The Panther® System LIS Host Interface Guide

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1. Purpose

The purpose of this Supplemental Information Sheet is to specify the interface for exchanging information between the Panther system. This includes both settings to be made to adapt the communication to lab specific properties as well as a description of message content and tools for trouble shooting.

Additionally, the Panther Workcell Management System (WMS) utilizes a portion of this interface. WMS does not transmit results and will only accept broadcast test orders or perform a query for test orders. Results instead will be transmitted from a Panther system only. The Panther Workcell requires that both WMS and the Panther System receive test orders from the LIS System.

2. Intended Use

This document will be effective upon receipt and is intended for:

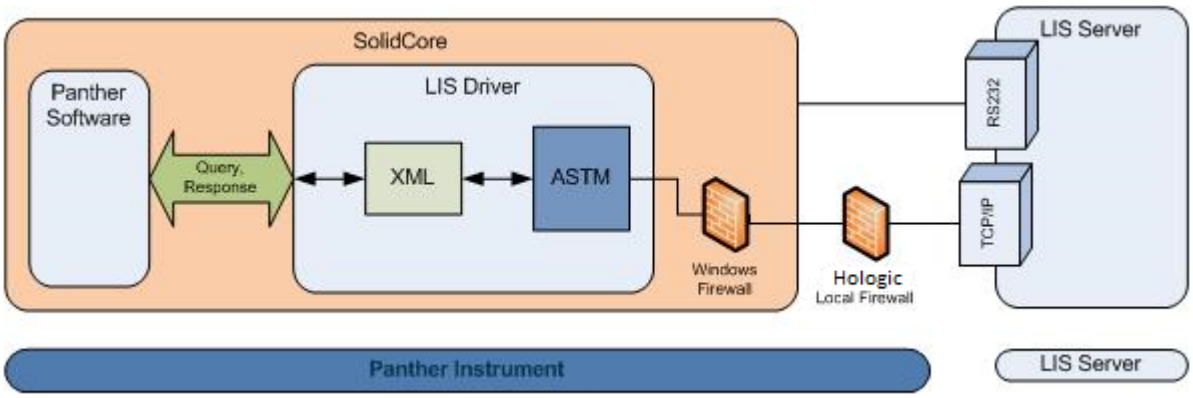
- Hologic Field Service Engineers.
- Hologic Technical Support personnel.
- Customer IT system engineers and LIS vendors seeking information about LIS – Laboratory Information Systems and how they can be utilized with the Panther system via computer interfaces.

3. Document Overview

This document is intended to specify the interface for exchanging information between the Panther system and a host computer. This includes both settings to be made to adapt the communication to lab specific properties as well as a description of message content and tools for trouble shooting. It is the responsibility of the user to validate the transmission of results and interface to their respective Laboratory Information System.

3.1. Communication Overview

The physical connection used by the Panther system host interface is a DB9 connection to the serial port using RS232 signaling or through an RJ45 port using TCP/IP on a standard Ethernet network card.


SolidCore
Panther Software
LIS Driver
Query, Response
XML
ASTM
Windows Firewall
Hologic Local Firewall
LIS Server
RS232
TCP/IP
Panther Instrument
LIS Server

The following transports are supported for CLSI (NCCLS) LIS1-A, CLSI (NCCLS) LIS2-A.

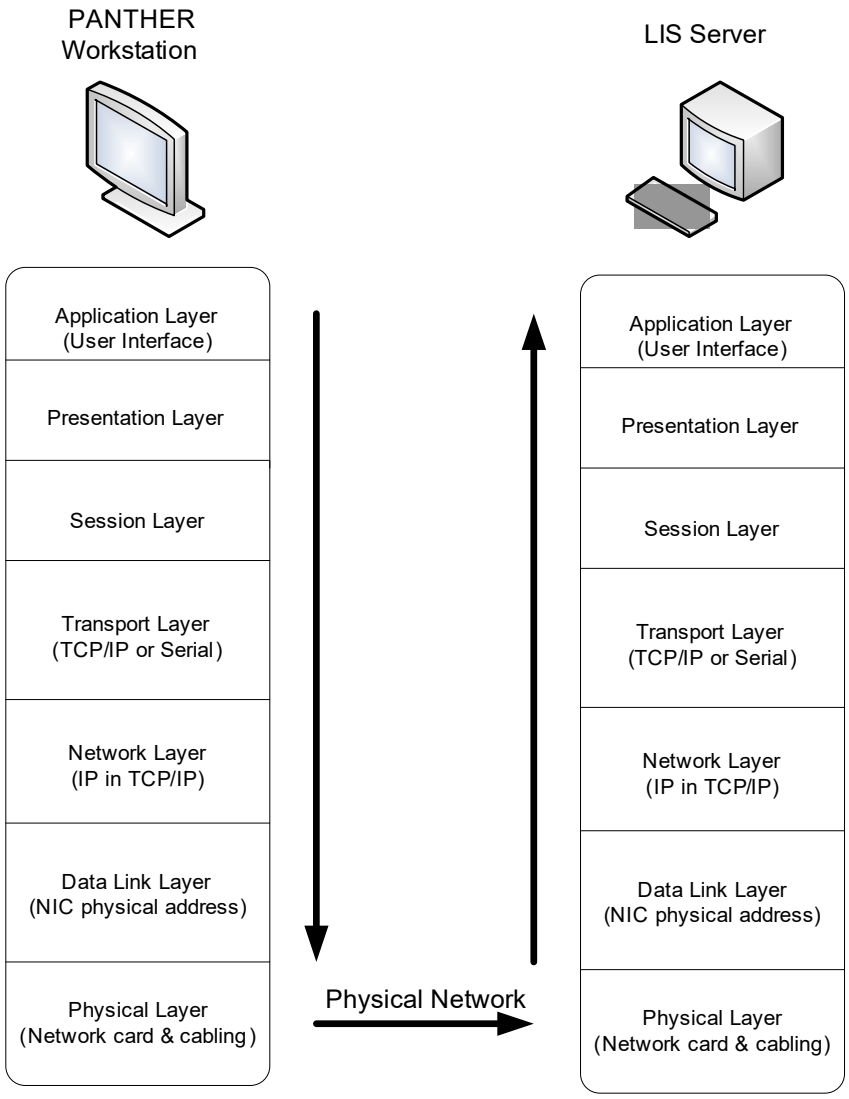
- Serial – the following serial parameters are configurable: (7.4 LIS Configuration Parameters)
  - Com Port
  - Baud Rate
  - Data Bits
  - Stop Bits
  - Parity

- TCP/IP – Hologic products always act as client and Hologic expects LIS to be the server. Typically, the instrument attempts to establish connection on port number 1787. The IP Address and Port number are configurable from within the Panther system software.

3.2. Communication Layers

As all the communication is based on network connections, this manual addresses mostly the upper layer (application) related topics.

This layer corresponds to the upper layer in the well-known OSI model:



4. Workflow

4.1. Communication Scenarios

Name	Description	Panther System Send	Panther System Receive
Panther System - Request Testorders (Host Query)	Panther system requests Test Orders for Samples as they are loaded, or because Operator initiates request.	SampleID or ALL	
LIS- Send Testorders to Panther System	LIS sends testorders when created in LIS system or when Panther system requests testorders for Loaded Samples.		Patient information, SampleID, Assay (test), Analyte Name, Priority, and Action Code.
Panther System - Export of Results to LIS	Panther system sends results as they become available or when the LIS requests them.	SampleID, Patient Information, Assays (test), Result Category, and Data/Measurement (interpretations), Result Status, Date and Time test completed, and error flags as applicable.	
LIS Request Results	LIS requests results from Panther system		SampleID or ALL or Test Name
Panther System - Export of Results to LIS **Unidirectional LIS**	Panther system sends results as they become available.	SampleID, Patient Information, Assays (test), Result Category, and Data/Measurement (interpretations), Result Status, Date and Time test completed.	

4.2. HL7 Interface

The Panther system has the capability of utilizing an HL7 interface with the utilization of a middleware device or through ASTM translation drivers. The preferred vendor for the interface device is Data Innovations. For ordering information and support of this device and/or application contact Data Innovations directly at:

Data Innovations
120 Kimball Ave Ste 100, S. Burlington, Vermont
(802) 658-2850 | northamerica-sales@datainnovations.com | datainnovations.com

Supplier Details for Ex-US Only:

Steve Bounichou
Data Innovations S.A/N.V
34 avenue Jacques Brel
1200 Brussels
Belgium
Tel: +32 2 770 6222
E: sbounichou@datainnovations.com

4.3. Host Query Enabled/Disabled Scenarios

LIS Enabled/Host Query Enabled: When samples are loaded, the Panther system will match Sample IDs to existing test orders in the Panther system database. The Panther system will also query the LIS for test orders matching the loaded sample IDs. The Panther System will update the database when the LIS returns appropriate test orders. If non-completed test orders are already present in the Panther database for the Sample ID, the corresponding test orders sent from the LIS will be ignored. If patient demographics information for the sample changed, the Panther database will be updated with the new information.

LIS Enabled/Host Query Disabled: When samples are loaded, the Panther system will match Sample IDs to test orders in the Panther system database.

4.4. Host Query - Panther system requests test orders

Example:

```
H|\^&|||Panther|||||LISHost||P|1|
Q|1|^SAMPLE01||ALL||||||||O
Q|2|^SAMPLE02||ALL||||||||O
Q|3|^BARCODE0815||ALL||||||||O
L|1|N
```

(If CompressedOrderQuery is enabled)

```
H|\^&|||Panther|||||LISHost||P|1|
Q|1|^SAMPLE01\^SAMPLE02\^BARCODE0815||ALL||||||||O
L|1|N
```

Panther System Data	ASTM Mapping	Examples
Record Code (Header)	H – 1 Record Identifier	Always set to 'H'
LIS Configuration – Delimiter Options	H – 2 Delimiters	|\^&
LIS Configuration – Instrument ID	H – 5 Sender Name or ID	Panther
LIS Configuration – Host ID	H – 10 Receiver ID	LISHost
	H – 12 Processing ID	Always set to 'P'
	H – 13 Version ID	Always set to '1'
	Q - 1 Record Identifier	Always set to 'Q'
	Q - 2 Sequence Number	Sequence number of 'Q' records
SampleID	Q – 3.2 Specimen ID	SAMPLE01, SAMPLE02, BARCODE0815
	Q – 5 Universal Test ID	Always set to 'ALL'
	Q – 13 Request Information status codes.	O – Request sample information.
	L – 1 Record Identifier	Always set to 'L'
	L - 2 Sequence Number	Sequence number of 'L' records
	L – 3 Termination Code	'N' for Normal

4.5. LIS to Panther System – Send Test orders

Example:

```
H|\^&|||LISHost|||||Panther||P|1|20130130183117|
P|1|PatID01|||Meier^Anna||19741001|F|||||Martinez
O|1|SAMPLE01||^^^CT/GC^^1^1|R|19980506090909|||||N||||Serum||||||||||O|
L|1|N|
```

Panther System Data	ASTM Mapping	Examples
	H – 1 Record Identifier	Always set to 'H'
LIS Configuration – Delimiter Options	H – 2 Delimiters	|\^&
LIS Configuration – Instrument ID	H – 5 Sender Name or ID	LISHost
LIS Configuration – Host ID	H – 10 Receiver ID	Panther
	H – 12 Processing ID	Always set to 'P'
	H – 13 Version ID	Always set to '1'
	H – 14 Time/Date Sent	20130130183117
PatientInformation	P – 1 Record Identifier	Always set to 'P'
	P - 2 Sequence Number	Sequence number of 'P' records
	P – 3 Patient ID	PatID01
	P – 6 Patient Name	Meier^Anna
	P – 8 Birth Date	19741001
	P – 9 Gender	F
	P – 14 Attending Physician	Martinez
	O – 1 Record Identifier	Always set to 'O'
	O - 2 Sequence Number	Sequence number of 'O' records
SampleID	O – 3 Specimen ID	SAMPLE01
AssayShortName from Assay Sequence File (needs to match).	O – 5.4 Assay Name(Manufacturers Code)	CT/GC (Table 3A)
AnalyteName from Assay Sequence File (needs to match).	O – 5.5 AnalyteName	(Table 4A) When empty means all analytes.
Number of Replicates	O – 5.6 Number of replicates	1 = one replicate Empty field implies "1" replicate.
Dilution factor	O – 5.7 Dilution factor	Dilution factor = 1 Empty field implies factor of "1".
Priority	O – 6 Priority	R – Routine

Panther System Data	ASTM Mapping	Examples
Panther system updates Test Order CreationTime.	O – 7 Date and Time Requested	19980506090909, Panther system does not store this date, it returns the date when the test order is created on Panther
	O – 12 Action Code	'N' for new. Empty field implies 'new'.
Future – will be stored in Panther system and returned to LIS	O – 16 Specimen Type	Serum
	O – 26 Report Type	'O' for Order.
	L – 1 Record Identifier	Always set to 'L'
	L - 2 Sequence Number	Sequence number of 'L' records
	L – 3 Termination Code	'N' for Normal

4.6. Panther System to LIS – Export of Results

Example:

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna||19741001|F|||||Martinez
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^CT/GC^GC CT^^1|R|20100506123145||||||||||||||||||||F
R|1|^^^CT/GC^TotalRLU^^1|5|||||F||||20100506123145
R|2|^^^CT/GC^CTResult^^1|CT neg|||||F||||20100506123145
R|3|^^^CT/GC^GCResult^^1|GC neg|||||F||||20100506123145
L|1|N
```

Panther System Data	ASTM Mapping	Examples
	H – 1 Record Identifier	Always set to 'H'
LIS Configuration – Delimiter Options	H – 2 Delimiters	|\^&
LIS Configuration – Instrument ID	H – 5 Sender Name or ID	Panther
LIS Configuration – Host ID	H – 10 Receiver ID	LISHost
	H – 12 Processing ID	Always set to 'P'
	H – 13 Version ID	Always set to '1'
PatientInformation	P – 1 Record Identifier	Always set to 'P'
	P - 2 Sequence Number	Sequence number of 'P' records
	P – 3 Patient ID	PatID01
	P – 6 Patient Name	Meier^Anna
	P – 8 Birth Date	19741001
	P – 9 Gender	F
	P – 14 Attending Physician	Martinez
	O – 1 Record Identifier	Always set to 'O'
	O - 2 Sequence Number	Sequence number of 'O' records
SampleID	O – 3 Specimen ID	SAMPLE01
TestOrder GUID	O – 4.1 Instrument Specimen ID/Unique ID assigned to testorder by instrument	C35B802B-B4F9-400A-9409-1FAB9D736C8D
TestOrder ID	O – 4.2 Instrument Specimen ID/Database ID of testorder.	1234
AssayName	O – 5.4 Assay short name (Manufacturers Code)	CT/GC, (Table 3A)

Panther System Data	ASTM Mapping	Examples
Analytes	O – 5.5 AnalyteName	GC CT (Table 4A) When empty means all analytes.
Number of replicates	O – 5.6 NumberOfReplicates	Empty field implies “1” replicate
Dilution Factor	O – 5.7 DilutionFactor	Dilution factor = 1 Empty field implies factor of “1”
Priority(Stat Flag)	O – 6 Priority	R = Routine Empty field implies ‘routine’
Creation Date/Time of TestOrder in Panther System	O – 7 Time/Date Requested	20100506123145
	O – 26 Report Types	F – Final Test Results
First Result Record	R – 1 Record Identifier, Test Order Result record	Always set to ‘R’
	R - 2 Sequence Number	Sequence number of ‘R’ records
AssayName	R – 3.4 Assay short name	CT/GC (Table 3A for enumerations)
Result Category, from Assay Sequence File	R - 3.5 Result Aspect	For CT/GC, TotalRLU
Replicate number	R - 3.6 Replicate Number	Empty field implies replicate “1”
Dilution Factor	R - 3.7 Dilution Factor	Dilution factor = 1 Empty field implies factor of “1”
Interpretations	R - 4 Data or Measurement value	For CT/GC, 5
	R - 5 Units	Empty
	R - 7 Abnormal Flag	Empty
	R – 9 Result Status	F – Final Test Results
Date/Time test completed	R – 13 Time/Date Completed	20100506123145
Second Result Record	R – 1 Record Identifier, Test Order Result record	Always set to ‘R’
	R - 2 Sequence Number	Sequence number of ‘R’ records
AssayName	R – 3.4 Assay short name	CT/GC (Table 3A for enumerations)
Result Category, from Assay Sequence File	R - 3.5 Result Aspect	For CT/GC, CTResult (Table 5A for enumerations)
Replicate number	R - 3.6 Replicate Number	Empty field implies replicate “1”
Dilution Factor	R - 3.7 Dilution Factor	Dilution factor = 1 Empty field implies factor of “1”
Interpretations	R - 4 Data or Measurement value	CT neg, (See Table 6A for enumerations)

Panther System Data	ASTM Mapping	Examples
	R - 5 Units	Empty
	R - 7 Abnormal Flag	Empty
	R – 9 Result Status	F – Final Test Results
Date/Time test completed	R – 13 Time/Date Completed	20100506123145
Third Result Record	R – 1 Record Identifier, Test Order Result record	Always set to 'R'
	R - 2 Sequence Number	Sequence number of 'R' records
AssayName	R – 3.4 Assay short name	CT/GC (Table 3A for enumerations)
Result Category, from Assay Sequence File	R - 3.5 Result Aspect	For CT/GC, GCResult (Table 5A for enumerations)
Replicate number	R - 3.6 Replicate Number	Empty field implies replicate "1"
Dilution Factor	R - 3.7 Dilution Factor	Dilution factor = 1 Empty field implies factor of "1"
Interpretations	R - 4 Data or Measurement value	GC neg, (See Table 6A for enumerations)
	R - 5 Units	Empty
	R - 7 Abnormal Flag	Empty
	R - 9 – Result Status	"F" for = Final Test Results
Date/Time test completed	R – 13 Time/Date Completed	20100506123145
	L – 1 Record Identifier	Always set to 'L'
	L - 2 Sequence Number	Sequence number of 'L' records
	L – 3 Termination Code	'N' for 'Normal

NOTE: If multiple results exist for the same Sample ID, Panther system may send multiple result records as part of a single order record. The example above shows 3 result records as part of a single order record.

4.7. Panther System to LIS – Export of Results – Assay Processing Failure

Example:

```
H|\^&|||Panther|||||LISHost|||1|19941115202738
P|1|PatID01|||Meier^Anna||19741001|F|||||Martinez
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234|^^^CT/GC^
GC CT^^1|R|20100506123145||||||||||||||||||X
R|1|^^^CT/GC^CTResult^^1||||||X||||20100506123145|
C|1|I|^RDFS - failure when dispensing sample\^CLT - Clot detected|I
L|1|N
```

Panther System Data	ASTM Mapping	Examples
	H – 1 Record Identifier	Always set to 'H'
LIS Configuration – Delimiter Options	H – 2 Delimiters	|\^&
LIS Configuration – Instrument ID	H – 5 Sender Name or ID	Panther
LIS Configuration – Host ID	H – 10 Receiver ID	LISHost
	H – 13 Version ID	Always set to '1'
	H – 14 Time/Date Sent	19941115202738 Date/Time not used
PatientInformation	P – 1 Record Identifier	Always set to 'P'
	P - 2 Sequence Number	Sequence number of 'P' records
	P – 3 Patient ID	PatID01
	P – 6 Patient Name	Meier^Anna
	P – 8 Birth Date	19741001
	P – 9 Gender	F
	P – 14 Attending Physician	Martinez
	O – 1 Record Identifier	Always set to 'O'
	O - 2 Sequence Number	Sequence number of 'O' records
SampleID	O – 3 Specimen ID	SAMPLE01.
TestOrder GUID	O – 4.1 Instrument Specimen ID	C35B802B-B4F9-400A-9409-1FAB9D736C8D
TestOrder ID	O – 4.2 Instrument Specimen ID/Component 2	1234
AssayName	O – 5.4 Assay short name (Manufacturers Code)	CT/GC, (Table 3A)
Analytes	O – 5.5 AnalyteName	GC CT (Table 4A) When empty means all analytes.

Panther System Data	ASTM Mapping	Examples
Number of replicates	O – 5.6 NumberOfReplicates	Empty field implies “1” replicate
Dilution Factor	O – 5.7 DilutionFactor	Dilution factor = 1 Empty field implies factor of “1”
Priority(Stat Flag)	O – 6 Priority	R = Routine Empty field implies ‘routine’
Creation Date/Time of TestOrder in Panther System	O – 7 Time/Date Requested	20100506123145
	O – 26 Report Types	X – Work cannot be done
First Result Record	R – 1 Record Identifier, Test Order Result record	Always set to ‘R’
	R - 2 Sequence Number	Sequence number of ‘R’ records
AssayName	R – 3.4 Assay short name	CT/GC (Table 3A for enumerations)
Result Category, from Assay Sequence File	R - 3.5 Result Aspect	For CT/GC, CTResult (Table 5A for enumerations)
Replicate number	R - 3.6 Replicate Number	Empty field implies replicate “1”
Dilution Factor	R - 3.7 Dilution Factor	Dilution factor = 1 Empty field implies factor of “1”
Interpretations	R - 4 Data or Measurement value	Empty
	R - 5 Units	Empty
	R - 7 Abnormal Flag	Empty
	R – 9 Result Status	X – Work cannot be done
Date/Time test completed	R – 13 Time/Date Completed	20100506123145
	C - 1 Record Identifier	Always set to ‘C’
	C - 2 Sequence Number	Sequence number of ‘C’ records
	C – 3 Comment Source	Always set to ‘I’
	C - 4 Comment	If configured for compressed comments, multiple comments with delimiters are allowed: ^RDFS - failure when dispensing sample\^CLT – Clot detected
	C - 5 Comment type	Always set to ‘I’
	L – 1 Record Identifier	Always set to ‘L’
	L - 2 Sequence Number	Sequence number of ‘L’ records
	L – 3 Termination Code	’N’ for Normal

4.8. Host Query – LIS requests results

Example:

```
H|\^&|||LISHost|||||Panther||P|1
Q|1|^SAMPLE01||ALL||||||||F|
L|1|N
```

Panther System Data	ASTM Mapping	Examples
LIS Configuration – Delimiter Options	H – 2 Delimiters	|\^&
LIS Configuration – Instrument ID	H – 5 Sender Name or ID	LISHost
LIS Configuration – Host ID	H – 10 Receiver ID	Panther
	H – 12 Processing ID	Always set to 'P'
	H – 13 Version ID	Always set to '1'
	Q – 2 Sequence Number	Sequence number of 'Q' records
SampleID	Q – 3.2 Specimen ID	SAMPLE01, Set to 'ALL' for send all testorders available.
	Q – 5 Universal Test ID	Always set to 'ALL'
	Q – 13 Request Information status codes.	F = Final result
	L – 1 Record Identifier	Always set to 'L'
	L - 2 Sequence Number	Sequence number of 'L' records
	L – 3 Termination Code	"N" for Normal

4.9. File Transfer Option

When the file transfer option is chosen in the LIS configuration screen the system will export results in a text file following ASTM 1394 format. The text file will be sent to a network drive that the Panther has been configured to connect to. The configuration of the network drive can only be completed by a Hologic Field Service Engineer. Below is an example of the contents of the text file that will be exported.

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|925f7749-d99d-4ae5-b093-0757230617f1^17355
|^^^dHCV^HCV^^1||20110126073327||||||||||||||||||||F
R|1|^^^dHCV^ICRLU^^1|209058|||||F\R||||20110126113924
R|2|^^^dHCV^ICInterpretation^^1|Valid|||||F\R||||20110126113924
R|3|^^^dHCV^AnalyteRLU^^1|4272|||||F\R||||20110126113924
R|4|^^^dHCV^AnalyteSCO^^1|0.09|||||F\R||||20110126113924
R|5|^^^dHCV^OverallInterpretation^^1|Nonreactive|||||F\R||||20110126113924
P|2|PatID02|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE02|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^CT/GC^GC^^1||20100506123145||||||||||||||||||F\Q
R|1|^^^CT/GC^TotalRLU^^1|2099|||||F\Q\R||||20100506123145
R|2|^^^CT/GC^CTResult^^1|No Test|||||F\Q\R||||20100506123145
R|3|^^^CT/GC^GCResult^^1|GC POS|||||F\Q\R||||20100506123145
P|3|PatID03|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE03|925f7749-d99d-4ae5-b093-0757230617f1^17355
|^^^HPV^HPV^^1||20110126073327||||||||||||||||||||F
R|1|^^^HPV^ICRLU^^1|386282|||||F||||20110126113924
R|2|^^^HPV^ICInterpretation^^1|Valid|||||F||||20110126113924
R|3|^^^HPV^AnalyteRLU^^1|1160565|||||F||||20110126113924
R|4|^^^HPV^AnalyteSCO^^1|8.65|||||F||||20110126113924
R|5|^^^HPV^OverallInterpretation^^1|POSITIVE|||||F||||20110126113924
R|6|^^^HPV^Analyte Cutoff^^1||||||F||||20110126113924
R|7|^^^HPV^IC Cutoff^^1||||||F||||20110126113924
L|1|N
```

4.10. Calibrator and Control Mapping Information

This information is to be used by the LIS to identify which type of control/calibrator result is returned when the information is selected to be sent by the Panther system.

4.10.1. Panther Assay

Barcode Information	Number of Digits	Examples
Assay Type	2 Digits	01 (APTIMA Combo 2)
Control/Cal Designator	2 Digits	11 (CT Positive Control)
Lot Number	6 Digits	613080
Expiration Date	6 Digits	150714 (DDMMYY)
Unique Serial Number	5 Digits	30861

Barcode Example: APTIMA Combo 2 CT Positive Control
Assay Type: 01
Control/Cal Designator: 11
Lot Number: 613080
Expiration Date: 150714
Unique Serial Number: 30861
Complete barcode: **011161308015071430861**

Assay Type + Control/Cal Designator	
0111	CT Positive Control
0112	GC Positive Control
1011	TRICH Positive Control
1014	TRICH Negative Control
1424	HPV Positive Calibrator
1425	HPV Negative Calibrator
2025	GT HPV Negative Calibrator
2024	GT HPV Positive Calibrator 1
2023	GT HPV Positive Calibrator 2
5225	Aptima ZIKV Negative Calibrator
5227	Aptima ZIKV Positive Calibrator
2824	qHIV-1 Positive Calibrator
2814	qHIV-1 Negative Control
2811	qHIV-1 Low Positive Control
2812	qHIV-1 High Positive Control
3424	qHBV Positive Calibrator
3414	qHBV Negative Control
3411	qHBV Low Positive Control
3412	qHBV High Positive Control
3224	qHCV Positive Calibrator
3214	qHCV Negative Control

3211	qHCV Low Positive Control
3212	qHCV High Positive Control
4010	HSV 1&2 Negative Control
4011	HSV 1&2 Positive Control
4325	Mgen Negative Calibrator
4324	Mgen Positive Calibrator
4611	BV Positive Control
4612	BV Negative Control
4624	BV Positive Calibrator
4811	CV Positive Control
4812	CV Negative Control
4824	CV Positive Calibrator
5511	qCMV Low Positive Control
5512	qCMV High Positive Control
5514	qCMV Negative Control
5524	qCMV Positive Calibrator
5725	Ultrioplex E Negative Calibrator
5723	HCV Calibrator
5724	HIV Calibrator
5726	HBV Calibrator
5727	HEV Calibrator
6225	SARS-CoV-2 Negative Calibrator
6227	SARS-CoV-2 Calibrator
6312	SARSCoV2 (Aptima) Positive Control
6311	SARSCoV2 (Aptima) Negative Control
5025	Babesia Negative Calibrator
5027	Babesia Calibrator
3625	DENV Negative Calibrator
3627	DENV Calibrator
3925	HEV Negative Calibrator
3927	HEV Calibrator
5125	ZIKV Negative Calibrator
5127	ZIKV Calibrator
0425	WNV Negative Calibrator
0427	WNV Calibrator
2925	Parvo Negative Calibrator 1
2924	HAV Calibrator 2
2931	Parvo Calibrator 3
2932	Parvo Calibrator 4
2933	Parvo Calibrator 5
2934	Parvo Calibrator 6
2914	Parvo Negative Control
2912	Parvo Positive Control

2911	HAV Positive Control

4.10.2. Fusion Assay

Barcode Information	Number of Digits	Examples
Assay Type	3 Digits	101 (Flu A/B/RSV)
Control/Cal Designator	2 Digits	10 (Flu A/B/RSV Positive Control)
Lot Number	6 Digits	778123
Expiration Date	6 Digits	221017 (DDMMYY)
Unique Serial Number	5 Digits	52368

Barcode Example: Flu A/B/RSV Positive Control
Assay Type: 101
Control/Cal Designator: 10
Lot Number: 778123
Expiration Date: 221017
Unique Serial Number: 52368
Complete barcode: **10110778123221017 52368**

Assay Type + Control/Cal Designator	
10111	All respiratory assay negative controls (Flu A/B/RSV, AdV/hMPV/RV, and Paraflu)
10110	Flu A/B/RSV Positive Control
10210	AdV/hMPV/RV Positive Control
10310	Paraflu Positive Control
10610	GBS Positive Control
10611	GBS Negative Control
10710	MRSA Positive Control
10711	MRSA Negative Control II
10510	Bordetella Positive Control
10511	Bordetella Negative Control

4.10.3. LDT Controls

With the myAccess tool, custom assays can be built for the Panther system. When a sample is loaded with the intentional use as a control for one of these assays, the system will autogenerate a barcode to be used to track the LDT control. The barcode scheme is as follows:

Barcode Information	Number of Digits	Examples
Default string	4 Characters	Ctrl
Control Designator	2 Digits	11
Loading Date	6 Digits	062519
Control Number	4 Digits	0001

Barcode Example: Ctrl-11-062519-0001
Default string: Ctrl
Control Designator: 11
Loading Date: 062519
Control Number: 0001

The Control Designator is defined within the myAccess software and defines the type of control. The Control Number starts at one for the first LDT control loaded that day and increments up by one with each successive control, regardless of type or assay. The Assay Type can be gathered from either field O5.4 or R3.4. Each field is separated with a hyphen.

Each Panther instrument uses the same auto-generation scheme to track the control barcodes and therefore it is possible to receive the same barcode from multiple instruments but, for different assays. In order to uniquely identify the control to the worklist, the worklist ID in field O4.3 can be used to uniquely identify the control.

4.11. HPV-GT, CT and GC Reflexing

With system software version 5.2 and higher, the Panther system now incorporates an automatic reflexing procedure. Upon receiving a positive HPV result or a positive COMBO 2 result, the Panther system can be configured to automatically create an HPV-GT test order, CT test order, or a GC test order. It is important that the LIS vendor is aware that an unsolicited result will be sent back to the LIS system. The result will contain the same information received with the HPV test order or the COMBO 2 test order.

(LIS to Panther System)

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^HPV^HPV^1^1|R|20110125023649|||||||||Serum||||||||||O|
L|1|N
```

(Panther System to LIS)

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|925f7749-d99d-4ae5-b093-0757230617f1^17355
|^^^HPV^HPV^^1||20110126073327||||||||||||||||||F
R|1|^^^HPV^ICRLU^^1|386282|||||F||||20110126113924
R|2|^^^HPV^ICInterpretation^^1|Valid|||||F||||20110126113924
R|3|^^^HPV^AnalyteRLU^^1|1160565|||||F||||20110126113924
R|4|^^^HPV^AnalyteSCO^^1|8.65|||||F||||20110126113924
R|5|^^^HPV^OverallInterpretation^^1|POSITIVE|||||F||||20110126113924
R|6|^^^HPV^Analyte Cutoff^^1||||||F||||20110126113924
R|7|^^^HPV^IC Cutoff^^1||||||F||||20110126113924
L|1|N
```

(Panther System to LIS, Unsolicited HPV-GT Result)

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|f72423fb-857d-4a97-9247-a26803c45070^19271
|^^^GT HPV^HPV 16 18/45^^1||20130517204617||||||||||||||||||F
R|1|^^^GT HPV^IC/HPV 16 RLU^^1|2319091|||||F\R||||20130518001747
R|2|^^^GT HPV^HPV 16 S/CO^^1|3.67|||||F\R||||20130518001747
R|3|^^^GT HPV^HPV 16 Result^^1|POSITIVE|||||F\R||||20130518001747
R|4|^^^GT HPV^HPV 18/45 RLU^^1|0|||||F\R||||20130518001747
R|5|^^^GT HPV^HPV 18/45 S/CO^^1|0.00|||||F\R||||20130518001747
R|6|^^^GT HPV^HPV 18/45 Result^^1|Negative|||||F\R||||20130518001747
R|7|^^^GT HPV^ICInterpretation^^1|Valid|||||F\R||||20130518001747
R|8|^^^GT HPV^HPV 16 Cutoff^^1||||||F\R||||20130518001747
R|9|^^^GT HPV^HPV 18/45 Cutoff^^1||||||F\R||||20130518001747
R|10|^^^GT HPV^IC Cutoff^^1||||||F\R||||20130518001747
L|1|N
```

(Panther System to LIS, Unsolicited Aptima Combo 2® Result)

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^CT/GC^GC CT^^1||20100506123145||||||||||||||||||F\Q
R|1|^^^CT/GC^TotalRLU^^1|148|||||F\Q\R||||20100506123145
R|2|^^^CT/GC^CTResult^^1|CT neg|||||F\Q\R||||20100506123145
R|3|^^^CT/GC^GCResult^^1|GC EQUIV|||||F\Q\R||||20100506123145
L|1|N
```

4.12. Site Information Manufacturer Record

The **Site Information Manufacturer Record** is used to transmit site details stored within the Panther system. When the Panther system is configured to send this record, it will appear immediately following the **Message Header Record**. The record will only be sent when the Panther system is transmitting results and will not be sent when the Panther system is performing a query for test orders. Line's 1 – 7 are taken directly for the Report Configuration section located with the Admin Configuration page.

```
H|\^&|||Panther|||||LISHost|||1|19941115121212
M|1|5.3.2.9|6.0.0.1|John Smith^Hologic Inc.^SW Department^Building 2^10210 Genetic
  Center Dr.^San Diego, CA^92121
```

#	Description	Delimiter	Example	Length	Received by Panther System	Sent from Panther System
1	Record Identifier		M	1	Ignored	Required
2	Sequence Number	|	1	Sent 1-5 Received 1 - N	Ignored	Required
3	System Software Version	|	5.3.2.9	11	Ignored	Required
4	Firmware Version	|	6.0.0.1	11	Ignored	Required
5.1	Site Information: Line 1	|	John Smith	70	Ignored	Required
5.2	Line 2	^	Hologic Inc.	70	Ignored	Required
5.3	Line 3	^	SW Department	70	Ignored	Required
5.4	Line 4	^	Building 2	70	Ignored	Required
5.5	Line 5	^	10210 Genetic Center Dr.	70	Ignored	Required
5.6	Line 6	^	San Diego, CA	70	Ignored	Required
5.7	Line 7	^	92121	70	Ignored	Required
6	End of Record	<CR>	<CR>	1	Ignored	Required

4.13. Procleix Run Data Manufacturer Record

The **Procleix Run Data Manufacturer Record** is used to transmit run specific details to the LIS. The fields are mapped generically between all assays with exceptions noted. All data contained within the record will be localized to the configured Culture of the Panther system. The record will follow the Order record.

```
H|\^&|||Panther|||||LISHost|||1|19941115121212
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^Parvo/HAV^Parvo Parvo/HAV^^1|R|20100506123145||||||||||||||||||F
M|1|45316.667^358857.000^1688731.333^6165206.333^1584.667^3939.333|113202.000^82081
.333^56221.333^0.000^3155736.333^120187.333|0^0^104.642506533195^98.5671926511015^8
7.6482741453833^108.145588770874|1000^48074^1.16319513576374^1017599
R|1|^^^Parvo/HAV^ICInterpretation^^1|Valid|||||F||||20100506123145
R|2|^^^Parvo/HAV^AnalyteSCO^^1|0.14|||||F||||20100506123145
R|3|^^^Parvo/HAV^HAVInterpretation^^1|Nonreactive|||||F||||20100506123145
R|4|^^^Parvo/HAV^Parvo^^1|<500|||||F||||20100506123145
R|5|^^^Parvo/HAV^OverallInterpretation^^1|Valid|||||F||||20100506123145
R|6|^^^Parvo/HAV^ParvoNumeric^^1|100000|||||F||||20100506123145
R|7|^^^Parvo/HAV^AdjustedFlasherRLU^^1|10|||||F||||20100506123145
R|8|^^^Parvo/HAV^AdjustedGlowerRLU^^1|100000|||||F||||20100506123145
L|1|N
```

#	Description	Delimiter	Example	Length	Received by Panther System	Sent from Panther System
1	Record Identifier		M	1	Ignored	Required
2	Sequence Number	|	1	Sent 1-5 Received 1 - N	Ignored	Required
3.1	Positive Calibrator 1 Analyte Average	|	45316.667	2020	Ignored	Required
3.2	Positive Calibrator 2 Analyte Average	^	358857.000	20	Ignored	Required
3.3	Positive Calibrator 3 Analyte Average	^	1688731.333	20	Ignored	Required
3.4	Parvo Positive Calibrator 4 Analyte Average (Blank if non-Parvo)	^	6165206.333	20	Ignored	Required
3.5	HAV Positive Calibrator Analyte Average (Blank if non-Parvo)	^	1584.667	20	Ignored	Required
3.6	Negative Calibrator Analyte Average	^	3939.333	20	Ignored	Required
4.1	Positive Calibrator 1 IC Average	|	113202.000	20	Ignored	Required
4.2	Positive Calibrator 2 IC Average	^	82081.333	20	Ignored	Required
4.3	Positive Calibrator 3 IC Average	^	56221.333	20	Ignored	Required

#	Description	Delimiter	Example	Length	Received by Panther System	Sent from Panther System
4.4	Parvo Positive Calibrator 4 IC Average (Blank if non-Parvo)	^	0.000	20	Ignored	Required
4.5	HAV Positive Calibrator IC Average (Blank if non-Parvo)	^	3155736.333	20	Ignored	Required
4.6	Negative Calibrator IC Average	^	120187.333	20	Ignored	Required
5.1	Parvo Positive Control 1 % Recovery (Blank if non-Parvo)	|	0	20	Ignored	Required
5.2	Parvo Positive Control 2 % Recovery (Blank if non-Parvo)	^	0	20	Ignored	Required
5.3	Parvo Positive Calibrator 1 % Recovery (Blank if non-Parvo)	^	104.642506533195	20	Ignored	Required
5.4	Parvo Positive Calibrator 2 % Recovery (Blank if non-Parvo)	^	98.5671926511015	20	Ignored	Required
5.5	Parvo Positive Calibrator 3 % Recovery (Blank if non-Parvo)	^	87.6482741453833	20	Ignored	Required
5.6	Parvo Positive Calibrator 4 % Recovery (Blank if non-Parvo)	^	108.145588770874	20	Ignored	Required
6.1	Analyte Cutoff (Parvo Cutoff for Parvo)	|	1000	20	Ignored	Required
6.2	IC Cutoff	^	48074	20	Ignored	Required
6.3	Kinetic Index	^	1.16319513576374	20	Ignored	Required
6.4	HAV Cutoff (Blank if non-Parvo)	^	1017599	20	Ignored	Required
7	End of Record	<CR>	<CR>	1	Ignored	Required

4.14. Cancellation of Test Orders

The Panther system can receive test order cancellation requests from the LIS and process these assuming the test order is not currently in process. A test order is considered in process if it has been pipetted by the system or it is in the current set of specimens to be pipetted by the instrument. In the case the Panther system cannot process the cancellation request it will notify the LIS as shown in the example below.

(LIS to Panther System) LIS sends cancellation request

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^CT/GC^^1^1|||||||C
L|1|N
```

(Panther System to LIS) Panther System rejects cancellation request

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther||||| LISHost||P|1|
P|1||PatID01||Meier^Anna|||Other||||||||^|^|||||||||||||||^|^|
O|1|SAMPLE01|^|^^^CT/GC^^^1||||||||||||||||||||X
R|1|^^^CT/GC^^^||||||X
C|1|I|RJ_cannotCancel^|I
L|1|N
```

4.15. Notification of Test Order State

The Panther allows for notification of test order states to the LIS system. This includes test orders which were not processed by the system as well as a notification when the test order begins processing on the system.

(Panther System to LIS) Panther System notifies LIS of test order processed

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result
C – Result Comment if any
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01|^|^^^CT/GC^^^1||||||||||||||||||||I
R|1|^^^CT/GC^^^||||||I
C|1|I|RJ_processingOrder^|I
L|1|N
```

(Panther System to LIS) Panther System notifies LIS of test order not processed

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result
C – Result Comment if any
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01|^|^^^CT/GC^^^1||||||||||||||||||||X
R|1|^^^CT/GC^^^||||||X
C|1|I|RJ_notProcessed^|I
L|1|N
```

5. CLSI (ASTM) PROTOCOL

5.1. ASTM Records

Level	Segment Name	Identifier (Record TypeID)	Comments
0	Message Header Record	'H'	
1	Patient Information Record	'P'	
1	Request Information Segment	'Q'	Panther System Host Query
1	Scientific Record	'S'	not allowed for Panther System
2	Test Order Record	'O'	
3	Result Record	'R'	
common	Comment Record	'C'	Same as level 1-4
4	Manufacturer Information Record	'M'	Panther System does not use this record.
0	Message Terminator Record	'L'	

A record is identified by the first field of a record, the RecordTypeID.

Most of the various record types are related to each other in a definite hierarchy:

A lower level record may never appear without the preceding higher level record.
(Order records must be preceded by a patient record, result records must be preceded by an order record.)

A sequence of records at one level is terminated by the appearance of a record of the same or higher level.

5.1.1. Message Header Record

The **Header record** is always the first record in an application message. It contains general sender and receiver information. Its hierarchical level is 0.

```
H|\^&|||Panther|||||LISHost|||1|19941115121212
H|\^&|||LISHost|||||Panther||P|1
```

#	Description	Delimiter	Example	Length	Received by Panther System	Sent from Panther System
1	Record Identifier		H	1	Required	Required
2	Delimiters:		Defined in LIS Setup		Required	Required
	Field	|		1		
	Repeat	\		1		
	Component	^		1		
	Escape	&		1		
3	Message Control ID	|			Ignored	No
4	Password	|			Ignored	No
5	Sender Name or ID	|	Panther or LISHost	1 - 10	Ignored	Yes, Defined in LIS Setup
6	Sender Street Address	|			Ignored	No
7	Reserved field	|			Ignored	No
8	Sender Telephone Number	|			Ignored	No
9	Characteristics of sender	|			Ignored	No
10	Receiver ID	|	Must match LIS setup	1 - 10	Yes	Yes, Defined in LIS Setup
11	Comments	|			Ignored	No
12	Processing ID	|	P	1	Ignored	Yes
13	Version Number	|	'1'	12	Ignored	Yes
14	Date and Time of Message	|		14	Ignored	No
15	End of Record	<CR>	<CR>	1	Required	Required

5.1.2. Patient Record

The patient record is used to supply patient demographic information for order and result records that follow it. Its hierarchical level is 1.

```
P|1|PatID01|||Meier^Anna||19741001|F|||||MARTINEZ
```

The patient data is sent in separate patient record fields. The Panther system stores the fields as encrypted values in the Panther System database. When patient information is sent back as part of the result record, the values are put back into the corresponding patient record fields.

For customers requiring the procedure reference ID: A procedure reference ID can be placed in any unused field of the patient record. The reference will be stored and sent from the Panther system with the result. However, it is important to note that each patient record received will overwrite a previously received patient record for a specific sampleID as the Panther system only keeps one patient record per sampleID.

#	Description	Delimiter	Example	Length	Received by Panther System	Sent From Panther System
1	Record Identifier		P	1	Required	Required
2	Sequence Number	|		Sent 1-5 Received 1 - N	Required	Required
3	Practice Assigned Patient ID	|	Patient Information sent as block Fields 3 - 36		Stored	Yes
4	Patient ID	|			Stored	Yes
5	Patient ID #3	|			Stored	Yes
6	Patient Name	|			Stored	Yes
	Last Name	^			Stored	Yes
	First Name	^			Stored	Yes
	Middle Initial	^			Stored	Yes
7	Mother's Maiden Name	|			Stored	Yes
8	Birth date	|			Stored	Yes
9	Sex	|			Stored	Yes
10	Patient Race	|			Stored	Yes
11	Patient Address	|			Stored	Yes
12	Reserved Field	|			Stored	Yes
13	Patient Telephone	|			Stored	Yes

#	Description	Delimiter	Example	Length	Received by Panther System	Sent From Panther System
14	Attending Physician Name	I			Stored	Yes
15	Special field 1	|			Stored	Yes
16	Body Surface Area (M2)	|			Stored	Yes
17	Patient Height	|			Stored	Yes
	Patient Height Unit	^			Stored	Yes
18	Patient Weight	|			Stored	Yes
	Patient Weight Unit	^			Stored	Yes
19	Patient Diagnosis	|			Stored	Yes
20	Patient Medications	|			Stored	Yes
21	Patient Diet	|			Stored	Yes
22	Practice Field #1	|			Stored	Yes
23	Practice Field #2	|			Stored	Yes
24	Admission and discharge dates	|			Stored	Yes
25	Admission Status	|			Stored	Yes
26	Location	|			Stored	Yes
27	Nature of alt. Diag. Code and Class.	|			Stored	Yes
28	Alt. Diag. Code and Class	|			Stored	Yes
29	Patient Religion	|			Stored	Yes
30	Marital Status	|			Stored	Yes
31	Isolation Status	|			Stored	Yes
32	Language	|			Stored	Yes
33	Hospital Service Code	|			Stored	Yes
	Hospital Service name	^			Stored	Yes
34	Hospital Institution Code	|			Stored	Yes
	Hospital Institution Name	^			Stored	Yes
35	Dosage Category	|			Stored	Yes
36	End of Record	<CR>	<CR>	1	Required	Required

5.1.3. Test Order Record

The test order record is used to supply information on a specific sample's test requests.

This information is necessary either for ordering tests on a specific sample or for reporting results for tests on a specific sample. A test order record is associated with the previous patient record. Its hierarchical level is 2.

Incoming to Panther – downloaded test order

```
O|1|SAMPLE01||^^^CT/GC^CT/GC^^1||19980506121212|||||||||Serum|||||||||O
```

Outgoing from Panther – part of results

```
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234|^^^CT/GC^GC CT^^1
||20100506123455|||||||||S|||||||||F
```

#	Description	Delimiter	Example	Length	Received by Panther System	Sent from Panther System
1	Record Identifier		O	1	Required	Required
2	Sequence Number	|		Sent 1-5 Received 1 - N	Required	Required
3	Specimen ID/ Control ID	|	SAMPLE01	3-20	Required	Required
4	Instrument Specimen ID (Test Order GUID)^ (Test Order ID) ^ (Worklist ID) **The Worklist ID will only be sent if the system is configured to do so.**	|	**Send:** C35B802B-B4F9-400A- 9409-1FAB9D736C8D ^1234^000937-20120829-02		Ignored	Yes
5	Universal Test ID: Identifier	|			Ignored	No
	Name	^			Ignored	No
	Type	^			Ignored	No
	Test ID or Name (Manufacturers Code)	^	CT/GC .		Yes	Required
	AnalyteName	^	Receive – CT/GC Send – GC CT If empty, all or valid Analyte(s) are Ordered		Yes	Yes
	Number of Replicates	^	(Empty implies 1 replicate) (Future use)	2	Yes	Yes
	Dilution Factor	^	1 (Empty implies dilution factor of 1)	5	Yes	Yes

#	Description	Delimiter	Example	Length	Received by Panther System	Sent from Panther System
6	Priority	|	S = Stat R = Routine	1	Yes	Yes
7	Requested Date and Time (Sample program creation date)	|	Panther creates test order with date and time test order received from LIS 20100506123455	14	Yes	Yes
8	Specimen Collection Date and Time	|			Ignored	No
9	Specimen Collection end Date and Time (used for timed urine samples)	|			Ignored	No
10	Collection Volume	|			Ignored	No
11	Collected by (ID or Name)	|			Ignored	No
12	Action Code	|	**For Send:** Q =Control Sample **For Receive:** C = Cancel Request A, N or any other = Panther creates new sample	1	Yes	Yes
13	Danger Code	|			Ignored	No
14	Amp Reagent Barcode **Will only be sent if the system is configured to do so.**	|	011644114431122500350	30	Ignored	No
	Probe Reagent Barcode **Will only be sent if the system is configured to do so.**	^	011844114431122500250	30	Ignored	Yes
15	Date/Time Specimen Received in the Lab.	|			Ignored	No
16	Specimen type **Will only be sent if the system is configured to do so. Field can be ignored by receiving system.**	|	Specimen, Calibrator, Control, ExternalQualityControl	22	Ignored	Yes
	Specimen source	^	…		Ignored	No
17	Ordering Physician	|			Ignored	No
18	Physician Phone number	|			Ignored	No
19	User Field #1	|		30	Yes	Yes

#	Description	Delimiter	Example	Length	Received by Panther System	Sent from Panther System
20	User Field #2	|		30	Yes	Yes
21	Laboratory field #1	|		30	Yes	Yes
22	Laboratory field #2	|		30	Yes	Yes
23	Date/Time Results Reported/Mod.	|			Ignored	No
24	Instrument Charge to computer system	|			Ignored	No
25	Instrument Section ID	|			Ignored	No
26	Report Type	|	**For Send:** X = Cannot Be Done F = Final Results Q = Response to a query I = Instrument Pending **For Receive:** O = for Orders Which are Not Cancelled Y, Z = no order (response to host query) Multiple values separated by a '\' are possible.	1 - N	Yes	Required
27	Master Lot Barcode **Will only be sent if the system is configured to do so.**	|	46000001311225600	25	Ignored	Yes
	Master Lot Expiration **Will only be sent if the system is configured to do so.**	^	20251030235959	14	Ignored	Yes
28	Location Specimen Collected	|			Ignored	No
29	Nosocomial Infection flag	|			Ignored	No
30	Specimen Service	|			Ignored	No
31	Specimen Institution	|			Ignored	No
	End of Record	<CR>	<CR>	1	Required	Required

5.1.4. Sample Result Record

The result record supplies the final test result information for a single test of a specific sample. Results of multiple tests are specified in separate result records.

The Panther system ignores incoming result records from a remote system. The hierarchical level is 3. The result record is associated with the previous order record. The following table describes the allowable values for each field.

Examples:

Outgoing from Panther only:

```
R|1|^^^CT/GC^TotalRLU^^1|5|||||F||||20100506123145
R|2|^^^CT/GC^CTResult^^1|CT neg|||||F||||20100506123145
R|3|^^^CT/GC^GCResult^^1|GC neg|||||F||||20100506123145
```

Outgoing result from Panther, unable to process

```
R|1|^^^CT/GC^TotalRLU^^1||||||X||||20100506123145
R|2|^^^CT/GC^CTResult^^1||||||X||||20100506123145
R|3|^^^CT/GC^GCResult^^1||||||X||||20100506123145
```

#	Description	Delimiter	Example	Length	Received by Panther System	Sent from Panther System
1	Record Identifier		R	1	Ignored	Required
2	Sequence Number	|	1	Sent 1 - 5	Ignored	Required
3.1	Universal Test ID: Identifier	|			Ignored	No
3.2	Name	^			Ignored	No
3.3	Type	^			Ignored	No
3.4	Test ID or Name (UDR) or Manufacturers Code	^	CT/GC		Ignored	Yes
3.5	Result Aspect	^	CTResult		Ignored	Required
3.6	Replicate Number	^	(Empty implies replicate 1) (Future use) (Can be ignored by receiving system)	2	Ignored	Yes
3.7	Dilution Factor	^	1 (Empty implies dilution factor of 1)	3	Ignored	Yes
4	Data or Measurement Value	|	“CT neg”, GC neg, “No Test”		Ignored	Yes
	Interpretation	^			Ignored	No
5	Units	|	copies/mL	12	Ignored	Yes

#	Description	Delimiter	Example	Length	Received by Panther System	Sent from Panther System
6	Result Enumeration **Will only be sent if the system is configured to do so.**	|	1	3	Ignored	Yes
	Reference Type	^			Ignored	No
7	Result Abnormal flag	|	"<" = Below Absolute low ">" = Above Absolute high Empty means normal. For qHIV-1 Assay "<" means result is < 30 ">" means result is > 10,000,000 For qHBV Assay "<" means result is < 10 ">" means result is > 1,000,000,000 For qHCV Assay "<" means result is < 10 ">" means result is > 100,000,000	4	Ignored	Yes
8	Nature of Abnormality Testing	|			Ignored	No
9	Result Status	|	X = Cannot Be Done F = Final Results Q = Response to a query I = Instrument Pending R = Resend	1	Ignored	Required
10	Date of change	|			Ignored	No

#	Description	Delimiter	Example	Length	Received by Panther System	Sent from Panther System
11	Operator identification **Will only be sent if the system is configured to do so.**	|	admin	20	Ignored	Yes
12	Date/time test started	|			Ignored	No
13	Date/Time test Completed (UTC)	|	20100506123145	14	Ignored	Yes
14	ADM Software Version **Will only be sent if system is configured to do so**	|			Ignored	Yes
	Device ID	^			Ignored	No
End of Record	<CR>		<CR>	1	Ignored	Required

NOTE: If multiple results exist for the same Sample ID, Panther System may send multiple result records as part of a single order record.

LIS should use “Assay short name” and “result aspect” components in the result record field R3, to identify the result.

The Combination of R3.4 and R3.5 is always unique.

Example:

```
R|1|^^^CT/GC^CTResult^^1|CT neg|||||F||||20100506123145|
```

The result can be identified by using “CT/GC^CTResult”.
R3.6 identifies the replicate (Empty implies replicate 1)
R3.7 identifies the dilution factor. (Empty implies dilution factor of 1)

5.1.5. Comment Record

The result comment record is used to communicate assay processing and result flags. The record is optional, it is not sent when there are no flags for the preceding result.

The Panther System ignores result data from a remote system. The system ignores incoming result comment records.

Its hierarchical level is 4. **The result comment record always follows an outgoing result record**.

```
C|1|I|^RDFS - failure when dispensing sample\^CLT – Clot detected|I
```

#	Description	Delimiter	Example	Length	Received by Panther System	Sent from Panther System
1	Record Identifier		C	1	Ignored	Required
2	Sequence Number	|		1 - 5	Ignored	Required
3	Comment Source	|	Always I	1	Ignored	Yes
4	Error code	|			No	No
	Comment/Result Error Codes	^	Result flags map to The values defined Assay sequence Files. If Compress Comments have been configured during LIS Configuration, this field can contain repeat delimiters and multiple comments	160	Ignored	Yes
5	Comment Type	|	Always I	1	Ignored	Yes
6	<CR>	|		1	Ignored	Required

5.1.6. Host Query Record

The query record is used to request data from host systems. Its hierarchical level is 1. The Panther System processes only one received query at a time. If a second query is received while the first is processing, the system cancels the second query.

Panther requests two sample IDs from LIS

```
Q|1|^SAMPLE01||ALL||||||||O
Q|2|^SAMPLE02||ALL||||||||O
```

Panther requests all sample IDs not sent or LIS requests all results

```
Q|1|^ALL||ALL||||||||O
```

#	Description	Delimiter	Example	Length	Received by Panther System	Sent from Panther System
1	Record Identifier		Q	1	Required	Required
2	Sequence Number	|		Sent 1-5 Received 1 - N	Required	Required
3	Patient ID/Starting Range ID	|		21	No	No
	Specimen ID	^	Send -Set to ALL if Worklist query, SAMPLE01	21	Yes	Yes
4	Ending Range ID	|			Ignored	No
5	Universal Test ID	|	Send – set to 'ALL' Receive - Assay Short name.		No	Yes
6	Nature of Request Time Limits	|			No	No
7	Beginning Request results date/time.	|			No	No
8	Ending Request results date/time	|			No	No
9	Requesting Physician name	|			No	No
10	Requesting Physician Telephone	|			No	No
11	User field # 1	|			No	No
12	User field # 2	|			No	No
13	Request Information status Codes	|	O = Request Sample Information on send. X = Ignore query when received. F = final results	1	Yes	Yes
	End of Record	<CR>		1	Required	Required

5.1.7. Message Terminator Record

The terminator record is the last record of a message and closes the message. It provides an explanation for ending the message. Its hierarchical level is 0.

L | 1 | N

#	Description	Delimiter	Example	Length	Receive Panther System	Send Panther System
1	Record Identifier		Send = L Receive = L or I	1	Yes	Required
2	Sequence Number	|	Send = 1	Send 1 Received 1 - N	Yes	Required
3	Termination Code	|	N = Normal I = No Information for all queried samples	1	Yes	Yes
4	End of Record	<CR>	<CR>	1	Required	Required

5.2. Panther System LIS Message Structure

5.2.1. Test Order Inquiry (Host Query) Records

(Panther System to LIS) Send Test Orders (Manual request)
-Fetch from LIS button clicked

H – Header record
Q – Sample information
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1
Q|1|^ALL||ALL||||||||O
L|1|N
```

(Panther System to LIS) Send Test Orders for given sample (Automatic)
-Automatic Test Order Query Enabled

H – Header record
Q – Sample information (multiple records)
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1
Q|1|^SAMPLE01||ALL||||||||O
Q|2|^SAMPLE02||ALL||||||||O
Q|3|^BARCODE0815||ALL||||||||O
Q|4|^12345||ALL||||||||O
L|1|N
```

(Panther System to LIS) Send Test Orders for given sample (Automatic, compressed format)
-Automatic Test Order Query Enabled
-Test Order Query in Compressed Format Enabled

H – Header record
Q – Sample information (single record)
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1
Q|1|^SAMPLE01\^SAMPLE02\^BARCODE0815\^12345||ALL||||||||O
L|1|N
```

(Panther System to LIS) Panther System rejects downloaded Test Orders

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther||||| LISHost||P|1|
P|1||PatID01||Meier^Anna|||Other||||||||^|^|||||||||||||||^|^|
O|1|SAMPLE01|^|^^^CT/GC^^^1||||||||||||||||||||X
R|1|^^^CT/GC^^^||||||X
C|1|I|RJ_badSampleId^|I
L|1|N
```

5.2.2. LIS Download of Test Orders to Panther System

When Panther system requests multiple test orders for multiple samples IDs, it is recommended for the LIS system to send test orders in one message, including all the requested orders, maximum of 15. As opposed to sending 15 separate messages with a sample ID contained in each. As soon as one sample order is received by Panther system the next order request (query) is sent by Panther System, even if all the orders are not included the message. Sending all sample IDs in one message will allow the current query to complete before the next is sent out.

(LIS to Panther System) Response to query for 15 sample ID

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||^|||||||||
O|1|SAMPLE01||^^^dHIV^HIV^^1|R|20130131105109|||||||||Serum||||||||||O|
P|2|PatID02|||^|||||||||
O|1|SAMPLE02||^^^dHIV^HIV^^1|R|20130131105110|||||||||Serum||||||||||O|
P|3|PatID03|||^|||||||||
O|1|SAMPLE03||^^^dHIV^HIV^^1|R|20130131105111|||||||||Serum||||||||||O|
P|4|PatID04|||^|||||||||
O|1|SAMPLE04||^^^dHIV^HIV^^1|R|20130131105209|||||||||Serum||||||||||O|
P|5|PatID05|||^|||||||||
O|1|SAMPLE05||^^^dHIV^HIV^^1|R|20130131105309|||||||||Serum||||||||||O|
P|6|PatID06|||^|||||||||
O|1|SAMPLE06||^^^dHIV^HIV^^1|R|20130131105210|||||||||Serum||||||||||O|
P|7|PatID07|||^|||||||||
O|1|SAMPLE07||^^^dHIV^HIV^^1|R|20130131105310|||||||||Serum||||||||||O|
P|8|PatID08|||^|||||||||
O|1|SAMPLE08||^^^dHIV^HIV^^1|R|20130131105109|||||||||Serum||||||||||O|
P|9|PatID09|||^|||||||||
O|1|SAMPLE09||^^^dHIV^HIV^^1|R|20130131105510|||||||||Serum||||||||||O|
P|10|PatID10|||^|||||||||
O|1|SAMPLE10||^^^dHIV^HIV^^1|R|20130131105140|||||||||Serum||||||||||O|
P|11|PatID11|||^|||||||||
O|1|SAMPLE11||^^^dHIV^HIV^^1|R|20130131105145|||||||||Serum||||||||||O|
P|12|PatID12|||^|||F|||||
O|1|SAMPLE12||^^^dHIV^HIV^^1|R|20130131105134|||||||||Serum||||||||||O|
P|13|PatID13|||^|||||||||
O|1|SAMPLE13||^^^dHIV^HIV^^1|R|20130131105125|||||||||Serum||||||||||O|
P|14|PatID14|||^|||||||||
O|1|SAMPLE14||^^^dHIV^HIV^^1|R|20130131105116|||||||||Serum||||||||||O|
P|15|PatID15|||^|||||||||
O|1|SAMPLE15||^^^dHIV^HIV^^1|R|20130131105311|||||||||Serum||||||||||O|
L|1|N|
```

LIS response when test orders available

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

LIS response using multiple order records

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||19741001|F|||||MARTINEZ
O|1|SAMPLE01||^^^CT/GC^^^1|R|20130131105109|||||||||Serum||||||||||O|
O|2|SAMPLE01||^^^TRICH^TRICH^^1|R|20130131105109|||||||||Serum||||||||||O|
L|1|N|
```

LIS response using one order record for multiple assays (compressed)

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||19741001|F|||||MARTINEZ
O|1|SAMPLE01||^^^CT/GC^^^1\^^^TRICH^TRICH^1^1
|R|19980506121212|||||||||Serum||||||||||O|
L|1|N|
```

LIS response using one order record for multiple analytes.

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||19741001|F|||||MARTINEZ
O|1|SAMPLE01||^^^Paraflu^P1^1^1\^^^Paraflu^P2^1^1
|R|19980506121212|||||||||Serum||||||||||O|
L|1|N|
```

LIS response using multiple order records for multiple analytes.

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||19741001|F|||||MARTINEZ
O|1|SAMPLE01||^^^Paraflu^P1^^1|R|20130131105109|||||||||Serum||||||||||O|
O|2|SAMPLE01||^^^Paraflu^P2^^1|R|20130131105109|||||||||Serum||||||||||O|
L|1|N|
```

LIS response when no test orders available

H – Header record
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
L|1|I
```

No order available for specimen ID 99999:

```
H|\^&|||LISHost|||||Panther||P|1
P|1||||^^||^^||||||||||||||||
O|1|99999^|R|20100825083624||||||||Serum||||||||||Y|
L|1|N|
```

5.2.3. Test Result Export Records

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

Export of Results.

```
H|\^&|||Panther|||||LISHost||P|1|
P|1||||^^|||||||||||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^CT/GC^GC^^1||20120914185132||||||||||||||||||F\Q
R|1|^^^CT/GC^TotalRLU^^1|2099|||||F\Q\R||||20100506123145
R|2|^^^CT/GC^CTResult^^1|No Test|||||F\Q\R||||20100506123145
R|3|^^^CT/GC^GCResult^^1|GC POS|||||F\Q\R||||20100506123145
L|1|N
```

Export of Results, with Result comments indicating failure.

```
H|\^&|||Panther|||||LISHost||P|1|
P|1||||^^|||||||||||^|^|||||||||||||||^|^|
O|1|PatID01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^CT/GC^GC^^1||20120914185132||||||||||||||||||X\Q
R|1|^^^CT/GC^TotalRLU^^1|662|||||X\Q\R||||20120914223731
C|1|I|^NTI - Sample not tested due to a fatal hardware error.|I
C|2|I|^VVFS - LLS measurement of TCR/Sample in MTU tube falls
      outside the expected volume|I
C|3|I|^RDFS - Sample dispense verification failed.|I
C|4|I|^p - Assay Processing Error.|I
R|2|^^^CT/GC^CTResult^^1|No Test|||||X\Q\R||||20100506123145
C|1|I|^NTI - Sample not tested due to a fatal hardware error.|I
C|2|I|^VVFS - LLS measurement of TCR/Sample in MTU tube falls
      outside the expected volume|I
C|3|I|^RDFS - Sample dispense verification failed.|I
C|4|I|^p - Assay Processing Error.|I
R|3|^^^CT/GC^GCResult^^1|Invalid|||||X\Q\R||||20100506123145
C|1|I|^NTI - Sample not tested due to a fatal hardware error.|I
C|2|I|^VVFS - LLS measurement of TCR/Sample in MTU tube falls
      outside the expected volume|I
C|3|I|^RDFS - Sample dispense verification failed.|
C|4|I|^p - Assay Processing Error.|
L|1|N
```

Export of Results, with Result comments indicating failure. Compressed Comments.

```
H|\^&|||Panther|||||LISHost||P|1|
P|1||||^^|||||||||||^|^|||||||||||||||^|^|
O|1|PatID01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^CT/GC^GC^^1||20120914185132|||||||||||||||||||X\Q
R|1|^^^CT/GC^TotalRLU^^1|662|||||X\Q\R||||20120914223731
C|1|I|^NTI - Sample not tested due to a fatal hardware error.\^VVFS - LLS
measurement of TCR/Sample in MTU tube falls outside the expected volume.\^RDFS -
Sample dispense verification failed.\^p - Assay Processing Error.|I
R|2|^^^CT/GC^CTResult^^1|No Test|||||X\Q\R||||20100506123145
C|1|I|^NTI - Sample not tested due to a fatal hardware error.\^VVFS - LLS
measurement of TCR/Sample in MTU tube falls outside the expected volume.\^RDFS -
Sample dispense verification failed.\^p - Assay Processing Error.|I
R|3|^^^CT/GC^GCResult^^1|Invalid|||||X\Q\R||||20100506123145
C|1|I|^NTI - Sample not tested due to a fatal hardware error.\^VVFS - LLS
measurement of TCR/Sample in MTU tube falls outside the expected volume.\^RDFS -
Sample dispense verification failed.^p - Assay Processing Error.|I
L|1|N
```

5.2.4. LIS Query of Panther System for Results

(LIS to Panther System)
-Host Query Responding enabled

H – Header record
Q – Query Record
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
Q|1|^ALL||ALL||||||||O
L|1|N
```

5.2.5. LIS requests Aptima Combo 2® Assay with all analytes.

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

(Because Analyte is empty (Order field 5.5), all analytes are requested.)

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^CT/GC^^1^1|R|19980506090909|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

(Panther System returns a result for each analyte.)

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^CT/GC^GC CT^^1||20100506123145||||||||||||||||||F\Q
R|1|^^^CT/GC^TotalRLU^^1|148|||||F\Q\R||||20100506123145
R|2|^^^CT/GC^CTResult^^1|CT neg|||||F\Q\R||||20100506123145
R|3|^^^CT/GC^GCResult^^1|GC EQUIV|||||F\Q\R||||20100506123145
L|1|N
```

5.2.6. LIS requests Aptima Combo 2® Assay with one analyte.

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

(One Analyte - GC is requested)

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^CT/GC^GC^^1|R|19980506090909|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

(Panther System returns a result for GC analyte.)

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^CT/GC^GC^^1||20100506123145||||||||||||||||||F\Q
R|1|^^^CT/GC^TotalRLU^^1|2099|||||F\Q\R||||20100506123145
R|2|^^^CT/GC^CTResult^^1|No Test|||||F\Q\R||||20100506123145
R|3|^^^CT/GC^GCResult^^1|GC POS|||||F\Q\R||||20100506123145
L|1|N
```

5.2.7. LIS requests APTIMA® CT Assay

(APTIMA® CT Assay available to Ex-US Only)

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^CT|R|19980506090909|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^CT^CT^^1||20120725232907||||||||||||||||||F
R|1|^^^CT^TotalRLU^^1|5983|||||F||||20100506123145
R|2|^^^CT^CTResult^^1|CT POS|||||F||||20100506123145
L|1|N
```

5.2.8. LIS requests APTIMA® GC Assay

(APTIMA® GC Assay available to ex-US only)

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^GC^^1|R|19980506090909|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01| C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^GC^GC^^1||20100506123145||||||||||||||||||F
R|1|^^^GC^TotalRLU^^1|1|||||F||||20100506123145
R|2|^^^GC^GCResult^^1|GC neg|||||F||||20100506123145
L|1|N
```

5.2.9. LIS requests APTIMA® TV Assay

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^TRICH^^^1|R|19980506090909|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01| C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^TRICH^TRICH^^1||20100506123145||||||||||||||||||F
R|1|^^^TRICH^Total RLU^^1|1|||||F\R||||20100506123145
R|2|^^^TRICH^TRICH Result^^1|TRICH neg|||||F\R||||20100506123145
L|1|N
```

5.2.10. LIS requests APTIMA® HPV Assay

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^HPV^HPV^1^1|R|20110125023649|||||||||Serum||||||||||O|
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result records
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|925f7749-d99d-4ae5-b093-0757230617f1^17355
|^^^HPV^HPV^^1||20110126073327||||||||||||||||||F
R|1|^^^HPV^ICRLU^^1|386282|||||F||||20110126113924
R|2|^^^HPV^ICInterpretation^^1|Valid|||||F||||20110126113924
R|3|^^^HPV^AnalyteRLU^^1|1160565|||||F||||20110126113924
R|4|^^^HPV^AnalyteSCO^^1|8.65|||||F||||20110126113924
R|5|^^^HPV^OverallInterpretation^^1|POSITIVE|||||F||||20110126113924
R|6|^^^HPV^AnalyteCutoff^^1||||||F||||20110126113924
R|7|^^^HPV^IC Cutoff^^1||||||F||||20110126113924
L|1|N
```

5.2.11. LIS requests Ultrio Elite Assay

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^Ultrio Elite^HIV/HCV/HBV^^1
|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|925f7749-d99d-4ae5-b093-0757230617f1^17355
|^^^Ultrio Elite^HIV/HCV/HBV^^1||20110126073327||||||||||||||||||F
R|1|^^^Ultrio Elite^ICRLU^^1|300350|||||F\R||||20110126113924
R|2|^^^Ultrio Elite^ICInterpretation^^1|Valid|||||F\R||||20110126113924
R|3|^^^Ultrio Elite^AnalyteRLU^^1|1095643|||||F\R||||20110126113924
R|4|^^^Ultrio Elite^AnalyteSCO^^1|12.54|||||F\R||||20110126113924
R|5|^^^Ultrio Elite^OverallInterpretation^^1|Reactive|||||F\R||||20110126113924
L|1|N
```

5.2.12. LIS requests dHBV Assay

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^dHBV^HBV^^1|R|20110125023649|||||N||||Serum|||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|925f7749-d99d-4ae5-b093-0757230617f1^17355
|^^^dHBV^HBV^^1||20110126073327||||||||||||||||||F
R|1|^^^dHBV^ICRLU^^1|209255|||||F\R||||20110126113924
R|2|^^^dHBV^ICInterpretation^^1|Valid|||||F\R||||20110126113924
R|3|^^^dHBV^AnalyteRLU^^1|4075|||||F\R||||20110126113924
R|4|^^^dHBV^AnalyteSCO^^1|0.06|||||F\R||||20110126113924
R|5|^^^dHBV^OverallInterpretation^^1|Nonreactive|||||F\R||||20110126113924
L|1|N
```

5.2.13. LIS requests dHCV Assay

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^dHCV^HCV^^1|R|20110125023649|||||N||||Serum|||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|925f7749-d99d-4ae5-b093-0757230617f1^17355
|^^^dHCV^HCV^^1||20110126073327||||||||||||||||||F
R|1|^^^dHCV^ICRLU^^1|209058|||||F\R||||20110126113924
R|2|^^^dHCV^ICInterpretation^^1|Valid|||||F\R||||20110126113924
R|3|^^^dHCV^AnalyteRLU^^1|4272|||||F\R||||20110126113924
R|4|^^^dHCV^AnalyteSCO^^1|0.09|||||F\R||||20110126113924
R|5|^^^dHCV^OverallInterpretation^^1|Nonreactive|||||F\R||||20110126113924
L|1|N
```

5.2.14. LIS requests dHIV Assay

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^dHIV^HIV^^1|R|20110125023649|||||N||||Serum|||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|925f7749-d99d-4ae5-b093-0757230617f1^17355
|^^^dHIV^HIV^^1||20110126073327||||||||||||||||||F
R|1|^^^dHIV^ICRLU^^1|291156|||||F\R||||20110126113924
R|2|^^^dHIV^ICInterpretation^^1|Valid|||||F\R||||20110126113924
R|3|^^^dHIV^AnalyteRLU^^1|925436|||||F\R||||20110126113924
R|4|^^^dHIV^AnalyteSCO^^1|19.61|||||F\R||||20110126113924
R|5|^^^dHIV^OverallInterpretation^^1|Reactive|||||F\R||||20110126113924
L|1|N
```

5.2.15. LIS requests WNV Assay

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^WNV^WNV^^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|925f7749-d99d-4ae5-b093-0757230617f1^17355
|^^^WNV^WNV^^1||20110126073327||||||||||||||||||F
R|1|^^^WNV^ICRLU^^1|143785|||||F\R||||20110126113924
R|2|^^^WNV^ICInterpretation^^1|Valid|||||F\R||||20110126113924
R|3|^^^WNV^AnalyteRLU^^1|1801488|||||F\R||||20110126113924
R|4|^^^WNV^AnalyteSCO^^1|34.82|||||F\R||||20110126113924
R|5|^^^WNV^OverallInterpretation^^1|Reactive|||||F\R||||20110126113924
L|1|N
```

5.2.16. LIS requests HPV_GT Assay

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^GT HPV^^1^1|R|20130528100714||||||||Serum||||||||||O|
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|f72423fb-857d-4a97-9247-a26803c45070^19271
|^^^GT HPV^HPV 16 18/45^^1||20130517204617||||||||||||||||||F
R|1|^^^GT HPV^IC/HPV 16 RLU^^1|2319091|||||F\R||||20130518001747
R|2|^^^GT HPV^HPV 16 S/CO^^1|3.67|||||F\R||||20130518001747
R|3|^^^GT HPV^HPV 16 Result^^1|POSITIVE|||||F\R||||20130518001747
R|4|^^^GT HPV^HPV 18/45 RLU^^1|0|||||F\R||||20130518001747
R|5|^^^GT HPV^HPV 18/45 S/CO^^1|0.00|||||F\R||||20130518001747
R|6|^^^GT HPV^HPV 18/45 Result^^1|Negative|||||F\R||||20130518001747
R|7|^^^GT HPV^ICInterpretation^^1|Valid|||||F\R||||20130518001747
R|8|^^^GT HPV^HPV 16 Cutoff^^1||||||F\R||||20130518001747
R|9|^^^GT HPV^HPV 18/45 Cutoff^^1||||||F\R||||20130518001747
R|10|^^^GT HPV^IC Cutoff^^1||||||F\R||||20130518001747
L|1|N
```

5.2.17. LIS requests HEV Assay

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^HEV^HEV^^1|R|20110125023649|||||N||||Serum|||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|925f7749-d99d-4ae5-b093-0757230617f1^17355
|^^^HEV^HEV^^1||20110126073327||||||||||||||||||F
R|1|^^^HEV^ICRLU^^1|143785|||||F\R||||20110126113924
R|2|^^^HEV^ICInterpretation^^1|Valid|||||F\R||||20110126113924
R|3|^^^HEV^AnalyteRLU^^1|1801488|||||F\R||||20110126113924
R|4|^^^HEV^AnalyteSCO^^1|34.82|||||F\R||||20110126113924
R|5|^^^HEV^OverallInterpretation^^1|Reactive|||||F\R||||20110126113924
L|1|N
```

5.2.18. LIS requests DENV Assay

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^DENV^DENV^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|925f7749-d99d-4ae5-b093-0757230617f1^17355
|^^^DENV^DENV^^1|R|20110126073327||||||||||||||||||F
R|1|^^^DENV^ICRLU^^1|105674|||||F||||20110126113924
R|2|^^^DENV^ICInterpretation^^1|Valid|||||F||||20110126113924
R|3|^^^DENV^AnalyteRLU^^1|1351429|||||F||||20110126113924
R|4|^^^DENV^AnalyteSCO^^1|22.51|||||F||||20110126113924
R|5|^^^DENV^OverallInterpretation^^1|Reactive|||||F||||20110126113924
L|1|N
```

5.2.19. LIS requests HSV 1&2 Assay

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^HSV 1&2^HSV 1&2^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|925f7749-d99d-4ae5-b093-0757230617f1^17355
|^^^HSV 1&2^HSV 1&2^^1|R|20110126073327||||||||||||||||||F
R|1|^^^HSV 1&2^ICTTime^^1|27.4|||||F||||20110126113924
R|2|^^^HSV 1&2^ICResult^^1|Valid|F||||20110126113924
R|3|^^^HSV 1&2^HSV1TTime^^1|25.8|||||F||||20110126113924
R|4|^^^HSV 1&2^HSV-1^^1|HSV1 POS|||||F||||20110126113924
R|5|^^^HSV 1&2^HSV2TTime^^1|No TTime|||||F||||20110126113924
R|6|^^^HSV 1&2^HSV-2^^1|HSV2 neg|||||F||||20110126113924
L|1|N
```

The HSV 1&2 assay uses an ‘&’ character within the assay name. This may conflict with some LIS systems as the Panther’s default escape delimiter is an ‘&’. Use of the ‘&’ character as a default delimiter and simultaneously as text within an assay test code may result in parsing errors.
If the naming of the HSV 1&2 assay will cause issues with the LIS system, configure the LIS system to use a different escape delimiter (e.g. %, @). The delimiter must be configured on both the Panther system and the LIS system.
With Panther system SW version 6.2.1.18 or higher, a configuration option has been added to enable escaping. This allows the ‘&” character to be properly escaped per the ASTM protocol.

5.2.20. LIS requests M gen Assay

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^M gen^MG^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|925f7749-d99d-4ae5-b093-0757230617f1^17355
|^^^M gen^MG^^1|R|20110126073327||||||||||||||||||F
R|1|^^^M gen^ICRLU^^1|344547|||||F||||20110126113924
R|2|^^^M gen^ICInterpretation^^1|Valid|F||||20110126113924
R|3|^^^M gen^AnalyteRLU^^1|1715281|||||F||||20110126113924
R|4|^^^M gen^AnalyteSCO^^1|25.33|||||F||||20110126113924
R|5|^^^M gen^OverallInterpretation^^1|POSITIVE|||||F||||20110126113924
R|6|^^^M gen^AnalyteCutoff^^1||||||F||||20110126113924
R|7|^^^M gen^ICCutoff^^1||||||F||||20110126113924
L|1|N
```

5.2.21. LIS requests Parvo/HAV Assay with all analytes

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

(Because Analyte is empty (Order field 5.5), all analytes are requested.)

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^Parvo/HAV^^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

(Panther System returns a result for each analyte.)

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^Parvo/HAV^Parvo Parvo/HAV^^1|R|20100506123145||||||||||||||||||F
R|1|^^^Parvo/HAV^ICInterpretation^^1|Valid|||||F||||20100506123145
R|2|^^^Parvo/HAV^AnalyteSCO^^1|0.14|||||F||||20100506123145
R|3|^^^Parvo/HAV^HAVInterpretation^^1|Nonreactive|||||F||||20100506123145
R|4|^^^Parvo/HAV^Parvo^^1|<500|||||F||||20100506123145
R|5|^^^Parvo/HAV^OverallInterpretation^^1|Valid|||||F||||20100506123145
R|6|^^^Parvo/HAV^ParvoNumeric^^1|100000|||||F||||20100506123145
R|7|^^^Parvo/HAV^AdjustedFlasherRLU^^1|10|||||F||||20100506123145
R|8|^^^Parvo/HAV^AdjustedGlowerRLU^^1|100000|||||F||||20100506123145
L|1|N
```

5.2.22. LIS requests Parvo/HAV Assay with one analyte

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

(One Analyte – Parvo is requested)

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01|| ^^^Parvo/HAV^Parvo^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

(Panther System returns a result for Parvo analyte.)

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^Parvo/HAV^Parvo^^1|R|20100506123145||||||||||||||||||F
R|1|^^^Parvo/HAV^ICInterpretation^^1|Valid|||||F||||20100506123145
R|2|^^^Parvo/HAV^AnalyteSCO^^1|No Test|||||F||||20100506123145
R|3|^^^Parvo/HAV^HAVInterpretation^^1|No Test|||||F||||20100506123145
R|4|^^^Parvo/HAV^Parvo^^1|<500|||||F||||20100506123145
R|5|^^^Parvo/HAV^OverallInterpretation^^1|Valid|||||F||||20100506123145
R|6|^^^Parvo/HAV^ParvoNumeric^^1|100000|||||F||||20100506123145
R|7|^^^Parvo/HAV^AdjustedFlasherRLU^^1|10|||||F||||20100506123145
R|8|^^^Parvo/HAV^AdjustedGlowerRLU^^1|100000|||||F||||20100506123145
L|1|N
```

5.2.23. LIS requests qHBV Assay

NOTE: The IU/mL interpretation will contain a thousand separator (a comma is the English thousand separator for example) specific to the culture set for the Panther system software. This localization will only occur for interpretations which are between the limits of detection. The upper and lower limits of detections will not be localized and will be sent using English numeric format.

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^qHBV^HBV^1^1|R|20110125023649|||||N||||Serum|||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^qHBV^HBV^^1|R|20100506123145||||||||||||||||||F
R|1|^^^qHBV^HBV^^1|14,954,267|IU/mL||||F||||20100506123145
R|2|^^^qHBV^ICResult^^1|16|||||F||||20100506123145
R|3|^^^qHBV^ResultValid^^1|Valid|||||F||||20100506123145
R|4|^^^qHBV^HBVLogBase10^^1|7.17|||||F||||20100506123145
L|1|N
```

(Panther System set to German Culture)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

(Between the limits of detection)

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^qHBV^HBV^^1|R|20100506123145||||||||||||||||||F
R|1|^^^qHBV^HBV^^1|3.589.455|IU/mL||||F||||20180328052147
R|2|^^^qHBV^ICResult^^1|13|||||F||||20180328052147
R|3|^^^qHBV^ResultValid^^1|Valid|||||F||||20180328052147
R|4|^^^qHBV^HBVLogBase10^^1|6,56|||||F||||20180328052147
L|1|N
```

(Lower limit of detection)

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^qHBV^HBV^^1|R|20100506123145||||||||||||||||||F
R|1|^^^qHBV^HBV^^1|<10|IU/mL||<||F||||20180328051644
R|2|^^^qHBV^ICResult^^1|13|||<||F||||20180328051644
R|3|^^^qHBV^ResultValid^^1|Valid|||<||F||||20180328051644
R|4|^^^qHBV^HBVLogBase10^^1|<1.00|||<||F||||20180328051644
L|1|N
```

(Upper limit of detection)

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^qHBV^HBV^^1|R|20100506123145||||||||||||||||||F
R|1|^^^qHBV^HBV^^1|>1.0e9|IU/mL||>||F||||20180328052147
R|2|^^^qHBV^ICResult^^1|26|||>||F||||20180328052147
R|3|^^^qHBV^ResultValid^^1|Valid|||>||F||||20180328052147
R|4|^^^qHBV^HBVLogBase10^^1|>9.00|||>||F||||20180328052147
L|1|N
```

5.2.24. LIS requests qHCV Assay

NOTE: The IU/mL interpretation will contain a thousand separator (a comma is the English thousand separator for example) specific to the culture set for the Panther system software. This localization will only occur for interpretations which are between the limits of detection. The upper and lower limits of detections will not be localized and will be sent using English numeric format.

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^qHCV^HCV^1^1|R|20110125023649|||||N||||Serum|||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^qHCV^HCV^^1|R|20100506123145||||||||||||||||||F
R|1|^^^qHCV^HCV^^1|161,211,351|IU/mL||||F||||20100506123145
R|2|^^^qHCV^ICResult^^1|20|||||F||||20100506123145
R|3|^^^qHCV^ResultValid^^1|Valid|||||F||||20100506123145
R|4|^^^qHCV^HCVLogBase10^^1|8.21|||||F||||20100506123145
L|1|N
```

(Panther System set to German Culture)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

(Between the limits of detection)

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^qHCV^HCV^^1|R|20100506123145||||||||||||||||||F
R|1|^^^qHCV^HCV^^1|1.222|IU/mL||||F||||20180328053147
R|2|^^^qHCV^ICResult^^1|15|||||F||||20180328053147
R|3|^^^qHCV^ResultValid^^1|Valid|||||F||||20180328053147
R|4|^^^qHCV^HCVLogBase10^^1|3,09|||||F||||20180328053147
L|1|N
```

(Lower limit of detection)

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^qHCV^HCV^^1|R|20100506123145||||||||||||||||||F
R|1|^^^qHCV^HCV^^1|<10|IU/mL||<||F||||20180328053147
R|2|^^^qHCV^ICResult^^1|14|||<||F||||20180328053147
R|3|^^^qHCV^ResultValid^^1|Valid|||<||F||||20180328053147
R|4|^^^qHCV^HCVLogBase10^^1|<1.00|||<||F||||20180328053147
L|1|N
```

(Upper limit of detection)

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^qHCV^HCV^^1|R|20100506123145||||||||||||||||||F
R|1|^^^qHCV^HCV^^1|>100,000,000|IU/mL||>||F||||20180328053647
R|2|^^^qHCV^ICResult^^1|20|||>||F||||20180328053647
R|3|^^^qHCV^ResultValid^^1|Valid|||>||F||||20180328053647
R|4|^^^qHCV^HCVLogBase10^^1|>8.00|||>||F||||20180328053647
L|1|N
```

5.2.25. LIS requests qHIV-1 Assay

NOTE: The copies/mL interpretation will contain a thousand separator (a comma is the English thousand separator for example) specific to the culture set for the Panther system software. This localization will only occur for interpretations which are between the limits of detection. The upper and lower limits of detections will not be localized and will be sent using English numeric format.

Dried Blood Spot (DBS) is manually applied to the HIV orders on the Panther user interface.

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^qHIV-1^HIV-1^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

(Non-DBS)

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^qHIV-1^HIV-1^^1|R|20100506123145||||||||||||||||||F
R|1|^^^qHIV-1^HIV-1^^1|8,651,721|copies/mL||||F||||20141016055823
R|2|^^^qHIV-1^ICResult^^1|24|||||F||||20141016055823
R|3|^^^qHIV-1^ResultValid^^1|Valid|||||F||||20141016055823
R|4|^^^qHIV-1^HIV-1LogBase10^^1|6.94|||||F||||20141016055823
L|1|N
```

(DBS)

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^qHIV-1^HIV-1^^29.1|R|20100506123145||||||||||||||||||F
R|1|^^^qHIV-1^HIV-1^^29.1|<873|copies/mL||<||F||||20171201035457
R|2|^^^qHIV-1^ICResult^^29.1|15|||<||F||||20171201035457
R|3|^^^qHIV-1^ResultValid^^29.1|Valid|||<||F||||20171201035457
R|4|^^^qHIV-1^HIV-1LogBase10^^29.1|<2.94|||<||F||||20171201035457
L|1|N
```

(Panther System to LIS)
(Panther System set to German Culture)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

(Between the limits of detection)

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^qHIV-1^HIV-1^^1|R|20100506123145||||||||||||||||||F
R|1|^^^qHIV-1^HIV-1^^1|9.469.097|copies/mL||||F||||20180328042148
R|2|^^^qHIV-1^ICResult^^1|25|||||F||||20180328042148
R|3|^^^qHIV-1^ResultValid^^1|Valid|||||F||||20180328042148
R|4|^^^qHIV-1^HIV-1LogBase10^^1|6,98|||||F||||20180328042148
L|1|N
```

(Lower limit of detection)

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^qHIV-1^HIV-1^^1|R|20100506123145||||||||||||||||||F
R|1|^^^qHIV-1^HIV-1^^1|<30|copies/mL||<||F||||20180328042147
R|2|^^^qHIV-1^ICResult^^1|15|||<||F||||20180328042147
R|3|^^^qHIV-1^ResultValid^^1|Valid|||<||F||||20180328042147
R|4|^^^qHIV-1^HIV-1LogBase10^^1|<1.47|||<||F||||20180328042147
L|1|N
```

(Upper limit of detection)

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^qHIV-1^HIV-1^^1|R|20100506123145||||||||||||||||||F
R|1|^^^qHIV-1^HIV-1^^1|>10,000,000|copies/mL||>||F||||20180328042647
R|2|^^^qHIV-1^ICResult^^1|29|||>||F||||20180328042647
R|3|^^^qHIV-1^ResultValid^^1|Valid|||>||F||||20180328042647
R|4|^^^qHIV-1^HIV-1LogBase10^^1|>7.00|||>||F||||20180328042647
L|1|N
```

5.2.26. LIS requests LDT TMA-x (1,2,3) Assay

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^LDT TMA-1^LDT TMA-1^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^LDT TMA-1^LDT TMA-1^^1|R|20100506123145||||||||||||||||||F
R|1| ^^^LDT TMA-1^TotalRLU^^1| 693808|||||F||||20141016055823
R|2| ^^^LDT TMA-1^Channel1Status^^1|Cutoff Not Defined|||||F||||20141016055823
L|1|N
```

5.2.27. LIS requests LDT RT TMA-x (1,2,3) Assay

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^LDT RT TMA-1^LDT RT TMA-1^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^LDT RT TMA-1^LDT RT TMA-1^1^1|R|20100506123145||||||||||||||||||||F
R|1|^^^LDT RT TMA-1^Channel1TTime^^1|4.9|||||F||||20141016055823
R|2|^^^LDT RT TMA-1^Channel3TTime^^1|-|||||F||||20141016055823
R|3|^^^LDT RT TMA-1^Channel5TTime^^1|-|||||F||||20141016055823
R|4|^^^LDT RT TMA-1^Channel1Status^^1|Cutoff Met|||||F||||20141016055823
R|5|^^^LDT RT TMA-1^Channel3Status^^1|Not Calculable|||||F||||20141016055823
R|6|^^^LDT RT TMA-1^Channel5Status^^1|Not Calculable|||||F||||20141016055823
L|1|N
```

5.2.28. LIS requests Flu A/B/RSV Assay with all analytes

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^Flu A/B/RSV^^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^Flu A/B/RSV^Flu A Flu B RSV^1^1|R|20100506123145||||||||||||||||||F
R|1|^^^Flu A/B/RSV^FluATCycle^^1|37.5|||||F||||20141016055823
R|2|^^^Flu A/B/RSV^FluBTCycle^^1|-|||||F||||20141016055823
R|3|^^^Flu A/B/RSV^RSVTCycle^^1|-|||||F||||20141016055823
R|4|^^^Flu A/B/RSV^ICTCycle^^1|31.9|||||F||||20141016055823
R|5|^^^Flu A/B/RSV^FluA^^1|Flu A POS|||||F||||20141016055823
R|6|^^^Flu A/B/RSV^FluB^^1|Flu B neg|||||F||||20141016055823
R|7|^^^Flu A/B/RSV^RSV^^1|RSV neg|||||F||||20141016055823
R|8|^^^Flu A/B/RSV^IC^^1|Valid|||||F||||20141016055823
L|1|N
```

5.2.29. LIS requests Flu A/B/RSV Assay with one analyte

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^Flu A/B/RSV^Flu A^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^Flu A/B/RSV^Flu A^1^1|R|20100506123145||||||||||||||||||F
R|1|^^^Flu A/B/RSV^FluATCycle^^1|37.5|||||F||||20141016055823
R|2|^^^Flu A/B/RSV^FluBTCycle^^1|No Test|||||F||||20141016055823
R|3|^^^Flu A/B/RSV^RSVTCycle^^1|No Test|||||F||||20141016055823
R|4|^^^Flu A/B/RSV^ICTCycle^^1|31.9|||||F||||20141016055823
R|5|^^^Flu A/B/RSV^FluA^^1|Flu A POS|||||F||||20141016055823
R|6|^^^Flu A/B/RSV^FluB^^1|No Test|||||F||||20141016055823
R|7|^^^Flu A/B/RSV^RSV^^1|No Test|||||F||||20141016055823
R|8|^^^Flu A/B/RSV^IC^^1|Valid|||||F||||20141016055823
L|1|N
```

5.2.30. LIS requests AdV/hMPV/RV Assay with all analytes

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^AdV/hMPV/RV^^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^AdV/hMPV/RV^AdV hMPV RV^1^1|R|20100506123145||||||||||||||||||F
R|1|^^^AdV/hMPV/RV^AdVTCycle^^1|37.5|||||F||||20141016055823
R|2|^^^AdV/hMPV/RV^hMPVTCycle^^1|-|||||F||||20141016055823
R|3|^^^AdV/hMPV/RV^RVTCycle^^1|-|||||F||||20141016055823
R|4|^^^AdV/hMPV/RV^ICTCycle^^1|31.9|||||F||||20141016055823
R|5|^^^AdV/hMPV/RV^AdV^^1|AdV POS|||||F||||20141016055823
R|6|^^^AdV/hMPV/RV^hMPV^^1|hMPV neg|||||F||||20141016055823
R|7|^^^AdV/hMPV/RV^RV^^1|RV neg|||||F||||20141016055823
R|8|^^^AdV/hMPV/RV^IC^^1|Valid|||||F||||20141016055823
L|1|N
```

5.2.31. LIS requests AdV/hMPV/RV Assay with one analyte

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^AdV/hMPV/RV^AdV^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^AdV/hMPV/RV^AdV^1^1|R|20100506123145||||||||||||||||||F
R|1|^^^AdV/hMPV/RV^AdVTCycle^^1|37.5|||||F||||20141016055823
R|2|^^^AdV/hMPV/RV^hMPVTCycle^^1|No Test|||||F||||20141016055823
R|3|^^^AdV/hMPV/RV^RVTCycle^^1|No Test|||||F||||20141016055823
R|4|^^^AdV/hMPV/RV^ICTCycle^^1|31.9|||||F||||20141016055823
R|5|^^^AdV/hMPV/RV^AdV^^1|AdV POS|||||F||||20141016055823
R|6|^^^AdV/hMPV/RV^hMPV^^1|No Test|||||F||||20141016055823
R|7|^^^AdV/hMPV/RV^RV^^1|No Test|||||F||||20141016055823
R|8|^^^AdV/hMPV/RV^IC^^1|Valid|||||F||||20141016055823
L|1|N
```

5.2.32. LIS requests Paraflu Assay with all analytes

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^Paraflu^^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^Paraflu^P1 P2 P3 P4^1^1|R|20100506123145||||||||||||||||||F
R|1|^^^Paraflu^P1TCycle^^1|37.5|||||F||||20141016055823
R|2|^^^Paraflu^P2TCycle^^1|-|||||F||||20141016055823
R|3|^^^Paraflu^P3TCycle^^1|-|||||F||||20141016055823
R|4|^^^Paraflu^P4TCycle^^1|-|||||F||||20141016055823
R|5|^^^Paraflu^ICTCycle^^1|31.9|||||F||||20141016055823
R|6|^^^Paraflu^P1^^1|P1 POS|||||F||||20141016055823
R|7|^^^Paraflu^P2^^1|P2 neg|||||F||||20141016055823
R|8|^^^Paraflu^P3^^1|P3 neg|||||F||||20141016055823
R|9|^^^Paraflu^P4^^1|P4 neg|||||F||||20141016055823
R|10|^^^Paraflu^IC^^1|Valid|||||F||||20141016055823
L|1|N
```

5.2.33. LIS requests Paraflu Assay with one analyte

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^Paraflu^P1^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^Paraflu^P1^1^1|R|20100506123145||||||||||||||||||F
R|1|^^^Paraflu^P1TCycle^^1|37.5|||||F||||20141016055823
R|2|^^^Paraflu^P2TCycle^^1|No Test|||||F||||20141016055823
R|3|^^^Paraflu^P3TCycle^^1|No Test|||||F||||20141016055823
R|4|^^^Paraflu^P4TCycle^^1|No Test|||||F||||20141016055823
R|5|^^^Paraflu^ICTCycle^^1|31.9|||||F||||20141016055823
R|6|^^^Paraflu^P1^^1|P1 POS|||||F||||20141016055823
R|7|^^^Paraflu^P2^^1|No Test|||||F||||20141016055823
R|8|^^^Paraflu^P3^^1|No Test|||||F||||20141016055823
R|9|^^^Paraflu^P4^^1|No Test|||||F||||20141016055823
R|10|^^^Paraflu^IC^^1|Valid|||||F||||20141016055823
L|1|N
```

5.2.34. LIS requests ZIKV Assay (Aptima)

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^ZIKV^ZIKV^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^ZIKV^ZIKV^^1|R|20100506123145||||||||||||||||||F
R|1|^^^ZIKV^ICRLU^^1|173742|||||F||||20141016055823
R|2|^^^ZIKV^ICInterpretation^^1|Valid|||||F||||20141016055823
R|3|^^^ZIKV^AnalyteRLU^^1|1325659|||||F||||20141016055823
R|4|^^^ZIKV^AnalyteSCO^^1|32.48|||||F||||20141016055823
R|5|^^^ZIKV^OverallInterpretation^^1|POSITIVE|||||F||||20141016055823
L|1|N
```

5.2.35. LIS requests ZIKV Assay (Procleix)

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^ZIKV^ZIKV^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^ZIKV^ZIKV^^1|R|20100506123145||||||||||||||||||F
R|1|^^^ZIKV^ICRLU^^1|173742|||||F||||20141016055823
R|2|^^^ZIKV^ICInterpretation^^1|Valid|||||F||||20141016055823
R|3|^^^ZIKV^AnalyteRLU^^1|1325659|||||F||||20141016055823
R|4|^^^ZIKV^AnalyteSCO^^1|32.48|||||F||||20141016055823
R|5|^^^ZIKV^OverallInterpretation^^1|Reactive|||||F||||20141016055823
L|1|N
```

5.2.36. LIS requests Babesia Assay

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^Babesia^Babesia^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^Babesia^Babesia^^1|R|20100506123145||||||||||||||||||F
R|1|^^^Babesia^ICRLU^^1|173742|||||F||||20141016055823
R|2|^^^Babesia^ICInterpretation^^1|Valid|||||F||||20141016055823
R|3|^^^Babesia^AnalyteRLU^^1|1325659|||||F||||20141016055823
R|4|^^^Babesia^AnalyteSCO^^1|32.48|||||F||||20141016055823
R|5|^^^Babesia^OverallInterpretation^^1|Reactive|||||F||||20141016055823
L|1|N
```

5.2.37. LIS requests GBS Assay

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01|| ^^^GBS^GBS^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|10468b8b-bb7e-48d3-aac0-
ecca4b559a6e^4024|^^^GBS^GBS^^1|R|20171013180059||||||||||||||||||F
R|1|^^^GBS^GBSTCycle^^1|-|||||F||||20171013221608
R|2|^^^GBS^ICTCycle^^1|35.0|||||F||||20171013221608
R|3|^^^GBS^GBS^^1|GBS neg|||||F||||20171013221608
R|4|^^^GBS^IC^^1|Valid|||||F||||20171013221608
L|1|N
```

5.2.38. LIS requests MRSA Assay

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01|| ^^^MRSA^MRSA^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|984ca013-a42d-4cd8-bcac-
410cfbc03695^4023|^^^MRSA^MRSA^^1|R|20171013180059||||||||||||||||||F
R|1|^^^MRSA^MREJTCycle^^1|-|||||F||||20171013221110
R|2|^^^MRSA^MECACTCycle^^1|-|||||F||||20171013221110
R|3|^^^MRSA^GAPDHTCycle^^1|-|||||F||||20171013221110
R|4|^^^MRSA^ICTCycle^^1|35.0|||||F||||20171013221110
R|5|^^^MRSA^MREJ^^1|OrfX/SCCmec neg|||||F||||20171013221110
R|6|^^^MRSA^MECAC^^1|mec A/C neg|||||F||||20171013221110
R|7|^^^MRSA^GAPDH^^1|GAPDH neg|||||F||||20171013221110
R|8|^^^MRSA^SA^^1|SA neg|||||F||||20171013221110
R|9|^^^MRSA^MRSA^^1|MRSA neg|||||F||||20171013221110
R|10|^^^MRSA^IC^^1|Valid|||||F||||20171013221110
L|1|N
```

5.2.39. LIS requests BV Assay

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^BV^^1^1|R|20110125023649|||||N||||Serum|||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|17ed6d92-33dd-4265-b2bc- 19cdcde6fb85^807
|^^^BV^BV^^1|R|20170925180950||||||||||||||||||F
R|1|^^^BV^BV^^1|BV neg|||||F||||20170925211214
L|1|N
```

5.2.40. LIS requests CV/TV Assay with all analytes

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^CV/TV^^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

(Panther System returns a result for each analyte.)

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^CV/TV^CV TV^^1|R|20100506123145||||||||||||||||||||F
R|1|^^^CV/TV^Cspp^^1|C. spp POS|||||F||||20170929211347
R|2|^^^CV/TV^Cgla^^1|C. gla neg|||||F||||20170929211347
R|3|^^^CV/TV^TRICH^^1|TRICH neg|||||F||||20170929211347
L|1|N
```

5.2.41. LIS requests CV/TV Assay with one analyte

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

(One Analyte – CV is requested)

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^CV/TV^CV^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

(Panther System returns a result for CV analyte.)

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^CV/TV^CV^^1|R|20100506123145||||||||||||||||||F
R|1|^^^CV/TV^Cspp^^1|C. spp POS|||||F||||20170929211347
R|2|^^^CV/TV^Cgla^^1|C. gla neg|||||F||||20170929211347
R|3|^^^CV/TV^TRICH^^1|No Test|||||F||||20170929211347
L|1|N
```

5.2.42. LIS requests myAccess Qualitative LDT protocol with all analytes

Example Qualitative protocol LDT-RNA with analytes: Target-1, Target-2, Target-3, Target-4 and Int. Ctrl.

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^LDT-RNA^^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|Sample-1|cd811333-4a01-493e-ba49-be371dab37bb^5089|^^^LDT-RNA^Target-1
Target-2 Target-3 Target-4 Int. Ctrl.^^1|R|20180321172058|||||||||||||||||||F
R|1|^^^LDT-RNA^Target-1TCycle^^1|37.0|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|2|^^^LDT-RNA^Target-2TCycle^^1|-|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|3|^^^LDT-RNA^Target-3TCycle^^1|-|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|4|^^^LDT-RNA^Target-4TCycle^^1|-|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|5|^^^LDT-RNA^Int.Ctrl.TCycle^^1|35.6|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|6|^^^LDT-RNA^Target-1Result^^1|Target-1 POS|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|7|^^^LDT-RNA^Target-2Result^^1|Target-2 neg|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|8|^^^LDT-RNA^Target-3Result^^1|Target-3 neg|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|9|^^^LDT-RNA^Target-4Result^^1|Target-4 neg|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|10|^^^LDT-RNA^Int.Ctrl.Result^^1|Valid|||||F||||2018032120180
C|1|I|^LDT - Laboratory Developed Test|I
L|1|N
```

5.2.43. LIS requests myAccess Qualitative LDT protocol with one analyte

Example Qualitative protocol LDT-RNA with one analyte: Target-1

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

(One Analyte – Target-1 is requested with IC enabled as Int.Ctrl.)

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^LDT-RNA^Target-1^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|Sample-1|cd811333-4a01-493e-ba49-be371dab37bb^5089|^^^LDT-RNA^Target-1
^^1|R|20180321172058||||||||||||||||||F
R|1|^^^LDT-RNA^Target-1TCycle^^1|37.0|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|2|^^^LDT-RNA^Target-2TCycle^^1|No Test|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|3|^^^LDT-RNA^Target-3TCycle^^1|No Test|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|4|^^^LDT-RNA^Target-4TCycle^^1|No Test|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|5|^^^LDT-RNA^Int.Ctrl.TCycle^^1|28.6|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|6|^^^LDT-RNA^Target-1Result^^1|Target-1 POS|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|7|^^^LDT-RNA^Target-2Result^^1|No Test|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|8|^^^LDT-RNA^Target-3Result^^1|No Test |||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|9|^^^LDT-RNA^Target-4Result^^1|No Test|||||F||||20180321201805
```

```
C|1|I|^LDT - Laboratory Developed Test|I
R|10|^^^LDT-RNA^Int.Ctrl.Result^^1|Valid|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
L|1|N
```

5.2.44. LIS requests myAccess Quantitative LDT protocol with all analytes

Example Quantitative protocol LDT-RNA with all analytes: Target-1, Target-2, Target-3, Target-4 and Int. Ctrl. No Standard Curve assigned to Target-4

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^LDT-RNA^^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|Sample-1|cd811333-4a01-493e-ba49-be371dab37bb^5089|^^^LDT-RNA^Target-1
Target-2 Target-3 Target-4 Int. Ctrl.^^1|R|20180321172058||||||||||||||||||F
R|1|^^^LDT-RNA^Target-1TCycle^^1|36.2|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|2|^^^LDT-RNA^Target-2TCycle^^1|36.1|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|3|^^^LDT-RNA^Target-3TCycle^^1|36.1|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|4|^^^LDT-RNA^Target-4TCycle^^1|36.4|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|5|^^^LDT-RNA^Int.Ctrl.TCycle^^1|28.6|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|6|^^^LDT-RNA^Target-1^^1|1,515||0|||F\R||admin||20200227143217|1.0.8.0
C|1|I|^LDT - Laboratory Developed Test|I
R|7|^^^LDT-RNA^Target-1LogBase10^^1|3.18||0|||F\R||admin||20200227143217|1.0.8.0
C|1|I|^LDT - Laboratory Developed Test|I
R|8|^^^LDT-RNA^Target-2^^1|<1e3||0|||F\R||admin||20200227143217|1.0.8.0
C|1|I|^LDT - Laboratory Developed Test|I
R|9|^^^LDT-RNA^Target-2LogBase10^^1|<3.00||0|||F\R||admin||20200227143217|1.0.8.0
C|1|I|^LDT - Laboratory Developed Test|I
R|10|^^^LDT-RNA^Target-3^^1|4,671||0|||F\R||admin||20200227143217|1.0.8.0
```

```
C|1|I|^LDT - Laboratory Developed Test|I
R|11|^^^LDT-RNA^Target-3LogBase10^^1|3.67||0|||F\R||admin||202002271432l7|1.0.8.0
C|1|I|^LDT - Laboratory Developed Test|I
R|12|^^^LDT-RNA^Target-4^^1|Detected||0|||F\R||admin||202002271432l7|1.0.8.0
C|1|I|^LDT - Laboratory Developed Test|I
R|13|^^^LDT-RNA^Target-4LogBase10^^1|Detected||0|||F\R||admin||202002271432l7|1.0.8.0
C|1|I|^LDT - Laboratory Developed Test|I
R|14|^^^LDT-RNA^Int.Ctrl.Result^^1|Valid/27.7||0|||F\R||admin||202002271432l7|1.0.8.0
C|1|I|^LDT - Laboratory Developed Test|I
R|15|^^^LDT-RNA^OverallResult^^1|Valid||0|||F\R||admin||202002271432l7|1.0.8.0
C|1|I|^LDT - Laboratory Developed Test|I
L|1|N
```

5.2.45. LIS requests myAccess Quantitative LDT protocol with one analyte

Example Quantitative protocol LDT-RNA with one analyte: Target-1

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

(One Analyte – Target-1 is requested with IC enabled as Int.Ctrl.)

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^LDT-RNA^Target-1^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|Sample-1|cd811333-4a01-493e-ba49-be371dab37bb^5089|^^^LDT-RNA^Target-1
Target-2 Target-3 Target-4 Int. Ctrl.^^1|R|20180321172058||||||||||||||||||F
R|1|^^^LDT-RNA^Target-1TCycle^^1|36.2|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|2|^^^LDT-RNA^Target-2TCycle^^1|No Test|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|3|^^^LDT-RNA^Target-3TCycle^^1|No Test|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|4|^^^LDT-RNA^Target-4TCycle^^1|No Test|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|5|^^^LDT-RNA^Int.Ctrl.TCycle^^1|28.6|||||F||||20180321201805
C|1|I|^LDT - Laboratory Developed Test|I
R|6|^^^LDT-RNA^Target-1^^1|1,515||0|||F\R||admin||20200227143217|1.0.8.0
C|1|I|^LDT - Laboratory Developed Test|I
R|7|^^^LDT-RNA^Target-1LogBase10^^1|No Test||0|||F\R||admin||20200227143217|1.0.8.0
C|1|I|^LDT - Laboratory Developed Test|I
R|8|^^^LDT-RNA^Target-2^^1|No Test||0|||F\R||admin||20200227143217|1.0.8.0
C|1|I|^LDT - Laboratory Developed Test|I
R|9|^^^LDT-RNA^Target-2LogBase10^^1|No Test||0|||F\R||admin||20200227143217|1.0.8.0
```

```
C|1|I|^LDT - Laboratory Developed Test|I
R|10|^^^LDT-RNA^Target-3^^1|No Test||0|||F\R||admin||20200227143217|1.0.8.0
C|1|I|^LDT - Laboratory Developed Test|I
R|11|^^^LDT-RNA^Target-3LogBase10^^1|No Test||0|||F\R||admin||20200227143217|1.0.8.0
C|1|I|^LDT - Laboratory Developed Test|I
R|12|^^^LDT-RNA^Target-4^^1|No Test||0|||F\R||admin||20200227143217|1.0.8.0
C|1|I|^LDT - Laboratory Developed Test|I
R|13|^^^LDT-RNA^Target-4LogBase10^^1|No Test||0|||F\R||admin||20200227143217|1.0.8.0
C|1|I|^LDT - Laboratory Developed Test|I
R|14|^^^LDT-RNA^Int.Ctrl.Result^^1|Valid/27.7||0|||F\R||admin||20200227143217|1.0.8.0
C|1|I|^LDT - Laboratory Developed Test|I
R|15|^^^LDT-RNA^OverallResult^^1|Valid||0|||F\R||admin||20200227143217|1.0.8.0
C|1|I|^LDT - Laboratory Developed Test|I
L|1|N
```

5.2.46. LIS requests Bordetella Assay

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^Bordetella^^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

For system software version 7.1 or above:

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|17ed6d92-33dd-4265-b2bc- 19cdcde6fb85^807
|^^^ Bordetella^ Bordetella^^1|R|20170925180950||||||||||||||||||F
R|1|^^^Bordetella^BpTCycle^^1|-|||||F||||20180522021935
R|2|^^^Bordetella^BppTCycle^^1|39.6|||||F||||20180522021935
R|3|^^^Bordetella^ICTCycle^^1|27.8|||||F||||20180522021935
R|4|^^^Bordetella^Bp^^1|Bp neg|||||F||||20180522021935
R|5|^^^Bordetella^Bpp^^1|Bpp POS|||||F||||20180522021935
R|6|^^^Bordetella^IC^^1|Valid|||||F||||20180522021935
L|1|N
```

Only for system software version 6.2:

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|17ed6d92-33dd-4265-b2bc- 19cdcde6fb85^807
|^^^Bordetella^Bordetella^^1|R|20170925180950||||||||||||||||||F
R|1|^^^Bordetella^PertussisTCycle^^1|-|||||F||||20180522021935
R|2|^^^Bordetella^ParapertussisTCycle^^1|39.6|||||F||||20180522021935
R|3|^^^Bordetella^ICTCycle^^1|27.8|||||F||||20180522021935
R|4|^^^Bordetella^Pertussis^^1| Pertussis neg|||||F||||20180522021935
R|5|^^^Bordetella^Parapertussis^^1| Parapertussis POS|||||F||||20180522021935
R|6|^^^Bordetella^IC^^1|Valid|||||F||||20180522021935
L|1|N
```

5.2.47. LIS requests qCMV Assay

NOTE: The IU/mL interpretation will contain a thousand separator (a comma is the English thousand separator for example) specific to the culture set for the Panther system software. This localization will only occur for interpretations which are between the limits of detection. The upper and lower limits of detections will not be localized and will be sent using English numeric format.

Whole Blood (WB) is manually applied to the qCMV orders on the Panther user interface.

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^qCMV^CMV^1^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

(Non-WB)

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|17ed6d92-33dd-4265-b2bc-
19cdcde6fb85^807|^^^qCMV^CMV^^1|R|20170925180950||||||||||||||||||F
R|1|^^^qCMV^CMVResult^^1|11,915|IU/mL||||F||||20180522021935
R|2|^^^qCMV^CMVLogBase10Result^^1|4.08|IU/mL||||F||||20180522021935
R|3|^^^qCMV^ICResult^^1|15|||||F||||20180522021935
R|4|^^^qCMV^ResultValid^^1|Valid|||||F||||20180522021935
L|1|N
```

(WB)

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|17ed6d92-33dd-4265-b2bc-
19cdcde6fb85^807|^^^qCMV^CMV^^1|R|20170925180950||||||||||||||||||F
R|1|^^^qCMV^CMVResult^^1|174,900|IU/mL||||F||||20180522021935
R|2|^^^qCMV^CMVLogBase10Result^^1|5.24|IU/mL||||F||||20180522021935
R|3|^^^qCMV^ICResult^^1|15|||||F||||20180522021935
R|4|^^^qCMV^ResultValid^^1|Valid|||||F||||20180522021935
L|1|N
```

(Lower limit of detection for non-WB)

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
 |^^^qCMV-1^CMV^^1|R|20100506123145||||||||||||||||||F
R|1|^^^qCMV^CMVResult^^1|<55 detected|IU/mL||<||F||||20180328042147
R|2|^^^qCMV^CMVLogBase10Result^^1|<1.74|IU/mL||<||F||||20180328042147
R|3|^^^qCMV^ICResult^^1|14|||<||F||||20180328042147
R|4|^^^qCMV^ResultValid^^1|Valid|||<||F||||20180328042147
L|1|N
```

(Lower limit of detection for WB)

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
 |^^^qCMV-1^CMV^^1|R|20100506123145||||||||||||||||||F
R|1|^^^qCMV^CMVResult^^1|<176 detected|IU/mL||<||F||||20180328042147
R|2|^^^qCMV^CMVLogBase10Result^^1|<2.24|IU/mL||<||F||||20180328042147
R|3|^^^qCMV^ICResult^^1|14|||<||F||||20180328042147
R|4|^^^qCMV^ResultValid^^1|Valid|||<||F||||20180328042147
L|1|
```

Upper limit of detection for non-WB and WB)

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
 |^^^qCMV-1^CMV^^1|R|20100506123145||||||||||||||||||F
R|1|^^^qCMV^CMVResult^^1|>10,000,000|IU/mL||>||F||||20180328042147
R|2|^^^qCMV^CMVLogBase10Result^^1|>7.00|IU/mL||>||F||||20180328042147
R|3|^^^qCMV^ICResult^^1|20|||>||F||||20180328042147
R|4|^^^qCMV^ResultValid^^1|Valid|||>||F||||20180328042147
L|1|
```

5.2.48. LIS requests UltrioPlex E Assay

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^UltrioPlex E^HEV/HIV/HCV/HBV^^1
|R|20110125023649|||||N||||Serum|||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|925f7749-d99d-4ae5-b093-0757230617f1^17355
|^^^UltrioPlex E^HEV/HIV/HCV/HBV^^1||20110126113924||||||||||||||||||F
R|1|^^^UltrioPlex E^ICInterpretation^^1|Valid|||||F||||20110126113924
R|2|^^^UltrioPlex E^UeRLU^^1|830611|||||F||||20110126113924
R|3|^^^UltrioPlex E^UeSCO^^1|10.12|||||F||||20110126113924
R|4|^^^UltrioPlex E^UEInterpretation^^1|Reactive|||||F||||20110126113924
R|5|^^^UltrioPlex E^HevSCO^^1|1.01|||||F||||20110126113924
R|6|^^^UltrioPlex E^HEVInterpretation^^1|Reactive|||||F||||20110126113924
R|7|^^^UltrioPlex E^ICHevRLU^^1|283806|||||F||||20110126113924
L|1|N
```

5.2.49. LIS requests dpHBV Assay

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^dpHBV^HBV^^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|925f7749-d99d-4ae5-b093-0757230617f1^17355
|^^^dpHBV^HBV^^1||20110126113924||||||||||||||||||F
R|1|^^^dpHBV^ICRLU^^1|293673|||||F||||20110126113924
R|2|^^^dpHBV^ICInterpretation^^1|Valid|||||F||||20110126113924
R|3|^^^dpHBV^AnalyteRLU^^1|1102320|||||F||||20110126113924
R|4|^^^dpHBV^AnalyteSCO^^1|18.09|||||F||||20110126113924
R|5|^^^dpHBV^OverallInterpretation^^1|Reactive|||||F||||20110126113924
L|1|N
```

5.2.50. LIS requests dpHCV Assay

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^dpHCV^HCV^^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|925f7749-d99d-4ae5-b093-0757230617f1^17355
|^^^dpHCV^HCV^^1||20110126113924||||||||||||||||||F
R|1|^^^dpHCV^ICRLU^^1|232394|||||F||||20110126113924
R|2|^^^dpHCV^ICInterpretation^^1|Valid|||||F||||20110126113924
R|3|^^^dpHCV^AnalyteRLU^^1|984198|||||F||||20110126113924
R|4|^^^dpHCV^AnalyteSCO^^1|21.10|||||F||||20110126113924
R|5|^^^dpHCV^OverallInterpretation^^1|Reactive|||||F||||20110126113924
L|1|N
```

5.2.51. LIS requests dpHIV Assay

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^dpHIV^HIV^^1|R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|925f7749-d99d-4ae5-b093-0757230617f1^17355
|^^^dHIV^HIV^^1||20110126113924||||||||||||||||||F
R|1|^^^dpHIV^ICRLU^^1|172672|||||F||||20110126113924
R|2|^^^dpHIV^ICInterpretation^^1|Valid|||||F||||20110126113924
R|3|^^^dpHIV^AnalyteRLU^^1|679869|||||F||||20110126113924
R|4|^^^dpHIV^AnalyteSCO^^1|14.40|||||F||||20110126113924
R|5|^^^dpHIV^OverallInterpretation^^1|Reactive|||||F||||20110126113924
L|1|N
```

5.2.52. LIS requests LDT-SARS-CoV-2 EUA

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^LDT-SARS-CoV-2^SARS-CoV-2^1^1
R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|Sample-1|cd811333-4a01-493e-ba49-be371dab37bb^5089|^^^LDT-SARS-CoV-2^SARS-CoV-2
^^1|R|20180321172058||||||||||||||||||F
R|1|^^^LDT-SARS-CoV-2^ SARS-CoV-2TCycle^^1|37.0|||||F||||20200321201805
R|2|^^^LDT-SARS-CoV-2^ICTCycle^^1|28.9|||||F||||20200321201805
R|3|^^^LDT-SARS-CoV-2^ SARS-CoV-2Result^^1| SARS-CoV-2 POS|||||F||||20200321201805
R|4|^^^LDT-SARS-CoV-2^ICResult^^1|Valid|||||F||||20200321201805
L|1|N
```

5.2.53. LIS requests SARS-CoV-2 (Procleix)

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^SARS-CoV-2^SARS-CoV-2^1^1
R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||Host||P|1|
P|1||||^^|||||||||||^|^|||||||||||||||^|^|
O|1|PANEL-C-333555|6ac5e51b-886a-4261-b740-e79838856b77^9|^^^SARS-CoV-2^SARS-CoV-
2^^1|R|20181126143144||||||||||||||||||F
R|1|^^^SARS-CoV-2^ICRLU^^1|162515|||||F||||20181126181828
R|2|^^^SARS-CoV-2^ICInterpretation^^1|Valid|||||F||||20181126181828
R|3|^^^SARS-CoV-2^AnalyteRLU^^1|344639|||||F||||20181126181828
R|4|^^^SARS-CoV-2^AnalyteSCO^^1|3.22|||||F||||20181126181828
R|5|^^^SARS-CoV-2^OverallInterpretation^^1|Reactive|||||F||||20181126181828
L|1|N
```

5.2.54. LIS requests SARSCoV2 (Aptima)

(LIS to Panther System)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^SARSCoV2^SARSCoV2^1^1
R|20110125023649|||||N||||Serum||||||||||O
L|1|N
```

(Panther System to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||Host||P|1|
P|1||TEST-121||^^|||Other||||||||^|^|||||||||||||||^|^|
O|1|TEST-121|fc965584-e853-4541-bf65-88410baf0460^65|^^^SARSCoV2^SARSCoV2
^^1|R|20200324203149||||||||||||||||||F
R|1|^^^SARSCoV2^TotalRLU^^1|1062|||||F||||20200325011426|
R|2|^^^SARSCoV2^ICResult^^1|Valid|||||F||||20200325011426|
R|3|^^^SARSCoV2^CoVResult^^1|Negative|||||F||||20200325011426|
L|1|N
```

5.2.55. Host Query is not enabled

(LIS to Panther System, test order download in advance of samples being loaded)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
L – Terminator record

```
H|\^&|||LISHost|||||Panther||P|1
P|1|PatID01|||Meier^Anna||1974100123|F|||||MARTINEZ
O|1|SAMPLE01||^^^CT/GC^GC^^1|R|19980506090909|||||N||||Serum|||||||||O
L|1|N
```

(When samples are loaded, sampleIDs are matched to sampleIDs/test orders available on test order table)

(Panther System to LIS, results sent up to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01| C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^CT/GC^GC^^1||20100506123145||||||||||||||||||F
R|1|^^^CT/GC^TotalRLU^^1|959|||||F\R||||20100506123145
R|2|^^^CT/GC^CTResult^^1|No Test|||||F\R||||20100506123145
R|3|^^^CT/GC^GCResult^^1|GC EQUIV|||||F\R||||20100506123145
L|1|N
```

5.2.56. Unidirectional LIS, No test order downloads, Panther System sends Results to LIS

(Samples loaded and test orders created similar to Panther Systems with no LIS connections)

(Panther System to LIS, results sent up to LIS)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1||||^^|||||||||||^|^|||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234
|^^^CT/GC^GC^^1||20100506123145||||||||||||||||||F
R|1|^^^CT/GC^TotalRLU^^1|959|||||F\R||||20100506123145
R|2|^^^CT/GC^CTResult^^1|No Test|||||F\R||||20100506123145
R|3|^^^CT/GC^GCResult^^1|GC EQUIV|||||F\R||||20100506123145
L|1|N
```

5.2.57. System Configured to send Additional Information

(Panther System to LIS)
(MasterLot enabled to be sent)
(ReagentSet enabled to be sent)
(User credentials enabled to be sent)
(ADM version enabled to be sent)
(Result Enumeration enabled to be sent)
(WorklistID enabled to be sent)
(Sample Type enabled to be sent)

H – Header record
P – Patient information (demographics)
O – Order (sample information)
R – Result record
C – Result Comment if any
L – Terminator record

```
H|\^&|||Panther|||||LISHost||P|1|
P|1|PatID01|||Meier^Anna^||1974100123|F|||||MARTINEZ|||^|^|||||||||||||||^|^|
O|1|SAMPLE01|C35B802B-B4F9-400A-9409-1FAB9D736C8D^1234^000937-20120829-02
      |^^^Babesia^Babesia^^1|R|20100506123145|||||||011844114431122500250^01164411443
  1122500350|| Specimen||||||||||F|46000001311225600^20120506
R|1|^^^Babesia^ICRLU^^1|173742||5|||F||admin||20141016055823|4.17.4
R|2|^^^Babesia^ICInterpretation^^1|Valid||5|||F||admin||20141016055823|4.17.4
R|3|^^^Babesia^AnalyteRLU^^1|1325659||5|||F||admin||20141016055823|4.17.4
R|4|^^^Babesia^AnalyteSCO^^1|32.48||5|||F||admin||20141016055823|4.17.4
R|5|^^^Babesia^OverallInterpretation^^1|Reactive||5|||F||admin||20141016055823|4.17.4
R|6|^^^Babesia^AnalyteCutoff^^1|100000||5|||F||admin||20141016055823|4.17.4
R|7|^^^Babesia^ICCutoff^^1|100000||5|||F||admin||20141016055823|4.17.4
R|8|^^^Babesia^KineticIndex^^1|10||5|||F||admin||20141016055823|4.17.4
L|1|N
```

6. Communication Setup

6.1. Network Connection

For redundancy, the Panther System is equipped with two standard network interface cards (NICs) supporting Ethernet protocol. Whenever a Panther System is required to connect to a client's network, an optional Hologic configured hardware firewall and a windows firewall will be utilized to provide security between the Panther System and the client network.

To support LIS functionality, both firewalls will be configured to allow the Panther System to communicate with the LIS system, via a local administrator specified static IP address and a TCP Port number.

6.2. Instrument Setup

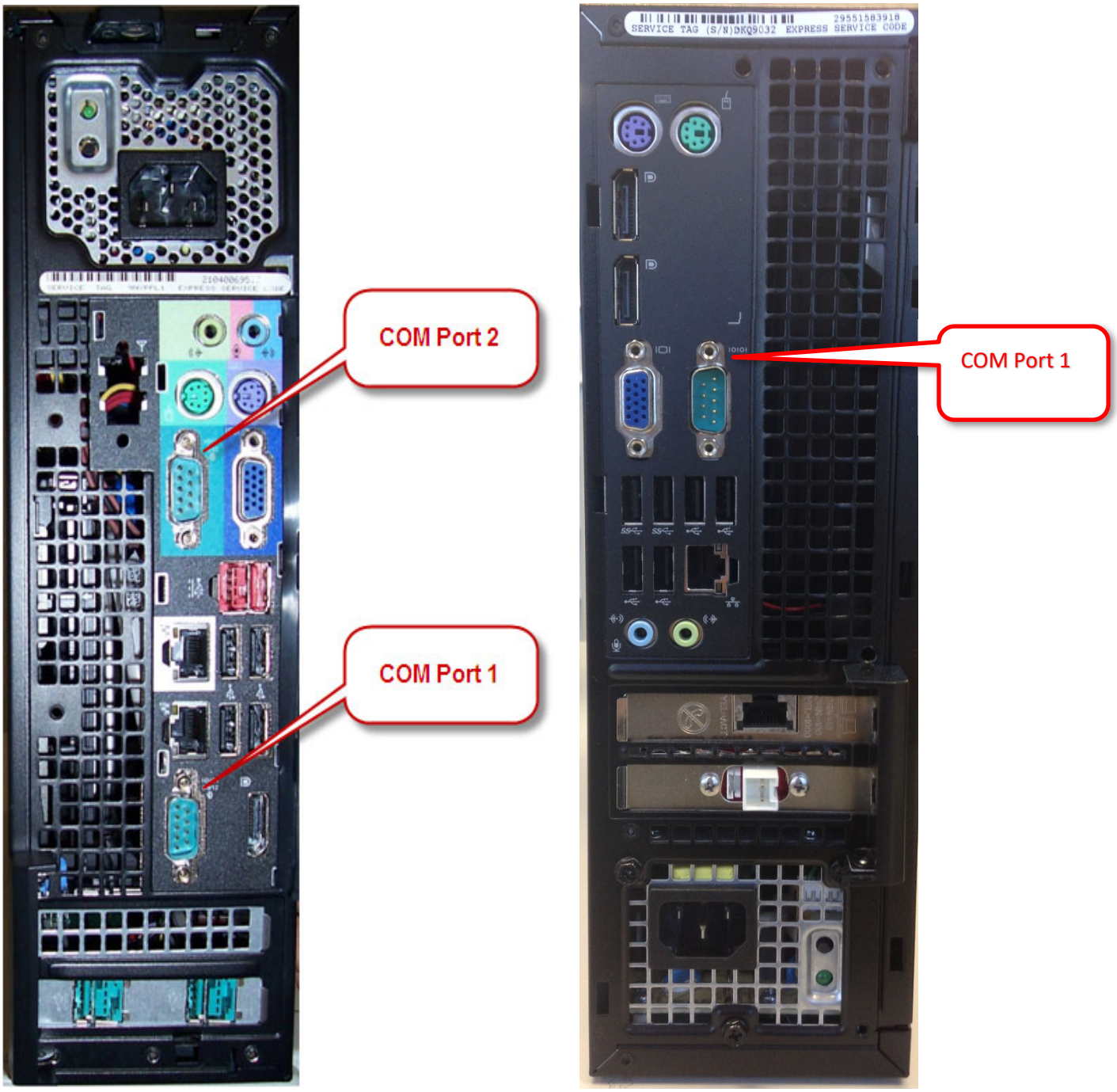
The physical connection adheres to the CLSI LIS1-A standards. The method of data transmission is serial bit by bit. The connection utilizes a configurable serial port of the Panther system workstation.

The Panther system port is a nine-pin male connection with a standard RS232 configuration. It is connected to the back of the Panther system workstation CPU and is labeled COM Port2.
The communication protocol for data transfer adheres to the CLSI LIS1-A standard.

The Panther system strictly adheres to sections 6.2.7.1 and 8.2.7.1 of the LIS1-A standard. These two sections deal with the subject of contention. Both sections state that the LIS server must give priority to the Panther when there is a line contention.

Wiring and Signal to Pin Configuration for the Panther system LIS COM port and Connector

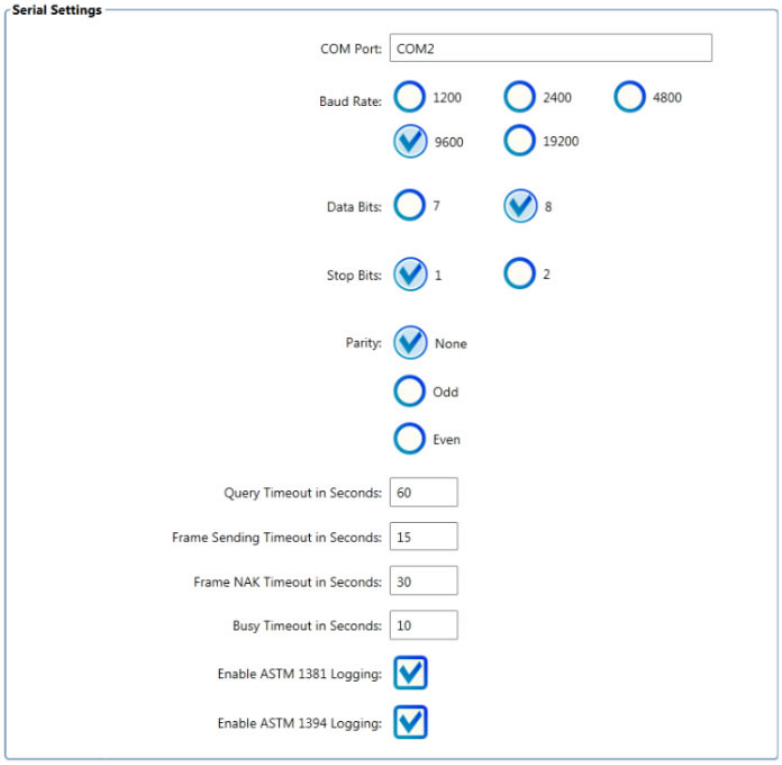
Description	Signal	9 Pin DTE	Usage	Comments
(shield)		1		No termination at LIS end
Receive Data	RD	2	Must	From LIS to Panther System
Transmit Data	TD	3	Must	From Panther System to LIS
Data Terminal Ready	DTR	4	Optional	Jumper to DSR (Pin 6)
Signal Ground	SG/GND	5	Must	
Data Set Ready	DSR	6	Optional	
Request to Send	RTS	7	Optional	Jumper to CTS (Pin 8)
Clear to Send	CTS	8	Optional	
		9		


COM Port 2
COM Port 1
COM Port 1

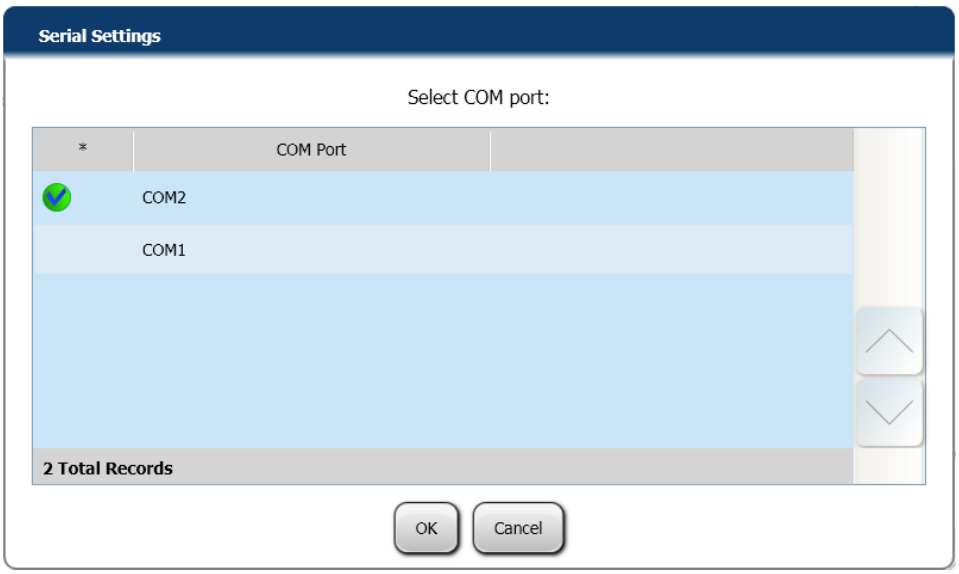

COM Port 1

7. LIS Configuration

7.1. LIS Serial Interface

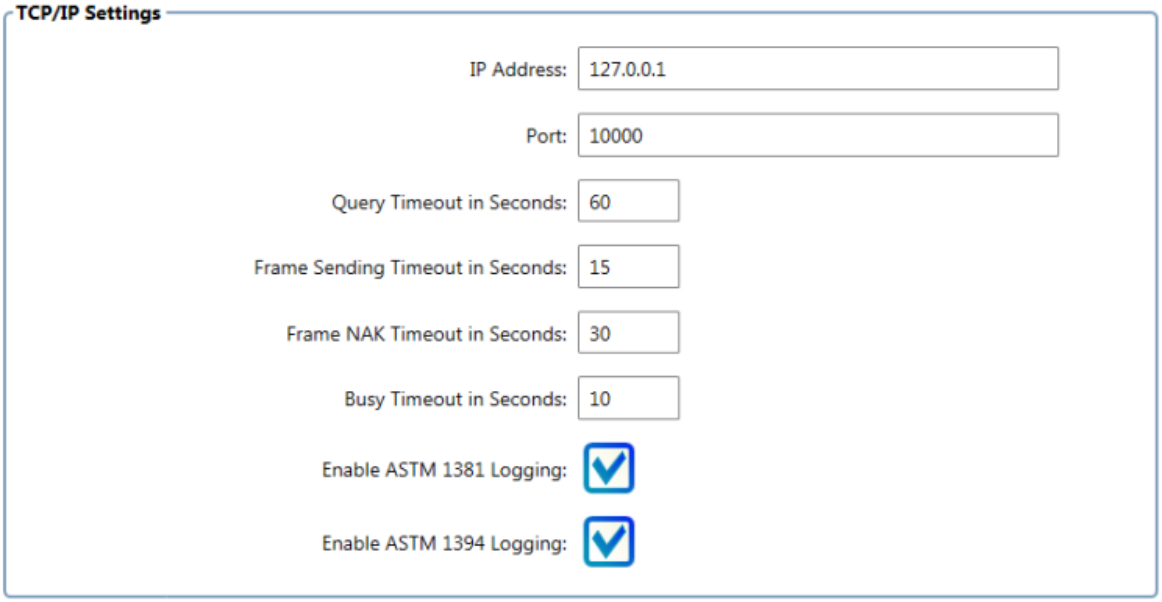


LIS Configuration Screen for Serial Interface



Serial COM Port Selection Screen

7.2. LIS TCP/IP Configuration

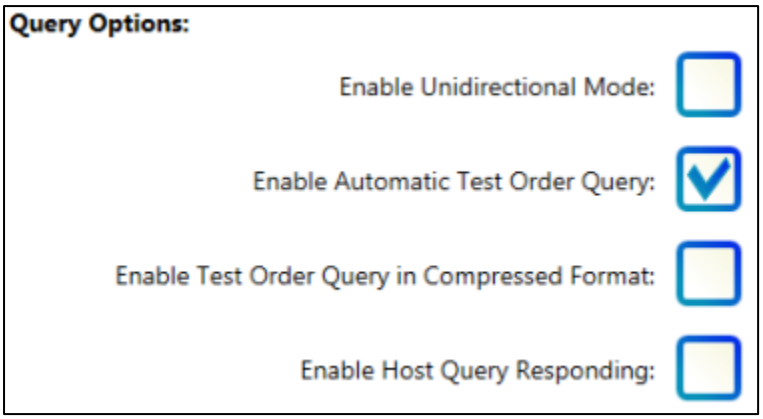


LIS Configuration Screen for TCP/IP Interface

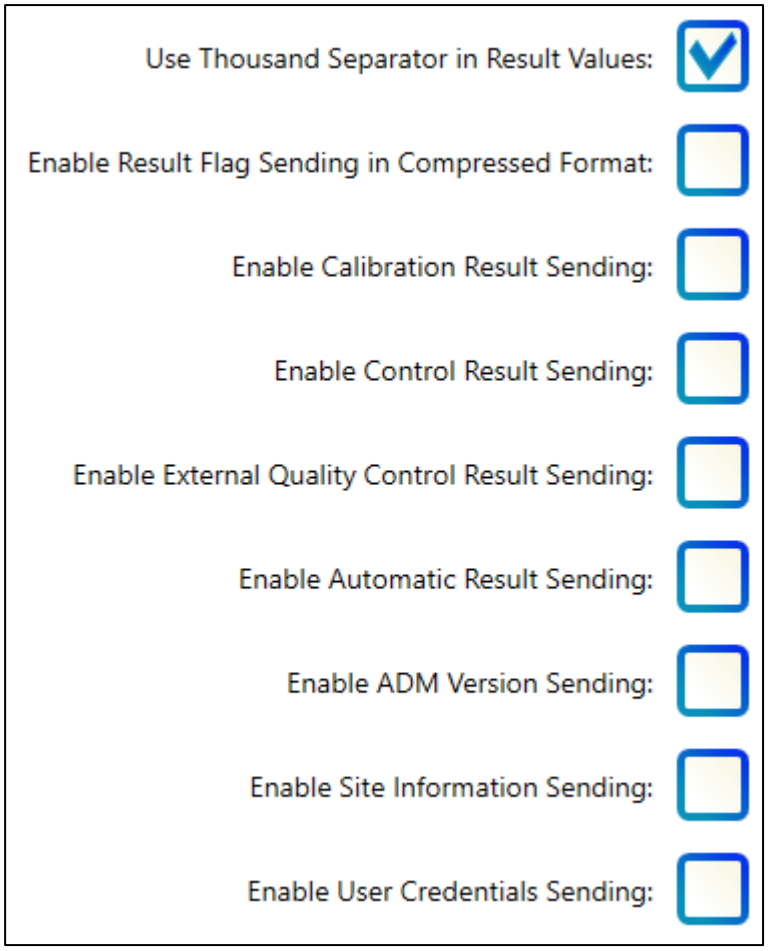
7.3. LIS File Transfer Configuration

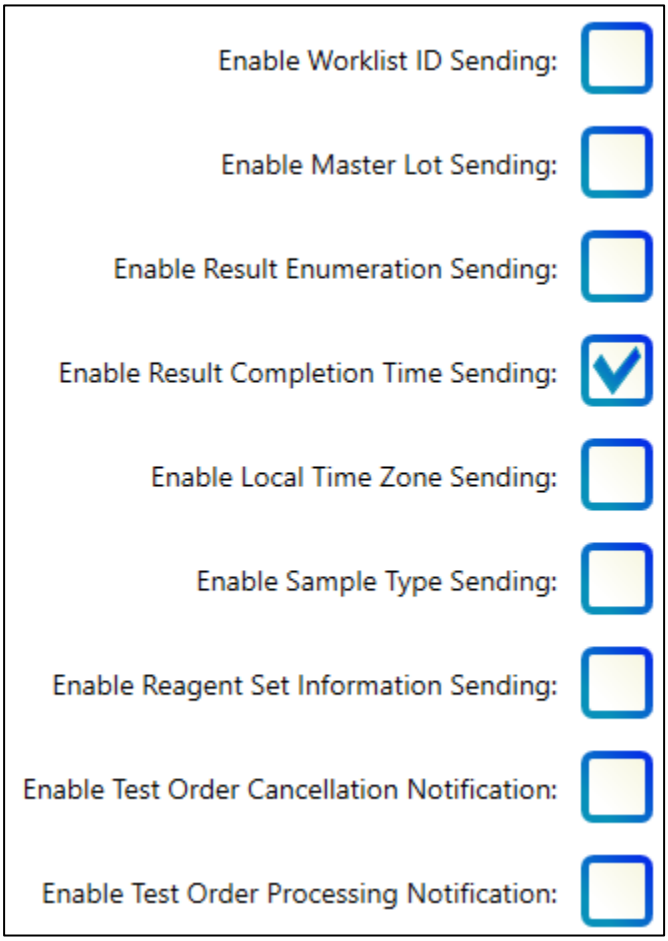
LIS Configuration Screen for File Transfer Interface

7.4. LIS Query Options

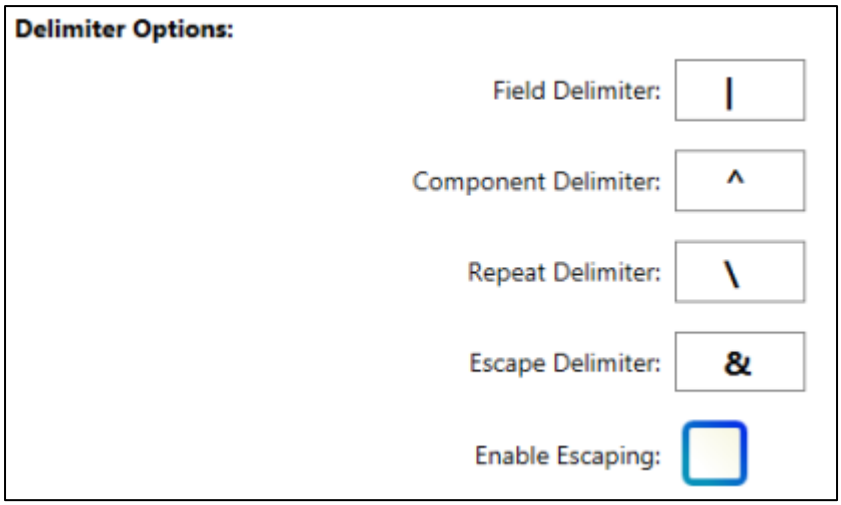


7.5. LIS Send Options



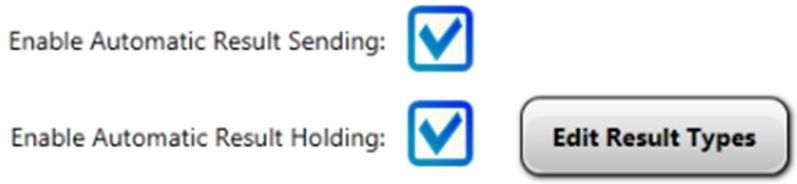


7.6. LIS Delimiter Options

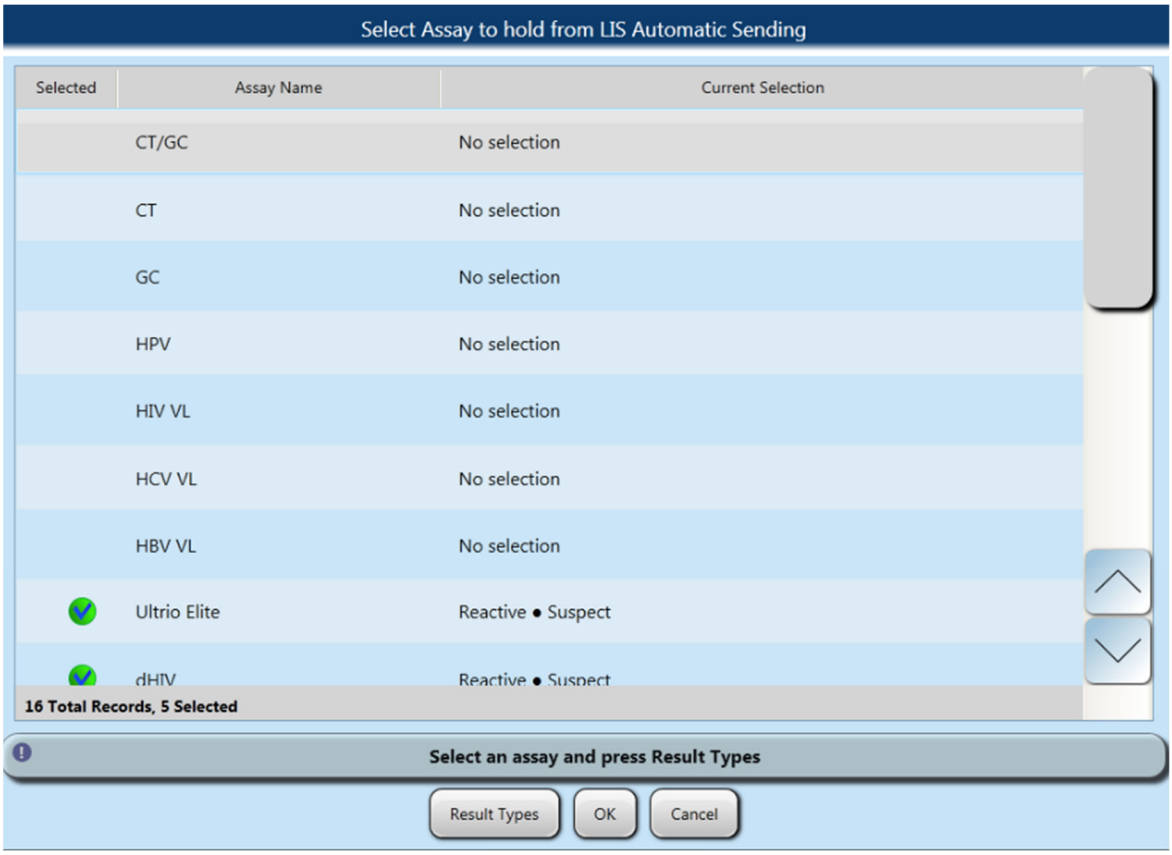


7.7. Automatic Result Holding Feature

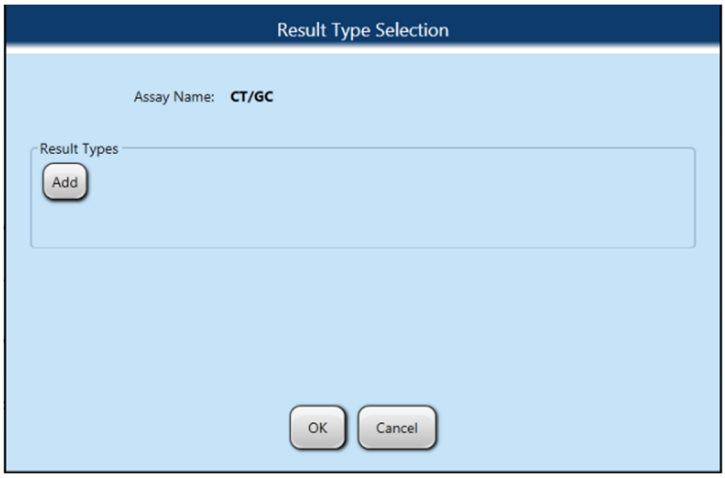
When Automatic Result Sending is enabled the option for Automatic Result Holding appears. When enabled the Edit Result Types button appears.



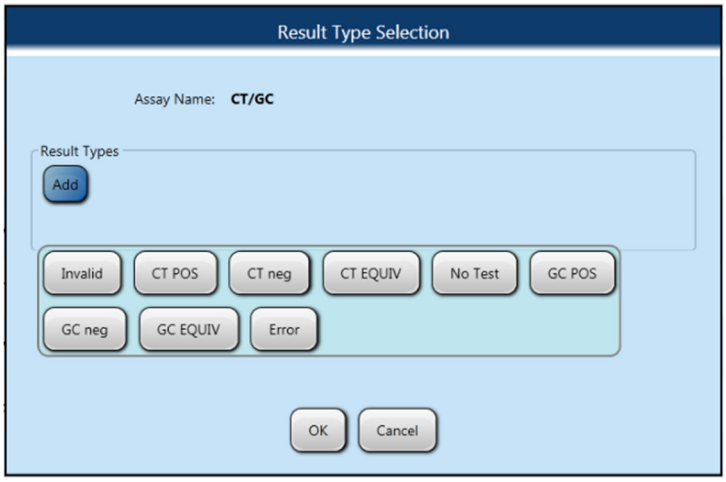
Enable Automatic Result Holding Option



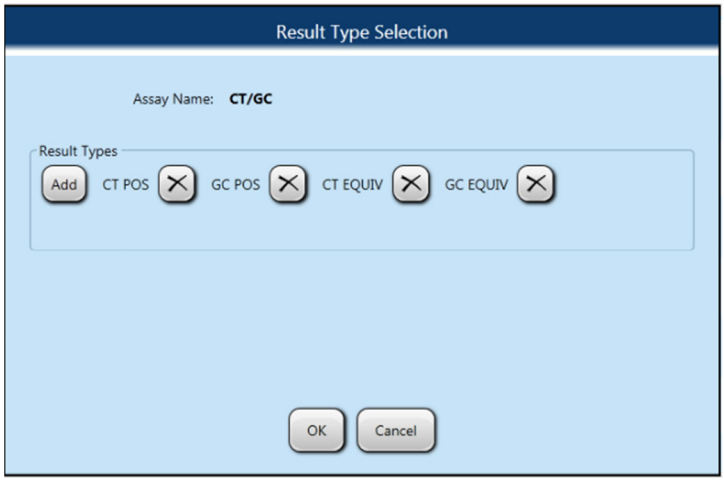
Result Holding Main Window



Result Type Selection Main Window



Result Types to Select



Selected Result Types

7.8. LIS Configuration Parameters

#	Item	Range	Description
1	**Enable LIS Connection**	Checked/unchecked.	Check to Enable LIS Connection.
2	**Interface Layer**	Serial (RS232) TCP/IP File Transfer	Choose the Interface.
3	**InstrumentID**	Name of Panther system	This field allows assigning a unique InstrumentID to the Panther system. It is used to verify that a transmission is intended for the Panther system.
4	**HostID**	Name of LIS Host	Enter Name for your LIS Host
		Query Options	
5	**Enable Unidirectional Mode**	Default is unchecked Check to enable	Panther system transmits results to LIS only. No downloading from LIS or query use.
6	**Enable automatic Test Order Query**	Default is unchecked Check to enable	Panther system will generate query messages during sample loading to query test orders for barcoded patient samples.
7	**Enable automatic Test Order Query in compressed mode**	Default is unchecked Check to enable	The query for test orders will be generated using repeat delimiters.
8	**Enable Host Query Responding**	Default is unchecked Check to enable	If selected, Panther system will respond to queries for results.
		Send Options	
9	**Use Thousand Separator in Result Values**	Default is checked Check to enable	If checked, result interpretations will contain a thousand separator
10	**Enable Result Flag Sending in a Compressed Format**	Default is unchecked Check to enable	If checked, the result comment record is generated using repeat delimiters.
11	**Enable Calibration Result sending**	Default is unchecked Check to enable	If checked, Calibration results will be transmitted to LIS.
12	**Enable Control Result sending.**	Default is unchecked Check to enable	If checked, Control results will be transmitted to LIS.

#	Item	Range	Description
13	**Enable External Quality Control Result Sending**	Default is unchecked Check to enable	If checked, quality control results can be sent.
14	**Enable Automatic Result Sending**	Default is unchecked Check to enable	If checked, results are transmitted automatically as they are generated.
15	**Enable Automatic Result Holding**	Default is unchecked Enable Automatic Result Sending to configure Check to enable	If checked and configured only certain result types are held for review.
16	**Enable ADM Version Sending**	Default is unchecked Check to enable	If checked, the assay definition version will be sent.
17	**Enable Site Information Sending**	Default is unchecked Check to enable	If checked, site information configured under Admin settings will be sent.
18	**Enable User Credentials Sending**	Default is unchecked Check to enable	If checked, the user credentials of the operator whom created the test order will be sent.
19	**Enable Worklist ID Sending**	Default is unchecked Check to enable	If checked, the Worklist ID will be sent.
20	**Enable Master Lot Sending**	Default is unchecked Check to enable	If checked, the Master Lot barcode and expiration will be sent.
21	**Enable Result Enumeration Sending**	Default is unchecked Check to enable	If checked, the position in the worklist will be sent.
22	**Enable Result Completion Time Sending**	Default is checked Check to enable	If checked, the result completion time will be sent.
23	**Enable Local Time Zone Sending**	Default is unchecked Check to enable	If checked, the result completed time zone will be in local time.
24	**Enable Sample Type Sending**	Default is unchecked Check to enable	If checked, the type of sample (specimen, calibrator, control, etc.) will be sent.
25	**Enable Reagent Set Information Sending**	Default is unchecked Check to enable	If checked, the Amp and Probe barcode will be sent.
26	**Enable Test Order Cancellation Notification**	Default is unchecked Check to enable	If checked, the system will respond to cancel notifications if the test order could not be cancelled.
27	**Enable Test Order Processing Notification**	Default is unchecked Check to enable	If checked, the system will send notifications if a test order is processing or did not get processed.

#	Item	Range	Description
		Delimiter Options	
28	**Delimiters**	4 characters, default is |\^& | is the default Field delimiter \ is the default repeat delimiter ^ is the default component delimiter & is the default escape delimiter	The delimiters used for outgoing messages. Incoming messages may have different delimiters.
29	**Enable Escaping**	Default is unchecked Check to enable	If checked, the system will escape characters as defined within the ASTM 1394 protocol.
		Other Information –	
30	**DateTemplate**	YYYYMMDD default	Dates will be recorded in the YYYYMMDD format as required in the ASTM1394 standard.
31	**TimeTemplate**	HHMMSS default	Times will be recorded in the HHMMSS format as required in the ASTM1394 standard.
32	**LIS Directory**	C:\Panther\Software\PC\Bin\Output\LIS	Where LIS files are stored.
33	**LOG Directory**	C:\Panther\Software\PC\Bin\Output\LIS\LOG	Protocol files of data transmitted on ASTM1381 and 1394 protocols will be logged in this directory.
		Serial Settings	
34	**COM Port**	COM1, or COM2 only COM3 is the instrument connection, do not use for LIS. Enter COM Port	This field specifies the serial port used for host transmissions.
35	**BaudRate**	Select Baud Rate 19200, 9600, 4800, 2400 or 1200 Default is 9600	Specifies the Baud rate used for transmissions between the Panther system and the host.
36	**Data Bits**	7 or 8 Default is 8	Overwrites the ASTM1381 requirements.
37	**StopBits**	0 or 1 Default is 1	Overwrites the ASTM1381 requirements.
38	**Parity**	Even, Odd or None Default is None	Overwrites the ASTM1381 requirements.

#	Item	Range	Description
		Time Out Settings	
39	**Query Timeout in seconds**	Range 30-300 Default 60s	Within <Timeout> seconds the Panther system expects a response to a query message sent to the host. If the LIS system does not respond to Panther's query within the <Timeout> seconds, Panther sends the next Query message.
40	**Frame Sending Timeout in Seconds**	15-60 Default is 15 seconds	Overwrites the ASTM1381 "Send Frame Timer"
41	**Frame <NAK> Timeout in Seconds**	Range 30-60 Default is 30 seconds	Overwrites the ASTM1381 "Bad Frame Send <NAK> Timer"
42	**Busy Timeout in Seconds**	Range 10-300 Default 10 seconds	Overwrites the ASTM1381 "Busy Timer"
		TCP-IP Settings	
43	**IP Address**	For example: 10.3.77.47	The IP address of the host computer system, obtain from host system
44	**Port Number**	Typically 10,000 or greater	The port number of the host computer system obtain from host system
		File Transfer Folders	
45	**LIS Sending Directory**	C:\Panther\Software\PC\Bin\Output\LIS\send	Default Directory on Panther system for messages sent to LIS. Not designed for customer use.
		LIS Logging Options	
46	**Enabling Logging Of ASTM 1381 LIS transactions.**	Default is unchecked Check to enable	Lower Level Protocol.
47	**Enabling Logging Of ASTM 1394 LIS transactions.**	Default is unchecked Check to enable	Higher Level Protocol.

8. Troubleshooting

When an issue is observed with LIS communication, ASTM 1381 and ASTM 1394 logging should be enabled in the Panther LIS Configuration screen. A user account with administrative privileges will be needed for the options to appear. The scenario for which the issue was observed should be repeated to capture the LIS communication in the logs.

For Hologic customers in Europe, please contact EU Technical Support at +49 6122 7076 451 or by e-mail at technicalsupport@gen-probe.eu.

For Hologic customers outside of Europe, please contact Hologic Technical Support at +1 888 484 4747 or 1 858 410 8511 or by e-mail at molecularsupport@hologic.com.

8.1. Panther System Event Log Error Messages for LIS.

- Event ID 272.000.00002, **LIS: Cannot establish connection.**
    - The Panther was unable to establish the initial connection to the LIS server.
- Event ID 272.000.00003, **LIS: The connection to the host was lost.**
    - The Panther lost connection with the LIS server.
- Event ID 272.000.00005, **Structure of message received from LIS was incorrect.**
    - The structure or framing of the ASTM records received by Panther is incorrect. Recommend to review section 3.1 for structure issues.
- Event ID 272.000.00006, **Error while transmitting data to LIS.**
    - During results transfer to the LIS there was a connection issue causing the results transfer to fail.
- Event ID 272.000.00007, **Pending results automatically removed from the queue after transmission error.**
    - When a result is chosen to be sent with a status of transmission pending, the Panther will attempt to send the results. If the transfer fails the results will be removed from the transmission queue and will need to be selected again manually for transmission.
- Event ID 272.000.00008**, LIS: System not configured to respond to query for results.**
    - The LIS server queried the Panther for results but, “Enable Host Query Responding” configuration option is not enabled.

- Event ID 272.000.00016, **New LIS Test Order for Sample ID {a} lane {b} position {c}, assay {d}, analytes {e} was detected as a repeat of a Completed test order.**
    - a is the sampleID, b is the lane the rack is loaded in, c is the position the sample is loaded in the rack, d is the assay being ran, and e is the analyte(s). A test order received from the LIS is a repeat.
- Event ID 272.000.00018, **Existing LIS Test Order for Sample ID {a} lane {b} position {c}, assay {d}, analytes {e} was detected as a repeat of a Completed test order.**
    - a is the sampleID, b is the lane the rack is loaded in, c is the position the sample is loaded in the rack, d is the assay being ran, and e is the analyte(s). A pending test order previously received by the LIS is a repeat.
- Event ID 272.000.00020, **LIS order for sample {a} rejected. Test order is not compatible with existing sample dilution.**
    - a is the sampleID. The test order received does not have a compatible dilution.
- Event ID 272.000.00023, **LIS order for sample {a} rejected. LIS test orders that include dilution factors are not accepted by the system.**
    - a is the sampleID. The Panther system is not configured to receive dilution factors from the LIS.
- Event ID 272.000.00024, **Error while receiving data from LIS.**
    - An error occurred while receiving data from the LIS.

8.1. Panther System Error and Status Codes

Under certain conditions the Panther system will respond back to a message with an error or status code listed below.

Code	Description
RJ_badTest	The test code received does not match a valid installed assay name.
RJ_qcSampleId	The SampleID received does not have appropriate QC material.
RJ_badSampleId	The SampleID was empty, too long, or contained invalid characters.
RJ_badDilution	The ordered dilution is not supported by the instrument.
RJ_notMatchingSampleDilution	The ordered dilution does not match with a previously configured dilution for the test order.
RJ_badAnalyte	The specified analyte is not defined for the requested assay.
RJ_wrongInstrument	The InstrumentID in the Header record does not match with the configured InstrumentID in LIS Configuration.
RJ_notProcessed	The test order was not processed by the system.
RJ_processingOrder	The test order has begun processing on the instrument.
RJ_cannotCancel	A cancel request was sent for a test order which cannot be cancelled.
RJ_detectedAsRepeat	The test order was detected as a repeat of a test order already completed on the system.
RJ_otherError	Please contact technical support for troubleshooting regarding this error type.

9. Restrictions and Limitations

As a consequence of the allowed character set specified for ASTM1381 (does not allow transmitting non-ASCII characters), for non-ASCII languages like Japanese or Chinese some information cannot be transmitted (e.g. patient names, demographic information or localized flags or qualitative result labels.)

Hologic advises Panther system customers to use Industry Best Practices regarding patient health information and does not recommend using Patient identifying information in the Sample id field on the Panther system.

The Panther system does not support IEC-8859-1 for Code-128.

Panther system software lower than 5.2 only supports 7-bit ASCII characters (0-127) as shown in the following table.

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

30	1E	RS	62	3E	>	94	5E	^	126	7E	~
31	1F	US	63	3F	?	95	5F	_	127	7F	DEL

System software 5.2 and higher supports 8-bit ASCII characters. The PANTER System can receive local language 8-bit ASCII characters and will return the characters to the LIS without any change.

10. Appendices

10.1. Appendix A - Aptima CT/GC, Aptima TV and Aptima SARSCoV2 Assay Result Processing Flags

Results Processing (RP) flags are added to tubes during result processing by the assay software. RP flags indicate error conditions that occurred during assay calculations and range tests. An example is flasher average is out of range. The RP flags are defined in the assay definition file and are specific to the assay. Each flag is defined by a FlagID and FlagName.

Flag Name	Flag ID	Flag Description
f	1001	Invalid Results Due to Calibration Failure
x	1002	Invalid Results Due to Control Failure
ub	1003	User bracket control failure
p	1004	Assay Processing Error (Pre-invalidated)
e	1005	Data Analysis Error
n	1010	Empty Tube
r	1011	RLUOverLimit
z	1012	A Kinetic Interval is zero
a	1013	Invalid Kinetic Profile - AFitFail
asl	1014	Invalid Kinetic Profile – AslopeLow
ash	1015	Invalid Kinetic Profile - ASlopehigh
arl	1016	Invalid Kinetic Profile - ARsqLow
b	1017	Invalid Kinetic Profile - BFitFail
bsl	1018	Invalid Kinetic Profile - BSlopeLow
bsh	1019	Invalid Kinetic Profile - BSlopeHigh
brl	1020	Invalid Kinetic Profile - BRsqLow
fe	1021	Indeterminate Kinetic Profile – Flasher Equivocal
ge	1022	Indeterminate Kinetic Profile – Glower Equivocal
fge	1023	Indeterminate Kinetic Profile – FlasherGlowerEquivocal
ze	1024	Invalid Kinetic Profile – Zone Invalid
cl	1025	Control Total RLU Below Minimum Limit - ControlRLULow
ch	1026	Control Total RLU Over Maximum Limit - ControlRLUHigh
ci	1027	Control Does Not Have Required Kinetic Profile - ControlZoneInvalid

10.2. Appendix B - APTIMA HPV, GT HPV, Ultrio Elite, dHBV, dHCV, dHIV, HEV, WNV, Dengue, Mgen, Parvo/HAV, and Babesia Assay Result Processing Flags

Results Processing (RP) flags are added to tubes during result processing by the assay software. RP flags indicate error conditions that occurred during assay calculations and range tests. An example is flasher average is out of range. The RP flags are defined in the assay definition file and are specific to the assay. Each flag is defined by a FlagID and FlagName.

Flag Name	Flag ID	Flag Description
f	1001	Invalid Results Due to Calibration Failure
x	1002	Invalid Results Due to Control Failure
p	1004	Assay Processing Error (Pre-invalidated)
e	1005	Data Analysis Error
sl	2010	Slope Out of Range
r	2011	R Squared Out of Range
fb	2012	Front to Back Ratio Out of Range
sp	2013	Spike Detected
fl	2014	Calibrator Flasher Out of Range
g	2015	Results interpretation Error
t	2016	RLU Total Out of Range
pn	2017	Negative Calibrator Peak Out of Range
pp	2018	Positive Calibrator Peak Out of Range
af	2019	Post KI Adjustment Flasher Out of Range for Cal/Ctrl
ag	2020	Post KI Adjustment Glower Out of Range for Cal/Ctrl
afc	2021	Post KI Adjustment Flasher Above Cutoff
agc	2022	Post KI Adjustment Glower Above Cutoff
ts	2023	Invalid calculation occurred, contact tech service.
m	2024	Early Maximum Allowable RLU
ic	2025	Invalid Sample Crossover
cv	2026	%CV Out of Range
fa	2027	Flasher Avg Out of Range
ga	2028	Glower Avg Out of Range
ta	2029	Total Avg Out of Range
ts	2030	Invalid Calculation

10.3. Appendix C – HSV 1&2, AdV/hMPV/RV, Flu A/B/RSV, Paraflu, MRSA, GBS and Bordetella Assay Result Processing Flags

Results Processing (RP) flags are added to tubes during result processing by the assay software. RP flags indicate error conditions that occurred during assay calculations and range tests. An example is flasher average is out of range. The RP flags are defined in the assay definition file and are specific to the assay. Each flag is defined by a FlagID and FlagName.

Flag Name	Flag ID	Flag Description
x	1002	Invalid Results Due to Control Failure
p	1004	Assay Processing Error (Pre-invalidated)
e	1005	Data Analysis Error

10.4. Appendix D – qHBV, qHCV, and qHIV-1 Assay Result Processing Flags

Results Processing (RP) flags are added to tubes during result processing by the assay software. RP flags indicate error conditions that occurred during assay calculations and range tests. An example is flasher average is out of range. The RP flags are defined in the assay definition file and are specific to the assay. Each flag is defined by a FlagID and FlagName.

Flag Name	Flag ID	Flag Description
f	1001	Invalid Results Due to Calibration Failure
x	1002	Invalid Results Due to Control Failure
p	1004	Assay Processing Error (Pre-invalidated)
e	1005	Data Analysis Error
DIL1	1601	Sample is 1:3 diluted
DIL2	1602	Sample is 1:100 diluted
DILC	1600	Sample is custom diluted
t	4001	Analyte emergence time analysis error
rm	4002	Emergence slope analysis error
rwb	4003	IC emergence time analysis error
bcin	4004	Recovery range analysis error
rtf	4005	Fluorescence range analysis error
DBS	1603	Dried Blood Spot

10.5. Appendix E – LDT TMA Assay Result Processing Flag

Results Processing (RP) flags are added to tubes during result processing by the assay software. RP flags indicate error conditions that occurred during assay calculations and range tests. An example is flasher average is out of range. The RP flags are defined in the assay definition file and are specific to the assay. Each flag is defined by a FlagID and FlagName.

Flag Name	Flag ID	Flag Description
v	5001	Value is greater than or equal to user defined cutoff.

10.6. Appendix F – LDT RT TMA Assay Result Processing Flag

Results Processing (RP) flags are added to tubes during result processing by the assay software. RP flags indicate error conditions that occurred during assay calculations and range tests. An example is flasher average is out of range. The RP flags are defined in the assay definition file and are specific to the assay. Each flag is defined by a FlagID and FlagName.

Flag Name	Flag ID	Flag Description
e	1005	Data analysis error
v1	1201	Value met cutoff specification for FAM
v2	1203	Value met cutoff specification for HEX
v3	1205	Value met cutoff specification for ROX
irr1	2201	Irregular Curve for FAM - check curve
irr3	2203	Irregular Curve for HEX - check curve
irr5	2205	Irregular Curve for ROX - check curve

10.7. Appendix G – ZIKV (Aptima and Procleix) Assay Result Processing Flags

Results Processing (RP) flags are added to tubes during result processing by the assay software. RP flags indicate error conditions that occurred during assay calculations and range tests. An example is flasher average is out of range. The RP flags are defined in the assay definition file and are specific to the assay. Each flag is defined by a FlagID and FlagName.

Flag Name	Flag ID	Flag Description
f	1001	Invalid Results Due to Calibration Failure
x	1002	Invalid Results Due to Control Failure
p	1004	Assay Processing Error (Pre-invalidated)
e	1005	Data Analysis Error
sl	2010	Slope Out of Range
r	2011	R Squared Out of Range
fb	2012	Front to Back Ratio Out of Range
sp	2013	Spike Detected
fl	2014	Calibrator Flasher Out of Range
g	2015	Results interpretation Error
t	2016	RLU Total Out of Range
pn	2017	Negative Calibrator Peak Out of Range
pp	2018	Positive Calibrator Peak Out of Range
af	2019	Post KI Adjustment Flasher Out of Range for Cal/Ctrl
ag	2020	Post KI Adjustment Glower Out of Range for Cal/Ctrl
afc	2021	Post KI Adjustment Flasher Above Cutoff
agc	2022	Post KI Adjustment Glower Above Cutoff
ts	2023	Invalid calculation occurred, contact tech service.
m	2024	Early Maximum Allowable RLU
ic	2025	Invalid Sample Crossover
cv	2026	%CV Out of Range
fa	2027	Flasher Avg Out of Range
ga	2028	Glower Avg Out of Range
ta	2029	Total Avg Out of Range
ts	2030	Invalid Calculation
EUA	1099	For Emergency Use Authorization

10.8. Appendix H – BV and CV/TV Assay Result Processing Flags

Results Processing (RP) flags are added to tubes during result processing by the assay software. RP flags indicate error conditions that occurred during assay calculations and range tests. An example is flasher average is out of range. The RP flags are defined in the assay definition file and are specific to the assay. Each flag is defined by a FlagID and FlagName.

Flag Name	Flag ID	Flag Description
f	1001	Invalid Results Due to Calibration Failure
x	1002	Invalid Results Due to Control Failure
p	1004	Assay Processing Error (Pre-invalidated)
e	1005	Data Analysis Error
ebl	2001	Calculated estimated baseline is below the threshold value
ebh	2002	Calculated estimated baseline is above the threshold value
cce	2003	Calibration Channel Error

10.9. Appendix I – qCMV Assay Result Processing Flags

Flag Name	Flag ID	Flag Description
f	1001	Invalid Results Due to Calibration Failure
x	1002	Invalid Results Due to Control Failure
p	1004	Assay Processing Error (Pre-invalidated)
e	1005	Data Analysis Error
DILC	1600	Sample is custom diluted
DIL1	1601	Sample is 1:3 diluted
DIL2	1602	Sample is 1:100 diluted
WB	1603	Whole Blood
ebl	2001	Calculated estimated baseline is below the threshold value
ebh	2002	Calculated estimated baseline is above the threshold value
t	4001	Analyte emergence time analysis error
rm	4002	Emergence slope analysis error
rwb	4003	IC emergence time analysis error
bcin	4004	Recovery range analysis error
rtf	4005	Fluorescence range analysis error

10.10. Appendix J – Ultrioplex E Assay Result Processing Flags

Results Processing (RP) flags are added to tubes during result processing by the assay software. RP flags indicate error conditions that occurred during assay calculations and range tests. An example is flasher average is out of range. The RP flags are defined in the assay definition file and are specific to the assay. Each flag is defined by a FlagID and FlagName.

Flag Name	Flag ID	Flag Description
f	1001	Invalid Results Due to Calibration Failure
x	1002	Invalid Results Due to Control Failure
p	1004	Assay Processing Error (Pre-invalidated)
e	1004	Data Analysis Error
sl	1010	Data Analysis Error
r	1004	Data Analysis Error
fb	1012	Data Analysis Error
sp	1013	Data Analysis Error
fl	1004	Results interpretation Error
g	1004	Results interpretation Error
t	1004	Results interpretation Error
pn	1017	Data Analysis Error
pp	1018	Data Analysis Error
af	1004	Results interpretation Error
ag	1004	Results interpretation Error
afc	1004	Results interpretation Error
agc	1004	Results interpretation Error
ts	1004	Invalid calculation occurred, contact tech service.
m	1004	Results interpretation Error
ic	1004	Results interpretation Error
cv	1004	Results interpretation Error
fa	1004	Results interpretation Error
ga	1004	Results interpretation Error
ta	1004	Results interpretation Error
ts	1004	Invalid Calculation
inh	1004	Sample inhibited
bkg	1004	Background test failed
c	1004	Calibrator or Control Outlier Z-test failed
d	2004	Incalculable low concentration
erh	2005	Incalculable high concentration
orh	2006	Out-of-range high
orl	2007	Below limit of quantitation
h	1004	Insufficient number of valid specimen replicates

Flag Name	Flag ID	Flag Description
cvh	1004	Specimen %CV high
cvl	1004	Specimen %CV low
ts	1004	Invalid calculation occurred, contact Tech. Service
ts	1004	Invalid calculation occurred, contact Tech. Service
cec	2008	Concentration equal to or exceeded cutoff
cqf	1004	Control quantitation out of range
p	1004	Assay processing error

10.11. Appendix K – dpHBV, dpHCV, dpHIV and Procleix SARS-CoV-2 Assay Result Processing Flags

Results Processing (RP) flags are added to tubes during result processing by the assay software. RP flags indicate error conditions that occurred during assay calculations and range tests. An example is flasher average is out of range. The RP flags are defined in the assay definition file and are specific to the assay. Each flag is defined by a FlagID and FlagName.

Flag Name	Flag ID	Flag Description
f	1001	Calibration failed
x	1002	Control invalidated
p	1004	Assay Processing Error
e	1004	Data Analysis Error
sl	1010	Data Analysis Error
r	1004	Data Analysis Error
fb	1012	Data Analysis Error
sp	1013	Data Analysis Error
fl	1004	Results Interpretation Error
g	1004	Results Interpretation Error
t	1004	Results Interpretation Error
pn	1017	Data Analysis Error
pp	1018	Data Analysis Error
af	1004	Results Interpretation Error
ag	1004	Results Interpretation Error
afc	1004	Results Interpretation Error
agc	1004	Results Interpretation Error
ts	1004	Invalid calculation occurred
m	1004	Results Interpretation Error
ic	1004	Results Interpretation Error
cv	1004	Results Interpretation Error
fa	1004	Results Interpretation Error
ga	1004	Results Interpretation Error
ta	1004	Results Interpretation Error
ts	1004	Invalid Calculation Occurred

10.12. Appendix L – General Assay Processing Flags

Flag	Flag ID	Applied
APV	1	The Assay Processes Verifier (APV) detected an issue with the assay process.
ARR	105	Assay reagent pipetting operation aborted
CLT	79	Clot detected.
CPF	7	Cap pierce failure
FDF1	8	Oil pump dispense failure detected
FDF3	10	Auto Detect1 pump dispense failure detected
FDF4	11	Auto Detect2 pump dispense failure detected
FW	?	Firmware
HB	12	High background detected at the luminometer
IDF	114	Incubator door failure
IFF1	110	Incubator fan failure incubator 1
IFF2	111	Incubator fan failure incubator 2
IFF3	112	Incubator fan failure incubator 3
IHF1	92	Incubator heater foil failure incubator 1
IHF2	93	Incubator heater foil failure incubator 2
IHF3	94	Incubator heater foil failure incubator 3
IT1	49	Incubator 1 temperature was out of range
IT2	50	Incubator 2 temperature was out of range
IT3	51	Incubator 3 temperature was out of range
ITF1	107	Incubator 1 dual thermistors have exceeded allowable range.
ITF2	108	Incubator 2 dual thermistors have exceeded allowable range.
ITF3	109	Incubator 3 dual thermistors have exceeded allowable range.
IUO	14	The replicate was tested using an assay installed as investigational use only.
LDF	16	Luminometer read delay failure.
LSF	101	Load station heater foil failure
LWF	85	Liquid waste container full.
M	17	Sample ID of a new test request was manually entered via the keyboard when a barcode was not readable by the instrument.
MFM	113	Movement failure mag wash magnet
ML1	20	Mag wash failed a fluid level check due to fluid present at the residual position after TCR/Sample has been aspirated
ML2	21	Mag wash failed a fluid level check due to fluid height too high after wash buffer has been dispensed.
ML3	22	Mag wash failed a fluid level check due to fluid height too low after wash buffer has been dispensed.
ML5	24	Mag wash failed a fluid level check due to fluid present at the residual sense position after the wash buffer has been aspirated on the last wash

Flag	Flag ID	Applied
MT1	25	1 or more tiplets are not present on the aspirators at the start of the Mag Wash operation
MOS	106	Mag Wash station taken out of service
NTI	28	The system did not test this sample due to a fatal hardware error
NTP	77	No pipettor tips available
PCL1	71	ProcessControlFailure for AutoDetect1
PCL2	72	ProcessControlFailure for AutoDetect1
PCO	84	Process Control check failed for oil – Pump Monitor
PEO	89	The replicate was tested using an assay installed as performance evaluation only.
PFR	80	Pump failure during reagent pipetting
PFS	29	Pump failure during specimen pipetting (aspirate or dispense process)
PFT	30	Pump failure during TCR pipetting (aspirate or dispense process)
PMFR	81	Pipettor Movement failure during reagent pipetting (Stratec)
PMFS	19	Pipettor movement failure during specimen pipetting
PMFT	18	Pipettor movement failure during TCR pipetting
PTF	48	Failure to pick a tip
QNS	78	Quantity not sufficient
RBEA	116	Amp Reagent Bottle Empty
RBEE	117	Enzyme Reagent Bottle Empty
RBEP	118	Probe Reagent Bottle Empty
RBESL	119	Selection Reagent Bottle Empty
RBET	120	TCR Reagent Bottle Empty
RBETR	121	TER Reagent Bottle Empty
RDFP	39	RDV indicated a failure during dispensing of Probe reagent.
RDFA	37	RDV indicated a failure during dispensing of Amplification reagent.
RDFE	38	RDV indicated a failure during dispensing of Enzyme reagent.
RDFSL	40	RDV indicated a failure during dispensing of Selection reagent.
RDFT	41	Reagent dispense failure during dispense of TCR reagent
RDFTR	70	Reagent dispense failure during dispense of TER reagent
RT	122	Repeat Sample Barcode – sample accepted by the user for repeat testing.
RTL	76	Reagent pipettor tip loss
RVHA	60	Amp reagent bottle above the expected volume.
RVHE	61	Enzyme reagent bottle above the expected volume.
RVHP	62	Probe reagent bottle above the expected volume.
RVHSL	63	Select reagent bottle above the expected volume.
RVHT	67	TCR reagent bottle above the expected volume.
RVHTR	68	TER reagent bottle above the expected volume.
S	45	Sample ID of a new test request was manually entered via the handheld scanner when a barcode was not readable by the instrument.

Flag	Flag ID	Applied
SID	46	The system assigned a default specimen ID. The system is configured not to require the user to fix unreadable barcodes, so the system generated an ID and assigned it to the specimen.
SRR	103	Sample pipetting operation aborted
STL	75	Sample pipettor tip loss
SW	59	System experienced software error, including the following: Software is unable to load the data reduction assembly specified in the assay XML file. There is no kinetic collected for the test and an NTI flag was not applied to the test. Test order integrity check failure.
TC	52	Chiller temperature was out of range
TLS	74	The temperature of the load station was out of range
TRC	64	Reagent bay temperature is out of range.
UMTU	66	An unexpected MTU has been placed in the luminometer.
URM2	56	The MTU barcode is unreadable at the barcode scanner prior to entering the luminometer
VACF	115	Vacuum system failure
VVFS	57	LLS measurement of TCR/Sample in MTU tube falls outside than expected volume
VVFT	58	LLS measurement of TCR in MTU tube falls outside (i.e. higher or lower) than expected volume. TCR volume check out of assay defined range.

10.13. Appendix M – Upload and Download Codes

10.13.1. Table 3A - Assays (Tests)

Assay Long Name	Assay Short Name
AdV/hMPV/RV	AdV/hMPV/RV
AptimaCombo2	CT/GC
AptimaCT	CT
AptimaGC	GC
AptimaTV	TRICH
Babesia	Babesia
Bordetella	Bordetella
BV	BV
CV/TV	CV/TV
Dengue	DENV
dHBV	dHBV
dHCV	dHCV
dHIV	dHIV
dpHBV	dpHBV
dpHCV	dpHCV
dpHIV	dpHIV
Flu A/B/RSV	Flu A/B/RSV
GBS	GBS
GT HPV	GT HPV
HEV	HEV
HPV	HPV
HSV 1&2	HSV 1&2
LDT RT TMA-1	LDT RT TMA-1
LDT RT TMA-2	LDT RT TMA-2
LDT RT TMA-3	LDT RT TMA-3
LDT TMA-1	LDT TMA-1
LDT TMA-2	LDT TMA-2
LDT TMA-3	LDT TMA-3
LDT-SARS-CoV-2	LDT-SARS-CoV-2
M gen	M gen
MRSA	MRSA
Paraflu	Paraflu
Parvo/HAV	Parvo/HAV
qCMV	qCMV
qHBV	qHBV

qHCV	qHCV
qHIV-1	qHIV-1
SARSCoV2	SARSCoV2
SARS-CoV-2	SARS-CoV-2
Ultrio Elite	Ultrio Elite
UltrioPlex E	UltrioPlex E
WNV	WNV
ZIKV	ZIKV

10.13.2. Table 4A - Analytes

Assay Long Name	Assay Short Name	Analyte Name
AdV/hMPV/RV	AdV/hMPV/RV	AdV
AdV/hMPV/RV	AdV/hMPV/RV	hMPV
AdV/hMPV/RV	AdV/hMPV/RV	RV
Aptima TV	TRICH	TRICH
AptimaCombo2	CT/GC	CT
AptimaCombo2	CT/GC	GC
AptimaCT	CT	CT
AptimaGC	GC	GC
Babesia	Babesia	Babesia
Bordetella	Bordetella	Pertussis
Bordetella	Bordetella	Parapertussis
BV	BV	BV
CV/TV	CV/TV	CV
CV/TV	CV/TV	TV
Dengue	DENV	DENV
dHBV	dHBV	HBV
dHCV	dHCV	HCV
dHIV	dHIV	HIV
dpHBV	dpHBV	HBV
dpHCV	dpHCV	HCV
dpHIV	dpHIV	HIV
Flu A/B/RSV	Flu A/B/RSV	Flu A
Flu A/B/RSV	Flu A/B/RSV	Flu B
Flu A/B/RSV	Flu A/B/RSV	RSV
GBS	GBS	GBS
GT HPV	GT HPV	HPV 16 18/45
HEV	HEV	HEV
HPV	HPV	HPV
HSV 1&2	HSV 1&2	HSV 1&2

LDT RT TMA-x (1,2,3)	LDT RT TMA-x (1,2,3)	LDT RT TMA-x (1,2,3)
LDT TMA-x (1,2,3)	LDT TMA-x (1,2,3)	LDT TMA-x (1,2,3)
LDT-SARS-CoV-2	LDT-SARS-CoV-2	SARS-CoV-2
M gen	M gen	MG
MRSA	MRSA	MRSA
Paraflu	Paraflu	P1
Paraflu	Paraflu	P2
Paraflu	Paraflu	P3
Paraflu	Paraflu	P4
Parvo/HAV	Parvo/HAV	Parvo
Parvo/HAV	Parvo/HAV	Parvo/HAV
qCMV	qCMV	CMV
qHBV	qHBV	HBV
qHCV	qHCV	HCV
qHIV-1	qHIV-1	HIV-1
SARSCoV2	SARSCoV2	SARSCoV2
SARS-CoV-2	SARS-CoV-2	SARS-CoV-2
Ultrio Elite	Ultrio Elite	HIV/HCV/HBV
UltrioPlex E	UltrioPlex E	HEV/HIV/HCV/HBV
WNV	WNV	WNV
ZIKV	ZIKV	ZIKV

10.13.3. Table 5A - Result Categories/Result Aspects

Assay Long Name	Result Category
AdV/hMPV/RV	AdVTCycle
AdV/hMPV/RV	hMPVTCycle
AdV/hMPV/RV	RVTCycle
AdV/hMPV/RV	ICTCycle
AdV/hMPV/RV	AdV
AdV/hMPV/RV	hMPV
AdV/hMPV/RV	RV
AdV/hMPV/RV	IC
AptimaCombo2	CTResult
AptimaCombo2	GCResult
AptimaCombo2	TotalRLU
AptimaCT	CTResult
AptimaCT	TotalRLU
AptimaGC	GCResult
AptimaGC	TotalRLU
AptimaTV	TRICH Result
AptimaTV	Total RLU
Babesia	ICRLU
Babesia	ICInterpretation
Babesia	AnalyteRLU
Babesia	AnalyteSCO
Babesia	OverallInterpretation
Bordetella	BpTCycle
Bordetella	BppTCycle
Bordetella	ICTCycle
Bordetella	Bp
Bordetella	Bpp
Bordetella	IC
BV	BV
CV/TV	Cspp
CV/TV	Cgla
CV/TV	TRICH
Dengue	ICRLU
Dengue	ICInterpretation
Dengue	AnalyteRLU
Dengue	AnalyteSCO
Dengue	OverallInterpretation
dHBV	ICRLU

Assay Long Name	Result Category
dHBV	ICInterpretation
dHBV	AnalyteRLU
dHBV	AnalyteSCO
dHBV	OverallInterpretation
dHCV	ICRLU
dHCV	ICInterpretation
dHCV	AnalyteRLU
dHCV	AnalyteSCO
dHCV	OverallInterpretation
dHIV	ICRLU
dHIV	ICInterpretation
dHIV	AnalyteRLU
dHIV	AnalyteSCO
dHIV	OverallInterpretation
dpHBV	ICRLU
dpHBV	ICInterpretation
dpHBV	AnalyteRLU
dpHBV	AnalyteSCO
dpHBV	OverallInterpretation
dpHCV	ICRLU
dpHCV	ICInterpretation
dpHCV	AnalyteRLU
dpHCV	AnalyteSCO
dpHCV	OverallInterpretation
dpHIV	ICRLU
dpHIV	ICInterpretation
dpHIV	AnalyteRLU
dpHIV	AnalyteSCO
dpHIV	OverallInterpretation
Flu A/B/RSV	FluATCycle
Flu A/B/RSV	FluBTCycle
Flu A/B/RSV	RSVTCycle
Flu A/B/RSV	ICTCycle
Flu A/B/RSV	FluA
Flu A/B/RSV	FluB
Flu A/B/RSV	RSV
Flu A/B/RSV	IC
GBS	GBSTCycle
GBS	ICTCycle

Assay Long Name	Result Category
GBS	GBS
GBS	IC
GT HPV	IC/HPV 16 RLU
GT HPV	HPV 16 S/CO
GT HPV	HPV 16 Result
GT HPV	HPV 18/45 RLU
GT HPV	HPV 18/45 S/CO
GT HPV	HPV 18/45 Result
GT HPV	ICInterpretation
GT HPV	HPV 16 Cutoff
GT HPV	HPV 18/45 Cutoff
GT HPV	IC Cutoff
HEV	ICRLU
HEV	ICInterpretation
HEV	AnalyteRLU
HEV	AnalyteSCO
HEV	OverallInterpretation
HPV	ICInterpretation
HPV	OverallInterpretation
HPV	ICRLU
HPV	AnalyteRLU
HPV	AnalyteSCO
HPV	Analyte Cutoff
HPV	IC Cutoff
HSV 1&2	ICTTime
HSV 1&2	ICResult
HSV 1&2	HSV1TTime
HSV 1&2	HSV-1
HSV 1&2	HSV2TTime
HSV 1&2	HSV-2
LDT RT TMA-x (1,2,3)	Channel1TTime
LDT RT TMA-x (1,2,3)	Channel3TTime
LDT RT TMA-x (1,2,3)	Channel5TTime
LDT RT TMA-x (1,2,3)	Channel1Status
LDT RT TMA-x (1,2,3)	Channel3Status
LDT RT TMA-x (1,2,3)	Channel5Status
LDT TMA-x (1,2,3)	TotalRLU
LDT TMA-x (1,2,3)	Channel1Status
LDT-SARS-CoV-2	SARS-CoV-2TCycle

Assay Long Name	Result Category
LDT-SARS-CoV-2	ICTCycle
LDT-SARS-CoV-2	SARS-CoV-2Result
LDT-SARS-CoV-2	ICResult
M gen	ICRLU
M gen	ICInterpretation
M gen	AnalyteRLU
M gen	AnalyteSCO
M gen	OverallInterpretation
M gen	AnalyteCutoff
M gen	ICCutoff
MRSA	MREJTCycle
MRSA	MECACTCycle
MRSA	GAPDHTCycle
MRSA	ICTCycle
MRSA	MREJ
MRSA	MECAC
MRSA	GAPDH
MRSA	SA
MRSA	MRSA
MRSA	IC
Paraflu	P1TCycle
Paraflu	P2TCycle
Paraflu	P3TCycle
Paraflu	P4TCycle
Paraflu	ICTCycle
Paraflu	P1
Paraflu	P2
Paraflu	P3
Paraflu	P4
Paraflu	IC
Parvo/HAV	ICInterpretation
Parvo/HAV	AnalyteSCO
Parvo/HAV	HAVInterpretation
Parvo/HAV	Parvo
Parvo/HAV	OverallInterpretation
Parvo/HAV	ParvoNumeric
Parvo/HAV	AdjustedFlasherRLU
Parvo/HAV	AdjustedGlowerRLU
qCMV	CMVResult

Assay Long Name	Result Category
qCMV	CMVLogBase10Result
qCMV	ICResult
qCMV	ResultValid
qHBV	HBV
qHBV	ICResult
qHBV	ResultValid
qHBV	HBVLogBase10
qHCV	HCV
qHCV	ICResult
qHCV	ResultValid
qHCV	HCVLogBase10
qHIV-1	HIV-1
qHIV-1	ICResult
qHIV-1	ResultValid
qHIV-1	HIV-1LogBase10
SARS-CoV-2	ICRLU (Procleix Only)
SARS-CoV-2	ICInterpretation (Procleix Only)
SARS-CoV-2	AnalyteRLU (Procleix Only)
SARS-CoV-2	AnalyteSCO (Procleix Only)
SARS-CoV-2	OverallInterpretation (Procleix Only)
SARSCoV2	TotalRLU (Aptima Only)
SARSCoV2	ICResult (Aptima Only)
SARSCoV2	CoVResult (Aptima Only)
Ultrio Elite	ICRLU
Ultrio Elite	ICInterpretation
Ultrio Elite	AnalyteRLU
Ultrio Elite	AnalyteSCO
Ultrio Elite	OverallInterpretation
UltrioPlex E	ICInterpretation
UltrioPlex E	UeRLU
UltrioPlex E	UeSCO
UltrioPlex E	UEInterpretation

Assay Long Name	Result Category
UltrioPlex E	HevSCO
UltrioPlex E	HEVInterpretation
UltrioPlex E	ICHevRLU
WNV	ICRLU
WNV	ICInterpretation
WNV	AnalyteRLU
WNV	AnalyteSCO
WNV	OverallInterpretation
ZIKV	ICRLU
ZIKV	ICInterpretation
ZIKV	AnalyteRLU
ZIKV	AnalyteSCO
ZIKV	OverallInterpretation

10.13.4. Table 6A - Interpretations

Assay Long Name	Result Category	Interpretations
AdV/hMPV/RV	AdVTCycle	Invalid
AdV/hMPV/RV	AdVTCycle	- (No Ct)
AdV/hMPV/RV	AdVTCycle	Ct (threshold cycle)
AdV/hMPV/RV	AdVTCycle	No Test
AdV/hMPV/RV	hMPVTCycle	Invalid
AdV/hMPV/RV	hMPVTCycle	- (No Ct)
AdV/hMPV/RV	hMPVTCycle	Ct (threshold cycle)
AdV/hMPV/RV	hMPVTCycle	No Test
AdV/hMPV/RV	RVTCycle	Invalid
AdV/hMPV/RV	RVTCycle	- (No Ct)
AdV/hMPV/RV	RVTCycle	Ct (threshold cycle)
AdV/hMPV/RV	RVTCycle	No Test
AdV/hMPV/RV	ICTCycle	Invalid
AdV/hMPV/RV	ICTCycle	- (No Ct)
AdV/hMPV/RV	ICTCycle	Ct (threshold cycle)
AdV/hMPV/RV	AdV	Invalid
AdV/hMPV/RV	AdV	AdV neg
AdV/hMPV/RV	AdV	AdV POS
AdV/hMPV/RV	AdV	No Test
AdV/hMPV/RV	hMPV	Invalid
AdV/hMPV/RV	hMPV	hMPV neg
AdV/hMPV/RV	hMPV	hMPV POS
AdV/hMPV/RV	hMPV	No Test
AdV/hMPV/RV	RV	Invalid
AdV/hMPV/RV	RV	RV neg
AdV/hMPV/RV	RV	RV POS
AdV/hMPV/RV	RV	No Test
AdV/hMPV/RV	IC	Invalid
AdV/hMPV/RV	IC	Valid
AptimaCombo2	CTResult	Invalid
AptimaCombo2	CTResult	CT POS
AptimaCombo2	CTResult	CT neg
AptimaCombo2	CTResult	CT EQUIV
AptimaCombo2	CTResult	No Test
AptimaCombo2	GCResult	Invalid
AptimaCombo2	GCResult	GC POS

Assay Long Name	Result Category	Interpretations
AptimaCombo2	GCResult	GC neg
AptimaCombo2	GCResult	GC EQUIV
AptimaCombo2	GCResult	No Test
AptimaCombo2	TotalRLU	Integer Value
AptimaCT	CTResult	Invalid
AptimaCT	CTResult	CT POS
AptimaCT	CTResult	CT neg
AptimaCT	CTResult	CT EQUIV
AptimaCT	TotalRLU	Integer Value
AptimaGC	GCResult	Invalid
AptimaGC	GCResult	GC POS
AptimaGC	GCResult	GC neg
AptimaGC	GCResult	GC EQUIV
AptimaGC	TotalRLU	Integer Value
AptimaTV	TRICH Result	Invalid
AptimaTV	TRICH Result	TRICH POS
AptimaTV	TRICH Result	TRICH neg
AptimaTV	Total RLU	Integer Value
Babesia	ICRLU	Integer Value
Babesia	ICInterpretation	Invalid
Babesia	ICInterpretation	Valid
Babesia	AnalyteRLU	Integer Value
Babesia	AnalyteSCO	Real Value
Babesia	OverallInterpretation	Invalid
Babesia	OverallInterpretation	Valid
Babesia	OverallInterpretation	Nonreactive
Babesia	OverallInterpretation	Reactive
Bordetella	BpTCycle	Invalid
Bordetella	BpTCycle	- (No Ct)
Bordetella	BpTCycle	Ct (threshold cycle)
Bordetella	BppTCycle	Invalid
Bordetella	BppTCycle	- (No Ct)
Bordetella	BppTCycle	Ct (threshold cycle)
Bordetella	ICTCycle	Invalid
Bordetella	ICTCycle	- (No Ct)
Bordetella	ICTCycle	Ct (threshold cycle)
Bordetella	Bp	Invalid
Bordetella	Bp	Bp neg

Assay Long Name	Result Category	Interpretations
Bordetella	Bp	Bp POS
Bordetella	Bpp	Invalid
Bordetella	Bpp	Bpp neg
Bordetella	Bpp	Bpp POS
Bordetella	IC	Invalid
Bordetella	IC	Valid
BV	BV	BV neg
BV	BV	BV POS
BV	BV	Invalid
CV/TV	Cspp	C. spp neg
CV/TV	Cspp	C. spp POS
CV/TV	Cspp	Invalid
CV/TV	Cspp	No Test
CV/TV	Cgla	C. gla neg
CV/TV	Cgla	C. gla POS
CV/TV	Cgla	Invalid
CV/TV	Cgla	No Test
CV/TV	TRICH	TRICH neg
CV/TV	TRICH	TRICH POS
CV/TV	TRICH	Invalid
CV/TV	TRICH	No Test
Dengue	ICRLU	Integer Value
Dengue	ICInterpretation	Valid
Dengue	ICInterpretation	Invalid
Dengue	AnalyteRLU	Integer Value
Dengue	AnalyteSCO	Real Value
Dengue	OverallInterpretation	Valid
Dengue	OverallInterpretation	Invalid
Dengue	OverallInterpretation	Reactive
Dengue	OverallInterpretation	Nonreactive
dHBV	ICRLU	Integer Value
dHBV	ICInterpretation	Valid
dHBV	ICInterpretation	Invalid
dHBV	AnalyteRLU	Integer Value
dHBV	AnalyteSCO	Real Value
dHBV	OverallInterpretation	Valid
dHBV	OverallInterpretation	Invalid
dHBV	OverallInterpretation	Reactive

Assay Long Name	Result Category	Interpretations
dHBV	OverallInterpretation	Nonreactive
dHCV	ICRLU	Integer Value
dHCV	ICInterpretation	Valid
dHCV	ICInterpretation	Invalid
dHCV	AnalyteRLU	Integer Value
dHCV	AnalyteSCO	Real Value
dHCV	OverallInterpretation	Valid
dHCV	OverallInterpretation	Invalid
dHCV	OverallInterpretation	Reactive
dHCV	OverallInterpretation	Nonreactive
dHIV	ICRLU	Integer Value
dHIV	ICInterpretation	Valid
dHIV	ICInterpretation	Invalid
dHIV	AnalyteRLU	Integer Value
dHIV	AnalyteSCO	Real Value
dHIV	OverallInterpretation	Valid
dHIV	OverallInterpretation	Invalid
dHIV	OverallInterpretation	Reactive
dHIV	OverallInterpretation	Nonreactive
dpHBV	ICRLU	Integer Value
dpHBV	ICInterpretation	Valid
dpHBV	ICInterpretation	Invalid
dpHBV	AnalyteRLU	Integer Value
dpHBV	AnalyteSCO	Real Value
dpHBV	OverallInterpretation	Valid
dpHBV	OverallInterpretation	Invalid
dpHBV	OverallInterpretation	Reactive
dpHBV	OverallInterpretation	Nonreactive
dpHBV	OverallInterpretation	Suspect
dpHCV	ICRLU	Integer Value
dpHCV	ICInterpretation	Valid
dpHCV	ICInterpretation	Invalid
dpHCV	AnalyteRLU	Integer Value
dpHCV	AnalyteSCO	Real Value
dpHCV	OverallInterpretation	Valid
dpHCV	OverallInterpretation	Invalid
dpHCV	OverallInterpretation	Reactive
dpHCV	OverallInterpretation	Nonreactive

Assay Long Name	Result Category	Interpretations
dpHCV	OverallInterpretation	Suspect
dpHIV	ICRLU	Integer Value
dpHIV	ICInterpretation	Valid
dpHIV	ICInterpretation	Invalid
dpHIV	AnalyteRLU	Integer Value
dpHIV	AnalyteSCO	Real Value
dpHIV	OverallInterpretation	Valid
dpHIV	OverallInterpretation	Invalid
dpHIV	OverallInterpretation	Reactive
dpHIV	OverallInterpretation	Nonreactive
dpHIV	OverallInterpretation	Suspect
Flu A/B/RSV	FluATCycle	Invalid
Flu A/B/RSV	FluATCycle	- (No Ct)
Flu A/B/RSV	FluATCycle	Ct (threshold cycle)
Flu A/B/RSV	FluATCycle	No Test
Flu A/B/RSV	FluBTCycle	Invalid
Flu A/B/RSV	FluBTCycle	- (No Ct)
Flu A/B/RSV	FluBTCycle	Ct (threshold cycle)
Flu A/B/RSV	FluBTCycle	No Test
Flu A/B/RSV	RSVTCycle	Invalid
Flu A/B/RSV	RSVTCycle	- (No Ct)
Flu A/B/RSV	RSVTCycle	Ct (threshold cycle)
Flu A/B/RSV	RSVTCycle	No Test
Flu A/B/RSV	ICTCycle	Invalid
Flu A/B/RSV	ICTCycle	- (No Ct)
Flu A/B/RSV	ICTCycle	Ct (threshold cycle)
Flu A/B/RSV	FluA	Invalid
Flu A/B/RSV	FluA	Flu A neg
Flu A/B/RSV	FluA	Flu A POS
Flu A/B/RSV	FluA	No Test
Flu A/B/RSV	FluB	Invalid
Flu A/B/RSV	FluB	Flu B neg
Flu A/B/RSV	FluB	Flu B POS
Flu A/B/RSV	FluB	No Test
Flu A/B/RSV	RSV	Invalid
Flu A/B/RSV	RSV	RSV neg
Flu A/B/RSV	RSV	RSV POS
Flu A/B/RSV	RSV	No Test

Assay Long Name	Result Category	Interpretations
Flu A/B/RSV	IC	Invalid
Flu A/B/RSV	IC	Valid
GBS	GBSTCycle	Invalid
GBS	GBSTCycle	- (No Ct)
GBS	GBSTCycle	Ct (threshold cycle)
GBS	ICTCycle	Invalid
GBS	ICTCycle	- (No Ct)
GBS	ICTCycle	Ct (threshold cycle)
GBS	GBS	Invalid
GBS	GBS	GBS neg
GBS	GBS	GBS POS
GBS	IC	Invalid
GBS	IC	Valid
GT HPV	IC/HPV 16 RLU	Integer Value
GT HPV	HPV 16 S/CO	Real Value
GT HPV	HPV 16 Result	Valid
GT HPV	HPV 16 Result	Invalid
GT HPV	HPV 16 Result	Negative
GT HPV	HPV 16 Result	POSITIVE
GT HPV	HPV 18/45 RLU	Integer Value
GT HPV	HPV 18/45 SCO	Real Value
GT HPV	HPV 18/45 Result	Valid
GT HPV	HPV 18/45 Result	Invalid
GT HPV	HPV 18/45 Result	Negative
GT HPV	HPV 18/45 Result	POSITIVE
GT HPV	ICInterpretation	Valid
GT HPV	ICInterpretation	Invalid
GT HPV	HPV 16 Cutoff	Blank
GT HPV	HPV 18/45 Cutoff	Blank
GT HPV	IC Cutoff	Blank
HEV	ICRLU	Integer Value
HEV	ICInterpretation	Valid
HEV	ICInterpretation	Invalid
HEV	AnalyteRLU	Integer Value
HEV	AnalyteSCO	Real Value
HEV	OverallInterpretation	Valid
HEV	OverallInterpretation	Invalid
HEV	OverallInterpretation	Reactive

Assay Long Name	Result Category	Interpretations
HEV	OverallInterpretation	Nonreactive
HPV	ICInterpretation	Valid
HPV	ICInterpretation	Invalid
HPV	OverallInterpretation	Valid
HPV	OverallInterpretation	Invalid
HPV	OverallInterpretation	POSITIVE
HPV	OverallInterpretation	Negative
HPV	ICRLU	Integer Value
HPV	AnalyteRLU	Integer Value
HPV	AnalyteSCO	Real Value
HPV	AnalyteCutoff	Blank
HPV	ICCutoff	Blank
HSV 1&2	ICTTime	Time in minutes
HSV 1&2	ICTTime	Invalid
HSV 1&2	ICTTime	No TTime
HSV 1&2	ICResult	Valid
HSV 1&2	ICResult	Invalid
HSV 1&2	HSV1TTime	Time in minutes
HSV 1&2	HSV1TTime	Invalid
HSV 1&2	HSV1TTime	No TTime
HSV 1&2	HSV-1	HSV1 POS
HSV 1&2	HSV-1	HSV1 neg
HSV 1&2	HSV-1	Invalid
HSV 1&2	HSV2TTime	Time in minutes
HSV 1&2	HSV2TTime	Invalid
HSV 1&2	HSV2TTime	No TTime
HSV 1&2	HSV-2	HSV2 POS
HSV 1&2	HSV-2	HSV2 neg
HSV 1&2	HSV-2	Invalid
LDT RT TMA-x (1,2,3)	Channel1TTime	Time in Minutes
LDT RT TMA-x (1,2,3)	Channel1TTime	Invalid
LDT RT TMA-x (1,2,3)	Channel1TTime	- (No TTime)
LDT RT TMA-x (1,2,3)	Channel3TTime	Time in Minutes
LDT RT TMA-x (1,2,3)	Channel3TTime	Invalid
LDT RT TMA-x (1,2,3)	Channel3TTime	- (No TTime)
LDT RT TMA-x (1,2,3)	Channel5TTime	Time in Minutes
LDT RT TMA-x (1,2,3)	Channel5TTime	Invalid
LDT RT TMA-x (1,2,3)	Channel5TTime	- (No TTime)

Assay Long Name	Result Category	Interpretations
LDT RT TMA-x (1,2,3)	Channel1Status	Cutoff Met
LDT RT TMA-x (1,2,3)	Channel1Status	Cutoff Not Met
LDT RT TMA-x (1,2,3)	Channel1Status	Cutoff Not Defined
LDT RT TMA-x (1,2,3)	Channel1Status	Not Calculable
LDT RT TMA-x (1,2,3)	Channel1Status	Invalid
LDT RT TMA-x (1,2,3)	Channel3Status	Cutoff Met
LDT RT TMA-x (1,2,3)	Channel3Status	Cutoff Not Met
LDT RT TMA-x (1,2,3)	Channel3Status	Cutoff Not Defined
LDT RT TMA-x (1,2,3)	Channel3Status	Not Calculable
LDT RT TMA-x (1,2,3)	Channel3Status	Invalid
LDT RT TMA-x (1,2,3)	Channel5Status	Cutoff Met
LDT RT TMA-x (1,2,3)	Channel5Status	Cutoff Not Met
LDT RT TMA-x (1,2,3)	Channel5Status	Cutoff Not Defined
LDT RT TMA-x (1,2,3)	Channel5Status	Not Calculable
LDT RT TMA-x (1,2,3)	Channel5Status	Invalid
LDT TMA-x (1,2,3)	TotalRLU	Integer Value
LDT TMA-x (1,2,3)	Channel1Status	Cutoff Met
LDT TMA-x (1,2,3)	Channel1Status	Cutoff Not Met
LDT TMA-x (1,2,3)	Channel1Status	Cutoff Not Defined
LDT TMA-x (1,2,3)	Channel1Status	Invalid
LDT-SARS-CoV-2	SARS-CoV-2TCycle	Invalid
LDT-SARS-CoV-2	SARS-CoV-2TCycle	-
LDT-SARS-CoV-2	SARS-CoV-2TCycle	Ct (threshold cycle)
LDT-SARS-CoV-2	ICTCycle	Invalid
LDT-SARS-CoV-2	ICTCycle	-
LDT-SARS-CoV-2	ICTCycle	Ct (threshold cycle)
LDT-SARS-CoV-2	SARS-CoV-2Result	Invalid
LDT-SARS-CoV-2	SARS-CoV-2Result	SARS-CoV-2 neg
LDT-SARS-CoV-2	SARS-CoV-2Result	SARS-CoV-2 POS
LDT-SARS-CoV-2	ICResult	Invalid
LDT-SARS-CoV-2	ICResult	Valid
M gen	ICRLU	Integer Value
M gen	ICInterpretation	Valid
M gen	ICInterpretation	Invalid
M gen	AnalyteRLU	Integer Value
M gen	AnalyteSCO	Real Value
M gen	OverallInterpretation	Invalid
M gen	OverallInterpretation	POSITIVE

Assay Long Name	Result Category	Interpretations
M gen	OverallInterpretation	Negative
M gen	AnalyteCutoff	Blank
M gen	ICCutoff	Blank
MRSA	MREJTCycle	Invalid
MRSA	MREJTCycle	- (No Ct)
MRSA	MREJTCycle	Ct (threshold cycle)
MRSA	MECACTCycle	Invalid
MRSA	MECACTCycle	- (No Ct)
MRSA	MECACTCycle	Ct (threshold cycle)
MRSA	GAPDHTCycle	Invalid
MRSA	GAPDHTCycle	- (No Ct)
MRSA	GAPDHTCycle	Ct (threshold cycle)
MRSA	ICTCycle	Invalid
MRSA	ICTCycle	- (No Ct)
MRSA	ICTCycle	Ct (threshold cycle)
MRSA	MREJ	Invalid
MRSA	MREJ	OrfX/SCCmec neg
MRSA	MREJ	OrfX/SCCmec POS
MRSA	MECAC	Invalid
MRSA	MECAC	mec A/C neg
MRSA	MECAC	mec A/C POS
MRSA	GAPDH	Invalid
MRSA	GAPDH	GAPDH neg
MRSA	GAPDH	GAPDH POS
MRSA	SA	Invalid
MRSA	SA	SA neg
MRSA	SA	SA POS
MRSA	MRSA	Invalid
MRSA	MRSA	MRSA neg
MRSA	MRSA	MRSA POS
MRSA	IC	Invalid
MRSA	IC	Valid
Paraflu	P1TCycle	Invalid
Paraflu	P1TCycle	- (No Ct)
Paraflu	P1TCycle	Ct (threshold cycle)
Paraflu	P1TCycle	No Test
Paraflu	P2TCycle	Invalid
Paraflu	P2TCycle	- (No Ct)

Assay Long Name	Result Category	Interpretations
Paraflu	P2TCycle	Ct (threshold cycle)
Paraflu	P2TCycle	No Test
Paraflu	P3TCycle	Invalid
Paraflu	P3TCycle	- (No Ct)
Paraflu	P3TCycle	Ct (threshold cycle)
Paraflu	P3TCycle	No Test
Paraflu	P4TCycle	Invalid
Paraflu	P4TCycle	- (No Ct)
Paraflu	P4TCycle	Ct (threshold cycle)
Paraflu	P4TCycle	No Test
Paraflu	ICTCycle	Invalid
Paraflu	ICTCycle	- (No Ct)
Paraflu	ICTCycle	Ct (threshold cycle)
Paraflu	P1	Invalid
Paraflu	P1	P1 neg
Paraflu	P1	P1 POS
Paraflu	P1	No Test
Paraflu	P2	Invalid
Paraflu	P2	P2 neg
Paraflu	P2	P2 POS
Paraflu	P2	No Test
Paraflu	P3	Invalid
Paraflu	P3	P3 neg
Paraflu	P3	P3 POS
Paraflu	P3	No Test
Paraflu	P4	Invalid
Paraflu	P4	P4 neg
Paraflu	P4	P4 POS
Paraflu	P4	No Test
Paraflu	IC	Invalid
Paraflu	IC	Valid
Parvo/HAV	ICInterpretation	Valid
Parvo/HAV	ICInterpretation	Invalid
Parvo/HAV	AnalyteSCO	Invalid
Parvo/HAV	AnalyteSCO	No Test
Parvo/HAV	AnalyteSCO	Real Value
Parvo/HAV	HAVInterpretation	Valid
Parvo/HAV	HAVInterpretation	Invalid

Assay Long Name	Result Category	Interpretations
Parvo/HAV	HAVInterpretation	Reactive
Parvo/HAV	HAVInterpretation	Nonreactive
Parvo/HAV	HAVInterpretation	Suspect
Parvo/HAV	HAVInterpretation	No Test
Parvo/HAV	Parvo	Valid
Parvo/HAV	Parvo	Invalid
Parvo/HAV	Parvo	<500
Parvo/HAV	Parvo	>100,000
Parvo/HAV	Parvo	Integer Value
Parvo/HAV	OverallInterpretation	Valid
Parvo/HAV	OverallInterpretation	Invalid
Parvo/HAV	ParvoNumeric	Integer Value
Parvo/HAV	ParvoNumeric	Invalid
Parvo/HAV	AdjustedFlasherRLU	Integer Value
Parvo/HAV	AdjustedGlowerRLU	Integer Value
qCMV	CMVResult	Invalid
qCMV	CMVResult	Not Detected
qCMV	CMVResult	<55 detected
qCMV	CMVResult	<176 detected (Whole Blood)
qCMV	CMVResult	Integer Value
qCMV	CMVResult	Exponential Format (1.54e9 for example)
qCMV	CMVResult	>10,000,000
qCMV	CMVLogBase10Result	Invalid
qCMV	CMVLogBase10Result	Not Detected
qCMV	CMVLogBase10Result	<1.74
qCMV	CMVLogBase10Result	<2.24 (Whole Blood)
qCMV	CMVLogBase10Result	Real Value
qCMV	CMVLogBase10Result	>7.00
qCMV	ICResult	Invalid
qCMV	ICResult	Integer Value
qCMV	ResultValid	Valid
qCMV	ResultValid	Invalid
qHBV	HBV	Valid
qHBV	HBV	Invalid
qHBV	HBV	Not Detected

Assay Long Name	Result Category	Interpretations
qHBV	HBV	<10
qHBV	HBV	>1.0e9
qHBV	HBV	Integer Value
qHBV	HBV	Exponential Format (1.54e9 for example)
qHBV	ICResult	Integer Value
qHBV	ICResult	- (No TTime)
qHBV	ResultValid	Valid
qHBV	ResultValid	Invalid
qHBV	HBVLogBase10	Valid
qHBV	HBVLogBase10	Invalid
qHBV	HBVLogBase10	Not Detected
qHBV	HBVLogBase10	<1.0
qHBV	HBVLogBase10	>9.0
qHBV	HBVLogBase10	Real Value
qHCV	HCV	Valid
qHCV	HCV	Invalid
qHCV	HCV	Not Detected
qHCV	HCV	<10
qHCV	HCV	>100,000,000
qHCV	HCV	Integer Value
qHCV	HCV	Exponential Format (1.54e8 for example)
qHCV	ICResult	Integer Value
qHCV	ICResult	- (No TTime)
qHCV	ResultValid	Valid
qHCV	ResultValid	Invalid
qHCV	HCVLogBase10	Valid
qHCV	HCVLogBase10	Invalid
qHCV	HCVLogBase10	Not Detected
qHCV	HCVLogBase10	<1.00
qHCV	HCVLogBase10	>8.00
qHCV	HCVLogBase10	Real Value
qHIV-1	HIV-1	Valid
qHIV-1	HIV-1	Invalid
qHIV-1	HIV-1	Not Detected
qHIV-1	HIV-1	<30
qHIV-1	HIV-1	>10,000,000

Assay Long Name	Result Category	Interpretations
qHIV-1	HIV-1	<873
qHIV-1	HIV-1	Integer Value
qHIV-1	HIV-1	Exponential Format (1.54e7 for example)
qHIV-1	ICResult	Integer Value
qHIV-1	ICResult	- (No TTime)
qHIV-1	ResultValid	Valid
qHIV-1	ResultValid	Invalid
qHIV-1	HIV-1LogBase10	Valid
qHIV-1	HIV-1LogBase10	Invalid
qHIV-1	HIV-1LogBase10	Not Detected
qHIV-1	HIV-1LogBase10	<1.47
qHIV-1	HIV-1LogBase10	>7.00
qHIV-1	HIV-1LogBase10	<2.94
qHIV-1	HIV-1LogBase10	Real Value
SARS-CoV-2	ICRLU (Procleix Only)	Integer Value
SARS-CoV-2	ICInterpretation (Procleix Only)	Valid
SARS-CoV-2	ICInterpretation (Procleix Only)	Invalid
SARS-CoV-2	AnalyteRLU (Procleix Only)	Integer Value
SARS-CoV-2	AnalyteSCO (Procleix Only)	Real Value
SARS-CoV-2	OverallInterpretation (Procleix Only)	Valid
SARS-CoV-2	OverallInterpretation (Procleix Only)	Invalid
SARS-CoV-2	OverallInterpretation (Procleix Only)	Reactive
SARS-CoV-2	OverallInterpretation (Procleix Only)	Nonreactive
SARSCoV2	TotalRLU (Aptima Only)	Integer Value
SARSCoV2	ICResult (Aptima Only)	Invalid
SARSCoV2	ICResult (Aptima Only)	Valid

Assay Long Name	Result Category	Interpretations
SARSCoV2	CoVResult (Aptima Only)	Invalid
SARSCoV2	CoVResult (Aptima Only)	POSITIVE
SARSCoV2	CoVResult (Aptima Only)	Negative
Ultrio Elite	ICRLU	Integer Value
Ultrio Elite	ICInterpretation	Valid
Ultrio Elite	ICInterpretation	Invalid
Ultrio Elite	AnalyteRLU	Integer Value
Ultrio Elite	AnalyteSCO	Real Value
Ultrio Elite	OverallInterpretation	Valid
Ultrio Elite	OverallInterpretation	Invalid
Ultrio Elite	OverallInterpretation	Reactive
Ultrio Elite	OverallInterpretation	Nonreactive
UltrioPlex E	ICInterpretation	Valid
UltrioPlex E	ICInterpretation	Invalid
UltrioPlex E	UeRLU	Integer Value
UltrioPlex E	UeSCO	Real Value
UltrioPlex E	UEInterpretation	Valid
UltrioPlex E	UEInterpretation	Invalid
UltrioPlex E	UEInterpretation	Reactive
UltrioPlex E	UEInterpretation	Nonreactive
UltrioPlex E	UEInterpretation	Suspect
UltrioPlex E	UEInterpretation	No Test
UltrioPlex E	HevSCO	Real Value
UltrioPlex E	HEVInterpretation	Valid
UltrioPlex E	HEVInterpretation	Invalid
UltrioPlex E	HEVInterpretation	Reactive
UltrioPlex E	HEVInterpretation	Nonreactive
UltrioPlex E	HEVInterpretation	Suspect
UltrioPlex E	HEVInterpretation	No Test
UltrioPlex E	ICHevRLU	Integer Value
WNV	ICRLU	Integer Value
WNV	ICInterpretation	Valid
WNV	ICInterpretation	Invalid
WNV	AnalyteRLU	Integer Value
WNV	AnalyteSCO	Real Value

Assay Long Name	Result Category	Interpretations
WNV	OverallInterpretation	Valid
WNV	OverallInterpretation	Invalid
WNV	OverallInterpretation	Reactive
WNV	OverallInterpretation	Nonreactive
ZIKV	ICRLU	Integer Value
ZIKV	ICInterpretation	Invalid
ZIKV	ICInterpretation	Valid
ZIKV	AnalyteRLU	Integer Value
ZIKV	AnalyteSCO	Real Value
ZIKV	OverallInterpretation	Invalid
ZIKV	OverallInterpretation	Valid
ZIKV	OverallInterpretation (Aptima Only)	Negative
ZIKV	OverallInterpretation (Aptima Only)	POSITIVE
ZIKV	OverallInterpretation (Procleix Only)	Nonreactive
ZIKV	OverallInterpretation (Procleix Only)	Reactive

10.14. Appendix N - More Examples

10.14.1. Host Query Example

(CompressedOrderQuery is disabled)

Panther is sending Host Query for the following specimen IDs: 8563187293, 6063973541, 8563187289, 8563187296, 8563187288, 6063973531, 8563718615, 6063973533, 6063973544, 6063973532, 6063973534, 6063973535, 6063973537, 6063409623 and 8563187295

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-> Panther Receiving

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<- <EOT>
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-> <EOT>

What is Required

Ensure that all intended users are notified of the information documented in this Supplemental Information Sheet.

Please contact your local Technical Services representative if you have any questions or concerns regarding this communication.

For Hologic customers in Europe, please contact EU Technical Support at +49 6122 7076 451 or by e-mail at technicalsupport@gen-probe.eu.

For Hologic customers outside of Europe, please contact Hologic Technical Support at +1 888 484 4747 or 1 858 410 8511 or by e-mail at molecularsupport@hologic.com.

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