



The Savanna LIS Interface Specification

1 Overview

The scope of this document is to provide detail on the capabilities and requirements for implementing a Systems Interface between the Savanna[®] Real-Time PCR Testing Platform and a Laboratory Information System (LIS) or other compatible Data Management System. For the purposes of this guide, all system Interface connections may be referred to as "LIS connections."

The Savanna instrument implements an industry standard HL7 Interface and a standard POCT01-A2 (POCT) Interface for use over Ethernet networks. The Interface is designed to support unidirectional or bidirectional communications LIS and Point-of-Care Data Management Systems. The Systems Interface is built into the Savanna instrument and requires minimal configuration to utilize.

The instrument's connection for communications is by wired Ethernet or Wi-Fi. The data transport is via the Transmission Control Protocol/Internet Protocol (TCP/IP). The instrument has one standard Ethernet RJ-45 connector.

Test results may be configured to send to the LIS automatically upon completion of the test run, manually at the completion of the test run, or upon receipt of an LIS Order update for a completed test. When test results are sent, a communication session is initiated from the Savanna instrument to the LIS. The session may fail if the Savanna instrument is unable to connect to the LIS or doesn't receive the correct LIS response within 15 seconds. A communications failure error will be "Unable to Send Results to LIS". If the transmission fails, the results are stored and may be resent. A resend is initiated when the connection to LIS is reestablished and the Savanna User selects from the Savanna Menu the option to send test results.

When the the Savanna instrument has information to send, it will request a TCP Socket connection to the Host LIS System. If the Host System is available and accepts the connection, the Savanna instrument and the Host System will exchange the data. When the transaction is complete, the Savanna instrument will request a close of the Socket connection and the systems will negotiate a disconnect. The Host System must go back to a listening state awaiting the next communication. When the Savanna instrument has more information to send, it will request a new connection to the Host LIS. The Savanna instrument and Host Systems do not maintain a persistent network connection. The Savanna instrument is a Client and LIS is the Server in this Client/Server relationship.

The Savanna instrument has the ability to receive LIS Orders for tests. When configured to receive LIS Orders, the Savanna instrument will listen on its designated network address and Port for an LIS Orders Interface connection. For the Orders Interface, the Savanna instrument is the Server and LIS is the Client.

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2 Definitions/Acronyms

- HL7: Health Level Seven
- IP: Internet Protocol
- LIS: Laboratory Information Systems (for our purposes, this could also be a Middleware System servicing LIS)
- POC: Point-of-Care
- POCT: is a reference to the CLSI Standard "POCT01-A2"
- CLSI: Clinical and Laboratory Standards Institute

3 HL7 Interface – Functional Description

The HL7 Interface is compliant with version 2.6 of the Health Level Seven (HL7) standard for electronic data exchange. This Interface implements a subset of the HL7 standard; ORU messages for result transmissions and ORM messages for the ordering of tests. Additionally, it supports the ACK message for transmission acknowledgments.

3.1 HL7 LIS Interface Configuration

LIS Interface Setup Screen in Savanna

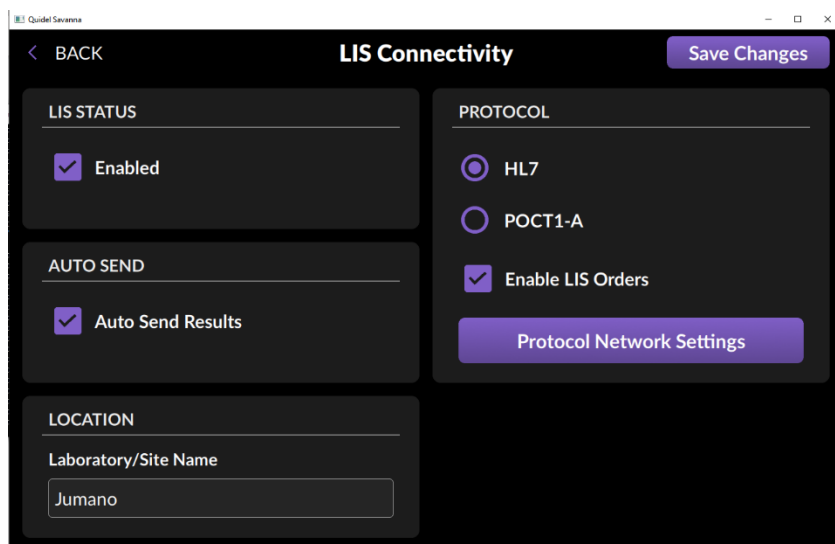


Figure 1: Savanna LIS Connectivity Setup Screen

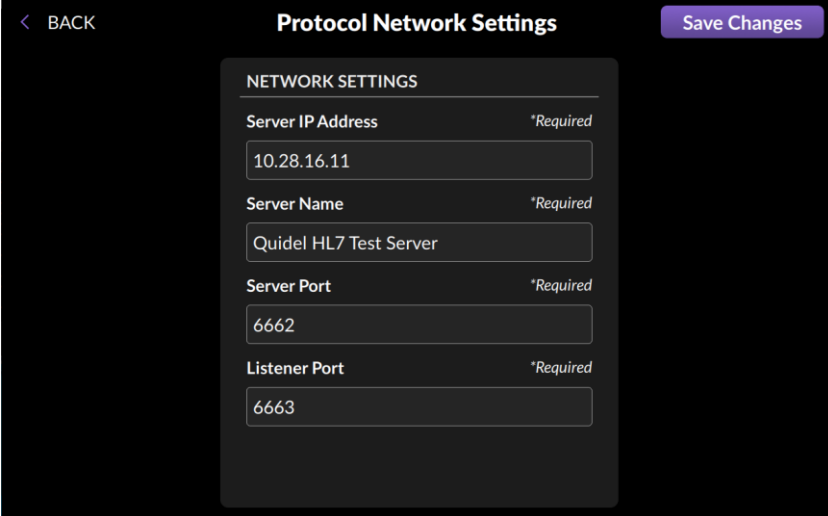
After setting up the Savanna instrument with an IP address for its network connection, configure the LIS Interface settings. See the Savanna User Guide for information on Network Setup and other configuration.

The example LIS Connectivity setup screen shown in *Figure 1* is where the connectivity settings are configured.

- The **LIS STATUS** checkbox may be checked to Enabled or unchecked to be Not Enabled. This will set LIS communication on or off.
- **AUTO SEND** is either checked for Auto Send Results to have the reported results sent automatically upon test completion or unchecked for manually only sending test results. At

the end of each test result, the user will be given the option to send the test results to the LIS server with a button.

- The **LOCATION** section should have the Laboratory/Site Name entered for the value that is sent over the Interface for the Performing Organization Name.
- **PROTOCOL** is set to HL7 for this Interface.
- Under PROTOCOL, "Enable LIS Orders" is checked if an LIS Orders Interface will be deployed.
- Select the **Protocol Network Settings** button to set the IP and Port settings for the HL7 Interface(s).



The screenshot shows a mobile application interface for configuring network settings. At the top, there is a navigation bar with a back arrow and the text 'BACK' on the left, the title 'Protocol Network Settings' in the center, and a purple 'Save Changes' button on the right. Below the navigation bar is a dark grey card titled 'NETWORK SETTINGS'. Inside this card, there are four input fields, each with a label and a '*Required' indicator to its right. The first field is 'Server IP Address' with the value '10.28.16.11'. The second is 'Server Name' with the value 'Quidel HL7 Test Server'. The third is 'Server Port' with the value '6662'. The fourth is 'Listener Port' with the value '6663'.

Figure 2: LIS Protocol Network Settings

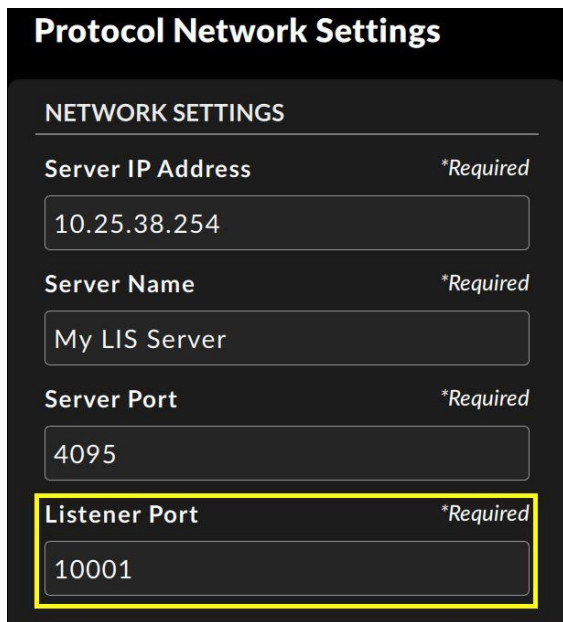
- The "Server IP Address" is the Network IP address where the Savanna instrument will send the Test Result messages.
- The "Server Name" is an identifier for the LIS server. This is the DNS "network name" for the LIS Host System. Consult your network support staff if you do not know the DNS name of the Host.
- The "Server Port" is the Port on which the LIS server is listening for test results from the Savanna instrument. The LIS Administrator or LIS support organization will advise on what Port to use for this setting.
- The "Listener Port" is the Port on which the Savanna instrument Listens for Orders from the LIS server. In the case of a unidirectional Interface where the order Interface is not implemented, and the prior screen checkbox for "Enable LIS Orders" is not checked, the "Listener Port" will not be displayed here. If an Orders Interface will be deployed, we advise that you coordinate the listener Port Number to utilize with your Network Support Staff. They may need to adjust network rules to allow connection from LIS to the Savanna instrument. Commonly used ports are 10001 or 10002.
- When all Protocol Network Settings are set as desired, select **Save Changes**.
- **Important Note:** The Server Ports and Listener Ports shown in *Figure 2* are examples only. They are not the ports designated for your use. Please coordinate with our LIS and Networking support for advice on the necessary ports for your implementation.

3.1.1 HL7 LIS Order Configuration

If the Orders Interface is implemented, coordinate with the LIS administrator regarding the **Listener Port** information from the **Protocol Network Settings** setup screen (Figure 3 below) and the IP address which has been assigned to this Savanna instrument. The Listener Port is the Port on which the Savanna instrument will listen for orders sent by the LIS.

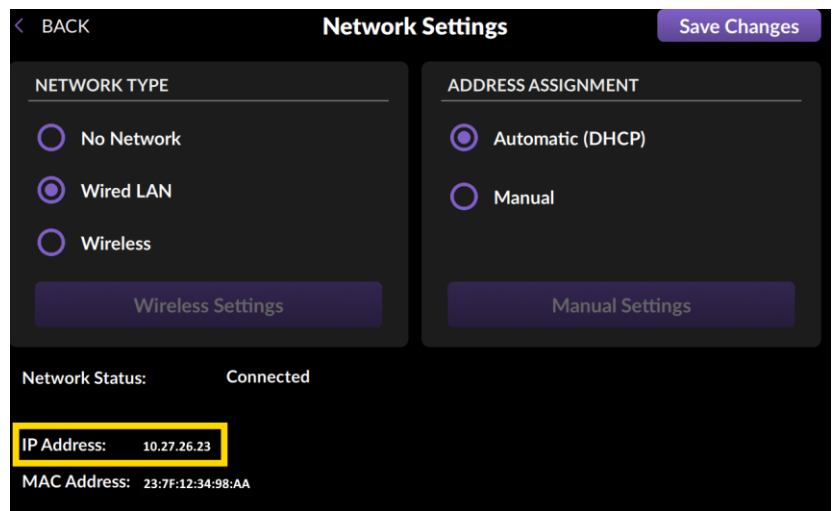
The Listener Port in *Figure 3* is an example. You may use any unassigned IP Port of your choice. Port 10001 is a commonly used IP Port. You may want to coordinate with your I.T. network support regarding which Port number they would advise. This collaboration will also give them the opportunity to make sure the Port used is available for communications and not blocked by Firewalls or Network Policy.

Note: Your Savanna IP address is not the address shown in the *Figure 4* example screen. The Savanna's Network Address is configured and viewed under the "Network Settings\LAN" settings screen in the Savanna Setup section. Additional configuration detail for both Savanna Network Address and LIS Server may be found in the Network Settings section in the Savanna User Guide at <https://www.quidelortho.com/global/en/products/savanna-platform>



The screenshot shows a dark-themed form titled "Protocol Network Settings". Under the "NETWORK SETTINGS" section, there are four input fields, each with a "*Required" label to its right. The fields are: "Server IP Address" with the value "10.25.38.254"; "Server Name" with the value "My LIS Server"; "Server Port" with the value "4095"; and "Listener Port" with the value "10001". The "Listener Port" field and its label are highlighted with a yellow border.

Figure 3: Orders Listener Port



The screenshot shows a dark-themed screen titled "Network Settings" with a "Save Changes" button in the top right. It is divided into two columns: "NETWORK TYPE" and "ADDRESS ASSIGNMENT". Under "NETWORK TYPE", there are three radio button options: "No Network", "Wired LAN" (which is selected), and "Wireless". Below these are two buttons: "Wireless Settings" and "Manual Settings". Under "ADDRESS ASSIGNMENT", there are two radio button options: "Automatic (DHCP)" (which is selected) and "Manual". Below these are two buttons: "Wireless Settings" and "Manual Settings". At the bottom, it shows "Network Status: Connected". Below that, there are two lines of text: "IP Address: 10.27.26.23" and "MAC Address: 23:7F:12:34:98:AA". The "IP Address" line is highlighted with a yellow border.

Figure 4: Savanna Network Address Highlighted

3.2 Bidirectional Interface

Bidirectional use of the HL7 LIS Interface means that the Savanna instrument in addition to sending results to LIS, can receive Orders for tests from the LIS System.

Implementation of a bidirectional Interface requires two (2) Interfaces be set up.

- One Interface from the Savanna instrument to the LIS for sending the test results.
- One Interface from the LIS to the Savanna instrument for the transmission of test orders.

Savanna Instrument	LIS System
Orders Interface ← Listening at Savanna’s IP address and designated Port number (Listener Port) for LIS Order transmissions.	Orders Interface ← LIS Connects to Savanna’s IP address and designated Port number (Listener Port) that’s setup to listen for LIS Orders.
Results Interface → Configured to send test results to the LIS at the LIS IP Address and Port number (Server Port) that’s listening for Test Results.	Results Interface → LIS listens for Test Results on its IP Address and designated Port number (Server Port).

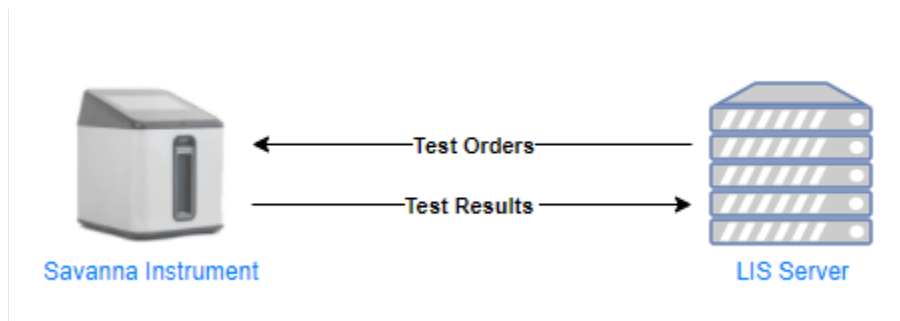


Figure 5: HL7 Bidirectional Communication

3.3 Unidirectional Interface

Receiving test Orders is not a requirement for operation; the Savanna instrument may be set up to send test results without implementing an Orders Interface, thus unidirectional. See section 3.5.1 for additional detail regarding operation without an Orders Interface.

Implementation of a unidirectional Interface requires one (1) Interface be set up.

- One Interface from the the Savanna instrument to LIS for sending the test results

Savanna Instrument	LIS System
Results Interface → Configured to send test results to the LIS at the LIS IP Address and Port number (Server Port) that’s listening for Test Results.	Results Interface → LIS listens for Test Results on its IP Address and designated Port number (Server Port).

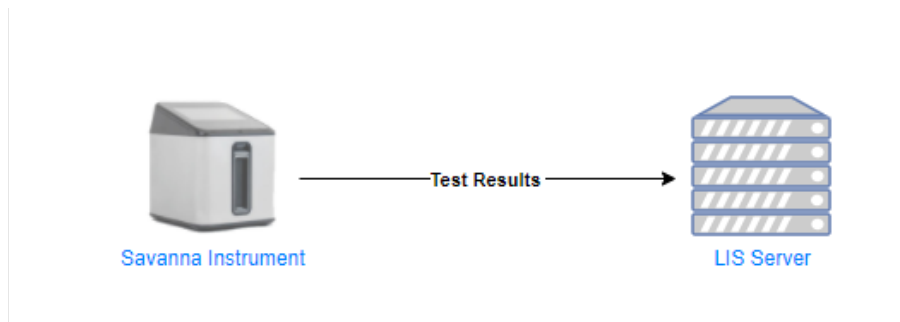


Figure 6: HL7 Unidirectional Communication

3.4 HL7 – Results Interface

When the test completes, the test results are sent to the LIS. If the transmission fails, the result is temporarily stored and can be resent. A resend may be initiated when the connection to LIS is reestablished.

It is possible to send a Result for which no previous Order was received from the LIS. In that case, the Savanna Operator will usually input the Order number manually while preparing the test. In the case of Point-of-Care (POC) operation, an LIS Interface designed for POC operation may be expecting a Patient ID instead of an LIS Order Number.

After the result is sent, the Savanna instrument expects an ACK message from the LIS, otherwise the transfer will be marked as failed and the results will be queued for a resend attempt.

3.4.1 Test Results Message (the ORU Message)

The instrument uses the ORU message type to transmit results to the LIS.

- ORU - unsolicited observation message
- The following data is included in the message
 - ▶ Savanna Serial Number
 - ▶ Patient ID / Order No.
 - ▶ Test identifier(s)
 - ▶ Date and time of result reporting
 - ▶ The analyte name and qualitative result(s)

The Savanna Test Results Message is made up of the following HL7 message segments.

- ▶ MSH Message Header
- ▶ PID Patient Identification
- ▶ ORC Common Order
- ▶ OBR Observation Request
- ▶ OBX Observation

Each of these message segments contain fields of data defined by the HL7 standard. Some fields of information are mandatory and sent, some are optional, and others are empty or not used. In the following tables that define the message segments, the abbreviations R, O and N indicate the status and use of a data field within the message segment.

Abbreviation	Meaning	Description	
		LIS → Instrument	Instrument → LIS
R	Required	Is required and analyzed	Is always present
O	Optional	If present, will be evaluated	Sometimes present
N	Not used	Ignored	Not sent

3.4.2 MSH: Message Header Segment

Field	R/O/N	Name	Description
MSH-1	R	Field separator	Always:
MSH-2	R	Encoding characters	Always: ^~\&
MSH-3	R	Sending Application	Always: Savanna^Savanna Serial Number
MSH-3.1	R	Instrument Platform	Always: Savanna
MSH-3.2	R	Instrument Serial Number	The Savanna's Serial Number. Example: 15020027
MSH-4	R	Sending Facility	Always: Quidel
MSH-5	N	Receiving Application	Empty
MSH-6	N	Receiving Facility	Empty
MSH-7	R	Date / Time of message	Timestamp when the message has been created. Format: YYYYMMDDHHMMSS
MSH-8	N	Security	Empty
MSH-9	R	Message type	Always: ORU^R01
MSH-10	R	Message Control ID	Unique Number to identify the message
MSH-11	R	Processing ID	Always: P
MSH-12	R	Version ID	Always: 2.6
...	N		Not used

MSH Example

MSH|^~\&|Savanna^15020027|Quidel|||20240115122201||ORU^R01|15428063489846|P|2.6

3.4.2.1 PID: Patient Identification Segment

Field	R/O/N	Name	Description
PID-1	O	Set ID – PID	PID 1 will always be set to "1"
PID-2	N	Patient ID	Empty
PID-3	O	Patient identifier list	"Patient ID" from Patient ID in Savanna list For QC Results, this will be the Cartridge Lot Number.
PID-4	O	Alternate Patient ID	Copied from Order, or if no Order exists: Empty
PID-5	O	Patient Name	Copied from Order, or if no Order exists: Empty. Format LastName^FirstName
PID-6	O	Mother's Maiden Name	Copied from Order, or if no Order exists: Empty
PID-7	O	Date/Time of Birth	Copied from Order or from Input, or if no data exists: Empty. Time can be set to 000000. Format: YYYYMMDDHHMMSS Ex: 20101108000000
...	N		Not used

PID Example

PID|1||Patient10||Smith^John||20101108000000

QC Result Example

PID|1||CARTLOT12

3.4.2.2 ORC: Common Order Segment

Field	R/O/N	Name	Description
ORC-1	R	Order Control	"RE" if using an Order Number "NW" if no Order Number (only Patient ID) is used. For QC Results, this will be the "NW".
ORC-2	O	Placer Order Number	Order number sent by Savanna For QC Results, this will be the QC Sample Lot Number.
ORC-3	O	Filler Order Number	Order number sent by Savanna For QC Results, this will be the QC Sample Lot Number.
...	N		Not used

ORC Example
 ORC|RE|15020027064701|15020027064701

QC Example
 ORC|NW|QCLOT12|QCLOT12

3.4.2.3 OBR: Observation Request Segment

Field	R/O/N	Name	Description
OBR-1	R	Set ID - OBR	Segment counter for repeated use
OBR-2	R	Placer Order Number	This field is identical to ORC-2
OBR-3	R	Filler Order Number	This field is identical to ORC-3
OBR-4	R	Universal Service Identifier	The Test Identifier in format: ^ HSV 1+2-VZV OBR-4.2 Name of Test e.g., HSV 1+2-VZV
OBR-5	N	Priority	Not used
OBR-6	N	Requested Date/Time	Not used
OBR-7	R	Observation Date/Time	Timestamp when the test has completed. Format: YYYYMMDDHHMMSS
OBR-8	R	Observation End Date/Time	Timestamp when the test has completed. Format: YYYYMMDDHHMMSS
OBR-9	N	Collection Volume	Not used
OBR-10	N	Collector Identifier	Not used
OBR-11	N	Specimen Action Code	Not used
OBR-12	N	Danger Code	Not used
OBR-13	N	Relevant Clinical Information	Not used
OBR-14	N	Specimen received Date/Time	Not used
OBR-15	O	Specimen Source	Sample Source "P" for patient sample "Q" for a quality control sample
OBR -34	R	Technician	For result User ID will be sent in this field. For QC result User ID will be sent in this field.
...	N		Not used

OBR Example
 OBR|1|15020027064701|15020027064701|^RPV4|||20240115122052|20240115122052|P|||||
 P|||||Mai Nguyen|

3.4.2.4 OBX: Clinical Observations / Results Reporting

Field	R/O/N	Name	Description
OBX-1	R	Set ID – OBX	ID
OBX-2	R	Data type	Always "ST" for String type.
OBX-3	R	Observation identifier	Name of Test
OBX-3.4	R	Observation Alternate identifier	LOINC Code for the test.
OBX-4	N	Observation sub-id	Not Used
OBX-5	R	Observation value	Result value, text string for a qualitative result, numerical value for a quantitative result. Ct value is enabled.
OBX-6	O	Units	Empty for a qualitative result, units for a quantitative result
OBX-7	N	Reference range	Not used
OBX-8	N	Abnormal flags	Not used
OBX-9	N	Probability	Not used
OBX-10	N	Nature of abnormal test	Not used
OBX-11	R	Observation Result Status	Always "F"
OBX-12	N	Danger Code	Not used
OBX-13	N	Relevant Clinical Information	Not used
OBX-14	R	Specimen Received Date/Time	Timestamp when the test has completed. Format: YYYYMMDDHHMMSS [Local Time]
OBX-15	N	Producer's ID	Not used
OBX-16	N	Ordering Provider	Not used
OBX-17	O	Observation Method	Not used
OBX-18	R	Equipment Instance Identifier	Savanna Serial Number
OBX-19	R	Date/Time of the Analysis	Timestamp when the test has completed. Format: YYYYMMDDHHMMSS [Local Time]
OBX-20	N	Observation Site	Not used
OBX-21	N	Observation Instance Identifier	Not used
OBX-22	N	Mood Code	Not used
OBX-23	O	Performing Organization Name	Laboratory/Site Name from LIS Connectivity screen.
...	N		Not used

OBX Example

```
OBX|1|ST|Flu A^^^92142-9||Positive||||F||20240115122052|||64110212345601|20240115122052|||Lab
OBX|2|ST|Flu ACt^^^92142-9||6||||F||20240115122052|||64110212345601|20240115122052|||Lab
OBX|3|ST|Flu B^^^92141-1||Positive||||F||20240115122052|||64110212345601|20240115122052|||Lab
OBX|4|ST|Flu BCt^^^92141-1||4||||F||20240115122052|||64110212345601|20240115122052|||Lab
OBX|5|ST|RSV^^^92131-2||Positive||||F||20240115122052|||64110212345601|20240115122052|||Lab
OBX|6|ST|RSVct^^^92131-2||6||||F||20240115122052|||64110212345601|20240115122052|||Lab
OBX|7|ST|SARS-CoV-2^^^94500-6||Positive||||F||20240115122052|||64110212345601|20240115122052
|||Lab
OBX|8|ST|SARS-CoV-2Ct^^^94500-6||5||||F||20240115122052|||64110212345601|20240115122052|||Lab
```

3.4.3 LIS Transmission Acknowledgement

After each transmission of results, an acknowledgment message is required from LIS. The structure of the message is;

- ▶ MSH Message Header
- ▶ MSA Message Acknowledgement Type

3.4.3.1 MSH: Message Header Segment

Field	R/O/N	Name	Description
MSH-1	R	Field separator	Always:
MSH-2	R	Encoding characters	Always: ^~\&
MSH-3	N	Sending Application	May be used to identify the sending application
MSH-4	N	Sending Facility	May be used to identify the sending facility
MSH-5	N	Receiving Application	May be used to identify the receiving application
MSH-6	N	Receiving Facility	May be used to identify the receiving facility
MSH-7	N	Date / Time of message	Timestamp when the message has been created. Format: YYYYMMDDHHMMSS
MSH-8	N	Security	Empty
MSH-9	R	Message type	Always starts with: ACK
MSH-10	R	Message Control ID	Unique Number to identify the message
MSH-11	N	Processing ID	Describes processing rules
MSH-12	N	Version ID	Version of standard used, shall be 2.6
...	N		Not used

LIS Acknowledgement MSH Segment

```
MSH|^~\&||Savanna^15020027|Quidel |20240115122257||ACK|14543174849305|P|2.6
```

3.4.3.2 MSA: Acknowledgment Code Segment

Field	R/O/N	Name	Description
MSA-1	R	Acknowledgement Code	Positive acknowledge: "AA" or "CA" Negative acknowledge: "AR" or "CR"
MSA-2	R	Message Control ID	Must be MSH-10 of corresponding result
...	N	Not used	

MSA Acknowledgement Example
MSA|AA|15428063489846

3.5 HL7 - Orders Interface

When configured for an Orders Interface, the the Savanna instrument will receive and store test orders sent from the LIS. During a test initiation, the Savanna User will select from the Received Orders List, an order to associate with the test being performed. When the test measurements are complete the results will be forwarded to the LIS server over the Results Interface.

3.5.1 An Orders Interface is not required

An Orders Interface is not required for Savanna instrument operation. The Savanna instrument may be Interfaced in a unidirectional fashion where a single Interface is utilized to send test results to LIS.

If the Orders Interface is not enabled, the Savanna User may assign LIS Order numbers to the samples via a barcode scanner or from the Savanna keypad when setting up the test parameters. When the test results are received by the LIS, the LIS will use the manually input Order number to match the results to a pending LIS Order.

For Point-of-Care (POC) operation, an LIS Order may not exist prior to performing Savanna instrument tests. For LIS Interfaces that support a POC methodology, a Patient ID may be used to identify which Patient the test was for. Upon receiving the results transmission, the LIS POC Interface will create an order for the Patient ID that was sent with the results from the Savanna instrument and then fill that pending LIS Order.

3.5.2 Order Updates

The Savanna instrument can receive order updates and send analyte results that were previously measured but not included in the original order.

For example, the RPV4 test cartridge includes 4 analytes which are Flu A, Flu B, RSV and SARS-CoV-2. If an order for Flu A and Flu B is received and the RVP4 panel is run to fill that order, those results will be sent to LIS to fill the order. The Savanna instrument will have also measured, but not displayed or transmitted, RSV and SARS-CoV-2 results.

The Savanna instrument will hold in memory the unreported results for 48 hours. If an updated order is received within that 48-hour window that includes RSV and SARS-CoV-2, the Savanna instrument will report those results to LIS fulfilling the order update. 48 hours after the original

cartridge is measured, any unreported results will no longer be available for reporting via an order update.

Note: If results are desired from a fresh sample and new cartridge measurement within 48 hours of the original test run, a new order should be sent to the Savanna instrument instead of an order update.

3.5.3 Orders Expiration

An order update received 48 hours or later after the original order was resulted will be considered a duplicate order and rejected as already fulfilled.

New orders must be completed within 72 hours of order reception by the Savanna instrument. After 72 hours, orders will "Age-Out" of the Orders List and not be available for selection during test initiation.

3.5.4 The Order Message (ORM Message)

The LIS must use the ORM^O01 message type to transmit orders to the instrument. The LIS Order Message is made up of the following HL7 message segments.

- ▶ MSH Message Header
- ▶ PID Patient Identification
- ▶ ORC Common Order
- ▶ OBR Observation Request

Any additional segments that comply with the message structure defined in HL7 2.6 may be received, but the content will be ignored.

Each of these message segments contain fields of data defined by the HL7 standard. Some fields of information are mandatory, some are optional, and others are empty or not used. In the following tables that define the message segments, the abbreviations R, O and N indicate the status and use of a data field within the message segment.

Abbreviation	Meaning	Description	
		LIS → Instrument	Instrument → LIS
R	Required	Is required and analyzed	Is always present
O	Optional	If present, will be evaluated	Sometimes present
N	Not used	Ignored	Not filled

3.5.4.1 MSH: Message Header Segment

Field	R/O/N	Name	Description
MSH-1	R	Field separator	Always:
MSH-2	R	Encoding characters	Always: ^~\&
MSH-3	N	Sending Application	May be used to identify the sending application

Field	R/O/N	Name	Description
MSH-4	N	Sending Facility	May be used to identify the sending facility
MSH-5	N	Receiving Application	May be used to identify the receiving application
MSH-6	N	Receiving Facility	May be used to identify the receiving facility
MSH-7	N	Date / Time of message	Timestamp when the message has been created. Format: YYYYMMDDHHMMSS
MSH-8	N	Security	Not used
MSH-9	R	Message type	Always: ORM^O01
MSH-10	R	Message Control ID	Unique Number to identify the message
MSH-11	N	Processing ID	Describes processing rules
MSH-12	R	Version ID	Version of standard used, shall be 2.6
...	N		Not used

MSH Example

MSH|^~\&|LIS|LIS|Savanna|Quidel|20240116143200||ORM^O01|15428056991525||2.6

3.5.4.2 PID: Patient Identification Segment

Field	R/O/N	Name	Description
PID-1	O	Set ID - PID	
PID-2	N	Patient ID	Not Used - Deprecated in HL7 2.6. Use PID 3.1
PID-3	R	Patient identifier list	Patient ID (any following fields after 3.1 ignored)
PID-4	O	Alternate Patient ID	Alternate ID
PID-5	O	Patient Name	Format: Lastname^Firstname
PID-6	O	Mother's Maiden Name	Empty
PID-7	R	Date/Time of Birth	Format: YYYYMMDDHHMMSS Note: HHMMSS may be 000000
...	N		Not used

PID Example

PID|1||P0011^^^|Smith^John||19731106134713

3.5.4.3 ORC: Common Order Segment

Field	R/O/N	Name	Description
ORC-1	R	Order Control	"NW" or "RE" - depending on the LIS
ORC-2	R	Placer Order Number	Order number sent by LIS

...	N		Not used
-----	---	--	----------

ORC Example

ORC|RE|15020027064701

3.5.4.4 OBR: Observation Request Segment

Field	R/O/N	Name	Description
OBR-1	N	Set ID - OBR	Segment counter for repeated use
OBR-2	N	Placer Order Number	This field is identical to ORC-2
OBR-3	N	Filler Order Number	Can be used by filler for identification
OBR-4	R	Universal Service Identifier	The Test Identifier in format: ^ RVP4+
OBR-4.1	O	An Order Code	123xyz
OBR-4.2	R	Panel or analyte name	Name of the test e.g., RPV4+
OBR-5	N	Priority	Not used
OBR-6	N	Requested Date/Time	Not used
OBR-7	O	Observation Date/Time	Date and Time of specimen collection Format: YYYYMMDDHHMMSS
OBR-8	O	Observation End Date/Time	Date and Time of specimen collection Format: YYYYMMDDHHMMSS
OBR-9	N	Collection Volume	Not used
OBR-10	N	Collector Identifier	Not used
OBR-11	N	Specimen Action Code	Not used
OBR-12	N	Danger Code	Not used
OBR-13	N	Relevant Clinical Info	Not used
OBR-14	N	Specimen received Date/Time	Not used
OBR-15	R	Specimen Source	Sample Source "P" for patient sample "Q" for a quality control sample, and "C" for calibration.
...	N		Not used

OBR Example

Order by Assay Panel

OBR|1|||1234^RVP4|||20181121131908|20181121131908|||||P

Order by Individual Analyte Name

OBR|1|||1235^Flu A|||20181121131908|20181121131908|||||P

OBR|2|||1236^Flu B|||20181121131908|20181121131908|||||P

Note: The field OBR-4.2 defines the assay or analyte to run on the instrument. The text in this field must match exactly the name of the assay/analyte as it appears in the instrument (see Result Assay Panel Definition Table at the end of this document). This includes being case sensitive. If the order message received by the Savanna instrument contains specific analyte names in OBR-4, then Savanna will send results for the listed analytes. If the assay is specified, all the available results will be sent.

3.5.5 Order Received Acknowledgement

Each received order message will be acknowledged with an ACK-message back to LIS. The structure of this message is

- ▶ MSH Message Header
- ▶ MSA Message Acknowledgement Type

3.5.5.1 MSH: Message Header Segment

Field	R/O/N	Name	Description
MSH-1	R	Field separator	Always:
MSH-2	R	Encoding characters	Always: ^~\&
MSH-3	R	Sending Application	Always: Savanna
MSH-4	R	Sending Facility	Always: Quidel
MSH-5	N	Receiving Application	Shall be used to identify the receiving system
MSH-6	N	Receiving Facility	Shall be used to identify the receiving system
MSH-7	R	Date / Time of message	Timestamp when the message has been created. Format: YYYYMMDDHHMMSS
MSH-8	N	Security	Empty
MSH-9	R	Message type	Always starts with: ACK
MSH-10	R	Message Control ID	Unique Number to identify the message
MSH-11	R	Processing ID	Always: P
MSH-12	R	Version ID	Always: 2.6
...	N		Not used

MSH ACK Example

```
MSH|^~\&|Savanna|Quidel|20190108134142||ACK|15469630785135|P|2.6
```

3.5.5.2 MSA: Acknowledgment Code Segment

Field	R/O/N	Name	Description
MSA-1	R	Acknowledgement Code	Positive acknowledge: "AA" Negative acknowledge: "AR"
MSA-2	R	Message Control ID	Must be MSH-10 of corresponding order
...	N	Not used	

MSA Acknowledgement Example

```
MSA|AA|15428056991525
```

3.6 HL7 Examples

Order Transmission by Assay Panel

```
MSH|^~\&||||20190106112236||ORM^O01|0011||2.6
PID||P0011||Smith^John||19731106134713
ORC|NW|0000011
OBR|1||^HSV 1+2-VZV||20181121131908|20181121131908|||||P
```

Order Transmission by Analyte

```
MSH|^~\&||||20190106112236||ORM^O01|0011||2.6
PID||P0011||Smith^John||19731106134713
ORC|NW|0000011
OBR|1||^HSV-1||20181121131908|20181121131908|||||P
OBR|2||^HSV-2||20181121131908|20181121131908|||||P
OBR|2||^VZV||20181121131908|20181121131908|||||P
```

Order Received Acknowledgement

```
MSH|^~\&|Savanna|Quidel|||20190106112242||ACK^O01|14543173625293|P|2.6
MSA|AA|0011
```

Patient Result – From Savanna to LIS

```
MSH|^~\&|Savanna^15020027|Quidel|||20190106114744||ORU^R01|14543174849305|P|2.6
PID|1||P0011||Smith^John||19731106134713
ORC|RE|0000011|0000011
OBR|1|0000011|0000011|^HSV 1+2-
VZV||20190106114744|20190106114744|||||P|||||TestUser|
OBX|1|ST|HSV-1^^^LOINC||positive|||||F||20190106114744|||15020027|20181121131908|||Site1
OBX|2|ST|HSV-1Ct^^^LOINC||27|||||F||20190106114744|||15020027|20181121131908|||Site1
OBX|3|ST|HSV-2^^^LOINC||negative|||||F||20190106114744|||15020027|20181121131908|||Site1
OBX|4|ST|HSV-2Ct^^^LOINC||26|||||F||20190106114744|||15020027|20181121131908|||Site1
OBX|5|ST|VZV^^^LOINC||negative|||||F||20190106114744|||15020027|20181121131908|||Site1
OBX|6|ST|VZVct^^^LOINC||25|||||F||20190106114744|||15020027|20181121131908|||Site1
```

Transmission Acknowledge – From LIS to Savanna

```
MSH|^~\&||Savanna^15020027|Quidel |20190106114746||ACK|14543174849305|P|2.6
MSA|AA|14543174849305
```

QC Result – From Savanna to LIS

```
MSH|^~\&|Savanna^15020027|Quidel|||20190106114744||ORU^R01|14543174849305|P|2.6
PID|1||CASSETLOT12||
ORC|NW|KITLOT12|KITLOT12
OBR|1|KITLOT12|KITLOT12|^Flu
A+B||20190106114744|20190106114744|||||Q|||||Testuser|
OBX|1|ST|POS||passed|||||F||20190106114744||2142||15020027|20181121131908
```

Transmission Acknowledge

```
MSH|^~\&||Savanna^15020027|Quidel |20190106114746||ACK|14543174849305|P|2.6
MSA|AA|14543174849305
```

Transmission Acknowledge

```
MSH|^~\&||Savanna^15020027|Quidel |20190106114746||ACK|14543174849305|P|2.6
MSA|AA|14543174849305
```

4 The POCT Bidirectional Interface – Functional Description

The Savanna POCT Interface is compliant with version POCT01-A2 of the Clinical and Laboratory Standards Institute (CLSI) standard for electronic data exchange. This Interface implements a subset of the POCT01-A2 standard; Observation messages for result transmissions, date/time updates, and operator list management messages. Additionally, it supports the ACK message for transmission acknowledgments.

The bidirectional use of the POCT LIS Interface means that the Savanna instrument can receive date and time updates and Operator List management from an LIS system and send the results to the LIS system upon completion of those tests.

Implementation of a bidirectional POCT Interface requires one (1) Interface be setup

Savanna Instrument	POCT System
<p>Bidirectional Interface ↔</p> <p>Configured to request Date/Time updates, Operator List management, and send test results to the LIS at the LIS IP Address and Port number that is listening for the Savanna's POCT connection.</p>	<p>Bidirectional Interface ↔</p> <p>The POCT Server listens for the Savanna request for Date/Time updates, Operator List management, and Savanna send test results on its IP Address and designated Port number.</p>

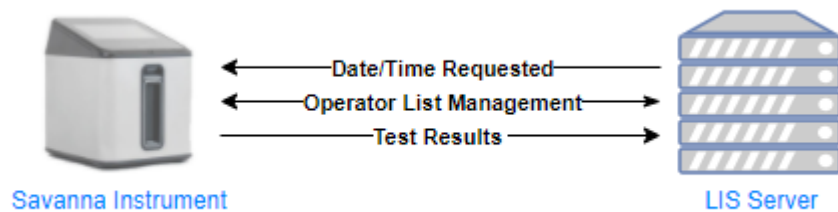


Figure 7: POCT Bidirectional Interface

4.1 Savanna POCT LIS Interface Configuration

The screenshot shows the 'LIS Connectivity' configuration screen. At the top left is a '< BACK' button, and at the top right is a 'Save Changes' button. The screen is divided into two main columns. The left column contains two sections: 'LIS STATUS' with a checked checkbox for 'Enabled', and 'AUTO SEND' with a checked checkbox for 'Auto Send Results'. The right column contains the 'PROTOCOL' section with two radio buttons: 'HL7' (unselected) and 'POCT1-A' (selected). Below the radio buttons is a checked checkbox for 'Use LIS Operators'. At the bottom of the right column is a 'Protocol Network Settings' button.

Figure 8: POCT Interface Setup

After setting up the Savanna instrument with an IP address for its network connection, configure the LIS Connectivity setup.

The example LIS Connectivity setup screen above is where the connectivity settings are configured.

- The **LIS STATUS** is either checked to confirm Enabled or unchecked to be Not Enabled.
- **AUTO SEND** is either checked for Auto Send Results to have the reported results sent upon test completion or unchecked for manual only send.
- **PROTOCOL** is set to "POCT1-A".
- Under PROTOCOL, "Use LIS Operators" is used to allow the LIS server to manage the operators on the device.
- Select the **Protocol Network Settings** button to set the IP and Port settings for the HL7 Interface(s).

4.1.1 Protocol Network Settings

Protocol Network Settings

Save Changes

NETWORK SETTINGS

Server IP Address *Required
192.168.1.149

Server Name *Required
POCT1a Server Alpha

Server Port *Required
4095

Figure 9: POCT01-A2 Protocol Network Settings

- The "Server IP Address" is the Network IP address where the Savanna Instrument will send the Test Result messages.
- The "Server Name" is a User defined identifier for the LIS server.
- The "Server Port" is the Port on which the POCT Server is Listening for test results from the Savanna.
- Select **Save Changes** to save all inputs.

Note: The values in *Figure 10* are only examples. Your specific configuration will be different.

The LIS Administrator or LIS Vendor Support will advise on the correct Server IP and Server Port number for the POCT Interface.

4.2 Operator List Management

POCT allows for operator list management in Savanna. The user can add users manually on the Savanna instrument or receive users from the LIS server. When the LIS server sends a new user list, the instrument will remove all the current users that were added from the previous LIS user list. It will then add the new LIS user list. When the instrument receives the user list, it must be the complete list because it will remove the previous users received from the LIS server. The instrument will not remove or modify any users that were manually entered by the Administrator. If the user already exists when the LIS user list is received, it will not modify this existing user.

4.3 POCT Introduction Message Sequence

After the connection has been established between the Savanna instrument and the LIS, a conversation starts with the Hello message and ends with the Terminate message. During the conversation, Savanna and the LIS send messages to each other. Messages are always acknowledged by the other conversation participant. Messages are in xml format.

After each message is sent, the Savanna instrument expects an ACK message from the LIS, otherwise the transfer will report as failed and the results will need to be resent.

A communication session (conversation) is always initiated by the Savanna. The conversation has two phases:

A logical representation of a successful introduction sequence below.

Savanna	LIS
HEL The Savanna initiates the conversation	
	ACK.R01
DST.R01 The Savanna sends its status to the LIS (always 0 not transmitted results).	
	ACK.R01
	DTV.R02 Set time
ACK.R01 Savanna sets the current time/date as sent by the DTV.R02 message	
	OPL.R01 Send Operator List
ACK.R01 Savanna deletes the User DB, inserts the default supervisor, and adds the operator list as sent by the OPL.R01 messages.	
There can be multiple calls of OPL.R01 if there are many operators. Continue to append to the operator list until EOT.R01 is received.	
	...
...	
	EOT.R01 End Operator List
	DTV.R01 Start continuous.
ACK.R01 The Savanna switches to LIS continuous phase.	

The introduction sequence starts if the Savanna instrument intends to send results to LIS. Note that the Savanna instrument always declares a value of 0 not-transmitted results during the introduction and then switches to continuous mode.

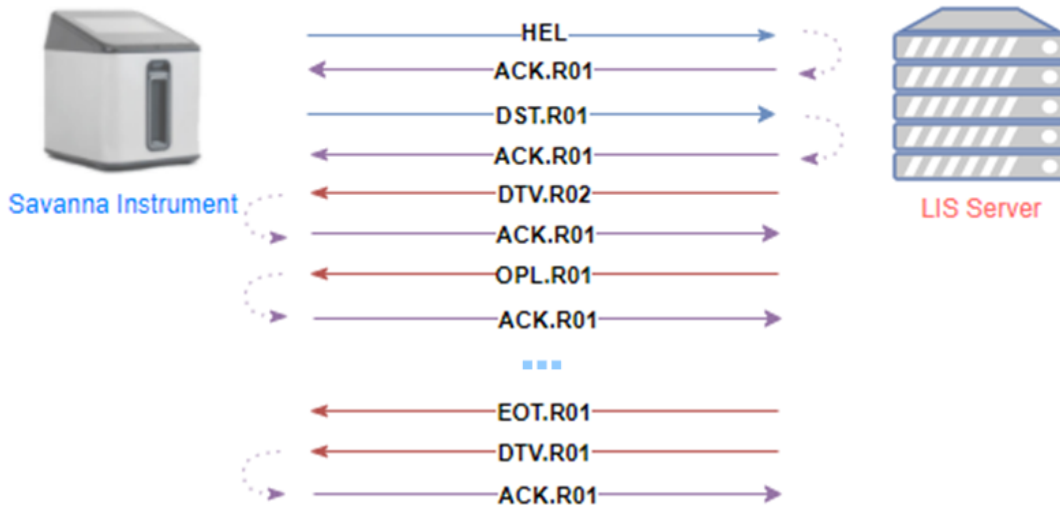


Figure 10: Phase 1 Introduction Sequence

4.4 POCT Continuous Phase Sequence

During this 2nd phase of communication, the Savanna instrument will transmit, without any request from the LIS, new measurement results or unsent results stored in the Savanna to the LIS.

Savanna	LIS
OBS.R01 The Savanna sends a new/stored patient result to the LIS.	
	ACK.R01
OBS.R02 The Savanna sends a new/stored non-patient result to the LIS.	
	ACK.R01
...	...
END.R01 The Savanna end the current conversation.	
	ACK.R01

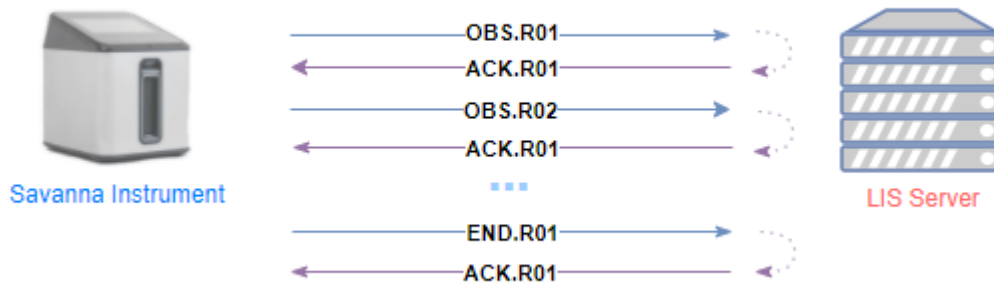


Figure 11: Continuous Phase – Sending Test Result

The continuous phase will be terminated by any of the conversation participants by sending a termination message. The Savanna instrument will send a termination message if the sending of the result/results is finished.

An Error Ack message is sent by the Savanna instrument if it gets invalid data. If the Savanna instrument receives an "error ack", it resends the message 3 times. If this also ends up in an error ack message:

- It sends a termination message and the conversation ends during the introduction phase.
- It does not change state during the continuous phase.

If any unexpected message is received by the Savanna instrument, it transmits an ESC and an END message and disconnects from the LIS

4.5 Introduction Message Phase Detail and Examples

The Introduction message phase is made up of the following xml messages.

Xml-Header	Always: <?xml version="1.0" encoding="UTF-8"?>
HEL.R01	Hello Message
ACK.R01	Acknowledgement Message
DST.R01	Device Status Message
DTV.R02	Complex Directive Message
OPL.R01	Operator List Message
EOT.R01	End Of Topic Message (at the end of the Operator List topic)
DTV.R01	Basic Directive Message

Each of these message segments contain fields of data defined by the POCT01-A2 standard. The fields listed below are mandatory and sent. In the following tables defining the message segments, a description and example of each data field is presented.

The XML header should be included in every frame from server and client.

4.5.1 HEL.R01 – Hello Message

Field	Description	Example
HDR.control_id	A string guaranteed to uniquely identify this message throughout the conversation. Savanna implements this as an integer value.	"00001"
HDR.version_id	Version ID	Always: "POCT1"
HDR.creation_dttm	Savanna date and time when the message was sent.	"2015-08-11T10:17:03-00:00"
DEV.device_id	Savanna MAC Address	"00:20:4a:be:cf:a5"
DEV.serial_id	Savanna Serial Number	"00010387"
DEV.manufacturer_name	The Savanna's corporate name	Always: "QUIDEL"
DEV.hw_version	The version number for the Savanna hardware	"00.03.01"
DEV.sw_version	The version number for the Savanna software	"02.03.01"
DEV.device_name	The model name for the Savanna	Always: "Savanna"
DCP.application_timeout	Savanna application timeout in seconds	Always: "60"
DSC.connection_profile_cd	CIC messaging profile that Savanna supports	Always: "CS"
DSC.topics_supported_cd	The message topics (beyond the minimum) supported. Device supports Device Event topic.	Always: "DTV"
DSC.topics_supported_cd	The message topics (beyond the minimum) supported. Device supports Operator List topic.	Always: "OP_LST"
DSC.directives_supported_cd	The Directive commands that Savanna supports	Always: "SET_TIME"
DSC.directives_supported_cd	The Directive commands that Savanna supports	Always: "START_CONTINUOUS"
DSC.max_message_sz	The max size message (in bytes) that Savanna can handle	Always: "65535"

HEL.R01 Example

```
<?xml version="1.0" encoding="UTF-8"?>
<HEL.R01>
  <HDR>
    <HDR.control_id V="00001"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2015-08-11T10:17:03-00:00"/>
  </HDR>
```

```

<DEV>
  <DEV.device_id V="00:20:4a:be:cf:a5"/>
  <DEV.serial_id V="00010387"/>
  <DEV.manufacturer_name V="QUIDEL"/>
  <DEV.hw_version V="00.03.01"/><DEV.sw_version V="02.03.01"/>
  <DEV.device_name V="Savanna"/>
  <DCP>
    <DCP.application_timeout V="60"/>
  </DCP>
  <DSC>
    <DSC.connection_profile_cd V="CS"/>
    <DSC.topics_supported_cd V="DTV"/>
    <DSC.topics_supported_cd V=" OP_LST"/>
    <DSC.directives_supported_cd V="SET_TIME"/>
    <DSC.directives_supported_cd V="START_CONTINUOUS"/>
    <DSC.max_message_sz V="65535"/>
  </DSC>
</DEV>
</HEL.R01>

```

4.5.2 ACK.R01 – Acknowledgement Message

Field	Description	Example
HDR.control_id	A string guaranteed to uniquely identify this message throughout the conversation.	"4011"
HDR.version_id	Version ID	Always: "POCT1"
HDR.creation_dttm	LIS date and time when the message was sent.	"2015-05-20T08:21:50-00:00"
ACK.type_cd	A code indicating whether the associated message was accepted (AA), in error (AE) or was rejected (AE).	"AA"
ACK.ack_control_id	The control ID of the message that this message is in acknowledgement of.	"1"

ACK.R01 Example

```

<?xml version="1.0" encoding="UTF-8"?>
<ACK.R01>
  <HDR>
    <HDR.control_id V="4011"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2015-05-20T08:21:50-00:00"/>
  </HDR>
  <ACK>
    <ACK.type_cd V="AA"/>
    <ACK.ack_control_id V="1"/>
  </ACK>

```

</ACK.R01>

4.5.3 DST.R01 – Device Status Message

Field	Description	Example
HDR.control_id	A string guaranteed to uniquely identify this message throughout the conversation.	"00002"
HDR.version_id	Version ID	Always: "POCT1"
HDR.creation_dttm	Savanna date and time when the message was sent.	"2015-05-20T08:56:22-00:00"
DST.status_dttm	The time from the Savanna that this status was observed.	"2015-05-20T08:56:22-00:00"
DST.new_observations_qty	The number of observations that Savanna has to report. In Introduction, this value is always 0.	Always: "0"
DST.condition_cd	The current level of readiness of the Savanna.	Always: "R"

DST.R01 Example

```
<?xml version="1.0" encoding="UTF-8"?>
<DST.R01>
  <HDR>
    <HDR.control_id V="00002" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2015-05-20T08:56:22-00:00" />
  </HDR>
  <DST>
    <DST.status_dttm V="2015-05-20T08:56:22-00:00" />
    <DST.new_observations_qty V="0" />
    <DST.condition_cd V="R" />
  </DST>
</DST.R01>
```

4.5.4 DTV.R02 – Complex Directive Message

Field	Description	Example
HDR.control_id	A string guaranteed to uniquely identify this message throughout the conversation.	"4013"
HDR.version_id	Version ID	Always: "POCT1"
HDR.creation_dttm	LIS date and time when the message was sent.	"2015-05-20T08:56:24-00:00"
DTV.command_cd	The Directive commands that Savanna supports to set the date and time, "SET_TIME".	Always: "SET_TIME"
TM.dttm	Observation Reviewer date-time stamp, conforming to the TS data	"2019-05-20T08:56:24+00:00"

	type rules. Since Savanna does not address time zone, the time zone offset is always "+00:00"	
--	---	--

DTV.R02 Example

```
<?xml version="1.0" encoding="UTF-8"?>
<DTV.R02>
  <HDR>
    <HDR.control_id V="4013" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2015-05-20T08:56:22-00:00" />
  </HDR>
  <DTV>
    <DTV.command_cd V="SET_TIME" />
  </DTV>
  <TM>
    <TM. dttm V="2019-05-04T11:48:51+00:00" />
  </TM>
</DTV.R02>
```

4.5.5 OPL.R01 – Operator List Message

LIS User Importing Process:

- Remove all (existing/previous) LIS users
- Insert list of LIS users to the instrument list until the EOT.R01 message is received. May be done in multiple OPL

Note: Imported Operator ID (Savanna User ID) cannot be equal to Built-in users; Supervisor, Operator or Service.

Field	Description	Example
HDR.control_id	A string guaranteed to uniquely identify this message throughout the conversation.	"4014"
HDR.version_id	Version ID	Always: "POCT1"
HDR.creation_dttm	Savanna date and time when the message was sent.	"2019-05-04T11:48:54-05:00"
OPR.operator_id	The unique identifier for the operator.	"Franklin" (Savanna User ID)
OPR.name	The full name of the operator.	"Franklin Johnson"
ACC.method_cd	Savanna operators are granted permission to use all methods.	Always: "ALL"
ACC.permission_level_cd	The code that notates the Savanna access level of the operator. 1 = SUPERVISOR, 4 = USER	"1"
NTE.text	The Savanna value for operator to transmit as the Surveillance ID for Virena.	"20"

OPL.R01 Example

```
<?xml version="1.0" encoding="UTF-8"?>
<OPL.R01>
  <HDR>
    <HDR.control_id V="4014" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2019-05-04T11:48:54-05:00"/>
  </HDR>
  <OPR>
    <OPR.operator_id V=" Franklin" />
    <OPR.name V="Franklin Johnson"/>
    <ACC>
      <ACC.method_cd V="ALL"/>
      <ACC.permission_level_cd V="1"/>
    </ACC>
    <NTE>
      <NTE.text V="20"/>
    </NTE>
  </OPR>
  <OPR>
    .
    .
    .
  </OPR>
</OPL.R01>
```

4.5.6 EOT.R01 – End of Topic Message (at the end of the Operator List topic)

EOT.R01 Example

```
<?xml version="1.0" encoding="UTF-8"?>
<EOT.R01>
  <HDR>
    <HDR.control_id V="4015" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2019-05-04T11:52:54-05:00" />
  </HDR>
  <EOT>
    <EOT.topic_cd V="OPL" />
  </EOT>
</EOT.R01>
```

4.5.7 DTV.R01 – Basic Directive Message

Field	Description	Example
HDR.control_id	A string guaranteed to uniquely identify this message throughout the conversation.	"4016"
HDR.version_id	Version ID	Always: "POCT1"
HDR.creation_dttm	Savanna date and time when the message was sent.	"2019-05-04T11:53:54-05:00"
DTV.command_cd	The Directive commands that Savanna supports	Always: "START_CONTINUOUS"

DTV.R01 Example

```
<?xml version="1.0" encoding="UTF-8"?>
<DTV.R01>
  <HDR>
    <HDR.control_id V="4016" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2019-05-04T11:53:54-05:00" />
  </HDR>
<DTV>
  <DTV.command_cd V="START_CONTINUOUS" />
</DTV>
</DTV.R01>
```

4.6 LIS Continuous Message Phase

The LIS Continuous message phase is made up of the following xml messages.

Xml-Header Always: <?xml version="1.0" encoding="UTF-8"?>
 OBS.R01 Patient Test Observation Message
 OBS.R02 Non-Patient Test Observation Message
 ACK.R01 Acknowledgement Message
 END.R01 Terminate Message

Each of these message segments contain fields of data defined by the POCT1-A2 standard. The fields listed below are mandatory and sent. In the following tables defining the message segments, a description and example of each data field is presented.

4.6.1 OBS.R01 – Patient Test Observation Message

Field	Description	Example
HDR.control_id	A string guaranteed to uniquely identify this message throughout the conversation. Savanna implements this as an integer value.	"00027"
HDR.version_id	Version ID	Always: "POCT1"
HDR.creation_dttm	Savanna date and time when the message was sent.	"2019-02-22T11:02:44-00:00"
SVC.role_cd	For a patient test, this value is always "OBS".	Always: "OBS"
SVC.observation_dttm	Savanna date and time when the test completed.	"2019-02-22T11:01:29-00:00"
SVC.reason_cd	Is the observation NEW or RES for resend?	"NEW"
PT.patient_id	The Savanna patient id entry.	"Y B1232"
OBS.observation_id	The analyte name from the Test Type File.	"HSV-1" append SN="QUIDEL" if it is a datatype unique to Quidel. (i.e. not in a POCT1 table).
OBS.qualitative_value	The qualitative result value from Savanna.	"negative"
OBS.value	The quantitative Ct value from Savanna if enabled.	"26"
OBS.method_cd	Savanna value determination, Measured "M", not Calculated "C".	Always: "M"
OPR.operator_id	The unique identifier for the operator.	"5010"
ORD.universal_service_id	The assay long name from the Test Type File.	"HSV 1+2-VZV"
ORD.order_id	Order Number from the Savanna.	"1232Y B" append SN="QUIDEL" if it is a datatype unique to Quidel. (i.e. not in a POCT1 table).
RGT.name	The assay long name from the Test Type File.	"HSV 1+2-VZV"
RGT.lot_number	The cassette lot number.	"140403"
RGT.expiration_date	The cassette expiration date in format YYYY-MM-DD.	"2025-04-03"

OBS.R01 Example

```
<?xml version="1.0" encoding="UTF-8"?>
<OBS.R01>
  <HDR>
    <HDR.control_id V="00027"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2019-02-22T11:02:44-00:00"/>
  </HDR>
  <SVC>
    <SVC.role_cd V="OBS"/>
    <SVC.observation_dttm V="2019-02-22T11:01:29-00:00"/>
  </SVC>
</OBS.R01>
```



```

<SVC.reason_cd V="NEW"/>
<PT>
  <PT.patient_id V="Y B1232"/>
  <OBS>
    <OBS.observation_id V="HSV-1" SN="QUIDEL"/>
    <OBS.qualitative_value V="positive"/>
    <OBS.method_cd V="M"/>
  </OBS>
  <OBS>
    <OBS.observation_id V="HSV-1Ct" SN="QUIDEL"/>
    <OBS.value V="27"/>
    <OBS.method_cd V="M"/>
  </OBS>
  <OBS>
    <OBS.observation_id V="HSV-2" SN="QUIDEL"/>
    <OBS.qualitative_value V="negative"/>
    <OBS.method_cd V="M"/>
  </OBS>
  <OBS>
    <OBS.observation_id V="VZV" SN="QUIDEL"/>
    <OBS.qualitative_value V="negative"/>
    <OBS.method_cd V="M"/>
  </OBS>
</PT>
<OPR>
  <OPR.operator_id V="5010"/>
</OPR>
<ORD>
  <ORD.universal_service_id V="HSV 1+2-VZV"/>
  <ORD.order_id V="1232Y B" SN="QUIDEL"/>
</ORD>
<RGT>
  <RGT.name V="Savanna HSV 1+2-VZV"/>
  <RGT.lot_number V="140403"/>
  <RGT.expiration_date V="2025-04-03"/>
</RGT>
</SVC>
</OBS.R01>

```

4.6.2 OBS.R02 – Non-Patient Test Observation Message

Field	Description	Example
HDR.control_id	A string guaranteed to uniquely identify this message throughout the conversation. Savanna implements this as an integer value.	"00027"
HDR.version_id	Version ID	Always: "POCT1"
HDR.creation_dttm	Savanna date and time when the message was sent.	"2019-02-22T11:02:44-00:00"

Field	Description	Example
SVC.role_cd	For a Calibration test "CAL" and for a QC test "LQC".	"CAL"
SVC.observation_dttm	Savanna date and time when the test completed.	"2019-02-22T11:01:29-00:00"
SVC.reason_cd	Is the observation NEW or RES for resend?	"NEW"
CTC.name	For a Calibration test, "Calibration Result". For a QC test, "QC Result".	"Calibration Result"
CTC.lot_number	The cassette lot number for a Calibration test. The kit lot number for a QC test.	"103533"
CTC.expiration_date	The expiration date of the QC kit in format YYYY-MM-DD.	"2020-06-30"
CTC.level_cd	For a QC test either "Positive Control" or "Negative Control". For a Calibration this field is omitted.	"Positive Control"
OBS.observation_id	The analyte name from the Test Type File.	"Overall Result", append SN="QUIDEL" if the datatype is unique to Quidel. (i.e. not listed in POCT1 tables.)
OBS.qualitative_value	The qualitative result value from Savanna.	"passed"
OBS.method_cd	Savanna value determination, Measured "M", not Calculated "C".	Always: "M"
OPR.operator_id	The unique identifier for the operator.	"5010"
RGT.name	For a QC test, the assay long name from the Test Type File.	"HSV 1+2-VZV"
RGT.lot_number	For a QC test, the cassette lot number.	"140403"
RGT.expiration_date	For a QC test, the cassette expiration date in format YYYY-MM-DD.	"2025-04-03"

OBS.R02 Example

```
<?xml version="1.0" encoding="UTF-8"?>
<OBS.R02>
  <HDR>
    <HDR.control_id V="00018"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2019-02-22T11:02:25-00:00"/>
  </HDR>
  <SVC>
    <SVC.role_cd V="OBS"/>
    <SVC.observation_dttm V="2016-05-19T07:51:22-00:00"/>
    <SVC.reason_cd V="RES"/>
    <CTC>
      <CTC.name V="Calibration Result"/>
    </CTC>
  </SVC>
</OBS.R02>
```

```

    <CTC.lot_number V="103533"/>
    <CTC.expiration_date V="2020-06-30"/>
    <OBS>
      <OBS.observation_id V="Overall Result" SN="QUIDEL"/>
      <OBS.qualitative_value V="passed"/>
      <OBS.method_cd V="M"/>
    </OBS>
  </CTC>
  <OPR>
    <OPR.operator_id V="5010"/>
  </OPR>
</SVC>
</OBS.R02>

```

4.6.3 ACK.R01 – Acknowledgement Message

Field	Description	Example
HDR.control_id	A string guaranteed to uniquely identify this message throughout the conversation.	"4011"
HDR.version_id	Version ID	Always: "POCT1"
HDR.creation_dttm	Savanna date and time when the message was sent.	"2015-05-20T08:21:50-00:00"
ACK.type_cd	A code indicating whether the associated message was accepted (AA), in error (AE) or was rejected (AE).	"AA"
ACK.ack_control_id	The control ID of the message that this message is in acknowledgement of.	"1"
ACK.error_detail_cd	If it gets invalid data.	"234" [In SW version after 6.0]

ACK.R01 Example

```

<?xml version="1.0" encoding="UTF-8"?>
<ACK.R01>
  <HDR>
    <HDR.control_id V="4011"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2015-05-20T08:21:50-00:00"/>
  </HDR>
  <ACK>
    <ACK.type_cd V="AA"/>
    <ACK.ack_control_id V="1"/>
  </ACK>
</ACK.R01>

```

4.7 POCT Message Examples

4.7.1 Example A: Savanna instrument initiating the conversation with LIS

```
Savanna: <?xml version="1.0" encoding="UTF-8"?>
  <HEL.R01>
    <HDR>
      <HDR.control_id V="00001"/>
      <HDR.version_id V="POCT1"/>
      <HDR.creation_dttm V="2017-12-07T11:48:49-00:00"/>
    </HDR>
    <DEV>
      <DEV.device_id V="00:20:4a:ec:12:7a"/>
      <DEV.serial_id V="00018029"/>
      <DEV.manufacturer_name V="QUIDEL"/>
      <DEV.hw_version V="00.03.01"/>
      <DEV.sw_version V="02.03.00"/>
      <DEV.device_name V="Savanna"/>
      <DCP>
        <DCP.application_timeout V="10"/>
      </DCP>
      <DSC>
        <DSC.connection_profile_cd V="CS"/>
        <DSC.topics_supported_cd V="DTV"/>
        <DSC.topics_supported_cd V="OP_LST"/>
        <DSC.directives_supported_cd V="SET_TIME"/>
        <DSC.directives_supported_cd V="START_CONTINUOUS"/>
        <DSC.max_message_sz V="65535"/>
      </DSC>
    </DEV>
  </HEL.R01>
```

```
LIS: <?xml version="1.0" encoding="UTF-8"?>
  <ACK.R01>
    <HDR>
      <HDR.control_id V="1"/>
      <HDR.version_id V="POCT1"/>
      <HDR.creation_dttm V="2018-12-07T11:48:39-05:00"/>
    </HDR>
    <ACK>
      <ACK.type_cd V="AA"/>
      <ACK.ack_control_id V="00001"/>
    </ACK>
  </ACK.R01>
```

4.7.2 Example B: Savanna instrument sending status to LIS

```
Savanna: <?xml version="1.0" encoding="UTF-8"?>
  <DST.R01>
    <HDR>
      <HDR.control_id V="00002" />
      <HDR.version_id V="POCT1" />
      <HDR.creation_dttm V="2017-12-07T11:48:51-00:00" />
    </HDR>
    <DST>
      <DST.status_dttm V="2017-12-07T11:48:51-00:00" />
      <DST.new_observations_qty V="0" />
      <DST.condition_cd V="R" />
    </DST>
  </DST.R01>
```

```
LIS: <?xml version="1.0" encoding="UTF-8"?>
  <ACK.R01>
    <HDR>
      <HDR.control_id V="2"/>
      <HDR.version_id V="POCT1"/>
      <HDR.creation_dttm V="2018-12-07T11:48:40-05:00"/>
    </HDR>
    <ACK>
      <ACK.type_cd V="AA"/>
      <ACK.ack_control_id V="00002"/>
    </ACK>
  </ACK.R01>
```

4.7.3 Example C: LIS DTV.R02 Set Time command to Savanna instrument

```
LIS: <?xml version="1.0" encoding="UTF-8"?>
  <DTV.R02>
    <HDR>
      <HDR.control_id V="3" />
      <HDR.version_id V="POCT1" />
      <HDR.creation_dttm V="2018-12-07T11:48:41-05:00" />
    </HDR>
    <DTV>
      <DTV.command_cd V="SET_TIME" />
    </DTV>
    <TM>
      <TM. dttm V="2018-12-07T11:48:41+00:00" />
    </TM>
  </DTV.R02>
```

```
Savanna: <?xml version="1.0" encoding="UTF-8"?>
  <ACK.R01>
    <HDR>
```

```

        <HDR.control_id V="00003"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2018-12-07T11:48:41-00:00"/>
    </HDR>
    <ACK>
        <ACK.type_cd V="AA"/>
        <ACK.ack_control_id V="3"/>
    </ACK>
</ACK.R01>

```

4.7.4 Example D: LIS OPL.R01 Send Operator List of 2 Users and 1 Supervisor to Savanna instrument

```

LIS: <?xml version="1.0" encoding="UTF-8"?>
    <OPL.R01>
        <HDR>
            <HDR.control_id V="4"/>
            <HDR.version_id V="POCT1"/>
            <HDR.creation_dttm V="2018-12-07T11:48:42-05:00"/>
        </HDR>
        <OPR>
            <OPR.operator_id V="5000"/>
            <OPR.name V="Chen"/>
            <ACC>
                <ACC.method_cd V="ALL"/>
                <ACC.permission_level_cd V="4"/>
            </ACC>
            <NTE>
                <NTE.text V="10"/>
            </NTE>
        </OPR>
        <OPR>
            <OPR.operator_id V="5001"/>
            <OPR.name V="Majors"/>
            <ACC>
                <ACC.method_cd V="ALL"/>
                <ACC.permission_level_cd V="1"/>
            </ACC>
            <NTE>
                <NTE.text V="11"/>
            </NTE>
        </OPR>
        <OPR>
            <OPR.operator_id V="5002"/>
            <OPR.name V="Snowden"/>
            <ACC>
                <ACC.method_cd V="ALL"/>
                <ACC.permission_level_cd V="1"/>
            </ACC>
            <NTE>

```

```
        <NTE.text V="12"/>
    </NTE>
</OPR>
</OPL.R01>
```

```
Savanna: <?xml version="1.0" encoding="UTF-8"?>
<ACK.R01>
  <HDR>
    <HDR.control_id V="00004" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2018-12-07T11:49:04-00:00" />
  </HDR>
  <ACK>
    <ACK.type_cd V="AA" />
    <ACK.ack_control_id V="4" />
    <ACK.error_detail_cd V="123" />
  </ACK>
</ACK.R01>
```

```
LIS: <?xml version="1.0" encoding="UTF-8"?>
<EOT.R01>
  <HDR>
    <HDR.control_id V="5"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2018-12-07T11:49:04-05:00"/>
  </HDR>
  <EOT>
    <EOT.topic_cd V="OPL"/>
  </EOT>
</EOT.R01>
```

4.7.5 Example E: LIS DTV.R01 Start Continuous command to Savanna instrument

```
LIS: <?xml version="1.0" encoding="UTF-8"?>
<DTV.R01>
  <HDR>
    <HDR.control_id V="6"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2018-12-07T11:49:04-05:00"/>
  </HDR>
  <DTV>
    <DTV.command_cd V="START_CONTINUOUS"/>
  </DTV>
</DTV.R01>
```

```
Savanna: <?xml version="1.0" encoding="UTF-8"?>
<ACK.R01>
  <HDR>
    <HDR.control_id V="00005" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2018-12-07T11:49:10-00:00" />
```

```

</HDR>
<ACK>
  <ACK.type_cd V="AA" />
  <ACK.ack_control_id V="6" />
  <ACK.error_detail_cd V="0" />
</ACK>
</ACK.R01>

```

4.7.6 Example F: Savanna send an OBS.R01 patient result, an OBS.R02 calibration result, and OBS.R02 QC result to LIS

```

Savanna: <?xml version="1.0" encoding="UTF-8"?>
<OBS.R01>
  <HDR>
    <HDR.control_id V="00006"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2018-12-07T11:49:12-00:00"/>
  </HDR>
  <SVC>
    <SVC.role_cd V="OBS"/>
    <SVC.observation_dttm V="2018-10-22T10:52:17-00:00"/>
    <SVC.reason_cd V="RES"/>
    <PT>
      <PT.patient_id V="218223"/>
      <OBS>
        <OBS.observation_id V="HSV-1" SN="QUIDEL"/>
        <OBS.qualitative_value V="positive"/>
        <OBS.method_cd V="M"/>
      </OBS>
      <OBS>
        <OBS.observation_id V="HSV-1Ct" />
        <OBS.value V="27"/>
        <OBS.method_cd V="M"/>
      </OBS>
      <OBS>
        <OBS.observation_id V="HSV-2" SN="QUIDEL"/>
        <OBS.qualitative_value V="negative"/>
        <OBS.method_cd V="M"/>
      </OBS>
      <OBS>
        <OBS.observation_id V="VZV" SN="QUIDEL"/>
        <OBS.qualitative_value V="negative"/>
        <OBS.method_cd V="M"/>
      </OBS>
    </PT>
    <OPR>
      <OPR.operator_id V="Supervisor"/>
    </OPR>
    <ORD>
      <ORD.universal_service_id V="HSV 1+2-VZV"/>
    </ORD>
  </SVC>
</OBS.R01>

```



```
        <ORD.order_id V="225" SN="QUIDEL"/>
    </ORD>
    <RGT>
        <RGT.name V="Savanna HSV 1+2-VZV"/>
        <RGT.lot_number V="129826"/>
        <RGT.expiration_date V="2020-04-06"/>
    </RGT>
</SVC>
</OBS.R01>
```

```
LIS: <?xml version="1.0" encoding="UTF-8"?>
<ACK.R01>
    <HDR>
        <HDR.control_id V="7"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2018-12-07T11:49:21-05:00"/>
    </HDR>
    <ACK>
        <ACK.type_cd V="AA"/>
        <ACK.ack_control_id V="00006"/>
    </ACK>
</ACK.R01>
```

```
Savanna: <?xml version="1.0" encoding="UTF-8"?>
<OBS.R02>
    <HDR>
        <HDR.control_id V="00008"/>
        <HDR.version_id V="POCT1"/>
        <HDR.creation_dttm V="2018-12-07T11:49:14-00:00"/>
    </HDR>
    <SVC>
        <SVC.role_cd V="CAL"/>
        <SVC.observation_dttm V="2018-11-22T14:59:38-00:00"/>
        <SVC.reason_cd V="RES"/>
        <CTC>
            <CTC.name V="Calibration Result"/>
            <CTC.lot_number V="103324"/>
            <CTC.expiration_date V="2020-06-30"/>
        <OBS>
            <OBS.observation_id V="Overall Result" SN="QUIDEL"/>
            <OBS.qualitative_value V="passed"/>
            <OBS.method_cd V="M"/>
        </OBS>
    </CTC>
    <OPR>
        <OPR.operator_id V="Supervisor"/>
    </OPR>
</SVC>
</OBS.R02>
```

```
LIS: <?xml version="1.0" encoding="UTF-8"?>
```

```

<ACK.R01>
  <HDR>
    <HDR.control_id V="9"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2018-12-07T11:49:24-05:00"/>
  </HDR>
  <ACK>
    <ACK.type_cd V="AA"/>
    <ACK.ack_control_id V="00008"/>
  </ACK>
</ACK.R01>

```

Savanna: <?xml version="1.0" encoding="UTF-8"?>

```

<OBS.R02>
  <HDR>
    <HDR.control_id V="00010"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2018-12-07T11:49:14-00:00"/>
  </HDR>
  <SVC>
    <SVC.role_cd V="LQC"/>
    <SVC.observation_dttm V="2018-11-22T14:59:38-00:00"/>
    <SVC.reason_cd V="RES"/>
    <CTC>
      <CTC.name V="QC Result"/>
      <CTC.lot_number V="106342"/>
      <CTC.expiration_date V="2020-06-30"/>
      <CTC.level_cd V="Positive Control"/>
      <OBS>
        <OBS.observation_id V="Overall Result" SN="QUIDEL"/>
        <OBS.qualitative_value V="passed"/>
        <OBS.method_cd V="M"/>
      </OBS>
    </CTC>
    <OPR>
      <OPR.operator_id V="Supervisor"/>
    </OPR>
  </SVC>
</OBS.R02>

```

LIS: <?xml version="1.0" encoding="UTF-8"?>

```

<ACK.R01>
  <HDR>
    <HDR.control_id V="11"/>
    <HDR.version_id V="POCT1"/>
    <HDR.creation_dttm V="2018-12-07T11:49:24-05:00"/>
  </HDR>
  <ACK>
    <ACK.type_cd V="AA"/>
    <ACK.ack_control_id V="000010"/>
  </ACK>

```

</ACK.R01>

Savanna: <?xml version="1.0" encoding="UTF-8"?>

<END.R01>

<HDR>

<HDR.control_id V="00012" />

<HDR.version_id V="POCT1" />

<HDR.creation_dttm V="2018-12-07T11:49:32-00:00" />

</HDR>

<TRM>

<TRM.reason_cd V="USR" />

</TRM>

</END.R01>

LIS: <?xml version="1.0" encoding="UTF-8"?>

<ACK.R01>

<HDR>

<HDR.control_id V="13"/>

<HDR.version_id V="POCT1"/>

<HDR.creation_dttm V="2018-12-07T11:49:22-05:00"/>

</HDR>

<ACK>

<ACK.type_cd V="AA"/>

<ACK.ack_control_id V="00012"/>

</ACK>

</ACK.R01>

5 Test Panel and Assay Names

The Table below outlines the Test Panel and individual Assay Name information.

- The Test Panel Name (HL7 = OBR-4.2) or (POCT = ORD.universal_service_id)
- The Analyte Name (HL7 = OBX-3.1) or (POCT = OBS.observation_id).
- The Observation Values (HL7 = OBX-5.1) or (POCT = OBS.qualitative_value)

Product Name	Test Panel Name	Analyte Names	Observation Values
STI Panel	STI Panel	CT	positive, negative, invalid
STI Panel	STI Panel	TV	positive, negative, invalid
STI Panel	STI Panel	NG	positive, negative, invalid
STI Panel	STI Panel	MG	positive, negative, invalid
HSV 1+2/VZV/TP Panel	HSV 1+2/VZV/TP	HSV 1	positive, negative, invalid
HSV 1+2/VZV/TP Panel	HSV 1+2/VZV/TP	HSV 2	positive, negative, invalid
HSV 1+2/VZV/TP Panel	HSV 1+2/VZV/TP	VZV	positive, negative, invalid
HSV 1+2/VZV/TP Panel	HSV 1+2/VZV/TP	Syphilis	positive, negative, invalid
Respiratory Viral Panel-4	RVP4	Flu A	positive, negative, invalid
Respiratory Viral Panel-4	RVP4	Flu B	positive, negative, invalid
Respiratory Viral Panel-4	RVP4	RSV	positive, negative, invalid
Respiratory Viral Panel-4	RVP4	SARS-CoV-2	positive, negative, invalid
Respiratory Viral Panel 4+	RVP4+	Flu A	positive, negative, invalid
Respiratory Viral Panel 4+	RVP4+	CoV-2	positive, negative, invalid
Respiratory Viral Panel 4+	RVP4+	RSV	positive, negative, invalid
Respiratory Viral Panel 4+	RVP4+	Flu B	positive, negative, invalid

Note 1: "invalid" result values will not be forwarded via the LIS Interface.

Note 2: This list may include products that are not available in your Country or Region and may include products planned for future release upon Regulatory approval.

6 Technical Support

If you have any questions regarding the use of this product or to report a problem, please contact QuidelOrtho Technical Support at 1.800.874.1517 (in the U.S.) or technicalsupport@quidel.com. If outside the U.S., further information can be obtained from your distributor, or directly from QuidelOrtho at one of the numbers listed below. Reference quidel.com to see more options for Support.

Country	Phone	E-Mail Address
Europe, Middle East, and Africa	+353 (91) 412 474 (main) 1800 200441 (toll free)	
Austria	+43 316 231239	
Belgium	+32 (2) 793 0180	
France	0 (805) 371674	
Germany	+49 (0) 7154 1593912	emeatechnicalsupport@quidel.com
Netherlands	0 800 0224198	
Switzerland	0 800 554864	
United Kingdom	0 800 3688248	
Ireland	+353 (91) 412 474	
Italy	+39 (800) 620 549	
North America, Asia-Pacific, Latin America	858 552 1100	technicalsupport@quidel.com
Canada	437 266 1704 (main) 888 415 8764 (toll free)	technicalsupport@quidel.com
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7 Revision History

Revision	Change Summary
A	This is the initial release