Siemens Medical Solutions Diagnostics

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IMMULITE®
LIS MANUAL

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IMMULITE/LIS INTERFACE POLICY

The IMMULITE Family of Systems (IMMULITE), including IMMULITE, IMMULITE 1000, IMMULITE 2000, IMMULITE 2500, and SMS, has been interfaced with many different LIS hardware and software configurations throughout the world. It has been our experience that the policy outlined below is the best way to ensure a smooth, successful interface with your LIS. It has also been our experience that every LIS interface is unique because individual laboratories have different needs, requirements, and hardware. Therefore, the LIS interface must be customized for each lab by the laboratory's software department or a software development vendor.

Siemens Diagnostics is responsible for providing LIS communication software on IMMULITE and IMMULITE 2000/2500 that performs according to standards specified in ASTM E1394 and ASTM E1381, and according to the Siemens Diagnostics LIS communications specifications. Siemens Diagnostics also is responsible for proper hardware functionality (serial port functionality) of the PC supplied with the IMMULITE systems. Siemens Diagnostics will supply the LIS communications specifications to the MIS director and the LIS developer. Siemens Diagnostics is not responsible for cabling errors, software or hardware errors on intermediary systems, or for software and hardware errors on the LIS.

A Siemens Diagnostics Field Service Engineer can be present on the day the IMMULITE/LIS interface is launched, at no charge to the customer. On that day, the lab director, MIS director and IMMULITE system must be available to facilitate the process. *Siemens Diagnostics recommends that a representative of the LIS developer be on-site the day the interface is launched.* The decision to have a representative present must be made by the laboratory and the LIS developer.

The Siemens Diagnostics Field Service Engineer present will have the appropriate tools to identify most problems encountered with the interface. If a problem is encountered, the Siemens Diagnostics Field Service Engineer will attempt to identify the cause and find a solution. Typically, when all parties are available when the interface is launched, problems are solved in a timely manner. If a problem is encountered that is not caused by Siemens Diagnostics and requires several days to repair, the Siemens Diagnostics service representative will depart only after demonstrating the proper operation of the IMMULITE portion of the LIS interface via diagnostic tools. If the problem is suspected to have been caused by the IMMULITE system at a later date, a Siemens Diagnostics Field Service Engineer will be sent to further evaluate the problem. If the Siemens Diagnostics Field Service Engineer determines that the cause of this subsequent visit is a defect in the Siemens Diagnostics software or hardware, the problem will be corrected under the IMMULITE warranty or service contract as applicable. If the instrument is no longer under warranty and a service contract is not in effect, the visit will be billed at the prevailing rates. If the problem is not the result of Siemens Diagnostics equipment or software, as in the case of cabling problems, the service call will be billed at prevailing rates regardless of IMMULITE warranty or service contract.

For the duration of the initial testing and validation process, the status of the IMMULITE system should be considered "under evaluation." The validation process is performed by the laboratory and the LIS developer and typically lasts one to two weeks. During the validation period, any problems can be identified and corrected. In extreme cases, it may be necessary to disable the LIS feature until a problem has been corrected.

During the validation period, it is the responsibility of the lab director to ensure that LIS communications are used on a daily basis (or whenever IMMULITE is used). All results sent to the LIS *must* be verified on the LIS by comparing results and patient information to the IMMULITE result printout. Any problems must be reported to Siemens Diagnostics and all other affected parties. Upon successful completion of the validation process, the system is upgraded to "on-line" status. When the system is "on-line", the requirement to verify results on the LIS should conform with the operating procedures of the lab.

BASIC LIS RELATED TERMS

ENQ (Enquiry) -	First character sent in a transaction, initiates communication session.
STX (Start of Text) -	Indicates start of text for a specific message.
ETX (End of Text) -	Indicates end of text for a specific message.
EOT (End Transmit) -	Indicates the sender is done sending and is entering "idle" mode. Terminates a communication session.
ACK (Acknowledge) -	Response to sender message was properly received.
NAK (Negative Acknowledge) -	Response to sender message was NOT properly received.
Record -	Also know as a message, contains ALL information for a particular item E.G. all information in a patient message.
Field -	An item within a record E.G. Patient Name in a patient message is a field.
Pipe Sign (|) -	A vertical bar that separates fields within a record.
Frame Number -	The first character sent in a message. The value increments by one every message until number 7. It is then reset to number 0 (0-7). The header message (first message sent) always begins with number one.
Sequence Number-	Each message type has its own sequence number. This number increments by one after each record is sent. A record sent of a higher hierarchy (see message hierarchy) resets this value to zero.
Checksum -	Calculation performed on each message to insure all characters are properly received.
Header Message ("H" message) -	First message sent in any transaction, contains system information such as sender ID, receiver ID, address, etc.
Patient Message ("P" message) -	Contains patient information, patient ID, name.

Order Message ("O" message) - Defines which test, such as TSH or HCG, should be performed on the sample for a particular accession number.

Result Message ("R" message) - Contains test results and additional information, such as Test Code and the units in which the results are delivered. This message is sent to the LIS.

Query Message ("Q" message) - A request to the LIS for patient information and test orders. Contains the primary tube accession number.

Terminator Message ("L" mesg.) - Last message sent in a transaction, contains termination codes.

Sender ID - The identity of the system sending a message. For example, If IMMULITE is sending a message the sender ID may be “IMMULITE”, if the LIS is sending a message the sender ID may be “LIS”. The data in this field is defined by the LIS software company.

Receiver ID - The identity of the system receiving a message. For example, If IMMULITE is receiving a message the receiver ID may be “IMMULITE”, if the LIS is receiving a message the receiver ID may be “LIS”. The data in this field is defined by the LIS software company.

Password - A password defined by the LIS software company. This field may be left blank if desired.

MESSAGE HIERARCHY

Basic Message Hierarchy (Lower number has higher priority)

(1) Header
    (2) Patient
        (3) Order
            (4) Result

Hierarchy Example of LIS to IMMULITE and IMMULITE 2000/2500 Transfer

<ENQ>
Header
    Patient 1
        Order 1
    Patient 2
        Order 1
        Order 2
        Order 3
    Patient 3
        Order 1
Terminator
<EOT>

Hierarchy Example of IMMULITE to LIS Transfer

<ENQ>
Header
    Patient 1
        Order 1
            Result 1
    Patient 2
        Order 1
            Result 1
        Order 2
            Result 1
        Order 3
            Result 1
    Patient 3
        Order 1
            Result 1
Terminator
<EOT>

Hierarchy Example of IMMULITE 2000/2500 to LIS Transfer (Immunoassay)

<ENQ>
Header
    Patient 1
        Order 1
            Result 1
    Patient 2
        Order 1
            Result 1
    Patient 3
        Order 1
            Result 1
    Patient 4
        Order 1
            Result 1
    Patient 5
        Order 1
            Result 1
Terminator
<EOT>

Hierarchy Example of IMMULITE 2000/2500 to LIS Transfer (Allergy)

<ENQ>
Header
    Patient 1
        Order 1
            Result 1
            Result 2

    Patient 2
        Order 1
            Result 1
            Result 2

    Patient 3
        Order 1
            Result 1
            Result 2

Terminator
<EOT>

Hierarchy Example of Query to LIS

<ENQ>
Header
    Query
Terminator
<EOT>

Hierarchy Example of Response to Query

<ENQ>
Header
    Patient 1
        Order 1
        Order 2
        Order 3
Terminator
<EOT>

MESSAGE DEFINITIONS

BASIC FORMAT OF A MESSAGE:

[Start of Text <STX>][Frame Number][Message Type] [Message][Carriage Return <CR>][End of Text <ETX>][CHECKSUM] [Carriage Return <CR>][Line Feed <LF>]

HEADER MESSAGE:

[Record Type (H)] [Delimiter Def.] [Message Control ID] [Password] [Sending systems company name] [Sending Systems address] [Reserved] [Senders Phone#] [Communication parameters] [Receiver ID] [Comments/special instructions] [Processing ID] [Version#] [Message Date + Time]

1H|\^&||PASSWORD|DPC CIRRUS||Flanders^New^Jersey^07836||973-927-2828|N81|Your System||P|1|19940407120613<CR><ETX>[51 Checksum] <CR><LF>

PATIENT MESSAGE:

[Record Type (P)][Sequence #][Practice Assigned Patient ID][Laboratory Assigned Patient ID][Patient ID][Patient Name][Mother's Maiden Name][BirthDate][Patient Sex][Patient Race][Patient Address][Reserved][Patient Phone #][Attending Physician ID][Special Field 1][Special Field 2][Patient Height][Patient Weight][Patients Known or Suspected Diagnosis] [Patient active medications][Patients Diet][Practice Field #1][Practice Field #2][Admission and Discharge Dates][Admission Status][Location][Nature of Alternative Diagnostic Code and Classification][Alternative Diagnostic Code and Classification][Patient Religion][Marital Status][Isolation Status][Language][Hospital Service][Hospital Institution][Dosage Category]

2P|1|101|||Riker^Al||19611102|F|||||Bashere<CR><ETX>[2ACheckSum] <CR><LF>

ORDER MESSAGE:

[Record Type (O)][Sequence#][Specimen ID (Accession#)][Instrument Specimen ID][Universal Test ID][Priority][Order Date/Time][Collection Date/Time][Collection End Time][Collection Volume][Collector ID][Action Code][Danger Code][Relevant Clinical Info][Date/Time Specimen Received][Specimen Descriptor,Specimen Type,Specimen Source][Ordering Physician][Physician's Telephone Number][User Field No.1][User Field No.2][Lab Field No.1][Lab Field No.2][Date/Time results reported or last modified][Instrument Charge to Computer System][Instrument Section ID][Report Types][Reserved Field][Location or ward of Specimen Collection][Nosocomial Infection Flag][Specimen Service][Specimen Institution]

3O|1|1550623||^^^LH|R|19931011091233|19931011091233<CR><ETX>[6C Checksum] <CR><LF>

RESULT MESSAGE:

[Record Type (R)][Sequence #][Universal Test ID][Data (result)][Units][ReferenceRanges] [Result abnormal flags][Nature of Abnormality Testing][Result Status][Date of change in instruments normal values or units][Operator ID][Date\Time Test Started][Date\Time Test Completed][Instrument ID]

4R|1|^^^LH|8.2|mIU/mL|.7\.7^400\400|N|N|F||test|19931011091233|19931011091233|DPCCIRR US<CR><ETX>[8FCheckSum] <CR><LF>

MESSAGE TERMINATOR:
[Record Type ID (L)][Sequence Number][Termination Code]

5L|1|N<CR><ETX>[CheckSum]<CR><LF>

REQUEST INFORMATION (QUERY) MESSAGE

[Record Type ID (Q)][Sequence #][Starting Range][Ending Range][Test ID][Request Time Limits][Beginning request results date and time][Ending request results date and time][Physician name][Physician Phone Number][User Field 1]User Field 2][Status Codes]

2Q|1|^1234ABC||ALL|||||||O<CR><ETX>[CheckSum]<CR><LF>

MAXIMUM VALUES FOR DATABASE FIELDS ACROSS INSTRUMENTS

Database Fields (as of 12/7/01)				
Record Type	**Field**	**IMMULITE One**	**IMMULITE 1000**	**IMMULITE 2000/2500 & SMS**
HEADER	LIS Password	15	15	10
	LIS Receiver ID	15	15	10
	LIS Sender ID	20	20	10
PATIENT	Patient Last Name	20	30 (Last & First)	30 (Last & First)
	Patient First Name	15		
	Patient Birth Date	8	8	8
	Patient Sex	1	1	1
	Physician Name	20	30	30
	Patient ID	15	20	20
ORDER	Specimen ID (ACCN#)	20	20	20
	Test Type	6	6	6
	Allergen Code	--	--	6
	Priority	1	1	1
	Order Date/Time	14	14	14
	Collection Date/Time	14	14	14

BI-DIRECTIONAL TRANSFER EXAMPLE, IMMULITE TO LIS

1H|\^&||PASSWORD|SenderID|Randolph^New^Jersey^07869||(201)927-2828|8N1|ReceiverID||P|1|19950522092817
6F

2P|1|119813;TGH|||Last 1^First 1|||F|||||
46

3O|1|130000445||^^^TT4|||19950118085700
B4

4R|1|^^^TT4|10.3|ug/dL|4.5\.4^12.5\24|N|N|F||test|19950119084508|19950119092826|SenderID
0B

5O|2|130000445||^^^TU|||19950118085700
84

6R|1|^^^TU|26.6|Percnt|23\10^35\70|N|N|F||test|19950119084508|19950119092756|SenderID
07

7P|2|325031;AH|||Last 2^First 2|||F|||||
EB

0O|1|130000617||^^^FER|||19950118103000
A3

1R|1|^^^FER|173.|ng/mL|.5\.5^1500\1500|N|N|F||test|19950119084641|19950119092858|Sender ID
42

2P|3|326829;AH|||Last 3^First 3|||F|||||
F9

3O|1|130000722||^^^FER|||19950118102000
A2

4R|1|^^^FER|490.|ng/mL|.5\.5^1500\1500|N|N|F||test|19950119084741|19950119092928|Sender ID
46

5P|4|124462;TGH|||Last 4^First 4|||F|||||
4E

6O|1|130000724||^^^E2|||19950118122000
43

7R|1|^^^E2|25.3|pg/mL|12\12^2000\2000|N|N|F||test|19950119084815|19950119100049|SenderI
D
CC

0O|2|130000724||^^^FSH|||19950118122000
A8

1R|1|^^^FSH|60.6|mIU/mL|.1\.1^170\170|N|N|F||test|19950119084815|19950119093030|SenderI
D
0B

2O|3|130000724||^^^LH|||19950118122000
5E

3R|1|^^^LH|24.4|mIU/mL|.7\.7^400\400|N|N|F||test|19950119084815|19950119093101|SenderI
D
C1

4P|5|556395;AH|||Last 5^First 5|||M|||||
0B

5O|1|130000741||^^^FER|||19950118115500
AE

6R|1|^^^FER|238.|ng/mL|.5\.5^1500\1500|N|N|F||test|19950119084949|19950119093132|Sender
ID
46

7P|6|556357;MB|||Last 6^First 6|||M|||||
15

0O|1|130000790||^^^IGE|||19950118120000
9C

1R|1|^^^IGE|517.|IU/mL|.01\.01^600\600|N|N|F||test|19950119085018|19950119093202|SenderI
D
EC

2P|7|141053;TGH|||Last 7^First 7|||F|||||
4F

3O|1|130000805||^^^FER|||19950118120000
A4

4R|1|^^^FER|21.0|ng/mL|.5\.5^1500\1500|N|N|F||test|19950119085049|19950119093233|Sender
ID
34

5P|8|320439;TGH|||Last 8^First 8|||F|||||
5C

6O|1|130000890||^^^FER|||19950118130000
AC

7R|1|^^^FER|12.9|ng/mL|.5\.5^1500\1500|N|N|F||test|19950119085254|19950119093609|Sender
ID
45

0P|9||||Last 9^First 9|||||||
C1

1O|1|130000911||^^^E2
01

2R|1|^^^E2|71.3|pg/mL|12\12^2000\2000|N|N|F||test|19950119085423|19950119100800|SenderI
D
BF

3P|10|358069;TGH|||Last 10^First 10|||F|||||
DF

4O|1|130000929||^^^FER|||19950118123000
AF

5R|1|^^^FER|219.|ng/mL|.5\.5^1500\1500|N|N|F||test|19950119085628|19950119093843|Sender
ID
48

6L|1
3A

UNI-DIRECTIONAL TRANSFER EXAMPLE, IMMULITE TO LIS

1H|\^&||PASSWORD|DPC CIRRUS|Randolph^New^Jersey^07869||(201)927-2828|8N1|Your System||P|1|19940407085426
E1

2P|1||||Smith^||||||||
72

3O|1|123ABC||^^^TSH
18

4R|1|^^^TSH|2.09|uIU/mL|.4\.002^4\75|N|N|F||test|19940407084325|19940407084457|DPC CIRRUS
DF

5O|2|123ABC||^^^T4
B4

6R|1|^^^T4|3.7|ug/dL|4.5\.4^12.5\24|L|N|F||test|19940407084325|19940407084556|DPC CIRRUS
6A

7O|3|123ABC||^^^T3
B6

0R|1|^^^T3|35|ng/dL|82\35^179\600|<|N|F||test|19940407084325|19940407084630|DPC CIRRUS
F9

1O|4|123ABC||^^^TU
D3

2R|1|^^^TU|10|Percnt|23\10^35\70|<|N|F||test|19940407084325|19940407084645|DPC CIRRUS
60

3P|2||||^||||||||
6F

4O|1|789XYZ||^^^TSH
70

5R|1|^^^TSH|4.2|uIU/mL|.4\.002^4\75|H|N|F||test|19940407084907|19940407084923|DPC CIRRUS
A9
6P|3||||Jones^|||||||
72

7O|1|HIJ456||^^^TSH
3A

0R|1|^^^TSH|6.19|uIU/mL|.4\.002^4\75|H|N|F||test|19940407085044|19940407085148|DPC CIRRUS
D7

1P|4||||Riker^William||19601111|M|||||Doctor
87

2O|1|LMN141||^^^TSH
38

3R|1|^^^TSH|5.5|uIU/mL|.4\.002^4\75|H|N|F||test|19940407085234|19940407085352|DPC CIRRUS
A2

4L|1
3D

BI-DIRECTIONAL AND UNI-DIRECTIONAL TRANSFER EXAMPLES, IMMULITE 2000/2500 TO LIS and SMS to LIS

Example 1

1H|\^&||DPC|IMMU01R|111 Canfield Road^Randolph^NJ^07869||(201)927-2828|N81|IMMU01S||P|1|20001108161627
E2

2P|1||||||||||
0F

3O|1|00052111||^^^BMG|R||||||||||||||||||E0872
45

4R|1|^^^BMG|>500|ng/mL|0.30\0.30^500\500|>|N|F|||20001102140412|20001102144054|E0872
A7

5P|2|66412558||||||||||
B8

6O|1|66412558||^^^HCG|||200011081530||||||Normal||||||||||E0872
CB

7R|1|^^^HCG|>5000|mIU/mL|1.00\1.00^5000\5000|>|N|F|||20001108153251|20001108160934|E0872
7E

0P|3||||||||||
0F

1O|1|68031236||^^^TXQ|R||||||||||||||||||E0872
7D

2R|1|^^^TXQ|<5.00|IU/mL|5.00\5.00^250\250|<|N|F|||20001108112235|20001108123235|E0872
D3

3L|1
3C

Example 2

1H|\^&||DPC|IMMU01R|111 Canfield Road^Randolph^NJ^07869||(201)927-2828|N81|IMMU01S||P|1|20001107160944
E2

2P|1||||||||||
0F

3O|1|09861081||^^^fPS|R||||||||||||||||||E0872
8F

4R|1|^^^fPS|0.26|ng/mL|0.05\0.05^25.0\25.0|N|N|F|||20001107051521|20001107062514|E0872
4D

5P|2||||||||||
13

6O|1|09861081||^^^PSA|R||||||||||||||||||E0872
6D

7R|1|^^^PSA|0.28|ng/mL|0.04\0.04^150\150|N|N|F|||20001104035557|20001104043253|E0872
D1

0P|3||||||||||
0F

1O|1|09861081||^^^TSH|R||||||||||||||||||E0872
73

2R|1|^^^TSH|0.602|uIU/mL|0.400\0.002^4.00\75.0|N|N|F|||20001103035444|20001103050438|E0872
FD

3L|1
3C

Example 3

1H|\^&||DPC|IMMU01R|111 Canfield Road^Randolph^NJ^07869||(201)927-
2828|N81|IMMU01S||P|1|20001107162353
DE

2P|1||||||||||||
0F

3O|1|68552470||^^^DHS|R|||||||||||||||||E0872
69

4R|1|^^^DHS|178|ug/dL|30.0\30.0^1000\1000|N|N|F|||20001107115846|20001107123532|E0872
F8

5L|1
3E

Example 4 (Allergy)

1H|\^&||DPC|IMMU01R|111 Canfield Road^Randolph^NJ^07869||(201)927-
2828|N81|IMMU01S||P|1|20001107162353
A2

2P|1||||||||||||
0F

3O|1|Z00058364||^^^SPE E1|R|||||||||||||||||F1420
4E

4R|1|^^^SPE E1|3.23|KU/L|0.0\0.10^0.0\100|H|N|F|||20010619084600|20010619095655|
F1420
85

5R|2|^^^SPE E1|II|SCLASS||H|N|F|||20010619084600|20010619095655|
F1420
F9

Example 4

[New Receive Session]
3/21/05 2:29:21 PM 52161.91
[R] <ENQ>
3/21/05 2:29:21 PM 52161.91
[S] <ACK>
3/21/05 2:29:22 PM 52162.04
[R] _1H|\^&||MARY|MISYS|||||PATH||P|1
_B5

3/21/05 2:29:22 PM 52162.04
[S] <ACK>
3/21/05 2:29:22 PM 52162.22
[R] _2P|1|E05002027|E05002027||Doe^Jane
_25

3/21/05 2:29:22 PM 52162.22
[S] <ACK>
3/21/05 2:29:22 PM 52162.34
[R] _3O|1|E05002027||^^^sPS|R
_86

3/21/05 2:29:22 PM 52162.39
[S] <ACK>
3/21/05 2:29:22 PM 52162.48
[R] _4L|1|F
_FF

3/21/05 2:29:22 PM 52162.48
[S] <ACK>
3/21/05 2:29:22 PM 52162.54
[R] <EOT>
[New Send Session]
3/21/05 2:29:22 PM 52162.55
[S] <ENQ>
3/21/05 2:29:22 PM 52162.63
[R] <ACK>
3/21/05 2:29:22 PM 52162.63
[S] _1H|\^&||MARY|PATH|111 Canfield Ave^Randolph^NJ^07869||(201)927-
2828|N81|MISYS||P|1|20050321142922
_2D

3/21/05 2:29:22 PM 52162.8
[R] <ACK>
3/21/05 2:29:22 PM 52162.8

[S] _2Q|1|^E05002038||ALL|||||||O
_F1

3/21/05 2:29:22 PM 52162.86
[R] <ACK>
3/21/05 2:29:22 PM 52162.86
[S] _3L|1
_3C

3/21/05 2:29:22 PM 52162.95
[R] <ACK>
3/21/05 2:29:22 PM 52162.95
[S] <EOT>

HOST QUERY EXAMPLE, QUERY TO LIS

1H|\^&||PASSWORD|DPC CIRRUS||Randolph^New^Jersey^07869||(201)927-2828|N81|Your System||P|1|19940407120613
51

2Q|1|^123ABC||ALL|||||||O
76

3L|1
3C

IMMULITE CONFIGURATIONS

LIS Setup

Start Screen | LIS Params

The LIS Params screen is password protected. The password is CONNECT.

- Activate LIS Select Y or N
- Activate Host Query Select Y or N
- Activate Uni-Directional Select Y or N
    - Do not select Uni-directional if Host Query is selected or the LIS will send test orders
- Password LIS Vendor to provide
- Sender ID LIS Vendor to provide
- Receiver ID LIS Vendor to provide
- Baud Rate LIS Vendor to provide

See page 106 for LIS Cable specifications. The LIS cable is connected to serial port 2 of the IMMULITE computer.

Results

Results must be tagged and sent, and cannot be auto-sent to an LIS. Results are cleared from the LIS screen after sending to an LIS and cannot be re-sent.

Results are sent using floating decimals as follows

Result	# decimal places sent	Example
less than 1.00 *	2	0.45
1.00 – 9.99	2	1.23
10.0 - 99.9	1	10.2
100 and above	None	102

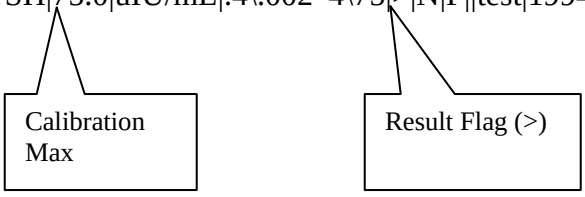
* Results for some assays (including third generation such as TSH and RTH) are reported with three decimal places if the result is less than 1.00.

Required flags:

Required flags include H, L, N, < and >.

Greater than (>) and Less than (<) calibration range results are sent as follows:

0R|1|^^^TSH|75.0|uIU/mL|.4\.002^4\75|>|N|F||test|19940407085044|19940407085148|DPC CIRRUS



Qualitative Tests
Qualitative tests result as Reactive, Non-Reactive or Indeterminate, and are sent to the LIS as follows:

Result	Sent to LIS as
Non-reactive	0
Reactive	1
Indeterminate	2

Upload/Download Codes
Siemens Diagnostics Test Codes are used for upload and download codes and can be found in Assay package inserts.

IMMULITE BI-DIRECTIONAL LIS SPECIFICATION
ASTM E1394

HEADER RECORD DEFINITION (7.1 - 7.1.14)
[Record Type (H)] [Delimiter Def.] [Message Control ID] [Password] [Sending systems company name] [Sending Systems address] [Reserved] [Senders Phone#] [Communication parameters] [Receiver ID] [Comments/special instructions] [Processing ID] [Version#] [Message Date + Time]
Sample Header Message:

<STX>[FrameNumber]H|\^&||Password|DPCCIRRUS|Randolph^New^Jersey^07869||(201)927-2828|8N1|YourSystem||P|1|19940323082858<CR><ETX>[CheckSum]<CR><LF>

(7.1.1) Record Types Definition-

H = Header record	REQUIRED

(7.1.2) Delimiter Definition-

¦ = Field Delimiter	REQUIRED
\ = Repeat Delimiter	REQUIRED
^ = Component Delimiter	REQUIRED
& = Escape Delimiter	DEFINED, NOT SUPPORTED

(7.1.3) Message Control ID- NOT SUPPORTED

(7.1.4) Access Password REQUIRED
(Configurable in LIS Param screen;
Maximum of 15 characters)

(7.1.5) Sender Name or ID- REQUIRED
(Configurable in LIS Param screen;
Maximum of 20 characters)

(7.1.6) Sender Street Address- SUPPORTED

(7.1.7) Reserved Field- NOT SUPPORTED

(7.1.8) Senders Telephone Number- SUPPORTED

(7.1.9) Characteristics of Sender- SUPPORTED
(8 bits No Parity 1 Stop Bit)

(7.1.10) Receiver ID- REQUIRED
(Configurable in LIS Param screen;
Maximum of 15 characters)

(7.1.11) Comments/Special Instructions- NOT SUPPORTED

(7.1.12) Processing ID Definition-

P = "Normal" production/running message	SUPPORTED
T = Training message	NOT SUPPORTED
D = Debugging, used to debug a program(s)	NOT SUPPORTED
Q = Message is for QC/regulatory purposes	NOT SUPPORTED

(7.1.13) Version Number- SUPPORTED
(Currently 1)

(7.1.14) Date + Time of Message SUPPORTED
(YYYYMMDDHHMMSS)

PATIENT INFORMATION RECORD DEFINITION (8.1 - 8.1.35)
[Record Type (P)][Sequence #][Practice Assigned Patient ID][Laboratory Assigned Patient ID][Patient ID][Patient Name][Mother's Maiden Name][BirthDate][Patient Sex][Patient Race][Patient Address][Reserved][Patient Phone #][Attending Physician ID][Special Field 1][Special Field 2][Patient Height][Patient Weight][Patients Known or Suspected Diagnosis] [Patient active medications][Patients Diet][Practice Field #1][Practice Field #2][Admission and Discharge Dates][Admission Status][Location][Nature of Alternative Diagnostic Code and Classification][Alternative Diagnostic Code and Classification][Patient Religion][Marital Status][Isolation Status][Language][Hospital Service][Hospital Institution][Dosage Category]

Sample Patient Information Record:
<STX>[FrameNumber]P|1|101|||Riker^Al||19611102|F|||||Bashere<CR><ETX>[CheckSum]<CR><LF>

(8.1.1) Record Types Definition-
P = Patient Identity Record REQUIRED

(8.1.2) Sequence # Definition- REQUIRED

(8.1.3) Practice Assigned Patient ID- REQUIRED
(maximum of 15 characters)
(8.1.4) Laboratory Assigned Patient ID- NOT SUPPORTED

(8.1.5) Patient ID- NOT SUPPORTED

(8.1.6) Patient Name- SUPPORTED
(Last^First^Initial; Maximum of 20 characters for Last Name;
Maximum of 15 characters for First Name)
(8.1.7) Mother's Maiden Name- NOT SUPPORTED

(8.1.8) Birthdate- SUPPORTED
(YYYYMMDD;
Maximum of 8 characters)
(8.1.9) Patient's Sex- SUPPORTED
(M or F; maximum of 1 character)

(8.1.10)Patient Race-Ethnic Origin- NOT SUPPORTED

(8.1.11)Patient's Address- NOT SUPPORTED

(8.1.12)Reserved Field- NOT SUPPORTED

(8.1.13)Patient's Phone#- NOT SUPPORTED

(8.1.14)Attending Physician ID (Last Name Only)- SUPPORTED
(Maximum of 20 characters)

(8.1.15)Special Field 1-	NOT SUPPORTED
(8.1.16)Special Field 2-	NOT SUPPORTED
(8.1.17)Patient Height-	NOT SUPPORTED
(8.1.18)Patient Weight-	NOT SUPPORTED
(8.1.19)Known or Suspected Diagnosis-	NOT SUPPORTED
(8.1.20)Active Medications-	NOT SUPPORTED
(8.1.21)Patient's Diet-	NOT SUPPORTED
(8.1.22)Practice Field 1-	NOT SUPPORTED
(8.1.23)Practice Field 2-	NOT SUPPORTED
(8.1.24)Admission and Discharge Dates-	NOT SUPPORTED
(8.1.25)Admission Status-	NOT SUPPORTED
(8.1.26)Location-	NOT SUPPORTED
(8.1.27)Nature of Alt. Diag. Code.....-	NOT SUPPORTED
(8.1.28)Alt. Diag. Code and Classifications-	NOT SUPPORTED
(8.1.29)Patient Religion-	NOT SUPPORTED
(8.1.30)Marital Status-	NOT SUPPORTED
(8.1.31)Isolation Status-	NOT SUPPORTED
(8.1.32)Language-	NOT SUPPORTED
(8.1.33)Hospital Service-	NOT SUPPORTED
(8.1.34)Hospital Institution-	NOT SUPPORTED
(8.1.35)Dosage Category-	NOT SUPPORTED

ORDER RECORD DEFINITION (9.4.1-9.4.31)

[Record Type (O)][Sequence#][Specimen ID (Accession#)][Instrument Specimen ID][Universal Test ID][Priority][Order Date/Time][Collection Date/Time][Collection End Time][Collection Volume][Collector ID][Action Code][Danger Code][Relevant Clinical Info][Date/Time Specimen Received][Specimen Descriptor,Specimen Type,Specimen Source][Ordering Physician][Physician's Telephone Number][User Field No.1][User Field No.2][Lab Field No.1][Lab Field No.2][Date/Time results reported or last modified][Instrument Charge to Computer System][Instrument Section ID][Report Types][Reserved Field][Location or ward of Specimen Collection][Nosocomial Infection Flag][Specimen Service][Specimen Institution]

Sample Test Order Message:

<STX>[FrameNumber]O|1|1550623||^^^LH|R|19931011091233|19931011091233<CR><ETX>[CheckSum]<CR><LF>

(9.4.1) Record types Definition-
O = Test Order Record — REQUIRED

(9.4.2)Sequence #- — REQUIRED

(9.4.3) Specimen ID- — REQUIRED
(ACCESSION # ON PRIMARY TUBE;
Maximum of 20 characters)

(9.4.4) Instrument Specimen ID- — NOT SUPPORTED

(9.4.5) Universal Test ID — REQUIRED
(^^^[Test Code])
Example Test Codes: TSH, LH, FSH, DGX, T4, HCG, TU, RTH, T3, FER, PSA, PAP
(Maximum of 6 characters)

(9.4.6) Priority- — SUPPORTED
S-Stat
A-As soon as possible
R-Routine
C-Callback
P-Preoperative
(Maximum of 1 character)

(9.4.7) Requested/Ordered Date and Time- — SUPPORTED
(YYYYMMDDHHMMSS;
Maximum of 14 characters)

(9.4.8) Specimen Collection Date and Time- — SUPPORTED
(Maximum of 14 characters)

(9.4.9) Collection End Time- — NOT SUPPORTED

(9.4.10) Collection Volume- — NOT SUPPORTED

(9.4.11) Collector ID- — NOT SUPPORTED

(9.4.12) Action Code-	NOT SUPPORTED
(9.4.13) Danger Code-	NOT SUPPORTED
(9.4.14) Relevant Clinical Information-	NOT SUPPORTED
(9.4.15) Date/Time Specimen Received-	NOT SUPPORTED
(9.4.16) Specimen Descriptor-	NOT SUPPORTED
(9.4.16.1) Specimen Type-	NOT SUPPORTED
(9.4.17) Ordering Physician-	NOT SUPPORTED
(9.4.18) Physician's Telephone Number-	NOT SUPPORTED
(9.4.19) Users Field No. 1-	NOT SUPPORTED
(9.4.20) Users Field No. 2-	NOT SUPPORTED
(9.4.21) Lab Field No. 1-	NOT SUPPORTED
(9.4.22) Lab Field No. 2-	NOT SUPPORTED
(9.4.23) Date/Time Results Reported....-	NOT SUPPORTED
(9.4.24) Instrument Charge to Computer Sys.-	NOT SUPPORTED
(9.4.25) Instrument Section ID-	NOT SUPPORTED
(9.4.26) Report Types-	NOT SUPPORTED
(9.4.27) Reserved Field-	NOT SUPPORTED
(9.4.28) Location of Specimen Collection-	NOT SUPPORTED
(9.4.29) Nosocomial Infection Flag-	NOT SUPPORTED
(9.4.30) Specimen Service-	NOT SUPPORTED
(9.4.31) Specimen Institution-	NOT SUPPORTED

RESULT RECORD DEFINITION (10.1 - 10.1.14)
[Record Type (R)][Sequence #][Universal Test ID][Data (result)][Units][ReferenceRanges] [Result abnormal flags][Nature of Abnormality Testing][Result Status][Date of change in instruments normal values or units][Operator ID][Date\Time Test Started][Date\Time Test Completed][Instrument ID]

Sample Result Message:
<STX>[FrameNumber]R|1|^^^LH|8.2|mIU/mL|.7\.7^400\400|N|N|F||test|19931011091233|19931011091233|DPCCIRRUS<CR><ETX>[CheckSum]<CR><LF>

(10.1.1) Record Types Definition-

R = Result Record	REQUIRED

(10.1.2)Sequence #- REQUIRED

(10.1.3)Universal Test ID- PARTIALLY SUPPORTED \ REQUIRED
(^^^[Test Code])
Example Test Codes: TSH, LH, FSH, DGX, T4, HCG, TU, RTH, T3, FER, PSA, PAP

(10.1.4)Data or Measurement Value (Result)- REQUIRED

(10.1.5)Units- REQUIRED
Current Siemens Diagnostics Units of Measure: ng/mL, ng/dL, ug/dL, uIu/mL, mIU/mL, pg/mL, nmol/L, pmol/L, mIU/L, ug/L, IU/mL, IU/L,

(10.1.6)Reference Ranges- SUPPORTED
([Low]\[Panic\Low]^[High]\[Panic High])

(10.1.7)Result Abnormal Flags-
(Siemens Diagnostics may add in later revisions Instrument Failure Codes)

L = Below Normal	SUPPORTED
H = Above Normal	SUPPORTED
LL = Below Panic	NOT SUPPORTED
HH = Above Panic	NOT SUPPORTED
< = Below readable limit	REQUIRED
> = Above readable limit	REQUIRED
N = Normal	SUPPORTED
A = Abnormal	NOT SUPPORTED
U = Significant change UP	NOT SUPPORTED
D = Significant change DOWN	NOT SUPPORTED
B = Better	NOT SUPPORTED
W = Worse	NOT SUPPORTED

(10.1.8)Nature of Abnormality Testing-

A = Age population tested	NOT SUPPORTED
S = Sex based Population	NOT SUPPORTED
R = Race based Population	NOT SUPPORTED
N = Normal generic range	SUPPORTED

(10.1.9)Results Status-

C = Correction of previously sent results	NOT SUPPORTED
P = Preliminary Results	NOT SUPPORTED
F = Final Results	SUPPORTED
X = Results cannot be done. (Eg. Calculation Error)	NOT SUPPORTED
I = In instrument, results pending	NOT SUPPORTED
S = Partial Results	NOT SUPPORTED
M = Result is a MIC level	NOT SUPPORTED
R = This result was previously transmitted	NOT SUPPORTED
N = This result record contains necessary information to run a new order.	NOT SUPPORTED

(10.1.10)Date systems values/units changed- NOT SUPPORTED

(10.1.11)Operator Name/ID#- SUPPORTED

(10.1.12)Date+Time Test Started (YYYYMMDDHHMMSS) SUPPORTED

(10.1.13)Date+Time Test Completed (YYYYMMDDHHMMSS) SUPPORTED

(10.1.14)Instrument ID- SUPPORTED
(Configurable From Siemens Diagnostics 'KIT' Program)

REQUEST INFORMATION RECORD DEFINITION (HOST QUERY) (12.1 - 12.1.13)
[Record Type ID (Q)][Sequence #][Starting Range][Ending Range][Test ID][Request Time Limits][Beginning request results date and time][Ending request results date and time][Physician name][Physician Phone Number][User Field 1]User Field 2][Status Codes]

Example Request Record:
<STX>[FrameNumber]Q|1|^1234ABC||ALL|||||||O<CR><ETX>[CheckSum]<CR><LF>

(12.1.1) Record Types Definition-	
Q = Request information Record	SUPPORTED (UPLOAD ONLY)
(12.1.2) Sequence Number	SUPPORTED
(12.1.3) Starting Range ID Number	REQUIRED
(12.1.4) Ending Range ID Number	NOT SUPPORTED
(12.1.5) Universal Test ID	REQUIRED
(12.1.6) Request Time Limits	NOT SUPPORTED
(12.1.7) Beginning Request Results ...	NOT SUPPORTED
(12.1.8) Ending Request Results ...	NOT SUPPORTED
(12.1.9) Physician Name	NOT SUPPORTED
(12.1.10) Physician Phone #	NOT SUPPORTED
(12.1.11) User field #1	NOT SUPPORTED
(12.1.12) User field #2	NOT SUPPORTED
12.1.13) Request information status codes	
C- Correction of previous results	NOT SUPPORTED
P- Preliminary Results	NOT SUPPORTED
F- Final Results	NOT SUPPORTED
X- Results cannot be done, cancel	NOT SUPPORTED
I- Request Results Pending	NOT SUPPORTED
S- Request partial results	NOT SUPPORTED
M-Result is a MIC level	NOT SUPPORTED
R- Result previously transmitted	NOT SUPPORTED
A- Abort/cancel last request	REQUIRED
N- Requesting new results only	NOT SUPPORTED
O- Requesting orders and demographics	REQUIRED
D- Requesting demographics only	NOT SUPPORTED

MESSAGE TERMINATOR RECORD DEFINITION (13.1 - 13.1.3)
[Record Type ID (L)][Sequence Number][Temination Code]

Example Termination Record:
<STX>[FrameNumber]L|1|N<CR><ETX>[CheckSum]<CR><LF>

(13.1.1) Record Types Definition-

L = Terminator record	SUPPORTED

(13.1.2)Sequence # -	REQUIRED

(13.1.3)Termination Code-

N = Normal termination	SUPPORTED
T = Sender Aborted	NOT SUPPORTED
R = Receiver Abort	NOT SUPPORTED
E = Unknown system error	NOT SUPPORTED
Q = Error in last request for information	REQUIRED WITH QUERY
I = No information available from last query	REQUIRED WITH QUERY
F = Last request for information Processed	REQUIRED WITH QUERY

IMMULITE UNI-DIRECTIONAL LIS SPECIFICATION
ASTM E1394

HEADER RECORD DEFINITION (7.1 - 7.1.14)
[Record Type (H)] [Delimiter Def.] [Message Control ID] [Password] [Sending systems company name] [Sending Systems address] [Reserved] [Senders Phone#] [Communication parameters] [Receiver ID] [Comments/special instructions] [Processing ID] [Version#] [Message Date + Time]
Sample Header Message:

<STX>[FrameNumber]H|\^&||Password|DPCCIRRUS|Randolph^New^Jersey^07869||(201)927-2828|8N1|Receiver||P|1|19920521132100<CR><ETX>[CheckSum]<CR><LF>

(7.1.1) Record Types Definition-
H = Header record — REQUIRED

(7.1.2) Delimiter Definition-

¦ = Field Delimiter	REQUIRED
\ = Repeat Delimiter	REQUIRED
^ = Component Delimiter	REQUIRED
& = Escape Delimiter	DEFINED, NOT SUPPORTED

(7.1.3) Message Control ID- NOT SUPPORTED

(7.1.4) Access Password REQUIRED
(Configurable in LIS PARAMETERS window; Maximum of 15 characters)

(7.1.5) Sender Name or ID- REQUIRED
(Configurable in LIS PARAMETERS window; Maximum of 20 characters)

(7.1.6) Sender Street Address- SUPPORTED

(7.1.7) Reserved Field- NOT SUPPORTED

(7.1.8) Senders Telephone Number- SUPPORTED

(7.1.9) Characteristics of Sender- SUPPORTED
(8 bits No Parity 1 Stop Bit)

(7.1.10)Receiver ID- REQUIRED
(Configurable in the LIS PARAMETERS window; Maximum of 15 characters)

(7.1.11)Comments/Special Instructions- NOT SUPPORTED

(7.1.12) Processing ID Definition-

P = "Normal" production/running message	SUPPORTED
T = Training message	NOT SUPPORTED
D = Debugging, used to debug a program(s)	NOT SUPPORTED
Q = Message is for QC/regulatory purposes	NOT SUPPORTED

(7.1.13)Version Number- (Currently 1) SUPPORTED

(7.1.14)Date+Time of Message (YYYYMMDDHHMMSS) SUPPORTED

PATIENT INFORMATION RECORD DEFINITION (8.1 - 8.1.35)
[Record Type (P)][Sequence #][Practice Assigned Patient ID][Laboratory Assigned Patient ID][Patient ID][Patient Name][Mother's Maiden Name][BirthDate][Patient Sex][Patient Race][Patient Address][Reserved][Patient Phone #][Attending Physician ID][Special Field 1][Special Field 2][Patient Height][Patient Weight][Patients Known or Suspected Diagnosis] [Patient active medications][Patients Diet][Practice Field #1][Practice Field #2][Admission and Discharge Dates][Admission Status][Location][Nature of Alternative Diagnostic Code and Classification][Alternative Diagnostic Code and Classification][Patient Religion][Marital Status][Isolation Status][Language][Hospital Service][Hospital Institution][Dosage Category]

Sample Patient Information Record:
<STX>[FrameNumber]P|1||||Jones^Jane^L||19640804|F|||||Doctor<CR><ETX>[CheckSum]<CR><LF>

(8.1.1) Record Types Definition-
P = Patient Identity Record REQUIRED

(8.1.2) Sequence # Definition- REQUIRED

(8.1.3) Practice Assigned Patient ID- NOT SUPPORTED

(8.1.4) Laboratory Assigned Patient ID- NOT SUPPORTED

(8.1.5) Patient ID- NOT SUPPORTED

(8.1.6) Patient Name- SUPPORTED
(Last^First^Initial; maximum of 20 characters for Last Name; maximum of 15 characters for First Name)

(8.1.7) Mother's Maiden Name- NOT SUPPORTED

(8.1.8) Birthdate- SUPPORTED
(YYYYMMDD; maximum of 8 characters)

(8.1.9) Patient's Sex- SUPPORTED
(M or F; maximum of 1 character)

(8.1.10)Patient Race-Ethnic Origin- NOT SUPPORTED

(8.1.11)Patient's Address- NOT SUPPORTED

(8.1.12)Reserved Field- NOT SUPPORTED

(8.1.13)Patient's Phone#- NOT SUPPORTED

(8.1.14)Attending Physician ID- (Last Name Only; maximum of 20 characters)	SUPPORTED
(8.1.15)Special Field 1-	NOT SUPPORTED
(8.1.16)Special Field 2-	NOT SUPPORTED
(8.1.17)Patient Height-	NOT SUPPORTED
(8.1.18)Patient Weight-	NOT SUPPORTED
(8.1.19)Known or Suspected Diagnosis-	NOT SUPPORTED
(8.1.20)Active Medications-	NOT SUPPORTED
(8.1.21)Patient's Diet-	NOT SUPPORTED
(8.1.22)Practice Field 1-	NOT SUPPORTED
(8.1.23)Practice Field 2-	NOT SUPPORTED
(8.1.24)Admission and Discharge Dates-	NOT SUPPORTED
(8.1.25)Admission Status-	NOT SUPPORTED
(8.1.26)Location-	NOT SUPPORTED
(8.1.27)Nature of Alt. Diag. Code.....-	NOT SUPPORTED
(8.1.28)Alt. Diag. Code and Classifications-	NOT SUPPORTED
(8.1.29)Patient Religion-	NOT SUPPORTED
(8.1.30)Marital Status-	NOT SUPPORTED
(8.1.31)Isolation Status-	NOT SUPPORTED
(8.1.32)Language-	NOT SUPPORTED
(8.1.33)Hospital Service-	NOT SUPPORTED
(8.1.34)Hospital Institution-	NOT SUPPORTED
(8.1.35)Dosage Category-	NOT SUPPORTED

ORDER RECORD DEFINITION (9.4.1-9.4.31)
[Record Type (O)][Sequence#][Specimen ID (Accession#)][Instrument Specimen ID][Universal Test ID][Priority][Order Date/Time][Collection Date/Time][Collection End Time][Collection Volume][Collector ID][Action Code][Danger Code][Relevant Clinical Info][Date/Time Specimen Received][Specimen Descriptor,Specimen Type,Specimen Source][Ordering Physician][Physician's Telephone Number][User Field No.1][User Field No.2][Lab Field No.1][Lab Field No.2][Date/Time results reported or last modified][Instrument Charge to Computer System][Instrument Section ID][Report Types][Reserved Field][Location or ward of Specimen Collection][Nosocomial Infection Flag][Specimen Service][Specimen Institution]

Sample Test Order Message:
<STX>[FrameNumber]O|1|123456||^^^TSH<CR><ETX>[CheckSum]<CR><LF>

(9.4.1) Record types Definition-
O = Test Order Record — REQUIRED

(9.4.2)Sequence #- — REQUIRED

(9.4.3) Specimen ID- — REQUIRED
(ACCESSION # ON PRIMARY TUBE;
maximum of 20 characters)

(9.4.4) Instrument Specimen ID- — NOT SUPPORTED

(9.4.5) Universal Test ID — REQUIRED
(^^^[Test Code])
Example Test Codes: TSH, LH, FSH, DGX, TT4, HCG, TU, RTH, T3, FER, PSA, PAP
(maximum of 6 characters)

(9.4.6) Priority- — NOT SUPPORTED
(maximum of 1 character)

(9.4.7) Requested/Ordered Date and Time- — NOT SUPPORTED
(maximum of 14 characters)

(9.4.8) Specimen Collection Date and Time- — NOT SUPPORTED
(maximum of 14 characters)

(9.4.9) Collection End Time- — NOT SUPPORTED

(9.4.10) Collection Volume- — NOT SUPPORTED

(9.4.11) Collector ID- — NOT SUPPORTED

(9.4.12) Action Code- — NOT SUPPORTED

(9.4.13) Danger Code- — NOT SUPPORTED

(9.4.14) Relevant Clinical Information-	NOT SUPPORTED
(9.4.15) Date/Time Specimen Received-	NOT SUPPORTED
(9.4.16) Specimen Descriptor-	NOT SUPPORTED
(9.4.16.1) Specimen Type-	NOT SUPPORTED
(9.4.17) Ordering Physician-	NOT SUPPORTED
(9.4.18) Physician's Telephone Number-	NOT SUPPORTED
(9.4.19) Users Field No. 1-	NOT SUPPORTED
(9.4.20) Users Field No. 2-	NOT SUPPORTED
(9.4.21) Lab Field No. 1-	NOT SUPPORTED
(9.4.22) Lab Field No. 2-	NOT SUPPORTED
(9.4.23) Date/Time Results Reported....-	NOT SUPPORTED
(9.4.24) Instrument Charge to Computer Sys.-	NOT SUPPORTED
(9.4.25) Instrument Section ID-	NOT SUPPORTED
(9.4.26) Report Types-	NOT SUPPORTED
(9.4.27) Reserved Field-	NOT SUPPORTED
(9.4.28) Location of Specimen Collection-	NOT SUPPORTED
(9.4.29) Nosococmial Infection Flag-	NOT SUPPORTED
(9.4.30) Specimen Service-	NOT SUPPORTED
(9.4.31) Specimen Institution-	NOT SUPPORTED

RESULT RECORD DEFINITION (10.1 - 10.1.14)
[Record Type (R)][Sequence #][Universal Test ID][Data (result)][Units][ReferenceRanges] [Result abnormal flags][Nature of Abnormality Testing][Result Status][Date of change in instruments normal values or units][Operator ID][Date\Time Test Started][Date\Time Test Completed][Instrument ID]

Sample Result Message:
<STX>[FrameNumber]R|1|^^^TSH|8.19|uIU/mL|.4\.002^4\75|H|N|F||test|1994032810834|19920526110500|DPCCIRRUS<CR><ETX>[CheckSum]<CR><LF>

(10.1.1) Record Types Definition-

R = Result Record	REQUIRED

(10.1.2)Sequence #-	REQUIRED
(10.1.3)Universal Test ID-	PARTIALLY SUPPORTED \ REQUIRED

(^^^[Test Code])
Example Test Codes: TSH, LH, FSH, DGX, TT4, HCG, TU, RTH, T3, FER, PSA, PAP

(10.1.4)Data or Measurement Value (Result)- Current	REQUIRED
(10.1.5)Units-	REQUIRED

Current Siemens Diagnostics Units of Measure: ng/mL, ng/dL, ug/dL, uIu/mL, mIU/mL, pg/mL, nmol/L, pmol/L, mIU/L, ug/L, IU/mL, IU/L

(10.1.6)Reference Ranges- ([Low]\[Panic\Low]^[High]\[Panic High])	SUPPORTED

(10.1.7)Result Abnormal Flags-
(Siemens Diagnostics may add in later revisions Instrument Failure Codes)

L = Below Normal	SUPPORTED
H = Above Normal	SUPPORTED
LL = Below Panic	NOT SUPPORTED
HH = Above Panic	NOT SUPPORTED
< = Below readable limit	REQUIRED
> = Above readable limit	REQUIRED
N = Normal	SUPPORTED
A = Abnormal	NOT SUPPORTED
U = Significant change UP	NOT SUPPORTED
D = Significant change DOWN	NOT SUPPORTED
B = Better	NOT SUPPORTED
W = Worse	NOT SUPPORTED

(10.1.8)Nature of Abnormality Testing-

A = Age population tested	NOT SUPPORTED
S = Sex based Population	NOT SUPPORTED
R = Race based Population	NOT SUPPORTED
N = Normal generic range	SUPPORTED

(10.1.9)Results Status-

C = Correction of previously sent results	NOT SUPPORTED
P = Preliminary Results	NOT SUPPORTED
F = Final Results	SUPPORTED
X = Results cannot be done. (Eg. Calculation Error)	NOT SUPPORTED
I = In instrument, results pending	NOT SUPPORTED
S = Partial Results	NOT SUPPORTED
M = Result is a MIC level	NOT SUPPORTED
R = This result was previously transmitted	NOT SUPPORTED
N = This result record contains necessary information to run a new order.	NOT SUPPORTED

(10.1.10)Date systems values/units changed- NOT SUPPORTED

(10.1.11)Operator Name/ID#- SUPPORTED

(10.1.12)Date+Time Test Started (YYYYMMDDHHMMSS) SUPPORTED

(10.1.13)Date+Time Test Completed (YYYYMMDDHHMMSS) SUPPORTED

(10.1.14)Instrument ID- SUPPORTED
(Configurable From Siemens Diagnostics 'KIT' Program)

REQUEST INFORMATION RECORD (12.1 - 12.1.13)
NOT SUPPORTED IN UNI DIRECTIONAL MODE

MESSAGE TERMINATOR RECORD DEFINITION (13.1 - 13.1.3)
[Record Type ID (L)][Sequence Number][Temination Code]

Example Termination Record:
<STX>[FrameNumber]L|1|N<CR><ETX>[CheckSum]<CR><LF>

(13.1.1) Record Types Definition-

L = Terminator record	SUPPORTED

(13.1.2)Sequence # - REQUIRED

(13.1.3)Termination Code-

N = Normal termination	SUPPORTED
T = Sender Aborted	NOT SUPPORTED
R = Receiver Abort	NOT SUPPORTED
E = Unknown system error	NOT SUPPORTED
Q = Error in last request for information	NOT SUPPORTED
I = No information available from last query	NOT SUPPORTED
F = Last request for information Processed	NOT SUPPORTED

IMMULITE LIS ERROR MESSAGE DEFINITIONS

Invalid ID – This is the #1 question asked by LIS customers. The Sender ID and \ or Receiver ID is incorrect in the header message. These items need to be switched by the LIS when sending messages to IMMULITE.

Example:
Sender ID is set to "DPC" Receiver ID is set to "HOSPITAL" on IMMULITE

IMMULITE Sending: Sender ID field = "DPC", Receiver ID Field = "HOSPITAL"
LIS Sending: Sender ID Field = "HOSPITAL", Receiver ID field = "DPC"

Invalid Password – The password is incorrect in the header message. Correct by entering the proper password in the LIS PARAMETER section from the START menu. Siemens Diagnostics does not know this password, this is set by the software company. SUNQUEST does not use a password. This field should be left blank for SUNQUEST systems.

Bad or Missing Frame Number – The frame number in the message is not proper. Usually indicates a programming bug in the LIS software, but may be a bad message (E.G. line noise). See ASTM 1394 Logical layer section 6.3.2 for further detail

Invalid Sequence Number – The sequence number in the message is not proper. Usually indicates a programming bug in the LIS software, but may be a bad message (E.G. line noise). See ASTM 1394 section 6.6.7 for further detail

Message Too short – Data within the message was dropped or not sent. Usually indicates a programming bug in the LIS software, but may be a bad message (E.G. line noise).

LIS Timeout – The LIS is not responding to IMMULITE. Causes can be a cabling problem, communication problem (hardware related), or programming bug in the LIS software

<CR> or <LF> Missing in LIS Transmission – Usually indicates a programming bug in the LIS software, but may be a bad message (E.G. line noise).

Error in last request – This is a response FROM the LIS stating the LIS encountered an error to the IMMULITE's request for information.

No info on this # – A response from the LIS to a Query message. The LIS has no information for the sample (accession#).

IMMULITE 1000 LIS Features

The IMMULITE 1000 LIS features:

- Ability to autosend results.
- Ability to re-send results.
- Ability to receive test orders for Control samples. See pages 54-58 for instructions for sending test orders for control samples.
- Ability to send (autosend) Control sample results if the control test order was sent by the LIS.
- The IMMULITE 1000 can be configured for European numbers: 1.200,34. If configured for European numbers, the concentration in the result record will be in European number configuration. International LIS vendors should be aware of this, as the IMMULITE did not have the capability to be configured for European numbers.

Results

Results (including semi-quantitative ratio's) are sent using floating decimals as follows:

Result	# decimal places sent	Example
less than 1.00 *	2	0.45
1.00 – 9.99	2	1.23
10.0 - 99.9	1	10.2
100 and above	None	102

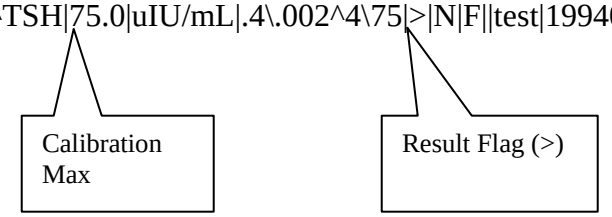
* Results for some assays (including third generation such as TSH, RTH) are reported with three decimal places if the result is less than 1.00.

Required Flags

Required flags include H, L, N, < and >.

Greater than (>) and Less than (<) calibration range results are sent as follows:

0R|1|^^^TSH|75.0|uIU/mL|.4\.002^4\75|>|N|F||test|19940407085044|19940407085148|DPC CIRRUS

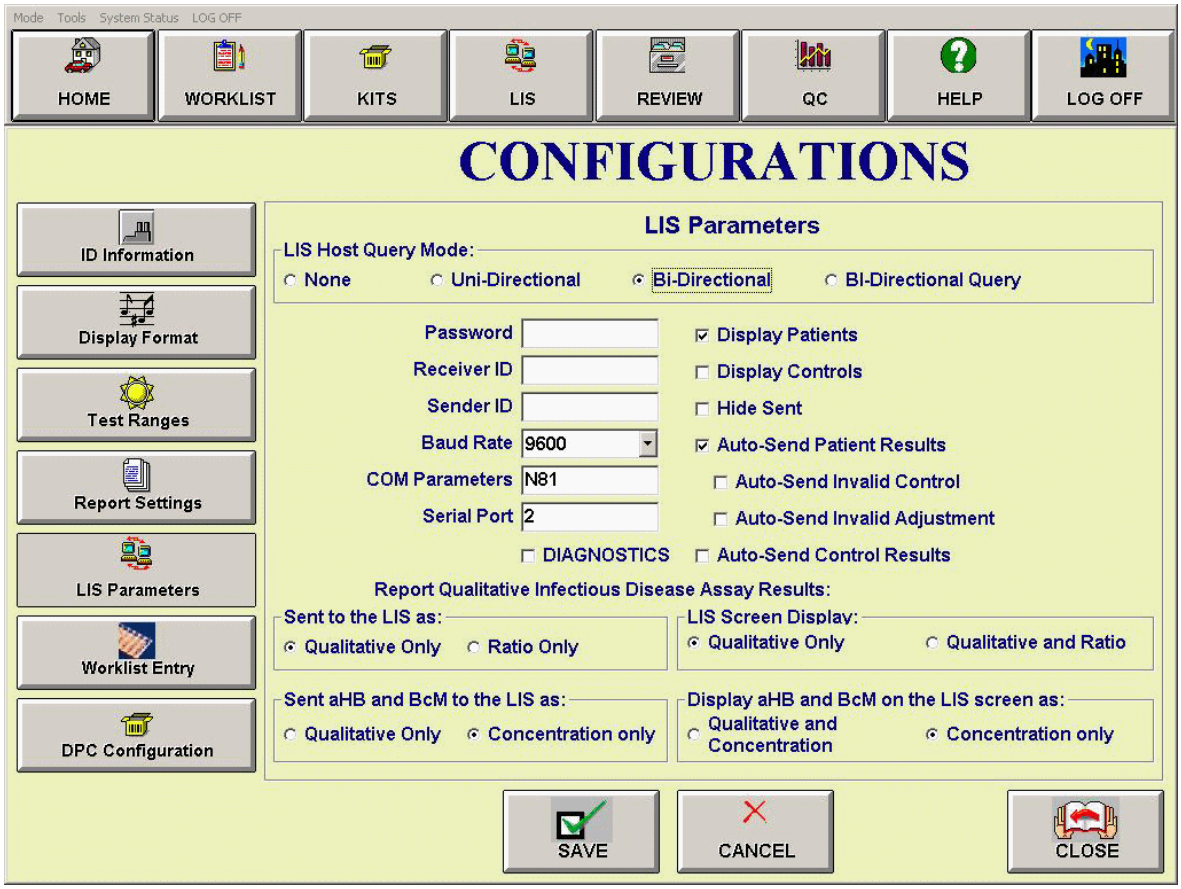


Qualitative Test Results

Qualitative tests result either as a qualitative interpretation for Reactive, Non-Reactive or Indeterminate or as a semi-quantitative ratio (patient CPS/Cutoff CPS), either of which is sent to the LIS (not both).

The qualitative interpretation is sent to the LIS as follows:

Result	Sent to LIS as Qualitative
Non-reactive	0
Reactive	1
Indeterminate	2



See assay package inserts for interpretation of qualitative assay ratio results.

IMMULITE 1000 LIS Configurations

- All Configurations require log off to activate changes
- Select Tools | Configurations | LIS Parameters
- The LIS Parameters screen is password protected. The password is CONNECT.
- Select the appropriate LIS Host Query Mode
- Password, Receiver ID and Sender ID should be provided by LIS Vendor
- COM Parameters must be N81 in LIS Configurations and if sent in Header Record from LIS
- The LIS serial port is labeled “4” on the back of the Instrument. See page 106 for LIS Cable Specifications.
- Select Diagnostics to enable a log of the communication between the IMMULITE 1000 and the LIS for troubleshooting. The LIS log should be disabled during normal operation.
- Select Display Patients
- Select Display Controls if the LIS sends test orders for control samples to the IMMULITE 2000.
- Select Hide Sent to hide sent results from view on the LIS screen.

- Select Auto-Send Patient Results to automatically send each completed result to the LIS. Completed results are not collated per accession number prior to sending.
- Auto-Send Invalid control is not available at this time.
- Select Auto-Send Invalid Adjustment to automatically send patient results flagged ADJ on review screens.
- Select Auto-Send Control Results only if the LIS sends test orders for control samples.
- Report Qualitative Assay Results
    - Sent to the LIS as: Select Qualitative Only or Ratio Only
- LIS Screen Display
    - Select Qualitative Only or Qualitative and Ratio
- Sent AHB and BCM to the LIS as:
    - Select Qualitative Only to send the qualitative interpretation to the LIS
    - Select Concentration Only to send the numeric result concentration to the LIS
- Display AHB and BCM on the LIS screen as:
    - Select Concentration only to display only the numeric result concentration
    - Select Qualitative and Concentration to display the numeric result concentration and the qualitative interpretation

Upload/Download Codes

- IMMUITE Test Codes are used for upload and download codes and can be found in IMMULITE Assay package inserts.

IMMULITE 1000 BI-DIRECTIONAL LIS SPECIFICATION
ASTM E1394

HEADER RECORD DEFINITION (7.1 - 7.1.14)
[Record Type (H)] [Delimiter Def.] [Message Control ID] [Password] [Sending systems company name] [Sending Systems address] [Reserved] [Senders Phone#] [Communication parameters] [Receiver ID] [Comments/special instructions] [Processing ID] [Version#] [Message Date + Time]
Sample Header Message:

<STX>[FrameNumber]H|\^&||Password|DPCCIRRUS|Flanders^New^Jersey^07836||973-927-2828|N81|YourSystem||P|1|19940323082858<CR><ETX>[CheckSum]<CR><LF>

(7.1.1) Record Types Definition-	
H = Header record	REQUIRED
(7.1.2) Delimiter Definition-	
¦ = Field Delimiter	REQUIRED
\ = Repeat Delimiter	REQUIRED
^ = Component Delimiter	REQUIRED
& = Escape Delimiter	DEFINED, NOT SUPPORTED
(7.1.3) Message Control ID-	NOT SUPPORTED
(7.1.4) Access Password (Configurable in LIS Parameters screen; Maximum of 15 characters)	REQUIRED
(7.1.5) Sender Name or ID- (Configurable in LIS Parameters screen; Maximum of 20 characters)	REQUIRED
(7.1.6) Sender Street Address-	SUPPORTED
(7.1.7) Reserved Field-	NOT SUPPORTED
(7.1.8) Senders Telephone Number-	SUPPORTED
(7.1.9) Characteristics of Sender- (No Parity 8 bits 1 Stop Bit)	SUPPORTED
(7.1.10) Receiver ID- (Configurable in LIS Parameters screen; Maximum of 15 characters)	REQUIRED

(7.1.11) Comments/Special Instructions- NOT SUPPORTED

(7.1.12) Processing ID Definition-

P = "Normal" production/running message	SUPPORTED
T = Training message	NOT SUPPORTED
D = Debugging, used to debug a program(s)	NOT SUPPORTED
Q = Message is for QC/regulatory purposes	NOT SUPPORTED

(7.1.13) Version Number- SUPPORTED
(Currently 1)

(7.1.14) Date + Time of Message SUPPORTED
(YYYYMMDDHHMMSS)

PATIENT INFORMATION RECORD DEFINITION (8.1 - 8.1.35)
[Record Type (P)][Sequence #][Practice Assigned Patient ID][Laboratory Assigned Patient ID][Patient ID][Patient Name][Mother's Maiden Name][BirthDate][Patient Sex][Patient Race][Patient Address][Reserved][Patient Phone #][Attending Physician ID][Special Field 1][Special Field 2][Patient Height][Patient Weight][Patients Known or Suspected Diagnosis] [Patient active medications][Patients Diet][Practice Field #1][Practice Field #2][Admission and Discharge Dates][Admission Status][Location][Nature of Alternative Diagnostic Code and Classification][Alternative Diagnostic Code and Classification][Patient Religion][Marital Status][Isolation Status][Language][Hospital Service][Hospital Institution][Dosage Category]

Sample Patient Information Record:
<STX>[FrameNumber]P|1|101|||Riker^Al||19611102|F|||||Bashere<CR><ETX>[CheckSum]<CR><LF>

(8.1.1) Record Types Definition-
P = Patient Identity Record — REQUIRED

(8.1.2) Sequence # Definition- — REQUIRED

(8.1.3) Practice Assigned Patient ID- (maximum of 20 characters) — REQUIRED

(8.1.4) Laboratory Assigned Patient ID- — NOT SUPPORTED

(8.1.5) Patient ID- — NOT SUPPORTED

(8.1.6) Patient Name- — SUPPORTED

For patient sample
(Last^First^Initial; Maximum of 30 characters for Last&First name)

For control sample

First 2 characters:	~C (use uppercase letter)
Next 6 characters:	Control Name (if fewer than 6 characters, right-padded with spaces; should not be empty)
Next 3 characters:	Control Lot (use 3 numeric digits; should not be empty)
Next 6 characters:	Expiration Date (use YYYYMM format; should not be empty)
Last 1 character:	Control Level (should not be empty)

For adjustor sample (SUPPORTED INTERNAL TO Siemens Diagnostics)
First 2 characters: ~A (use uppercase letter)
Next 6 characters: Test Code (should not be empty)
Next 3 characters: Kit Lot (use 3 numeric digits; should not be empty)
Next 3 characters: Adjustor Lot (use 3 numeric digits; should not be empty)
Last 2 characters: Level (use 2 numeric digits; should not be empty)

For verifier sample (SUPPORTED INTERNAL TO Siemens Diagnostics)
First 2 characters: ~V (use uppercase letter)
Next 6 characters: Test Code (should not be empty)
Next 3 characters: Verifier Lot (should not be empty)
Next 1 character: Level (numeric values should not be empty)
Next 4 characters: Range low (numeric value; should not be empty)
Next 4 characters: Range high (numeric value; should not be empty)

(8.1.7) Mother's Maiden Name- NOT SUPPORTED

(8.1.8) Birthdate- SUPPORTED
(YYYYMMDD;
Maximum of 8 characters)

(8.1.9) Patient's Sex- SUPPORTED
(M or F; maximum of 1 character)

(8.1.10)Patient Race-Ethnic Origin- NOT SUPPORTED

(8.1.11)Patient's Address- NOT SUPPORTED

(8.1.12)Reserved Field- NOT SUPPORTED

(8.1.13)Patient's Phone#- NOT SUPPORTED

(8.1.14)Attending Physician ID (Last Name Only)- SUPPORTED
(Maximum of 20 characters)

(8.1.15)Special Field 1- NOT SUPPORTED
(SUPPORTED INTERNAL TO Siemens Diagnostics)
(DPC Field 1)

(8.1.16)Special Field 2- NOT SUPPORTED

(8.1.17)Patient Height- NOT SUPPORTED

(8.1.18)Patient Weight- NOT SUPPORTED

(8.1.19)Known or Suspected Diagnosis- NOT SUPPORTED

(8.1.20)Active Medications-	NOT SUPPORTED
(8.1.21)Patient's Diet-	NOT SUPPORTED
(8.1.22)Practice Field 1-	NOT SUPPORTED
(8.1.23)Practice Field 2-	NOT SUPPORTED
(8.1.24)Admission and Discharge Dates-	NOT SUPPORTED
(8.1.25)Admission Status-	NOT SUPPORTED
(8.1.26)Location-	NOT SUPPORTED
(8.1.27)Nature of Alt. Diag. Code.....-	NOT SUPPORTED
(8.1.28)Alt. Diag. Code and Classifications-	NOT SUPPORTED
(8.1.29)Patient Religion-	NOT SUPPORTED
(8.1.30)Marital Status-	NOT SUPPORTED
(8.1.31)Isolation Status-	NOT SUPPORTED
(8.1.32)Language-	NOT SUPPORTED
(8.1.33)Hospital Service-	NOT SUPPORTED
(8.1.34)Hospital Institution-	NOT SUPPORTED
(8.1.35)Dosage Category-	NOT SUPPORTED

ORDER RECORD DEFINITION (9.4.1-9.4.31)

[Record Type (O)][Sequence#][Specimen ID (Accession#)][Instrument Specimen ID][Universal Test ID][Priority][Order Date/Time][Collection Date/Time][Collection End Time][Collection Volume][Collector ID][Action Code][Danger Code][Relevant Clinical Info][Date/Time Specimen Received][Specimen Descriptor,Specimen Type,Specimen Source][Ordering Physician][Physician's Telephone Number][User Field No.1][User Field No.2][Lab Field No.1][Lab Field No.2][Date/Time results reported or last modified][Instrument Charge to Computer System][Instrument Section ID][Report Types][Reserved Field][Location or ward of Specimen Collection][Nosocomial Infection Flag][Specimen Service][Specimen Institution]

Sample Test Order Message:

<STX>[FrameNumber]O|1|1550623||^^^LH|R|19931011091233|19931011091233<CR><ETX>[CheckSum]<CR><LF>

(9.4.1) Record types Definition-

O = Test Order Record REQUIRED

(9.4.2)Sequence #- REQUIRED

(9.4.3) Specimen ID- REQUIRED

(maximum of 30 characters)

For patient sample

Accession number on primary tube

For control

First 2 characters:	~C (use uppercase letter)
Next 6 characters:	Control Name (if fewer than 6 characters, right-padded with spaces; should not be empty)
Next 3 characters:	Control Lot (use 3 numeric digits; should not be empty)
Next 6 characters:	Expiration Date (use YYYYMM format; should not be empty)
Last 1 character:	Control Level (should not be empty)

For adjustor (SUPPORTED INTERNAL TO Siemens Diagnostics)

First 2 characters:	~A (use uppercase letter)
Next 6 characters:	Test Code (should not be empty)
Next 3 characters:	Kit Lot (use 3 numeric digits; should not be empty)
Next 3 characters:	Adjustor Lot (use 3 numeric digits; should not be empty)
Last 2 characters:	Level (use 2 numeric digits; should not be empty)

For verifier (SUPPORTED INTERNAL TO Siemens Diagnostics)

First 2 characters:	~V (use uppercase letter)
Next 6 characters:	Test Code (should not be empty)
Next 3 characters:	Verifier Lot (should not be empty)
Next 1 character:	Level (numeric values should not be empty)
Next 4 characters:	Range low (numeric value; should not be empty)
Next 4 characters:	Range high (numeric value; should not be empty)

(9.4.4) Instrument Specimen ID- NOT SUPPORTED
SUPPORTED INTERNAL TO Siemens Diagnostics
(Sample Cup #)

(9.4.5) Universal Test ID REQUIRED
(^^^[Test Code])
Example Test Codes: TSH, LH, FSH, DGX, T4, HCG, TU, RTH, T3, FER, PSA, PAP
(Maximum of 6 characters)

(9.4.6) Priority- SUPPORTED
S-Stat
A-As soon as possible
R-Routine
C-Callback
P-Preoperative
(Maximum of 1 character)

(9.4.7) Requested/Ordered Date and Time- SUPPORTED
(YYYYMMDDHHMMSS;
Maximum of 14 characters)

(9.4.8) Specimen Collection Date and Time- SUPPORTED
(Maximum of 14 characters)

(9.4.9) Collection End Time- NOT SUPPORTED

(9.4.10) Collection Volume- NOT SUPPORTED

(9.4.11) Collector ID- NOT SUPPORTED

(9.4.12) Action Code- NOT SUPPORTED

(9.4.13) Danger Code- NOT SUPPORTED

(9.4.14) Relevant Clinical Information- NOT SUPPORTED

(9.4.15) Date/Time Specimen Received- NOT SUPPORTED

(9.4.16) Specimen Descriptor- NOT SUPPORTED

(9.4.16.1) Specimen Type- NOT SUPPORTED

(9.4.17) Ordering Physician- NOT SUPPORTED

(9.4.18) Physician's Telephone Number- NOT SUPPORTED

(9.4.19) Users Field No. 1- NOT SUPPORTED
SUPPORTED INTERNAL TO Siemens Diagnostics
(DPC Field 2)

(9.4.20) Users Field No. 2- NOT SUPPORTED

(9.4.21) Lab Field No. 1- NOT SUPPORTED
SUPPORTED INTERNAL TO Siemens Diagnostics
(CPS)

(9.4.22) Lab Field No. 2- NOT SUPPORTED
SUPPORTED INTERNAL TO Siemens Diagnostics
(Kit Lot)

(9.4.23) Date/Time Results Reported....- NOT SUPPORTED

(9.4.24) Instrument Charge to Computer Sys.- NOT SUPPORTED

(9.4.25) Instrument Section ID- NOT SUPPORTED

(9.4.26) Report Types- NOT SUPPORTED

(9.4.27) Reserved Field- NOT SUPPORTED

(9.4.28) Location of Specimen Collection- NOT SUPPORTED

(9.4.29) Nosocomial Infection Flag- NOT SUPPORTED

(9.4.30) Specimen Service- NOT SUPPORTED

(9.4.31) Specimen Institution- NOT SUPPORTED

RESULT RECORD DEFINITION (10.1 - 10.1.14)
[Record Type (R)][Sequence #][Universal Test ID][Data (result)][Units][ReferenceRanges] [Result abnormal flags][Nature of Abnormality Testing][Result Status][Date of change in instruments normal values or units][Operator ID][Date\Time Test Started][Date\Time Test Completed][Instrument ID]

Sample Result Message:
<STX>[FrameNumber]R|1|^^^LH|8.2|mIU/mL|.7\.7^400\400|N|N|F||test|19931011091233|19931011091233|DPCCIRRUS<CR><ETX>[CheckSum]<CR><LF>

(10.1.1) Record Types Definition-

R = Result Record	REQUIRED

(10.1.2)Sequence #- REQUIRED

(10.1.3)Universal Test ID- PARTIALLY SUPPORTED \ REQUIRED
(^^^[Test Code])
Example Test Codes: TSH, LH, FSH, DGX, T4, HCG, TU, RTH, T3, FER, PSA, PAP

(10.1.4)Data or Measurement Value (Result)- REQUIRED

(10.1.5)Units- REQUIRED
Current Siemens Diagnostics Units of Measure: ng/mL, ng/dL, ug/dL, uIu/mL, mIU/mL, pg/mL, nmol/L, pmol/L, mIU/L, ug/L, IU/mL, IU/L,

(10.1.6)Reference Ranges- SUPPORTED
([Low]\[Panic\Low]^[High]\[Panic High])

(10.1.7)Result Abnormal Flags-
(Siemens Diagnostics may add in later revisions Instrument Failure Codes)

L = Below Normal	SUPPORTED
H = Above Normal	SUPPORTED
LL = Below Panic	NOT SUPPORTED
HH = Above Panic	NOT SUPPORTED
< = Below readable limit	REQUIRED
> = Above readable limit	REQUIRED
N = Normal	SUPPORTED
A = Abnormal	NOT SUPPORTED
U = Significant change UP	NOT SUPPORTED
D = Significant change DOWN	NOT SUPPORTED
B = Better	NOT SUPPORTED
W = Worse	NOT SUPPORTED

(10.1.8)Nature of Abnormality Testing-

A = Age population tested	NOT SUPPORTED
S = Sex based Population	NOT SUPPORTED
R = Race based Population	NOT SUPPORTED
N = Normal generic range	SUPPORTED

(10.1.9)Results Status-

C = Correction of previously sent results	NOT SUPPORTED
P = Preliminary Results	NOT SUPPORTED
F = Final Results	SUPPORTED
X = Results cannot be done. (Eg. Calculation Error)	NOT SUPPORTED
I = In instrument, results pending	NOT SUPPORTED
S = Partial Results	NOT SUPPORTED
M = Result is a MIC level	NOT SUPPORTED
R = This result was previously transmitted	SUPPORTED
N = This result record contains necessary information to run a new order.	NOT SUPPORTED

(10.1.10)Date systems values/units changed- NOT SUPPORTED

(10.1.11)Operator Name/ID#- SUPPORTED

(10.1.12)Date+Time Test Started (YYYYMMDDHHMMSS) SUPPORTED

(10.1.13)Date+Time Test Completed (YYYYMMDDHHMMSS) SUPPORTED

(10.1.14)Instrument ID- SUPPORTED
(Configurable From Siemens Diagnostics 'KIT' Program)

REQUEST INFORMATION RECORD DEFINITION (HOST QUERY) (12.1 - 12.1.13)
[Record Type ID (Q)][Sequence #][Starting Range][Ending Range][Test ID][Request Time Limits][Beginning request results date and time][Ending request results date and time][Physician name][Physician Phone Number][User Field 1]User Field 2][Status Codes]

Example Request Record:
<STX>[FrameNumber]Q|1|^1234ABC||ALL|||||||O<CR><ETX>[CheckSum]<CR><LF>

(12.1.1) Record Types Definition-	
Q = Request information Record	SUPPORTED (UPLOAD ONLY)
(12.1.2) Sequence Number	SUPPORTED
(12.1.3) Starting Range ID Number	REQUIRED
(12.1.4) Ending Range ID Number	NOT SUPPORTED
(12.1.5) Universal Test ID	REQUIRED
(12.1.6) Request Time Limits	NOT SUPPORTED
(12.1.7) Beginning Request Results ...	NOT SUPPORTED
(12.1.8) Ending Request Results ...	NOT SUPPORTED
(12.1.9) Physician Name	NOT SUPPORTED
(12.1.10) Physician Phone #	NOT SUPPORTED
(12.1.11) User field #1	NOT SUPPORTED
(12.1.12) User field #2	NOT SUPPORTED
12.1.13) Request information status codes	
C- Correction of previous results	NOT SUPPORTED
P- Preliminary Results	NOT SUPPORTED
F- Final Results	NOT SUPPORTED
X- Results cannot be done, cancel	NOT SUPPORTED
I- Request Results Pending	NOT SUPPORTED
S- Request partial results	NOT SUPPORTED
M-Result is a MIC level	NOT SUPPORTED
R- Result previously transmitted	NOT SUPPORTED
A- Abort/cancel last request	REQUIRED
N- Requesting new results only	NOT SUPPORTED
O- Requesting orders and demographics	REQUIRED
D- Requesting demographics only	NOT SUPPORTED

MESSAGE TERMINATOR RECORD DEFINITION (13.1 - 13.1.3)
[Record Type ID (L)][Sequence Number][Temination Code]

Example Termination Record:
<STX>[FrameNumber]L|1|N<CR><ETX>[CheckSum]<CR><LF>

(13.1.1) Record Types Definition-

L = Terminator record	SUPPORTED

(13.1.2)Sequence # - REQUIRED

(13.1.3)Termination Code-

N = Normal termination	SUPPORTED
T = Sender Aborted	NOT SUPPORTED
R = Receiver Abort	NOT SUPPORTED
E = Unknown system error	NOT SUPPORTED
Q = Error in last request for information	REQUIRED WITH QUERY
I = No information available from last query	REQUIRED WITH QUERY
F = Last request for information Processed	REQUIRED WITH QUERY

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HEADER RECORD DEFINITION (7.1 - 7.1.14)
[Record Type (H)] [Delimiter Def.] [Message Control ID] [Password] [Sending systems company name] [Sending Systems address] [Reserved] [Senders Phone#] [Communication parameters] [Receiver ID] [Comments/special instructions] [Processing ID] [Version#] [Message Date + Time]
Sample Header Message:

<STX>[FrameNumber]H|\^&||Password|DPCCIRRUS|Flanders^New^Jersey^07836|| 973-927-2828|N81|Receiver||P|1|19920521132100<CR><ETX>[CheckSum]<CR><LF>

(7.1.1) Record Types Definition-	
H = Header record	REQUIRED
(7.1.2) Delimiter Definition-	
¦ = Field Delimiter	REQUIRED
\ = Repeat Delimiter	REQUIRED
^ = Component Delimiter	REQUIRED
& = Escape Delimiter	DEFINED, NOT SUPPORTED
(7.1.3) Message Control ID-	NOT SUPPORTED
(7.1.4) Access Password (Configurable in LIS Parameters window; Maximum of 15 characters)	REQUIRED
(7.1.5) Sender Name or ID- (Configurable in LIS Parameters window; Maximum of 20 characters)	REQUIRED
(7.1.6) Sender Street Address-	SUPPORTED
(7.1.7) Reserved Field-	NOT SUPPORTED
(7.1.8) Senders Telephone Number-	SUPPORTED
(7.1.9) Characteristics of Sender- (8 bits No Parity 1 Stop Bit)	SUPPORTED
(7.1.10)Receiver ID- (Configurable in the LIS Parameters window; Maximum of 15 characters)	REQUIRED

(7.1.11)Comments/Special Instructions- NOT SUPPORTED

(7.1.12) Processing ID Definition-

P = "Normal" production/running message	SUPPORTED
T = Training message	NOT SUPPORTED
D = Debugging, used to debug a program(s)	NOT SUPPORTED
Q = Message is for QC/regulatory purposes	NOT SUPPORTED

(7.1.13)Version Number- SUPPORTED
(Currently 1)

(7.1.14)Date+Time of Message SUPPORTED
(YYYYMMDDHHMMSS)

PATIENT INFORMATION RECORD DEFINITION (8.1 - 8.1.35)
[Record Type (P)][Sequence #][Practice Assigned Patient ID][Laboratory Assigned Patient ID][Patient ID][Patient Name][Mother's Maiden Name][BirthDate][Patient Sex][Patient Race][Patient Address][Reserved][Patient Phone #][Attending Physician ID][Special Field 1][Special Field 2][Patient Height][Patient Weight][Patients Known or Suspected Diagnosis] [Patient active medications][Patients Diet][Practice Field #1][Practice Field #2][Admission and Discharge Dates][Admission Status][Location][Nature of Alternative Diagnostic Code and Classification][Alternative Diagnostic Code and Classification][Patient Religion][Marital Status][Isolation Status][Language][Hospital Service][Hospital Institution][Dosage Category]

Sample Patient Information Record:
<STX>[FrameNumber]P|1||||Jones^Jane^L||19640804|F|||||Doctor<CR><ETX>[CheckSum]<CR><LF>

(8.1.1) Record Types Definition-
P = Patient Identity Record REQUIRED

(8.1.2) Sequence # Definition- REQUIRED

(8.1.3) Practice Assigned Patient ID- NOT SUPPORTED

(8.1.4) Laboratory Assigned Patient ID- NOT SUPPORTED

(8.1.5) Patient ID- NOT SUPPORTED

(8.1.6) Patient Name- SUPPORTED
(Last^First^Initial; maximum of 20 characters for Last Name; maximum of 15 characters for First Name)

(8.1.7) Mother's Maiden Name- NOT SUPPORTED

(8.1.8) Birthdate- SUPPORTED
(YYYYMMDD; maximum of 8 characters)

(8.1.9) Patient's Sex- SUPPORTED
(M or F; maximum of 1 character)

(8.1.10)Patient Race-Ethnic Origin- NOT SUPPORTED

(8.1.11)Patient's Address- NOT SUPPORTED

(8.1.12)Reserved Field- NOT SUPPORTED

(8.1.13)Patient's Phone#- NOT SUPPORTED

(8.1.14)Attending Physician ID- (Last Name Only; maximum of 20 characters)	SUPPORTED
(8.1.15)Special Field 1-	NOT SUPPORTED
(8.1.16)Special Field 2-	NOT SUPPORTED
(8.1.17)Patient Height-	NOT SUPPORTED
(8.1.18)Patient Weight-	NOT SUPPORTED
(8.1.19)Known or Suspected Diagnosis-	NOT SUPPORTED
(8.1.20)Active Medications-	NOT SUPPORTED
(8.1.21)Patient's Diet-	NOT SUPPORTED
(8.1.22)Practice Field 1-	NOT SUPPORTED
(8.1.23)Practice Field 2-	NOT SUPPORTED
(8.1.24)Admission and Discharge Dates-	NOT SUPPORTED
(8.1.25)Admission Status-	NOT SUPPORTED
(8.1.26)Location-	NOT SUPPORTED
(8.1.27)Nature of Alt. Diag. Code.....-	NOT SUPPORTED
(8.1.28)Alt. Diag. Code and Classifications-	NOT SUPPORTED
(8.1.29)Patient Religion-	NOT SUPPORTED
(8.1.30)Marital Status-	NOT SUPPORTED
(8.1.31)Isolation Status-	NOT SUPPORTED
(8.1.32)Language-	NOT SUPPORTED
(8.1.33)Hospital Service-	NOT SUPPORTED
(8.1.34)Hospital Institution-	NOT SUPPORTED
(8.1.35)Dosage Category-	NOT SUPPORTED

ORDER RECORD DEFINITION (9.4.1-9.4.31)

[Record Type (O)][Sequence#][Specimen ID (Accession#)][Instrument Specimen ID][Universal Test ID][Priority][Order Date/Time][Collection Date/Time][Collection End Time][Collection Volume][Collector ID][Action Code][Danger Code][Relevant Clinical Info][Date/Time Specimen Received][Specimen Descriptor,Specimen Type,Specimen Source][Ordering Physician][Physician's Telephone Number][User Field No.1][User Field No.2][Lab Field No.1][Lab Field No.2][Date/Time results reported or last modified][Instrument Charge to Computer System][Instrument Section ID][Report Types][Reserved Field][Location or ward of Specimen Collection][Nosocomial Infection Flag][Specimen Service][Specimen Institution]

Sample Test Order Message:
<STX>[FrameNumber]O|1|123456||^^^TSH<CR><ETX>[CheckSum]<CR><LF>

(9.4.1) Record types Definition-
O = Test Order Record REQUIRED

(9.4.2)Sequence #- REQUIRED

(9.4.3) Specimen ID- REQUIRED
(ACCESSION # ON PRIMARY TUBE;
maximum of 20 characters)

(9.4.4) Instrument Specimen ID- NOT SUPPORTED
SUPPORTED INTERNAL TO Siemens Diagnostics
Sample Cup #

(9.4.5) Universal Test ID REQUIRED
(^^^[Test Code])
Example Test Codes: TSH, LH, FSH, DGX, TT4, HCG, TU, RTH, T3, FER, PSA, PAP
(maximum of 6 characters)

(9.4.6) Priority- NOT SUPPORTED
(maximum of 1 character)

(9.4.7) Requested/Ordered Date and Time- NOT SUPPORTED
(maximum of 14 characters)

(9.4.8) Specimen Collection Date and Time- NOT SUPPORTED
(maximum of 14 characters)

(9.4.9) Collection End Time- NOT SUPPORTED

(9.4.10) Collection Volume- NOT SUPPORTED

(9.4.11) Collector ID- NOT SUPPORTED

(9.4.12) Action Code- NOT SUPPORTED

(9.4.13) Danger Code- NOT SUPPORTED

(9.4.14) Relevant Clinical Information- NOT SUPPORTED

(9.4.15) Date/Time Specimen Received- NOT SUPPORTED

(9.4.16) Specimen Descriptor- NOT SUPPORTED

(9.4.16.1) Specimen Type- NOT SUPPORTED

(9.4.17) Ordering Physician- NOT SUPPORTED

(9.4.18) Physician's Telephone Number- NOT SUPPORTED

(9.4.19) Users Field No. 1- NOT SUPPORTED

(9.4.20) Users Field No. 2- NOT SUPPORTED

(9.4.21) Lab Field No. 1- NOT SUPPORTED
SUPPORTED INTERNAL TO Siemens Diagnostics (CPS)

(9.4.22) Lab Field No. 2- NOT SUPPORTED
SUPPORTED INTERNAL TO Siemens Diagnostics (Kit Lot)

(9.4.23) Date/Time Results Reported....- NOT SUPPORTED

(9.4.24) Instrument Charge to Computer Sys.- NOT SUPPORTED

(9.4.25) Instrument Section ID- NOT SUPPORTED

(9.4.26) Report Types- NOT SUPPORTED

(9.4.27) Reserved Field- NOT SUPPORTED

(9.4.28) Location of Specimen Collection- NOT SUPPORTED

(9.4.29) Nosococmial Infection Flag- NOT SUPPORTED

(9.4.30) Specimen Service- NOT SUPPORTED

(9.4.31) Specimen Institution- NOT SUPPORTED

RESULT RECORD DEFINITION (10.1 - 10.1.14)
[Record Type (R)][Sequence #][Universal Test ID][Data (result)][Units][ReferenceRanges] [Result abnormal flags][Nature of Abnormality Testing][Result Status][Date of change in instruments normal values or units][Operator ID][Date\Time Test Started][Date\Time Test Completed][Instrument ID]

Sample Result Message:
<STX>[FrameNumber]R|1|^^^TSH|8.19|uIU/mL|.4\.002^4\75|H|N|F||test|1994032810834|19920526110500|DPCCIRRUS<CR><ETX>[CheckSum]<CR><LF>

(10.1.1) Record Types Definition-

R = Result Record	REQUIRED

(10.1.2)Sequence #- REQUIRED

(10.1.3)Universal Test ID- PARTIALLY SUPPORTED \ REQUIRED
(^^^[Test Code])
Example Test Codes: TSH, LH, FSH, DGX, TT4, HCG, TU, RTH, T3, FER, PSA, PAP

(10.1.4)Data or Measurement Value (Result)- REQUIRED
Current

(10.1.5)Units- REQUIRED
Current Siemens Diagnostics Units of Measure: ng/mL, ng/dL, ug/dL, uIu/mL, mIU/mL, pg/mL, nmol/L, pmol/L, mIU/L, ug/L, IU/mL, IU/L

(10.1.6)Reference Ranges- SUPPORTED
([Low]\[Panic\Low]^[High]\[Panic High])

(10.1.7)Result Abnormal Flags-
(Siemens Diagnostics may add in later revisions Instrument Failure Codes)

L = Below Normal	SUPPORTED
H = Above Normal	SUPPORTED
LL = Below Panic	NOT SUPPORTED
HH = Above Panic	NOT SUPPORTED
< = Below readable limit	REQUIRED
> = Above readable limit	REQUIRED
N = Normal	SUPPORTED
A = Abnormal	NOT SUPPORTED
U = Significant change UP	NOT SUPPORTED
D = Significant change DOWN	NOT SUPPORTED
B = Better	NOT SUPPORTED
W = Worse	NOT SUPPORTED

(10.1.8)Nature of Abnormality Testing-

A = Age population tested	NOT SUPPORTED
S = Sex based Population	NOT SUPPORTED
R = Race based Population	NOT SUPPORTED
N = Normal generic range	SUPPORTED

(10.1.9)Results Status-

C = Correction of previously sent results	NOT SUPPORTED
P = Preliminary Results	NOT SUPPORTED
F = Final Results	SUPPORTED
X = Results cannot be done. (Eg. Calculation Error)	NOT SUPPORTED
I = In instrument, results pending	NOT SUPPORTED
S = Partial Results	NOT SUPPORTED
M = Result is a MIC level	NOT SUPPORTED
R = This result was previously transmitted	SUPPORTED
N = This result record contains necessary information to run a new order.	NOT SUPPORTED

(10.1.10)Date systems values/units changed- NOT SUPPORTED

(10.1.11)Operator Name/ID#- SUPPORTED

(10.1.12)Date+Time Test Started (YYYYMMDDHHMMSS) SUPPORTED

(10.1.13)Date+Time Test Completed (YYYYMMDDHHMMSS) SUPPORTED

(10.1.14)Instrument ID- SUPPORTED
(Configurable From Siemens Diagnostics 'KIT' Program)

REQUEST INFORMATION RECORD (12.1 - 12.1.13)
NOT SUPPORTED IN UNI DIRECTIONAL MODE

MESSAGE TERMINATOR RECORD DEFINITION (13.1 - 13.1.3)
[Record Type ID (L)][Sequence Number][Temination Code]

Example Termination Record:
<STX>[FrameNumber]L|1|N<CR><ETX>[CheckSum]<CR><LF>

(13.1.2) Record Types Definition-

L = Terminator record	SUPPORTED

(13.1.2)Sequence # - REQUIRED

(13.1.3)Termination Code-

N = Normal termination	SUPPORTED
T = Sender Aborted	NOT SUPPORTED
R = Receiver Abort	NOT SUPPORTED
E = Unknown system error	NOT SUPPORTED
Q = Error in last request for information	NOT SUPPORTED
I = No information available from last query	NOT SUPPORTED
F = Last request for information Processed	NOT SUPPORTED

IMMULITE 1000 LIS ERROR MESSAGE DEFINITIONS

Error # 300 LIS Error: Timeout During Receive – The LIS is not responding to the IMMULITE 1000. Causes can be a cabling problem, hardware communication problem or a programming bug in the LIS software.

Error # 301 LIS Error: Invalid Frame Number – The frame number in the message is not proper. Usually indicates a programming bug in the LIS software, but may be a bad message (e.g. line noise). See ASTM 1381 Logical layer section 6.3.2.1 for further detail.

Error # 302 LIS Error: Invalid Checksum – Checksum did not match due to a transmission error.

Error # 303 LIS Error: Missing Control Character – Usually indicates a programming bug in the LIS software, but may be a bad message (e.g. line noise).

Error # 304 LIS Error: Invalid Message Length – Data within the message was dropped or not sent. Usually indicates a programming bug in the LIS software, but may be a bad message (e.g. line noise).

Error # 305 LIS Error: Invalid Frame Sequence – The sequence number in the message is not proper. Usually indicates a programming bug in the LIS software, but may be a bad message (E.G. line noise). See ASTM 1381 section 6.3.2.1 for further detail.

Error # 306 LIS Error: No Acknowledgement from LIS – There is no communication between the IMMULITE 1000 and the LIS.

Error # 307 LIS Error: Timeout During Send – The LIS is not responding to IMMULITE 1000. Causes can be a cabling problem, communication problem (hardware related), or programming bug in the LIS software

Error # 308 LIS Error: Excessive LIS errors are occurring – There are numerous LIS errors during a session.

Error # 309 LIS Error: Log File Error – There was an error while writing to the Log File.

Error # 314 LIS Error: Header Message Not Received – The Header Password is incorrect or there is no header message.

Error # 315 LIS Error: Patient Message Not Received – A record required for LIS communications is not found.

Error # 316 LIS Error: EOT received prior to ENQ – An LIS message was received out of sequence.

Error # 317 LIS Error: Invalid LIS Message – An invalid message type code was transmitted.

Error # 318 LIS Error: Unexpected Communication from LIS – Communication Error.

Error # 319 LIS Error: Cannot Open Communication Port – The serial port is not configured properly or is not configured at all.

Error # 31421 LIS Error: No Results Selected – Tagged records are not found in the database.

Error # 31422 LIS Error: LIS Unavailable – The LIS is not responding to the IMMULITE 1000. The causes can be a cabling problem, a hardware communication problem or a bug in the LIS software.

Error # 31423 LIS Error: Terminator Code Error – There is a terminator code error.

Error # 31424 LIS Error: LIS Terminator Code Invalid – The terminator code is invalid.

Error # 31425 LIS Error: Password Error – The password is incorrect in the header message. Correct by entering the proper password in the LIS PARAMETER section from the START menu. Siemens Diagnostics does not know this password, this is set by the software company. SUNQUEST does not use a password. This field should be left blank for SUNQUEST systems.

Error # 31427 LIS Error: Receiver ID Error – This is the #1 question asked by LIS customers. The Receiver ID is incorrect in the header message. These items need to be switched by the LIS when sending messages to IMMULITE 1000.
Example:
Receiver ID is set to "HOSPITAL" on IMMULITE 1000
IMMULITE Sending: Sender ID field = "DPC", Receiver ID Field = "HOSPITAL"
LIS Sending: Sender ID Field = "HOSPITAL", Receiver ID field = "DPC."

Error # 31428 LIS Error: Patient ID Missing – The LIS is missing a patient ID.

Error # 31429 LIS Error: Patient ID exceeded 20 characters – The Patient ID has exceeded the allowable number of characters.

Error # 31430 LIS Error: Accession Number Missing – The accession number is missing.

Error # 31431 LIS Error: Accession Number Exceeded 20 Characters – The accession number has exceeded the allowable number of characters.

Error # 31433 LIS Error: No Control Record Found – Control information is not in the database.

Error # 31435 LIS Error: Invalid Control Data – Control data is in an invalid format.

Error # 31437 LIS Error: LIS Unavailable in Test Mode – Occurs when an underlying hardware or configuration error causes a software communication error.

Error # 31439 LIS Error 31439: Call Technical Services – Occurs when an underlying hardware or configuration error causes a software communication issue.

Error # 31440 LIS Error: Query Failure – The LIS encountered an error when processing the IMMULITE 1000's request for information.

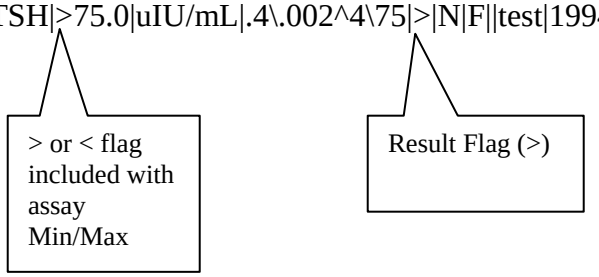
Error # 31520 LIS Error: Query Communication Error – The IMMULITE 1000 LIS software is not responding. The LIS configuration parameters may have changed.

IMMULITE 2000/2500 LIS Features

Results
Results are sent using floating decimals as follows

Result	# decimal places sent	Example
less than 1.00	3 *TSH, RTH	0.025
1.00 – 9.99	2	1.23
10.0 - 99.9	1	10.2
100 and above	None	102

Required Flags
Required flags include H, L, N, < and >.
Greater than (>) and Less than (<) calibration range results are sent as follows:
0R|1|^^^TSH|>75.0|uIU/mL|.4\.002^4\75|>|N|F||test|19940407085044|19940407085148|DPC CIRRUS



Qualitative Test Results
Qualitative tests result either as a qualitative interpretation for Reactive, Non-Reactive or Indeterminate or as a semi-quantitative ratio (patient CPS/Cutoff CPS), and can be sent to the LIS as either a qualitative interpretation or as a ratio (not both).
The qualitative interpretation is sent to the LIS as follows:

Result	Sent to LIS as Qualitative
Non-reactive	0.0
Reactive	1.00
Indeterminate	2.00

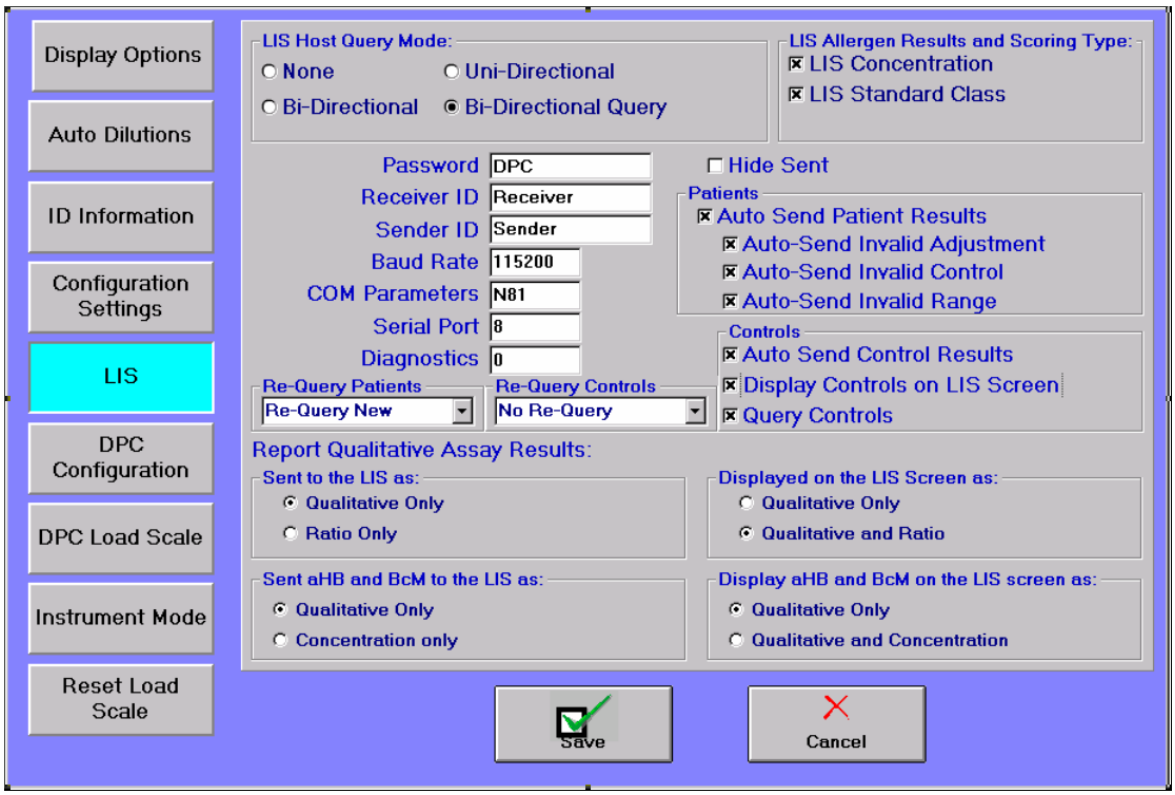
See assay package inserts for interpretation of qualitative assay ratio results.

IMMULITE 2000/2500 LIS Configurations

- Select Configurations | Configure | LIS
- Select the appropriate LIS Host Query Mode
- Password, Receiver and Sender ID's should be supplied by the LIS vendor.
- Baud Rate should be supplied by the LIS vendor
- COM Parameters are N81
- Serial Port 8 is labeled LIS on the Instrument I/O panel
- Replace "0" in the Diagnostics field with "1" to activate a log of the transmission between the Instrument and the LIS for troubleshooting. The log should not be active

during normal operation and should only be changed at the direction of Technical Service.

- Select Hide Sent to hide sent results from view on the LIS screen
- Select Auto-Send Patient Results to automatically send results.
    - Select Auto-Send Invalid Adjustment to automatically send patient results flagged ADJ
    - Select Auto-Send Invalid Control results to automatically send patient results if the controls for an assay are configured as single or multi-rule in the QC | Data Entry screen
    - Select Auto-Send Invalid Range to automatically send patient results that are greater than or less than the calibration range
- Select Auto Send Control Results to automatically send all results for control samples
- Select LIS Requery as appropriate:
    - No Requery – if an accession number is found in the Instrument database (pending or completed tests), the accession number will not be re-queried to an LIS
    - Requery New Orders – Accession numbers are always re-queried and duplicate test orders are not run if that test is currently in progress
    - Requery All – Accession numbers are always requeried and duplicate test orders are run
- Select LIS Query for Controls
    - Exclude Controls – Control samples are not queried to an LIS
    - Include Controls – All control samples are queried to an LIS
- Report Qualitative Assay Results to the LIS – Sent to the LIS as:
    - Qualitative Only
        - Non-Reactive – sent to LIS as 0.0
        - Reactive – sent to LIS as 1.00
        - Indeterminate – sent to LIS as 2.00
    - Ratio Only
        - Results sent as a ratio (Patient cps/cutoff cps)
    - Display on LIS screen as:
        - Qualitative only - Results display on LIS screen as
            - Reactive
            - Non-React
            - Indeterm
        - Qualitative and Ratio
            - Results display o n LIS screen as numerical ratio plus NR, R or I



Test Codes

IMMULITE 2000/2500 Test Codes are upload and download Test codes, and can be found in IMMULITE 2000/2500 Assay Test Kit package inserts.

- See page 19 for an example of sending a test order to the Instrument to perform a dilution.
  - If ^^^HCG^40 is downloaded, the Instrument dilutes HCG assay x40
  - The Instrument sends the result with test code ^^^HCG (dilution not included)
- Operators can create test panels on the Instrument
  - Panel names can be sent to the Instrument. All tests within a panel will be run.
  - Individual test codes are sent with results. The Panel name is not returned.
  - Panel names should be unique. Do not name a panel the same as an assay code.

SMS LIS Features

Results

Results are sent using floating decimals as follows

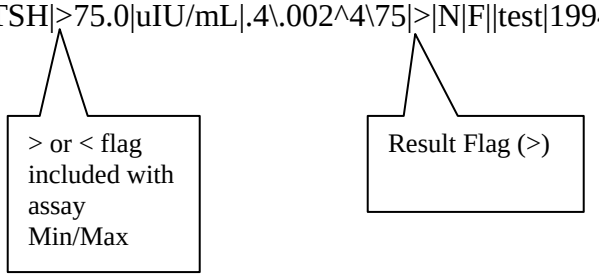
Result	# decimal places sent	Example
less than 1.00	3 *TSH, RTH	0.025
1.00 – 9.99	2	1.23
10.0 - 99.9	1	10.2
100 and above	None	102

Required Flags

Required flags include H, L, N, < and >.

Greater than (>) and Less than (<) calibration range results are sent as follows:

0R|1|^^^TSH|>75.0|uIU/mL|.4\.002^4\75|>|N|F||test|19940407085044|19940407085148|DPC CIRRUS



Qualitative Test Results

Qualitative tests result either as a qualitative interpretation for Reactive, Non-Reactive or Indeterminate or as a semi-quantitative ratio (patient CPS/Cutoff CPS), and can be sent to the LIS via the SMS as either a qualitative interpretation or as a ratio (not both).

The qualitative interpretation is sent to the LIS as follows:

Result	Sent to LIS as Qualitative
Non-reactive	0.0
Reactive	1.00
Indeterminate	2.00

See assay package inserts for interpretation of qualitative assay ratio results.

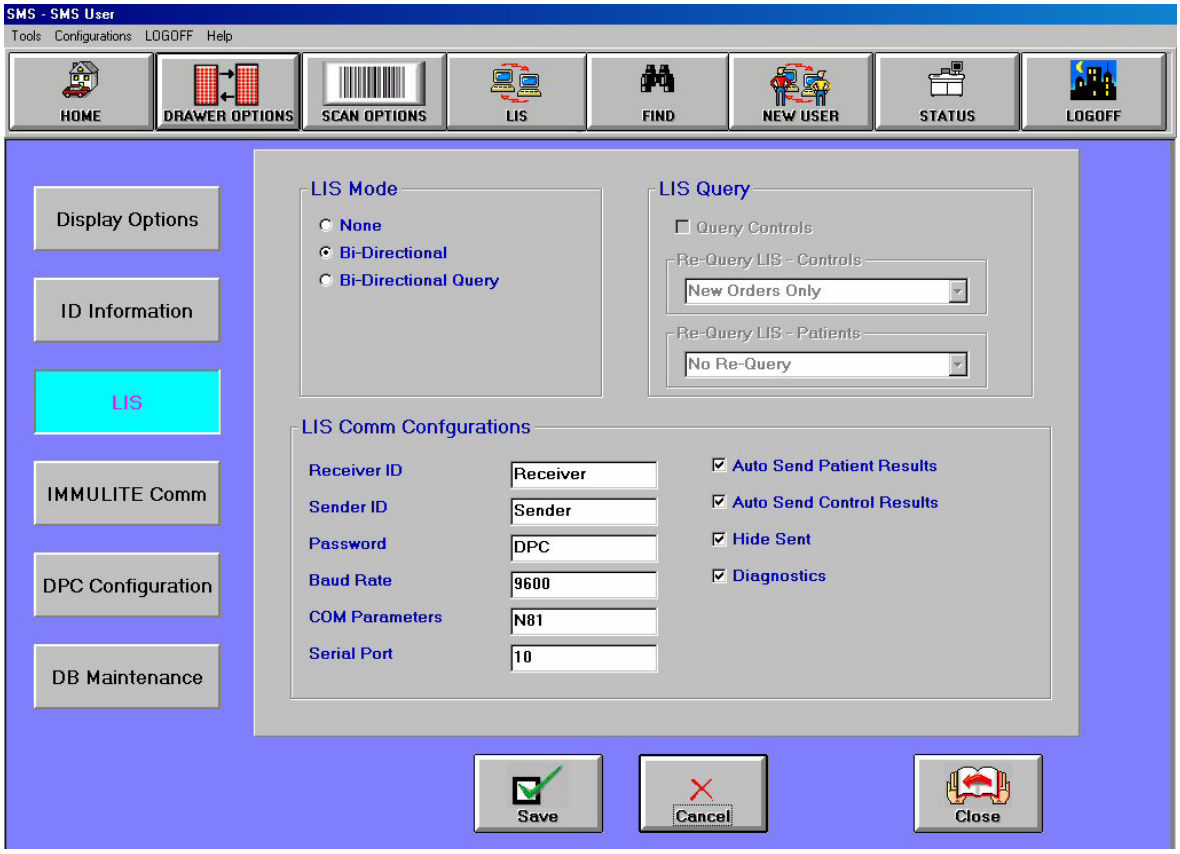
SMS LIS Configurations

- Select Configurations | Configure | LIS
- On the SMS, select the appropriate LIS Host Query Mode. On the IMMULITE 2000/2500, select the Bi-Directional LIS Host Query Mode.
- On the SMS, Password, Receiver and Sender IDs should be supplied by the LIS vendor.
- On the SMS, baud rate should be supplied by the LIS vendor. On the IMMULITE 2000/2500, the baud rate should be 115200.
- COM Parameters are N81
- On the SMS, Port 5 is used for IMMULITE A, while Port 7 is used for IMMULITE B. For the IMMULITE 2000/2500, Serial Port 8 is labeled LIS on the Instrument I/O panel. (The settings

for Ports 5 and 7 are set on the IMMULITE 2000/2500 Communication Configuration screen.) The SMS is connected to the LIS using Port 10.

- On the SMS, the Diagnostics checkbox should always remain selected. On the IMMULITE 2000/2500, replace "0" in the Diagnostics field with "1" to activate a log of the transmission between the Instrument and the LIS for troubleshooting. The log should not be active during normal operation.
- Select the Hide Sent option as the default to hide sent results from view on the LIS screen.
- On the SMS, select AutoSend Patient Results as desired. On the IMMULITE 2000/2500, you must select the AutoSend Patient Results option.
    - On the IMMULITE 2000/2500, optionally select Auto-Send Invalid Adjustment to automatically send patient results flagged ADJ
    - On the IMMULITE 2000/2500, optionally select Auto-Send Invalid Control results to automatically send patient results if the controls for an assay are configured as single or multi-rule in the QC | Data Entry screen
    - On the IMMULITE 2000/2500, optionally select auto-Send Invalid Range to automatically send patient results that are greater than and less than the calibration range
- On the SMS, select Auto Send Control Results as desired to automatically send all results for control samples. On the IMMULITE 2000/2500, select the Auto Send Control Results option.
- On the SMS, select Query Controls as appropriate. This setting is ignored on the IMMULITE 2000/2500.
- On the SMS, select a Re-Query LIS – Controls option as desired. These options are ignored on the IMMULITE 2000/2500.
    - No Requery – if an accession number is found in the Instrument database (pending or completed tests), the accession number will not be re-queried to an LIS
    - Requery New Orders – Accession numbers are always re-queried and duplicate test orders are not run if that test has not yet resulted
    - Requery All – Accession numbers are always requeried and duplicate test orders are run
- On the SMS, select Requery LIS – Patients as appropriate. These options are ignored on the IMMULITE 2000/2500.
    - No Requery – if an accession number is found in the Instrument database (pending or completed tests), the accession number will not be re-queried to an LIS
    - Requery New Orders – Accession numbers are always re-queried and duplicate test orders are not run if that test has not yet resulted
    - Requery All – Accession numbers are always requeried and duplicate test orders are run
- On the IMMULITE 2000/2500, report Qualitative Assay Results to the LIS – Sent to the LIS.
    - Qualitative Only
        - Non-Reactive – sent to LIS as 0.0
        - Reactive – sent to LIS as 1.00
        - Indeterminate – sent to LIS as 2.00
    - Ratio Only

        - Results sent as a ratio (Patient cps/cutoff cps)
    - Display on LIS screen as:
        - Qualitative only – Results display on LIS screen as
            - Reactive
            - Non-React
            - Indeterm
        - Qualitative and Ratio
            - Results display o n LIS screen as numerical ratio plus NR, R or I
- On the IMMULITE 2000/2500, report aHB and BcM to the LIS.
    - Qualitative Only – the Instrument performs qualitative interpretation
        - Non-Reactive – sent to LIS as 0.0
        - Reactive – sent to LIS as 1.00
        - Indeterminate – sent to LIS as 2.00
    - Concentration
        - Sent to LIS as numerical concentration (dose)
- On the IMMULITE 2000/2500, display aHB and BcM on the LIS screen.
    - Qualitative only – Results display on LIS screen as:
        - Reactive
        - Non-React
        - Indeterm
    - Qualitative and Ratio
        - Results display o n LIS screen as numerical concentration plus NR,R or I



Test Codes

IMMULITE 2000/2500 Test Codes are upload and download Test codes, and can be found in IMMULITE 2000/2500 Assay Test Kit package inserts.

- See page 19 for an example of sending a test order to the Instrument to perform a dilution.
    - If ^^^HCG^40 is downloaded, the Instrument dilutes HCG assay x40
    - The SMS sends the result with test code ^^^HCG (dilution not included)
- Operators can create test panels on the SMS
    - Panel names can be sent to the SMS. All tests within a panel will be run.
    - Individual test codes are sent with results. The Panel name is not returned.

IMMULITE 2000/2500 and SMS BI-DIRECTIONAL LIS SPECIFICATION ASTM E1394

HEADER RECORD DEFINITION (7.1 - 7.1.14)
[Record Type (H)] [Delimiter Def.] [Message Control ID] [Password] [Sending systems company name] [Sending Systems address] [Reserved] [Senders Phone#] [Communication parameters] [Receiver ID] [Comments/special instructions] [Processing ID] [Version#] [Message Date + Time]
Sample Header Message:

<STX>[FrameNumber]H|\^&||Password|DPCCIRRUS|Randolph^New^Jersey^07869||(201)927-2828|8N1|YourSystem||P|1|19940323082858<CR><ETX>[CheckSum]<CR><LF>

(7.1.1) Record Types Definition-
H = Header record REQUIRED

(7.1.2) Delimiter Definition- REQUIRED
¦ = Field Delimiter REQUIRED
\ = Repeat Delimiter REQUIRED
^ = Component Delimiter REQUIRED
DEFINED, NOT SUPPORTED
(7.1.3) Message Control ID- NOT SUPPORTED

(7.1.4) Access Password REQUIRED
(Configurable by Siemens Diagnostics Instrument Systems Division Software; Maximum of 10 characters)
(7.1.5) Sender Name or ID- REQUIRED
(Configurable by Siemens Diagnostics Instrument Systems Division Software; maximum of 10 characters)
(7.1.6) Sender Street Address- SUPPORTED

(7.1.7) Reserved Field- NOT SUPPORTED

(7.1.8) Senders Telephone Number- SUPPORTED

(7.1.9) Characteristics of Sender- SUPPORTED
(8 bits No Parity 1 Stop Bit)

(7.1.10)Receiver ID- REQUIRED
(Configurable by Siemens Diagnostics Instrument Systems Division Software; maximum of 10 characters)
(7.1.11)Comments/Special Instructions- NOT SUPPORTED

(7.1.12) Processing ID Definition-	
P = "Normal" production/running message	SUPPORTED
T = Training message	NOT SUPPORTED
D = Debugging, used to debug a program(s)	NOT SUPPORTED
Q = Message is for QC/regulatory purposes	NOT SUPPORTED
(7.1.13)Version Number- (Currently 1)	SUPPORTED
(7.1.14)Date+Time of Message (YYYYMMDDHHMMSS)	SUPPORTED

PATIENT INFORMATION RECORD DEFINITION (8.1 - 8.1.35)
[Record Type (P)][Sequence #][Practice Assigned Patient ID][Laboratory Assigned Patient ID][Patient ID][Patient Name][Mother's Maiden Name][BirthDate][Patient Sex][Patient Race][Patient Address][Reserved][Patient Phone #][Attending Physician ID][Special Field 1][Special Field 2][Patient Height][Patient Weight][Patients Known or Suspected Diagnosis] [Patient active medications][Patients Diet][Practice Field #1][Practice Field #2][Admission and Discharge Dates][Admission Status][Location][Nature of Alternative Diagnostic Code and Classification][Alternative Diagnostic Code and Classification][Patient Religion][Marital Status][Isolation Status][Language][Hospital Service][Hospital Institution][Dosage Category]

Sample Patient Information Record:
<STX>[FrameNumber]P|1|101|||Riker^Al||19611102|F|||||Bashere<CR><ETX>[CheckSum]<CR><LF>

(8.1.1) Record Types Definition-
P = Patient Identity Record REQUIRED

(8.1.2) Sequence # Definition- REQUIRED

(8.1.3) Practice Assigned Patient ID- REQUIRED
(maximum of 20 characters)

(8.1.4) Laboratory Assigned Patient ID- NOT SUPPORTED

(8.1.5) Patient ID- NOT SUPPORTED

(8.1.6) Patient Name- SUPPORTED

For patient sample
(Last^First^Initial; maximum of 30 characters for both Last&First name)

For control
First 2 characters: ~C (use uppercase letter)
Next 6 characters: Control Name (if fewer than 6 characters, right-padded with spaces; should not be empty)
Next 3 characters: Control Lot (use 3 numeric digits; should not be empty)
Next 6 characters: Expiration Date (use YYYYMM format; should not be empty)
Last 1 character: Control Level (should not be empty)

For adjustor (not supported on the SMS)
First 2 characters: ~A (use uppercase letter)
Next 6 characters: Test Code (should not be empty)
Next 3 characters: Kit Lot (use 3 numeric digits; should not be empty)
Next 3 characters: Adjustor Lot (use 3 numeric digits; should not be empty)
Last 2 characters: Level (use 2 numeric digits; should not be empty)

For verifier (not supported on the SMS)

First 2 characters: ~V (use uppercase letter)
Next 6 characters: Test Code (should not be empty)
Next 3 characters: Verifier Lot (should not be empty)
Next 1 character: Level (should not be empty)
Next 4 characters: Range low (numeric value; should not be empty)
Next 4 characters: Range high (numeric value; should not be empty)

(8.1.7) Mother's Maiden Name-	NOT SUPPORTED
(8.1.8) Birthdate- (YYYYMMDD; maximum of 8 characters)	SUPPORTED
(8.1.9) Patient's Sex- (M or F; maximum of 1 character)	SUPPORTED
(8.1.10)Patient Race-Ethnic Origin-	NOT SUPPORTED
(8.1.11)Patient's Address-	NOT SUPPORTED
(8.1.12)Reserved Field-	NOT SUPPORTED
(8.1.13)Patient's Phone#-	NOT SUPPORTED
(8.1.14)Attending Physician ID (Value is sent only from Instruments to LIS)	NOT SUPPORTED
(8.1.15)Special Field 1-	NOT SUPPORTED
(8.1.16)Special Field 2-	NOT SUPPORTED
(8.1.17)Patient Height-	NOT SUPPORTED
(8.1.18)Patient Weight-	NOT SUPPORTED
(8.1.19)Known or Suspected Diagnosis-	NOT SUPPORTED
(8.1.20)Active Medications-	NOT SUPPORTED
(8.1.21)Patient's Diet-	NOT SUPPORTED
(8.1.22)Practice Field 1-	NOT SUPPORTED
(8.1.23)Practice Field 2-	NOT SUPPORTED
(8.1.24)Admission and Discharge Dates-	NOT SUPPORTED

(8.1.25)Admission Status-	NOT SUPPORTED
(8.1.26)Location-	NOT SUPPORTED
(8.1.27)Nature of Alt. Diag. Code.....-	NOT SUPPORTED
(8.1.28)Alt. Diag. Code and Classifications-	NOT SUPPORTED
(8.1.29)Patient Religion-	NOT SUPPORTED
(8.1.30)Marital Status-	NOT SUPPORTED
(8.1.31)Isolation Status-	NOT SUPPORTED
(8.1.32)Language-	NOT SUPPORTED
(8.1.33)Hospital Service-	NOT SUPPORTED
(8.1.34)Hospital Institution-	NOT SUPPORTED
(8.1.35)Dosage Category-	NOT SUPPORTED

ORDER RECORD DEFINITION (9.4.1-9.4.31)
[Record Type (O)][Sequence#][Specimen ID (Accession#)][Instrument Specimen ID][Universal Test ID][Priority][Order Date/Time][Collection Date/Time][Collection End Time][Collection Volume][Collector ID][Action Code][Danger Code][Relevant Clinical Info][Date/Time Specimen Received][Specimen Descriptor,Specimen Type,Specimen Source][Ordering Physician][Physician's Telephone Number][User Field No.1][User Field No.2][Lab Field No.1][Lab Field No.2][Date/Time results reported or last modified][Instrument Charge to Computer System][Instrument Section ID][Report Types][Reserved Field][Location or ward of Specimen Collection][Nosocomial Infection Flag][Specimen Service][Specimen Institution]

Sample Test Order Message:
<STX>[FrameNumber]O|1|1550623||^^^LH|R|19931011091233|19931011091233||||||Post Menopausal<CR><ETX>[CheckSum]<CR><LF>

(9.4.1) Record types Definition-
O = Test Order Record REQUIRED

(9.4.2) Sequence #- REQUIRED

(9.4.3) Specimen ID- REQUIRED
(maximum of 20 characters)

For patient sample
Accession number on primary tube

For control
First 2 characters: ~C (use uppercase letter)
Next 6 characters: Control Name (if fewer than 6 characters, right-padded with spaces; should not be empty)
Next 3 characters: Control Lot (use 3 numeric digits; should not be empty)
Next 6 characters: Expiration Date (use YYYYMM format; should not be empty)
Last 1 character: Control Level (should not be empty)

For adjustor (not supported on the SMS)
First 2 characters: ~A (use uppercase letter)
Next 6 characters: Test Code (should not be empty)
Next 3 characters: Kit Lot (use 3 numeric digits; should not be empty)
Next 3 characters: Adjustor Lot (use 3 numeric digits; should not be empty)
Last 2 characters: Level (use 2 numeric digits; should not be empty)

For verifier (not supported on the SMS)
First 2 characters: ~V (use uppercase letter)
Next 6 characters: Test Code (should not be empty)
Next 3 characters: Verifier Lot (should not be empty)
Next 1 character: Level (should not be empty)
Next 4 characters: Range low (numeric value; should not be empty)

Next 4 characters: Range high (numeric value; should not be empty)

(9.4.4) Instrument Specimen ID- NOT SUPPORTED

(9.4.5) Universal Test ID REQUIRED
(^^^[Test Code]) Test Code can be up to 10 characters
Examples:

Order for TSH
^^^TSH

Order for multiple TSH tests
^^^TSH\^^^TSH

Order for TSH with ten-fold dilution
^^^TSH^10

Order for multiple TSH tests with dilutions
^^^TSH^10\^^^TSH^40

Order for a panel of tests called PANEL1
^^^PANEL1

Order for allergy
^^^ SPE D120
A maximum of 3 characters for the Universal Reagent (SPE), a space, and a maximum of 6 characters for the Allergen Code (D120).

(9.4.6) Priority- SUPPORTED
S-Stat
A-As soon as possible
R-Routine
C-Callback
P-Preoperative
(All maximum of 1 character)

(9.4.7) Requested/Ordered Date and Time- SUPPORTED
(YYYYMMDDHHMMSS; maximum of 14 characters)

(9.4.8) Specimen Collection Date and Time- SUPPORTED
(maximum of 14 characters)

(9.4.9) Collection End Time- NOT SUPPORTED

(9.4.10) Collection Volume- NOT SUPPORTED

(9.4.11) Collector ID-	NOT SUPPORTED
(9.4.12) Action Code-	NOT SUPPORTED
(9.4.13) Danger Code-	NOT SUPPORTED
(9.4.14) Relevant Clinical Information-	SUPPORTED
(9.4.15) Date/Time Specimen Received-	NOT SUPPORTED
(9.4.16) Specimen Descriptor-	NOT SUPPORTED
(9.4.17) Ordering Physician- Smith^Joseph (maximum of 30 characters)	SUPPORTED
(9.4.18) Physician's Telephone Number-	NOT SUPPORTED
(9.4.19) Users Field No. 1-	NOT SUPPORTED
(9.4.20) Users Field No. 2-	NOT SUPPORTED
(9.4.21) Lab Field No. 1-	NOT SUPPORTED
(9.4.22) Lab Field No. 2-	NOT SUPPORTED
(9.4.23) Date/Time Results Reported....-	NOT SUPPORTED
(9.4.24) Instrument Charge to Computer Sys.-	NOT SUPPORTED
(9.4.25) Instrument Section ID-	SUPPORTED
(9.4.26) Report Types-	NOT SUPPORTED
(9.4.27) Reserved Field-	NOT SUPPORTED
(9.4.28) Location of Specimen Collection-	NOT SUPPORTED
(9.4.29) Nosococmial Infection Flag-	NOT SUPPORTED
(9.4.30) Specimen Service-	NOT SUPPORTED
(9.4.31) Specimen Institution-	NOT SUPPORTED

RESULT RECORD DEFINITION (10.1 - 10.1.14)

[Record Type (R)][Sequence #][Universal Test ID][Data (result)][Units][ReferenceRanges] [Result abnormal flags][Nature of Abnormality Testing][Result Status][Date of change in instruments normal values or units][Operator ID][Date\Time Test Started][Date\Time Test Completed][Instrument ID]

Sample Result Message:
<STX>[FrameNumber]R|1|^^^LH|8.2|mIU/mL|.7\.7^400\400|N|N|F||test|19931011091233|19931011091233|DPCCIRRUS<CR><ETX>[CheckSum]<CR><LF>

(10.1.1) Record Types Definition-

R = Result Record	REQUIRED

(10.1.2)Sequence #- REQUIRED

(10.1.3)Universal Test ID REQUIRED
(^^^[Test Code])

Example Test Codes: TSH, LH, FSH, DGX, T4, HCG, RTH, SPE D120

(10.1.4)Data or Measurement Value (Result) REQUIRED

(10.1.5)Units- REQUIRED

Current Siemens Diagnostics Units of Measure: ng/mL, ng/dL, ug/dL, uIu/mL, mIU/mL, pg/mL, nmol/L, pmol/L, mIU/L, ug/L, IU/mL, IU/L, KU/L, SClass

(10.1.6)Reference Ranges- SUPPORTED
([Low]\[Panic\Low]^[High]\[Panic High])

(10.1.7)Result Abnormal Flags-

L = Below Normal	SUPPORTED
H = Above Normal	SUPPORTED
LL = Below Panic	NOT SUPPORTED
HH = Above Panic	NOT SUPPORTED
< = Below readable limit	REQUIRED
> = Above readable limit	REQUIRED
N = Normal	SUPPORTED
A = Abnormal	NOT SUPPORTED
U = Significant change UP	NOT SUPPORTED
D = Significant change DOWN	NOT SUPPORTED
B = Better	NOT SUPPORTED
W = Worse	NOT SUPPORTED

(10.1.8)Nature of Abnormality Testing-

A = Age population tested	NOT SUPPORTED
S = Sex based Population	NOT SUPPORTED
R = Race based Population	NOT SUPPORTED
N = Normal generic range	SUPPORTED

(10.1.9)Results Status-

C = Correction of previously sent results	NOT SUPPORTED
P = Preliminary Results	NOT SUPPORTED
F = Final Results	SUPPORTED
X = Results cannot be done. (Eg. Calculation Error)	NOT SUPPORTED
I = In instrument, results pending	NOT SUPPORTED
S = Partial Results	NOT SUPPORTED
M = Result is a MIC level	NOT SUPPORTED
R = This result was previously transmitted	SUPPORTED
N = This result record contains necessary information to run a new order.	NOT SUPPORTED

(10.1.10)Date systems values/units changed- NOT SUPPORTED

(10.1.11)Operator Name/ID#- SUPPORTED

(10.1.12)Date+Time Test Started (YYYYMMDDHHMMSS) SUPPORTED

(10.1.13)Date+Time Test Completed (YYYYMMDDHHMMSS) SUPPORTED

(10.1.14)Instrument ID- SUPPORTED
(Configurable From Siemens Diagnostics Instrument Systems Division software)

REQUEST INFORMATION RECORD DEFINITION (HOST QUERY) (12.1 - 12.1.13)
[Record Type ID (Q)][Sequence #][Starting Range][Ending Range][Test ID][Request Time Limits][Beginning request results date and time][Ending request results date and time][Physician name][Physician Phone Number][User Field 1]User Field 2][Status Codes]

Example Request Record:
<STX>[FrameNumber]Q|1|^1234ABC||ALL|||||||O<CR><ETX>[CheckSum]<CR><LF>

(12.1.1) Record Types Definition-	
Q = Request information Record	SUPPORTED (UPLOAD ONLY)
(12.1.2) Sequence Number	SUPPORTED
(12.1.3) Starting Range ID Number	REQUIRED
(12.1.4) Ending Range ID Number	NOT SUPPORTED
(12.1.5) Universal Test ID	REQUIRED
(12.1.6) Request Time Limits	NOT SUPPORTED
(12.1.7) Beginning Request Results ...	NOT SUPPORTED
(12.1.8) Ending Request Results ...	NOT SUPPORTED
(12.1.9) Physician Name	NOT SUPPORTED
(12.1.10) Physician Phone #	NOT SUPPORTED
(12.1.11) User field #1	NOT SUPPORTED
(12.1.12) User field #2	NOT SUPPORTED
(12.1.13) Request information status codes	
C- Correction of previous results	NOT SUPPORTED
P- Preliminary Results	NOT SUPPORTED
F- Final Results	NOT SUPPORTED
X- Results cannot be done, cancel	NOT SUPPORTED
I- Request Results Pending	NOT SUPPORTED
S- Request partial results	NOT SUPPORTED
M-Result is a MIC level	NOT SUPPORTED
R- Result previously transmitted	NOT SUPPORTED
A- Abort/cancel last request	REQUIRED
N- Requesting new results only	NOT SUPPORTED
O- Requesting orders and demographics	REQUIRED
D- Requesting demographics only	NOT SUPPORTED

MESSAGE TERMINATOR RECORD DEFINITION (13.1 - 13.1.3)
[Record Type ID (L)][Sequence Number][Temination Code]

Example Termination Record:
<STX>[FrameNumber]L|1|N<CR><ETX>[CheckSum]<CR><LF>

(13.1.1) Record Types Definition-

L = Terminator record	SUPPORTED

(13.1.2)Sequence # - REQUIRED

(13.1.3)Termination Code-

N = Normal termination	SUPPORTED
T = Sender Aborted	NOT SUPPORTED
R = Receiver Abort	NOT SUPPORTED
E = Unknown system error	NOT SUPPORTED
Q = Error in last request for information	REQUIRED WITH QUERY
I = No information available from last query	REQUIRED WITH QUERY
F = Last request for information Processed	REQUIRED WITH QUERY

Integrated Workcell Configurations

Although both the IMMULITE 2000/2500 and T60 use the same ASTM specifications, listed below are the differences that should be noted when setting-up an Integrated Workcell.

	2000/2500	T60	Comments
Case Sensitive	No	Yes	
PATIENT RECORDS			
Field 3: Patient ID	Required (20 char max)	Supported (16 char max)	T60 will default to the Patient Name if the Patient ID is not supplied
Field 6: Patient Name	Supported (30 char max)	Required (24 char max)	Patient Name is a primary identifier for the T60
Field 26: Location	Not Supported	Supported	
ORDER RECORDS			
Field 3: Accession Number	Supprted (20 char max)	Supported (16 char max)	
Field 5: Test ID	Required (7 char max)	Required (30 char max)	
Field 7: Requested Order Date and Time	Supported	Not Supported	Value is only returned to the LIS from IMMULITE 2000/2500 orders
Field 12: Action Code	Not Supported	Supported	Impacts the T60 Save Behavior
Field 14: Relevant Clinical Behavior	Supported	Supported	Please contact Technical Service for configuration assistance
Field 16: Specimen Descriptor	Not Supported	Supported	
Field 17: Physician Name	Supported	Not Supported	Value is only returned to the LIS from IMMULITE 2000/2500 orders
Field 26: Report Type	Not Supported	Supported	Workcell will default this value to an appropriate value for the T60 if no value is provided
RESULT RECORDS			
Field 7: Result Abnormal Flags	LL and HH not used	LL and HH Supported	L, H, >, <, N supported by both the 2000/2500 and T60
Field 9: Result Status	F (Final) R (Reported) Only	Supported: P (Preliminary) F (Final) X (Cancelled) I (Pending) R (Reported) Q (Query Response)	

IMMULITE 2000/2500 UNI-DIRECTIONAL LIS SPECIFICATION ASTM E1394

HEADER RECORD DEFINITION (7.1 - 7.1.14)

[Record Type (H)] [Delimiter Def.] [Message Control ID] [Password] [Sending systems company name] [Sending Systems address] [Reserved] [Senders Phone#] [Communication parameters] [Receiver ID] [Comments/special instructions] [Processing ID] [Version#] [Message Date + Time]

Sample Header Message:

<STX>[FrameNumber]H|\^&||Password|DPCCIRRUS|Randolph^New^Jersey^07869||(201)927-2828|8N1|Receiver||P|1|19920521132100<CR><ETX>[CheckSum]<CR><LF>

(7.1.1) Record Types Definition-

H = Header record	REQUIRED

(7.1.2) Delimiter Definition-

¦ = Field Delimiter	REQUIRED
\ = Repeat Delimiter	REQUIRED
^ = Component Delimiter	REQUIRED
& = Escape Delimiter	DEFINED, NOT SUPPORTED

(7.1.3) Message Control ID- NOT SUPPORTED

(7.1.4) Access Password REQUIRED
(Configurable by Siemens Diagnostics Instrument Systems Division Program; Maximum of 10 characters)

(7.1.5) Sender Name or ID- REQUIRED
(Configurable by Siemens Diagnostics Instrument Systems Division Program; maximum of 10 characters)

(7.1.6) Sender Street Address- SUPPORTED

(7.1.7) Reserved Field- NOT SUPPORTED

(7.1.8) Senders Telephone Number- SUPPORTED

(7.1.9) Characteristics of Sender- SUPPORTED
(8 bits No Parity 1 Stop Bit)

(7.1.10)Receiver ID- REQUIRED

(Configurable by Siemens Diagnostics Instrument Systems Division Program; maximum of 10 characters)

(7.1.11)Comments/Special Instructions- NOT SUPPORTED

(7.1.12) Processing ID Definition-

P = "Normal" production/running message	SUPPORTED
T = Training message	NOT SUPPORTED
D = Debugging, used to debug a program(s)	NOT SUPPORTED
Q = Message is for QC/regulatory purposes	NOT SUPPORTED

(7.1.13)Version Number- SUPPORTED
(Currently 1)

(7.1.14)Date+Time of Message SUPPORTED
(YYYYMMDDHHMMSS)

PATIENT INFORMATION RECORD DEFINITION (8.1 - 8.1.35)

[Record Type (P)][Sequence #][Practice Assigned Patient ID][Laboratory Assigned Patient ID][Patient ID][Patient Name][Mother's Maiden Name][BirthDate][Patient Sex][Patient Race][Patient Address][Reserved][Patient Phone #][Attending Physician ID][Special Field 1][Special Field 2][Patient Height][Patient Weight][Patients Known or Suspected Diagnosis] [Patient active medications][Patients Diet][Practice Field #1][Practice Field #2][Admission and Discharge Dates][Admission Status][Location][Nature of Alternative Diagnostic Code and Classification][Alternative Diagnostic Code and Classification][Patient Religion][Marital Status][Isolation Status][Language][Hospital Service][Hospital Institution][Dosage Category]

Sample Patient Information Record:

<STX>[FrameNumber]P|1||||Jones^Jane^L||19640804|F|||||Doctor<CR><ETX>[CheckSum]<CR><LF>

(8.1.1) Record Types Definition-

P = Patient Identity Record — REQUIRED

(8.1.2) Sequence # Definition- — REQUIRED

(8.1.3) Practice Assigned Patient ID- — NOT SUPPORTED

(8.1.4) Laboratory Assigned Patient ID- — NOT SUPPORTED

(8.1.5) Patient ID- — NOT SUPPORTED
(maximum of 20 characters)

(8.1.6) Patient Name- — SUPPORTED
(Last^First^Initial; maximum of 30 characters both First&Last name)

(8.1.7) Mother's Maiden Name- — NOT SUPPORTED

(8.1.8) Birthdate- — SUPPORTED
(YYYYMMDD; maximum of 8 characters)

(8.1.9) Patient's Sex- — SUPPORTED
(M or F; maximum of 1 character)

(8.1.10)Patient Race-Ethnic Origin- — NOT SUPPORTED

(8.1.11)Patient's Address- — NOT SUPPORTED

(8.1.12)Reserved Field- — NOT SUPPORTED

(8.1.13)Patient's Phone#- — NOT SUPPORTED

(8.1.14)Attending Physician ID- — NOT SUPPORTED

(8.1.15)Special Field 1-	NOT SUPPORTED
(8.1.16)Special Field 2-	NOT SUPPORTED
(8.1.17)Patient Height-	NOT SUPPORTED
(8.1.18)Patient Weight-	NOT SUPPORTED
(8.1.19)Known or Suspected Diagnosis-	NOT SUPPORTED
(8.1.20)Active Medications-	NOT SUPPORTED
(8.1.21)Patient's Diet-	NOT SUPPORTED
(8.1.22)Practice Field 1-	NOT SUPPORTED
(8.1.23)Practice Field 2-	NOT SUPPORTED
(8.1.24)Admission and Discharge Dates-	NOT SUPPORTED
(8.1.25)Admission Status-	NOT SUPPORTED
(8.1.26)Location-	NOT SUPPORTED
(8.1.27)Nature of Alt. Diag. Code.....-	NOT SUPPORTED
(8.1.28)Alt. Diag. Code and Classifications-	NOT SUPPORTED
(8.1.29)Patient Religion-	NOT SUPPORTED
(8.1.30)Marital Status-	NOT SUPPORTED
(8.1.31)Isolation Status-	NOT SUPPORTED
(8.1.32)Language-	NOT SUPPORTED
(8.1.33)Hospital Service-	NOT SUPPORTED
(8.1.34)Hospital Institution-	NOT SUPPORTED
(8.1.35)Dosage Category-	NOT SUPPORTED

ORDER RECORD DEFINITION (9.4.1-9.4.31)

[Record Type (O)][Sequence#][Specimen ID (Accession#)][Instrument Specimen ID][Universal Test ID][Priority][Order Date/Time][Collection Date/Time][Collection End Time][Collection Volume][Collector ID][Action Code][Danger Code][Relevant Clinical Info][Date/Time Specimen Received][Specimen Descriptor,Specimen Type,Specimen Source][Ordering Physician][Physician's Telephone Number][User Field No.1][User Field No.2][Lab Field No.1][Lab Field No.2][Date/Time results reported or last modified][Instrument Charge to Computer System][Instrument Section ID][Report Types][Reserved Field][Location or ward of Specimen Collection][Nosocomial Infection Flag][Specimen Service][Specimen Institution]

Sample Test Order Message:
<STX>[FrameNumber]O|1|123456||^^^TSH<CR><ETX>[CheckSum]<CR>
<LF>

(9.4.1) Record types Definition-
O = Test Order Record — REQUIRED

(9.4.2)Sequence #- — REQUIRED

(9.4.3) Specimen ID- — REQUIRED
(ACCESSION # ON PRIMARY TUBE;
maximum of 30 characters)

(9.4.4) Instrument Specimen ID- — NOT SUPPORTED

(9.4.5) Universal Test ID — REQUIRED
(^^^[Test Code]; maximum of 10 characters)
Example Test Codes: TSH, LH, FSH, DGX, T4, HCG, RTH, SPE D120

(9.4.6) Priority- — SUPPORTED
S-Stat
A-As soon as possible
R-Routine
C-Callback
P-Preoperative
(All maximum of 1 character)

(9.4.7) Requested/Ordered Date and Time- — NOT SUPPORTED
(maximum of 14 characters)

(9.4.8) Specimen Collection Date and Time- — NOT SUPPORTED

(9.4.9) Collection End Time- — NOT SUPPORTED

(9.4.10) Collection Volume- — NOT SUPPORTED

(9.4.11) Collector ID- — NOT SUPPORTED

(9.4.12) Action Code- NOT SUPPORTED

(9.4.13) Danger Code- NOT SUPPORTED

(9.4.14) Relevant Clinical Information- SUPPORTED

(9.4.15) Date/Time Specimen Received- NOT SUPPORTED

(9.4.16) Specimen Descriptor- NOT SUPPORTED

(9.4.16.1) Specimen Type- NOT SUPPORTED

(9.4.17) Ordering Physician- SUPPORTED
Smith^Joseph; maximum of 30 characters

(9.4.18) Physician's Telephone Number- NOT SUPPORTED

(9.4.19) Users Field No. 1- NOT SUPPORTED

(9.4.20) Users Field No. 2- NOT SUPPORTED

(9.4.21) Lab Field No. 1- NOT SUPPORTED
SUPPORTED Internal to Siemens Diagnostics
(CPS of result)

(9.4.22) Lab Field No. 2- NOT SUPPORTED
SUPPORTED Internal to Siemens Diagnostics
(Kit lot to run, or was run on test)

(9.4.23) Date/Time Results Reported....- NOT SUPPORTED

(9.4.24) Instrument Charge to Computer Sys.- NOT SUPPORTED

(9.4.25) Instrument Section ID- SUPPORTED

(9.4.26) Report Types- NOT SUPPORTED

(9.4.27) Reserved Field- NOT SUPPORTED

(9.4.28) Location of Specimen Collection- NOT SUPPORTED

(9.4.29) Nosococmial Infection Flag- NOT SUPPORTED

(9.4.30) Specimen Service- NOT SUPPORTED

(9.4.31) Specimen Institution- NOT SUPPORTED

RESULT RECORD DEFINITION (10.1 - 10.1.14)
[Record Type (R)][Sequence #][Universal Test ID][Data (result)][Units][ReferenceRanges] [Result abnormal flags][Nature of Abnormality Testing][Result Status][Date of change in instruments normal values or units][Operator ID][Date\Time Test Started][Date\Time Test Completed][Instrument ID]

Sample Result Message:
<STX>[FrameNumber]R|1|^^^TSH|8.19|uIU/mL|.4\.002^4\75|H|N|F||test|199403281083 4|19920526110500|DPCCIRRUS<CR><ETX>[CheckSum]<CR><LF>

(10.1.1) Record Types Definition-

R = Result Record	REQUIRED

(10.1.2) Sequence #- REQUIRED

(10.1.3) Universal Test ID- REQUIRED
(^^^[Test Code])
Example Test Codes: TSH, LH, FSH, DGX, TT4, HCG, TU, RTH, SPE D120

(10.1.4) Data or Measurement Value (Result)- REQUIRED

(10.1.5) Units- REQUIRED
Current Siemens Diagnostics Units of Measure: ng/mL, ng/dL, ug/dL, uIu/mL, mIU/mL, pg/mL, nmol/L, pmol/L, mIU/L, ug/L, IU/mL, IU/L, KU/L, SClass

(10.1.6) Reference Ranges- SUPPORTED
([Low]\[Panic\Low]^[High]\[Panic High])

(10.1.7) Result Abnormal Flags-

L = Below Normal	SUPPORTED
H = Above Normal	SUPPORTED
LL = Below Panic	NOT SUPPORTED
HH = Above Panic	NOT SUPPORTED
< = Below readable limit	REQUIRED
> = Above readable limit	REQUIRED
N = Normal	SUPPORTED
A = Abnormal	NOT SUPPORTED
U = Significant change UP	NOT SUPPORTED
D = Significant change DOWN	NOT SUPPORTED
B = Better	NOT SUPPORTED
W = Worse	NOT SUPPORTED

(10.1.8) Nature of Abnormality Testing-

A = Age population tested	NOT SUPPORTED
S = Sex based Population	NOT SUPPORTED
R = Race based Population	NOT SUPPORTED
N = Normal generic range	SUPPORTED

(10.1.9) Results Status-

C = Correction of previously sent results	REQUIRED
P = Preliminary Results	NOT SUPPORTED
F = Final Results	SUPPORTED
X = Results cannot be done. (Eg. Calculation Error)	NOT SUPPORTED
I = In instrument, results pending	NOT SUPPORTED
S = Partial Results	NOT SUPPORTED
M = Result is a MIC level	NOT SUPPORTED
R = This result was previously transmitted	REQUIRED
N = This result record contains necessary information to run a new order.	NOT SUPPORTED

(10.1.10) Date systems values/units changed- NOT SUPPORTED

(10.1.11) Operator Name/ID#- SUPPORTED

(10.1.12) Date+Time Test Started (YYYYMMDDHHMMSS) SUPPORTED

(10.1.13) Date+Time Test Completed (YYYYMMDDHHMMSS) SUPPORTED

(10.1.14) Instrument ID- SUPPORTED
(Configurable by Siemens Diagnostics SOFTWARE)

REQUEST INFORMATION RECORD (12.1 - 12.1.13)
NOT SUPPORTED IN UNI DIRECTIONAL MODE

MESSAGE TERMINATOR RECORD DEFINITION (13.1 - 13.1.3)
[Record Type ID (L)][Sequence Number][Temination Code]

Example Termination Record:
<STX>[FrameNumber]L|1|N<CR><ETX>[CheckSum]<CR><LF>

(13.1.1) Record Types Definition-

(13.1.2) L = Terminator record	SUPPORTED
(13.1.3)Sequence # -	REQUIRED

(13.1.4)Termination Code-

N = Normal termination	SUPPORTED
T = Sender Aborted	NOT SUPPORTED
R = Receiver Abort	NOT SUPPORTED
E = Unknown system error	NOT SUPPORTED
Q = Error in last request for information	NOT SUPPORTED
I = No information avail. from last query in uni-directional mode	NOT SUPPORTED
F = Last request for information Processed in uni-directional mode	NOT SUPPORTED

IMMULITE 2000/2500/SMS LIS ERROR MESSAGE DEFINITIONS

Error # 2550 LIS – Parse error due to unexpected sample type received from LIS. An invalid sample type (e.g., ~D) was received from the LIS.

Error # 2551 LIS –An unexpected error was encountered during query of the LIS. Unable to query the LIS and receive a response. The SMS will continue to re-query while there are still barcodes requiring a query.

Error # 2567 LIS – The LIS is not enabled. Enable the LIS to perform this action. This message appears when trying to pause or activate the LIS or trying to manually send or resend results from the LIS screen when the LIS is configured to "off". To resolve this issue from the SMS, set the LIS to bi-directional or bidirectional host query from the LIS screen, log off and then back on the SMS, and then select the RUN button.

Error # 2571 LIS Error: Patient ID exceeded 20 characters. An order downloaded from the LIS contains a patient ID exceeding 20 characters. The order is not accepted because Patient IDs cannot exceed 20 characters.

Error # 2572 LIS Error: Accession Number exceeded 20 characters. An order downloaded from the LIS contains an accession number exceeding 20 characters. The order is not accepted because accession numbers cannot exceed 20 characters.

Error # 12300 LIS – Carriage return or Line Feed missing from message. The message is missing a required Carriage return, line feed or both. Violates ASTM E1381 Section 6.3.1.2.

Error # 12301 LIS – Incorrect or Missing Frame Number. The frame number for a message is an incorrect value or is not present. Violates ASTM E1381 Section 6.3.2.1.

Error # 12302 LIS – Incorrect Checksum. The checksum, a scheme to indicate whether a message was received properly is incorrect. Violates ASTM E1381 Section 6.3.3.1.

Error # 12303 LIS – Message is too short (< 5 characters). LIS message received is less than the requisite five characters.

Error # 12304 LIS – Invalid Password in Header Message. The Password received does not match the password entered in the LIS configuration on IMMULITE 2000/2500. The LIS vendor needs to be contacted to determine the proper password. The LIS vendor may change the password parameter on the LIS *OR* request the password on IMMULITE is modified to the value they the LIS vendor indicates. Violates ASTM E1394 Section 7.1.4.

Error # 12305 LIS – Invalid Sender ID in Header Message. The Sender ID received does not match the Sender ID entered in the LIS configuration on IMMULITE 2000/2500. The LIS vendor needs to be contacted to determine the proper Sender ID. If the Sender ID is incorrect in the IMMULITE 2000/2500 software, the LIS vendor may change the Sender ID parameter on

the LIS *OR* request the Sender ID on IMMULITE 2000/2500 is modified to the value they the LIS vendor indicates. If the Sender ID is correct on IMMULITE 2000/2500, the LIS vendor most likely has an error in their code. When sending FROM the LIS to IMMULITE 2000/2500 the LIS vendor needs to place their ID (Designated on IMMULITE 2000/2500 as receiver ID) in the Sender ID field of the header message. Violates ASTM E1394 Section 7.1.5.

Error # 12306 LIS – Invalid Receiver ID in Header Message. The Receiver ID received does not match the Receiver ID entered in the LIS configuration on IMMULITE 2000/2500. The LIS vendor needs to be contacted to determine the proper Receiver ID. If the Receiver ID is incorrect in the IMMULITE 2000/2500 software, the LIS vendor may change the Receiver ID parameter on the LIS *OR* request the Receiver ID on IMMULITE 2000/2500 is modified to the value they the LIS vendor indicates. If the Receiver ID is correct on IMMULITE 2000/2500, the LIS vendor most likely has an error in their code. When sending FROM the LIS to IMMULITE 2000/2500 the LIS vendor needs to place the Instrument ID (Designated on IMMULITE 2000/2500 as sender ID) in the Receiver ID field of the header message. Violates ASTM E1394 Section 7.1.10.

Error # 12307 LIS – No Header message received. Records are being received from the LIS without sending an initial header message. Violates ASTM E1394 Section 5.2.

Error # 12308 LIS – Several LIS errors have occurred the past hour. There may be a communication Problem. More than 20 communication errors have occurred within a one-hour time frame. This is an IMMULITE 2000/2500 message only and is not part of the ASTM specification.

Error # 12309 LIS – Null or Missing Patient ID in Patient Record. The Patient ID field in the Patient message is not present. This is a required field for IMMULITE 2000/2500.

Error # 12310 LIS – Invalid Test Code or Format in Order record. The test code received in an order message does not match a test code on IMMULITE 2000/2500. The test code may be incorrect or an initial kit for the test code may not have been entered on IMMULITE 2000/2500. The format for separating multiple test orders in one order record may have been violated. Violates ASTM Section 9.4.5, and 6.6.1.

Error # 12311 LIS – LIS cannot accept message after sending message 7 times. A message was sent to the LIS seven times and was not accepted. The current communication session is aborted. Violates ASTM E1381 Section 6.5.1.2.

Error # 12312 LIS – Time out, 30 seconds expired and no data was received from LIS. Information was received from the LIS and a response to the message was returned to the LIS. No additional data was received from the LIS in 30 seconds. The current communication session is aborted. Violates ASTM E1381 Section 6.5.2.4.

Error # 12313 LIS – EOT received prematurely while receiving data. An EOT was sent before the transmission was completed.

Error # 12314 LIS- An error occurred sending LIS query request. Host query aborted. An unrecognized error occurred when sending a query to the LIS.
Error # 12315 LIS – Time out, No response from LIS after waiting 15 seconds. Information was sent to the LIS and there was no response after a 15 second time period. The current communication session is aborted. Violates ASTM E1381 Section 6.5.2.3.

Error # 12316 LIS – <ENQ> Contention. The LIS was attempting to initiate a communication session at the same moment the IMMULITE 2000/2500 was performing the same. This error is handled as described in ASTM E1381 Section 6.2.7.1.

Error # 12317 LIS – No accession number in order record. No accession number was received in an order record. This is a required field for IMMULITE.

Error # 12318 LIS – The LIS encountered an error for a query. The LIS informed IMMULITE 2000/2500 the *LIS* encountered an error in a request for a patient record from a query message as defined in ASTM E1394 13.1.3.

Error # 12319 LIS – The LIS has no information for query. The LIS did not have information on a requested sample (accession number) as defined in ASTM E1394 Section 13.1.3.

Error # 12320 LIS – An invalid terminator code was received from the LIS. An invalid or unsupported terminator code was received from the LIS. Violates ASTM E1394 Section 13.1.3.

Error # 12321 LIS - Unique ID does not match retrieved file. Please call Technical Services. All records are stored on the IMMULITE 2000/2500 with a unique number. A retrieved file was expected to have a particular number and was incorrect. This error should not be encountered and if so indicates a programming logic error.

Error # 12322 LIS - Record could not be marked sent, record not found. A sent record could not be found in the database to be sent to the LIS. This error should not be encountered and indicates a programming logic error.

Error # 12323 LIS – Record could not be sent to LIS, record not found. A tagged record could not be found in the database to be sent to the LIS. This error *may* indicate a programming logic error.

Error # 12324 LIS – There are no "TAGGED" records to sent to the LIS. The operator pressed the Send or RE-Send buttons on the LIS screen and no records are tagged.

Error # 12325 LIS – You can only display 10,000 records at one time. The LIS Screen has a limit of displaying 10,000 records at one time. The first 10,000 records meeting the sorting criteria are used. To view remaining records the operator is required to refine the date and time sorting criteria.

Error # 12326 LIS – Received Order Record before Patient Record. The patient message must precede the order message in the LIS message. The LIS has received the order message before receiving the patient message.

Error # 12327 LIS – Data is being received from the LIS or IMMULITE is already sending data to the LIS. The LIS is currently receiving data or the IMMULITE is actively sending data to the LIS.

Error # 12328 LIS– LIS reports an error in query request. There was an error in the query request as it was sent from the IMMULITE to the LIS.

Error # 12329 LIS – LIS reports no information for Accession Number in query request. There was no information for an Accession number in a query.

Error # 12330 LIS - An error occurred sending LIS query request. Host query aborted. An unrecognized error occurred when sending a query to the LIS

Error # 12331 LIS – Parse error occurred when downloading in Control format. The Control information was sent from the LIS in the wrong format. Contact your laboratory LIS provider. If the message persists, call Technical Service.

Error # 12332 LIS – Parse error occurred when downloading in Adjustor format. The Adjustor information was sent from the LIS in the wrong format.

Error # 12333 LIS – Control downloaded from LIS is new to the system. The control requested in the download from LIS is new to the system. The control order was not saved because the control has not yet been defined on the Instrument. Define the control before querying or downloading orders for this sample.

Error # 12334 LIS – Parse error occurred when downloading in Verifier format. The Calibration verifier information was sent from the LIS in the wrong format.

Error # 12335 LIS – Sort Error An error was exhibited when trying to sort in the LIS.

Error # 12339 LIS – Send LIS Error An application error generated when the mail procedure was running.

Error # 12341 LIS – Check Message Error An error occurred in the Check Sum Message routine when building the message.

Error # 12342 LIS – Parse Error A programmer error was generated during the parsing routine.

Error # 12343 LIS – Listen Error A programmer error occurred when receiving information from the LIS

Error # 12344 LIS – Check Error A check sum error occurred within the LIS program.

IMMULITE to LIS CABLE WIRING ASTM E1381 (5.2.4.2)

The following definition is the wiring “pin out” for the cable connecting IMMULITE to the LIS. The column labeled “Contact Number” is for the ***IMMULITE side of the cable only!***. The connector “pin out” for the LIS side of the cable must be supplied by your MIS department or LIS software company.

There are two possible connector types for the LIS - IMMULITE serial communication cable for IMMULITE. The computer will be configured with a 25-position connector, or a 9-position connector. The cable is connected to COM2 of the PC used by IMMULITE. The connector on the back of the PC should be examined to determine the proper connector type. Pin connections for a 25-position or a 9-position connector are defined below. Siemens Diagnostics suggests the use of shielded cable.

DB25 CONNECTOR:

Contact Number	EIA Circuit	Description	IMMULITE	COMPUTER (LIS)
1	...	Shield	...	No Connection
2	BA	Transmitted Data	Output	Input
3	BB	Received Data	Input	Output
7	AB	Signal Ground	...	...

DB9 CONNECTOR:

Contact Number	EIA Circuit	Description	IMMULITE	COMPUTER (LIS)
2	BB	Received Data	Input	Output
3	BA	Transmitted Data	Output	Input
5	AB	Signal Ground	...	...

APPENDIX