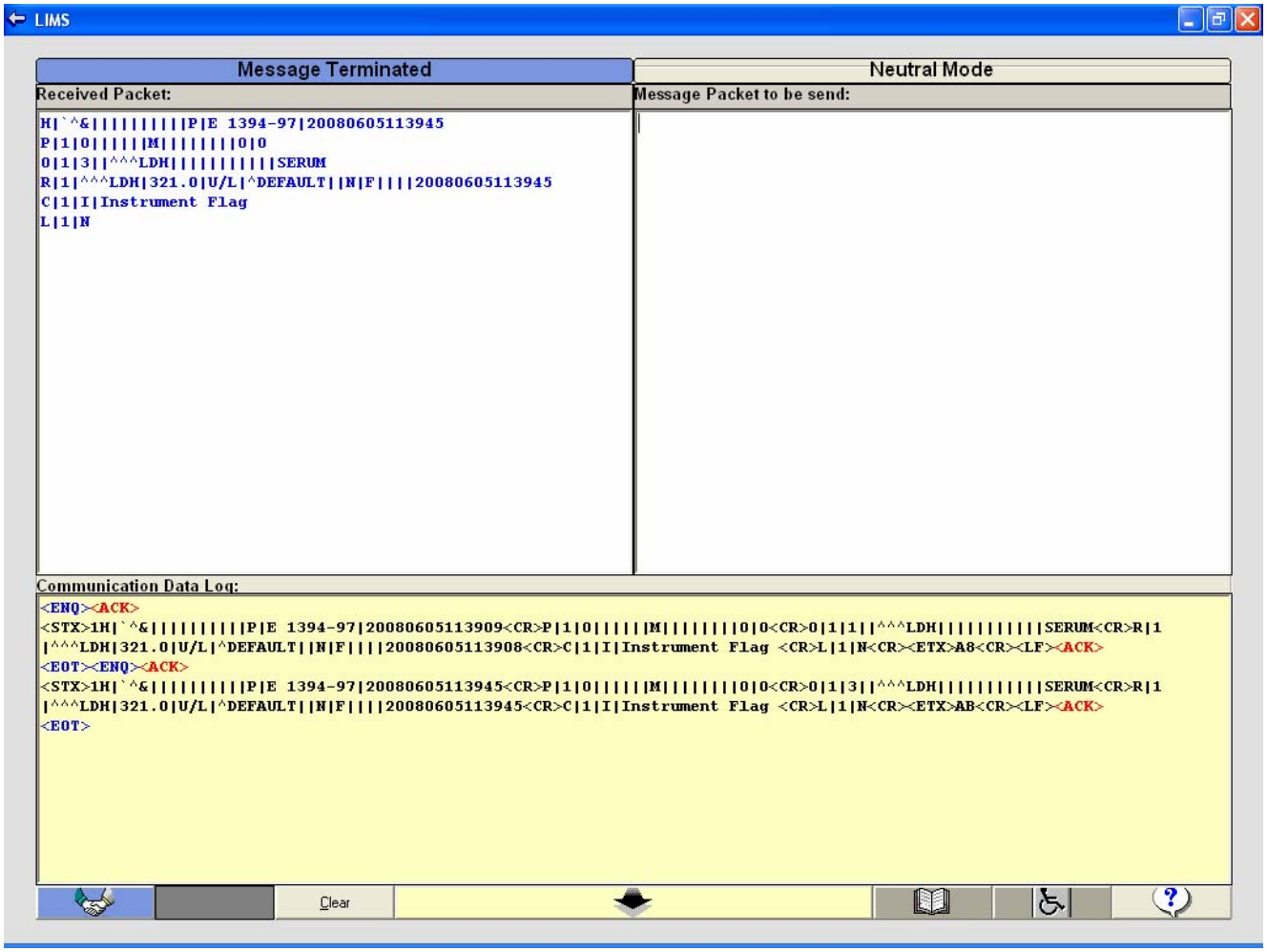


3) Results sent from ASTM to LIMS

i) Online



Result sent to LIMS

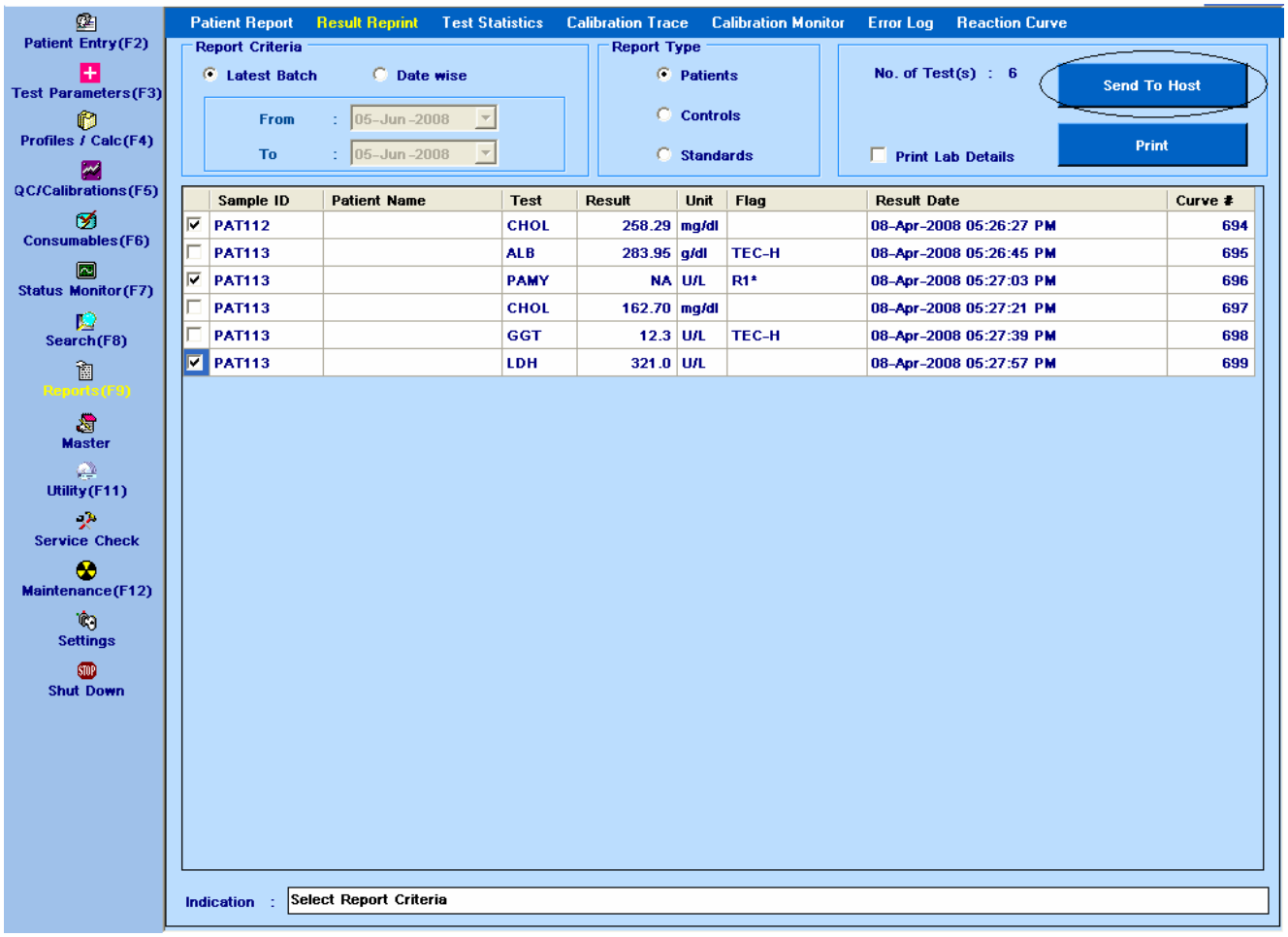


H|`^&|||||||||P|E 1394-97|20080605115331
P|1|0|||||||||||||0|0
O|1|1||^^^LDH|||||||||SERUM
R|1|^^^LDH|321|U/L|||N|F||||20080605120000
C|1|I|Instrument Flag
L|1|N

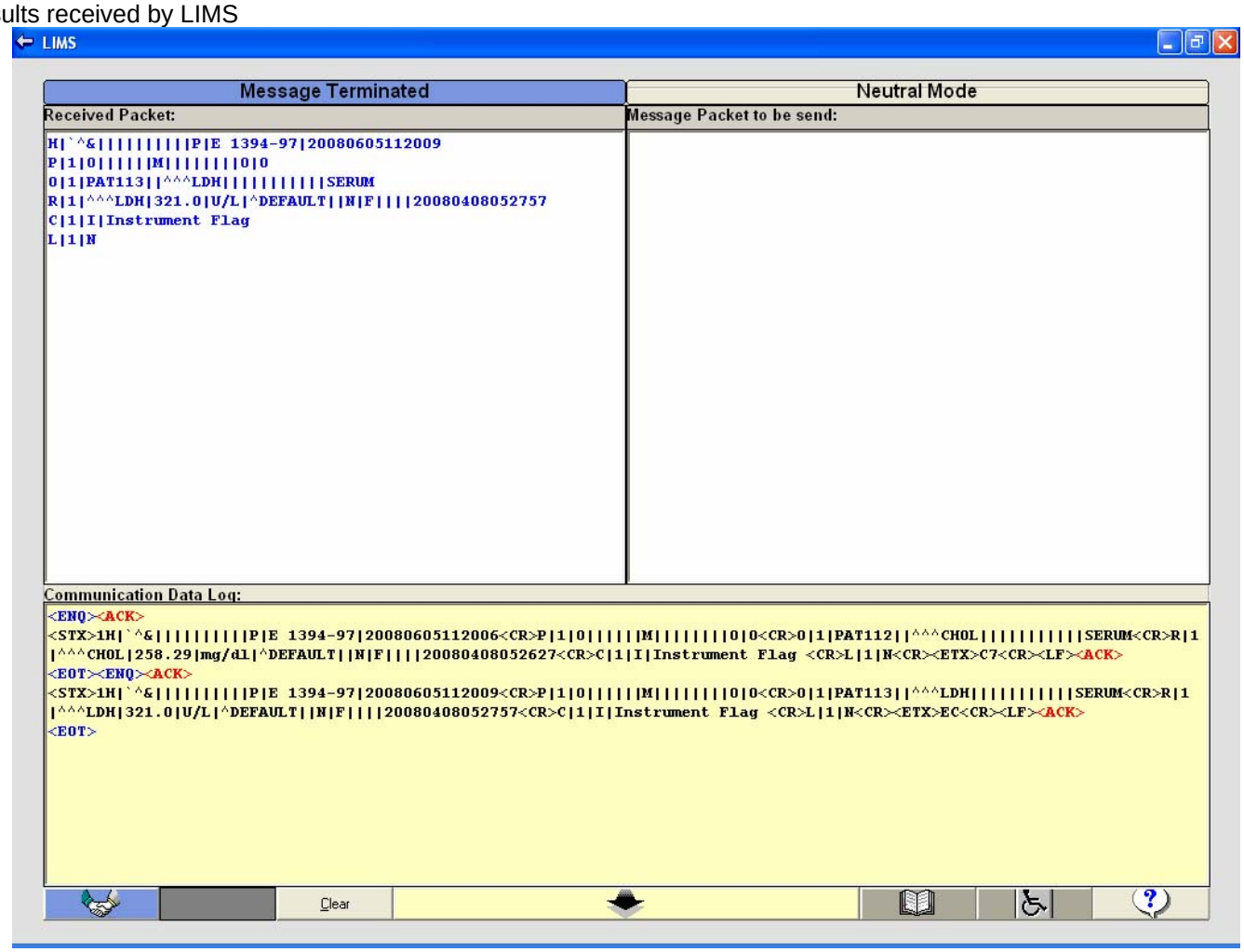
ii) Offline

Result sent from Result Reprint

1) Select the results to be sent to LIMS
2) Click on Send To Host



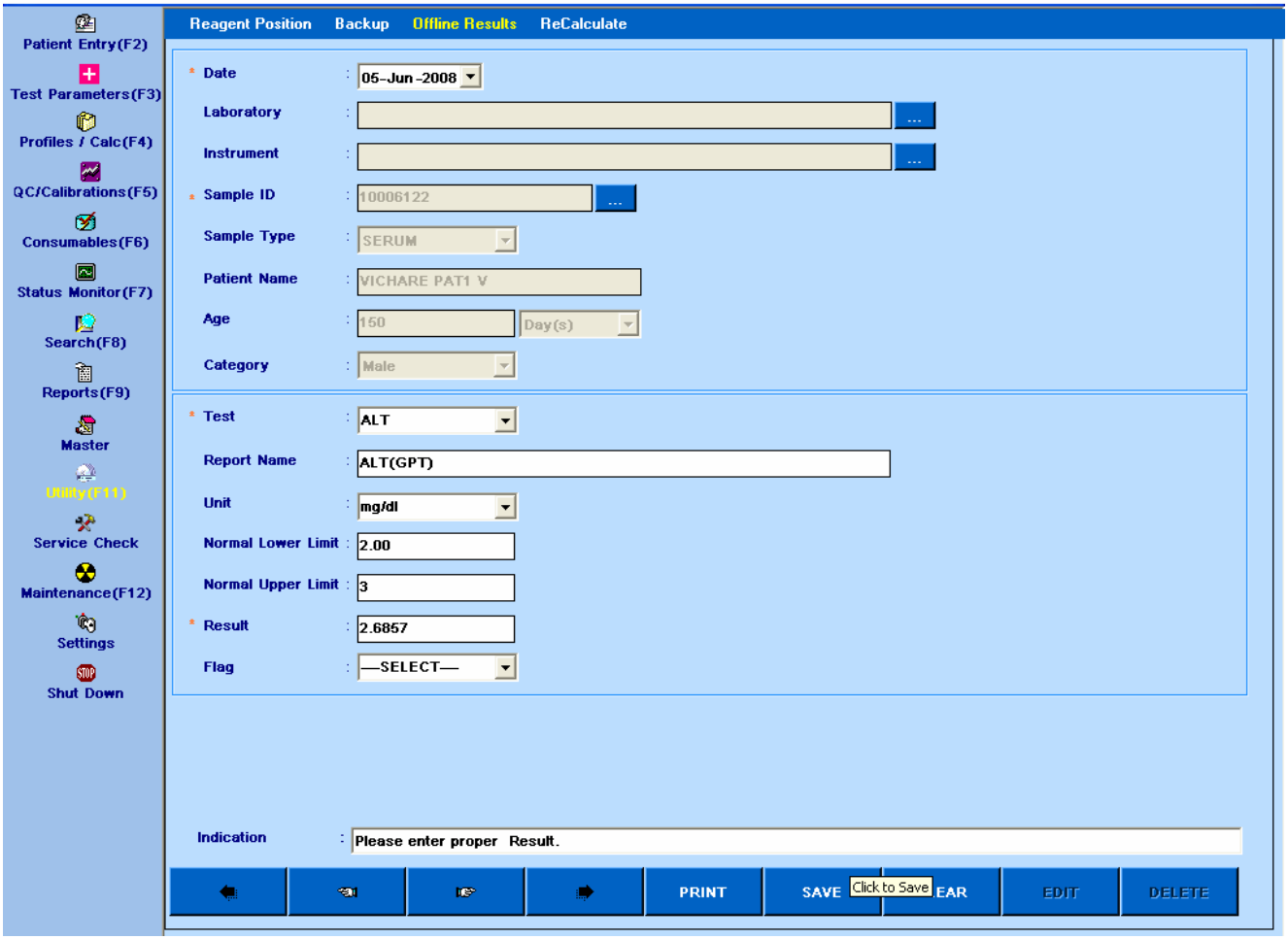
Results received by LIMS



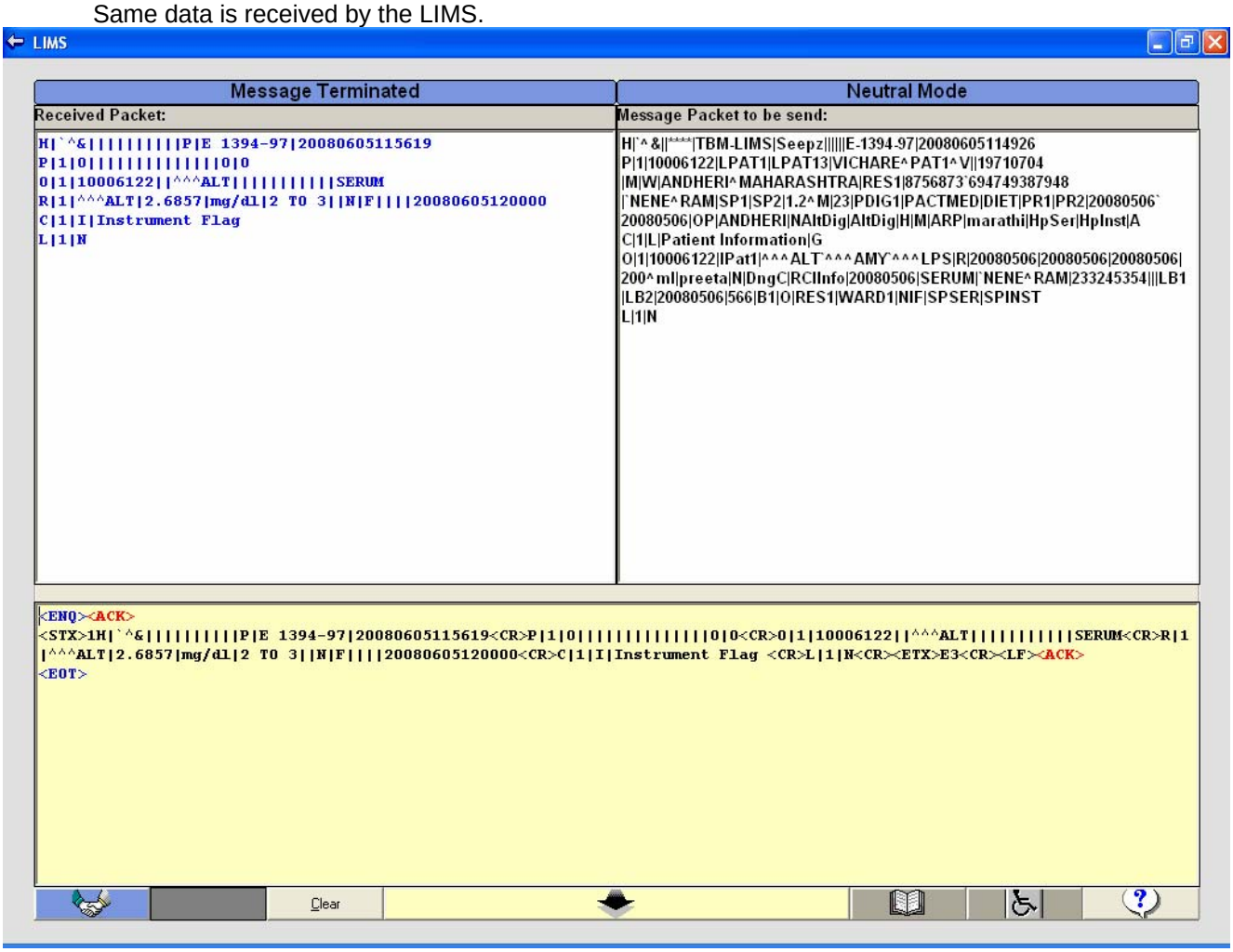
<ENQ><ACK>
<STX>1H|`^&|||||||||P|E 1394-
97|20080605112006<CR>P|1|0|||||M|||||||0|0<CR>O|1|PAT112||^^^CHOL||||
|||||||SERUM<CR>R|1|^^^CHOL|258.29|mg/dl|^DEFAULT||N|F||||2008040805262
7<CR>C|1|I|Instrument Flag <CR>L|1|N<CR><ETX>C7<CR><LF><ACK>
<EOT><ENQ><ACK>
<STX>1H|`^&|||||||||P|E 1394-
97|20080605112009<CR>P|1|0|||||M|||||||0|0<CR>O|1|PAT113||^^^LDH|||||
||||||SERUM<CR>R|1|^^^LDH|321.0|U/L|^DEFAULT||N|F||||20080408052757<CR>
C|1|I|Instrument Flag <CR>L|1|N<CR><ETX>EC<CR><LF><ACK>
<EOT>

IV) Offline Entry

Make offline entry in the application and click on Save.



Same data is received by the LIMS.



Sample BarcodeScan Testing :

(B- Barcoded ; NB- Non Barcoded)

Before Barcode Scan			After Barcode Scan
SamplePos	**SampleID**	**Tests**	
2 (NB)	10077127037056 (sample id of pos 6)	CKN**(NP)**,CALC1(ALB,AMY)	Pos replaced by 6 and tests appended as ALP and ISE
8 (B) SAMP123414	SAMP123414	ALB**(NP),** AMY**(NP)** ,ISE	ALP appended to same sampleid
10 (B) SAMPLE1147	SAMP10	CKMB,CKN	SampleID changed to SAMPLE1147 (actual barcode)
11 (B) SAMPLE12345	SAMPLE1157 (sample id of pos 15)	ALP,CKN	Sampleid replaced with SAMPLE12345

MultiXL – ASTM Testing (During Run)

Case 1 : During 'Run' the scheduled sample is replaced with the other one.

a) Old sample scheduling is in progress. Results are not yet out.

Test Case	Expected Result	Actual Result	Status
Program 'SAMP21' at pos 21.	Position 21 should not be replaced by new sample.	Position 21 remains unchanged.	OK
Start the Run. When scheduling starts , click on 'Sample Added'			
Replace sample on pos 21 by the other sample, manually.			
Wait till the LIS sends the requested sample information.			

b) Scheduling over and results are out.

Test Case	Expected Result	Actual Result	Status
Program 'SAMP21' at pos 21.	Position 21 should be replaced by the new sample.	Position 21 is replaced by new sample.	OK
Start the Run. Wait till schedule gets over.			
Once the results are out , click on 'Sample Added'.			
Replace sample on pos 21 by the other sample, manually.			
Wait till the LIS sends the requested sample information.			

Case 2 : Add new tests for the existing sample , from LIS.

Test Case	Expected Result	Actual Result	Status
Program CODE12812 at position 6, with tests ALB,CRE.	Existing test should not be scheduled again. But new tests should be added to the existing sample and get scheduled.	When testorder data is received from LIS , ALB is ignored and ALP, BIT are added to the sample CODE12812.	OK
Scan the barcode.			
Send few more tests say ALB,ALP,BIT from LIS for the same sample.			

Case 3 : During Run, emergency sample sent from LIS.

Test Case	Expected Result	Actual Result	Status
Program sample manually.	Emergency sample should be given high priority.	Emergency sample gets scheduled as soon as the current sample scheduling is over.	OK
Start the RUN.			
Send emergency sample from LIS.			

Case 4 : Fill all the positions in the sample tray , with the barcoded samples .Then query to LIS and chk if LIS sends sample information to all queried samples.

Test Case	Expected Result	Actual Result	Status
Fill whole sample tray with the barcodeed samples.	ASTM should query for the scanned barcodes and LIS in response should send the patient and testorder information.	ASTM sent query to the LIS for all the scanned samples. And LIS replied with the patient and testorder data, for all the queried samples.	OK
Programme all the samples in LIS			
Scan the barcode.			

Case 5 : Blank / Standard results should not get transferred to the LIS. Control Results if selected in Host Setting , then only get transferred to the LIS.

Test Case	Expected Result	Actual Result	Status
Programme all blank, std, control and patient in the application.	Blank , Standard results should not get transferred to the LIS.	Blank , Standard results are ignored in all cases.	OK
In Host setting screen, set 'Send Control Results' to false.	Only patient results should be sent to the LIS.	Only patient results are sent to the LIS.	OK
In Host setting screen, set 'Send Control Results' to true.	Only patient and control results should be sent to the LIS.	Patient and control both results are sent to LIS.	OK

Case 6 : ISE results **should get transferred to ASTM , only if , in system parameter 'ISE' is on.**

Test Case	Expected Result	Actual Result	Status
Programme one sample in application.			OK
Send ISE tests from LIS to ASTM.			
a) In System Parameter, put ISE module 'Off'.	ISE tests should not get programmed in application.	ISE tests are not programmed.	
b) In System Parameter, put ISE module 'On'.	ISE tests should get programmed as other photometric tests.	ISE tests got programmed.	

Case 7 : Cancel the test from LIMS.

Test Case	Expected Result	Actual Result	Status
Programme sample SAMP123450 with tests ALB,ALP and CRE			OK
Send from LIS , same sampleid with test ALB and actioncode as 'C'	ALB test should be removed from sample SAMP123450	Schedule for test 'ALB' is removed for the sample SAMP123450.	

Case 8 : Don't send Results with specific Flags (as per selection in Host Settings) to LIS.

Test Case	Expected Result	Actual Result	Status
In host setting , select the flags , for which we want to send the results to LIS			OK
In test parameters , make the appropriate changes to generate those flags.			
Start the RUN.			
Wait till results are out.	Only the selected flag results should get transferred to LIS	Only the selected flag results got transferred to LIS	

Contact Details:

TRANSASIA BIO-MEDICALS LTD.
Transasia House,
8 Chandivali Studio Road,
Mumbai – 400 072