



Sofia®

Technical Bulletin

LIS Interface Specification

1. Sofia Instrument Interface Specification – Overview

The scope of this document is to provide detail on the capabilities and requirements for implementing a Systems Interface between the Sofia Instrument and the LIS System.

The Sofia Instrument implements either an industry standard ASTM interface or POCT1a interface for use over Ethernet networks. The interface is designed to support uni-directional (ASTM) or bi-directional (POCT1a) communications with Laboratory Information Systems (LIS). The LIS interface is built into the Sofia instrument and requires minimal configuration to use.

The physical instrument connection is via Ethernet and the transport is via the TCP/IP Protocol. The instrument has one standard Ethernet RJ-45 connector.

Uni-directional (ASTM)

Sofia may be setup to only send test results, thus uni-directional. The ASTM interface is compliant with versions LIS1-A (formally ASTM E1381-91) and LIS2-A (formerly ASTM E1394-97) of the Clinical and Laboratory Standards Institute (CLSI) standard for electronic data exchange.

Implementation of a uni-directional interface requires one (1) interface be setup;

Sofia Instrument	LIS System
Results Interface ➡ Configured to send Test Results to the LIS at the LIS IP Address and Port number that's listening for Test Results.	Results Interface ➡ LIS listens for Test Results on its IP Address and designated Port number.

Bi-directional (POCT1a)

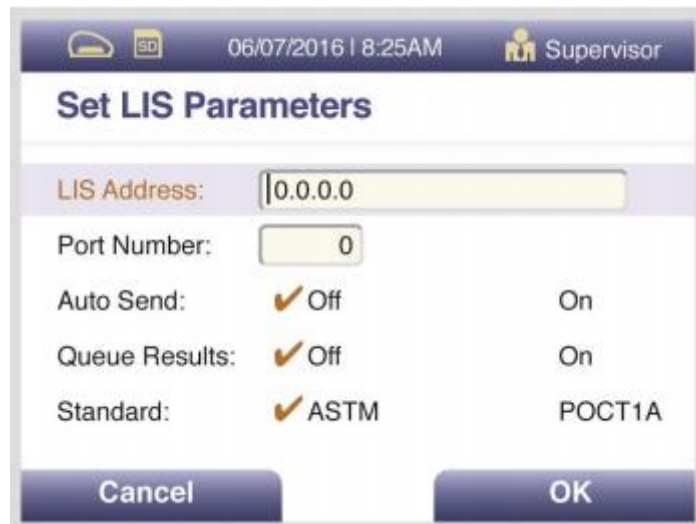
The bi-directional use of the LIS interface means that the Sofia Instrument can receive date and time updates and Operator List management from the LIS system and send the results to the LIS system upon completion of those tests. The POCT1a interface is compliant with version POCT1-A2 of the Clinical and Laboratory Standards Institute (CLSI) standard for electronic data exchange.

Implementation of a bi-directional interface requires one (1) interface be setup;

Sofia Instrument	LIS System
Bi-directional Interface ↔ 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 POCT1a interface.	Bi-directional Interface ↔ LIS listens for the Sofia request for date/time updates, operator list management, and test results on its IP address and designated port number.

1.1. LIS Interface configuration

LIS Interface setup screen in Sofia



After setting up the Sofia with an IP address for its network connection, configure the LIS interface settings.

The example “Set LIS Parameters” setup screen above is where the LIS interface is configured.

- The “LIS Address” field is for the IP address of the LIS server.
- The “Port Number” is the port on which the LIS is listening for communication from the Sofia
- The “Auto Send” setting is set to On to have the LIS communication occur after the completion of each test.
- The “Queue Results” setting designates the tests performed when this setting is set to On to be available to send to the LIS. If set to Off, then the tests performed are never available to send to LIS, even if the setting is later changed to On.
- The “Standard” setting is ASTM for uni-directional or POCT1a for bi-directional as determined by the LIS system.

The LIS administrator or LIS vendor support will advise on the correct IP address and port number for the LIS interface.

The Sofia’s network address is configured and viewed under the “Network Settings\Set Network Configuration” settings screen in the Sofia. Additional configuration detail for both Sofia network address and LIS server may be found in the Sofia User Manual at:

<http://www.quidel.com/immunoassays/sofia-tests-kits/sofia-analyzer>

Note: Unless the Sofia is attempting to communicate over the integrated Ethernet NIC, the Ethernet NIC is powered Off. The Ethernet NIC is powered up temporarily:

- a) when the Sofia attempts to send results after a test is complete,
- b) when a manual request to send results is initiated,
- c) when a manual request to test the connection to the LIS is initiated, or
- d) using the ‘5261’ code (entered at any menu prompt).

During normal operation, the Ethernet NIC turns on until its communication session is complete, and then the Ethernet NIC turns off.

When attempting to send data, if the Ethernet NIC does not receive the ACK response from LIS in the allotted timeout (approximately 15 secs), then the Sofia reports a “LAN Error” “Network cannot be configured. Code: 953 004.061.063”.

Troubleshooting a “LAN Error” condition

Step 1. LAN IP address – In consultation with your Network Administrator, confirm the Sofia Network Configuration is entered properly in the Sofia.

Step 2. LIS IP address and port number – Confirm that you have entered the IP address and port number for the destination LIS Address into the Sofia “Set LIS Parameters” screen.

Step 3. Manually turn on Ethernet NIC – From the Main Menu, select Review Data, select Send Results, select Send Results to LIS, and enter the ‘5261’ code. Success will be verified by an audible beep. Examine the Ethernet cable connector on the back of the instrument and confirm your network cable is connected and that you see a solid green LED next to the connector¹.

Step 4. Sofia ping response – Have the Network Administrator ping the Sofia at the Sofia’s assigned IP address in the Network Configuration screen. Success will be verified by a successful ping response.

Step 5. Turn the Ethernet NIC off (default condition) – Enter the ‘5260’ code. Success will be verified by an audible beep.

Step 6. Confirm the Sofia IP address is not shared – With the Ethernet NIC turned off and the network cable unplugged from the Sofia, have the Network Administrator ping the Sofia at the Sofia’s assigned IP address. Success will be verified by an unsuccessful ping response showing that the IP address is not assigned to another device. If ping receives a ping response instead of “Request timed out”, then have the Network Administrator resolve the IP conflict on your network as a ping response here indicates this IP address is available on the network when the Sofia is disconnected.

Step 7. Confirm LIS connectivity – Select Test LIS Connection. If Sofia responds with “The Analyzer can be connected to LIS” then select Send Last Result. If Sofia responds with “Data were transmitted successfully.”, then connectivity is resolved.

Step 8. LIS is unreachable or other network issues – Navigate to the “Test LIS Connection” option and select it. If Sofia responds with “The Analyzer cannot be connected to LIS” then notify the LIS support person to confirm that LIS is listening for the Sofia connection at the LIS address and port number configured in the Sofia “Set LIS Parameters” screen. If the LIS is listening at the designated address and port number, then ask the Network Administrator to check and confirm that Sofia’s connection path to LIS is not being blocked by network routing rules or network firewall settings.

2. The Uni-directional (ASTM) Results Interface – Functional Description

When the test completes, a result is sent to the LIS. If the transmission fails, the result is temporarily stored and can be resent. A Sofia user may resend results when the connection to the LIS is reestablished through the following:

From the Main Menu,
select Review Data
select Send Results
select Send Results to LIS
select one of the result options.

¹ Lack of a green “Link Light” is an indication that you do not have a good connection to an Ethernet Network. Check your cable connections and if that does not resolve the condition, seek help from your Network Support resource.

The following message format is used to report results:

- Sofia serial number
- Patient ID and/or order number
- Test identifier(s)
- Date and time of result reporting
- The analyte name and qualitative result(s)

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

2.1. The Test Results Message

The Sofia test results message is made up of the following ASTM message segments.

- H Message Header Record
- P Patient Identification Record
- O Order Record
- C Notes and Comments Record
- R Result Record
- L Terminator Record

Each of these message segments contain fields of data defined by the ASTM standard. Some fields of information are mandatory and sent, some are optional, and others are empty or not used. In the following tables defining 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

2.1.1. H: Message Header Record

Field	R/O/N	Name	Description
H-1	R	Record Type	Always: H
H-2	R	Encoding Characters (delimiters)	Always: \ ^ & field separator \ repetition separator ^ component separator & escape character
H-3	N	Message Control ID	Empty
H-4	N	Access Password	Empty
H-5.1	R	Analyzer Name	Always: Sofia
H-5.2	R	Serial Number	The Sofia's serial number. Example: 00012345
H-6 through H-11	N	Not Used	Empty
H-12	R	Processing ID	Always: P
H-13	R	Firmware Version	This represents the current firmware version of the Sofia. Example: 02.03.00

Field	R/O/N	Name	Description
H-14	R	Current Date and Time	Timestamp when the message has been created. Format: YYYYMMDDHHMMSS

H Example

H|\^&|||Sofia^12345678|||||P|02.03.00|20190414065327<CR>

2.1.2. P: Patient Identification Record

Field	R/O/N	Name	Description
P-1	R	Record Type	Always: P
P-2	R	Sequence Number	Always: 1
P-3	R	Patient ID	Assigned patient ID for patient result. For QC and Calibration result transmissions, this field will be the cassette serial number. Example: PID1234
P-4 through P-25	N	Not Used	Empty
P-26	O	Location	Location as configured by the user. Example: SITENAME

P Example

P|1|PID1234|||||||||||||||||SITENAME<CR>

2.1.3. O: Order Record

Field	R/O/N	Name	Description
O-1	R	Record Type	Always: O
O-2	R	Sequence Number	Sequence number for multiple O records.
O-3	O	Order ID	This is the order number as entered by the user. For QC this will be the kit lot number and for Calibration the calibration lot number.
O-4	N	Not Used	Empty
O-5	O	Test Type Name	Test type short name for the cassette used. Example: Flu A+B
O-6 through O-10	N	Not Used	Empty
O-11	O	Operator ID	The user name of the operator when the sample was run. Example: JSmith
O-12 through O-15	N	Not Used	Empty
O-16	R	Sample Type	This will be the sample type of the cassette, "P" for patient sample "Q" for a quality control sample, and "C" for calibration.
...	N		Not used

O Example

O|1|SAM1234||Flu A+B|||||JSmith|||||P<CR>

2.1.4. C: Notes and Comments Record

Field	R/O/N	Name	Description
C-1	R	Record Type	Always: C
C-2	R	Sequence Number	Always: 1
C-3	N	Not Used	Empty

Field	R/O/N	Name	Description
C-4	R	Sample Comment	Additional sample information: "Walk Away Mode" or "Read-Now Mode." Only transmitted on patient and QC results. Example: Read-Now Mode

C Example

C|1||Read-Now Mode<CR>

2.1.5. R: Result Record

Field	R/O/N	Name	Description
R-1	R	Record Type	Always: R
R-2	R	Sequence Number	Sequence number for multiple R records.
R-3	R	Analyte Name	^^^analyte name Example: ^^^Flu A
R-4	R	Test Value	Result of test. Possible values are numeric values, positive, negative and invalid for patient results, passed and failed for Calibration and QC results. Example: positive
R-5	O	Test Units	Units used to measure result value. Empty for qualitative tests. Example: mg/mL
R-6	O	Reference Range	Valid ranges for result. Empty for qualitative tests. Example: 0.5 – 1.5
R-7	O	Test Flag	Test Flag (See Chart Below). Not applicable for some tests. Example: H
R-8	N	Not Used	Empty
R-9	R	Test Result Type	The values used are "F" – Final "R" – Retransmitted
R-10 through R-12	R	Not Used	Empty
R-13	R	Date/time of Test Completion	The date and time that the test was completed Example: 20190414064534
...	N		Not used

R Example

R|1|^^^Flu A|negative| |||F|||20190414064534<CR>

R|2|^^^Flu B|negative| |||F|||20190414064534<CR>

...

R|n| ...

Test Flag	Description
>	Below Measurable Range
<	Above Measurable Range
L	Below Normal
H	Above Normal
HH	Above Panic Normal
LL	Below Panic Normal
N	Normal
A	Abnormal

2.1.6. L: Terminator Record

Field	R/O/N	Name	Description
L-1	R	Record Type	Always: L
L-2	R	Sequence Number	Always: 1
L-3	R	N	Always: N

L Example

```
L|1|N<CR>
```

2.2 ASTM Message Examples

HIGH LEVEL ASTM MESSAGE EXAMPLES

Example A: Outgoing Result Message

```
H|\^&||Sofia^12345678|||||P|02.03.00|20190414065327<CR>
P|1|PID1234|||||SITENAME<CR>
O|1|SAM1234|Flu A+B||||JSmith||||P<CR>
C|1||Read-Now Mode<CR>
R|1|^^^Flu A|negative||||F|||20190414064534<CR>
R|2|^^^Flu B|negative||||F|||20190414064534<CR>
L|1|N<CR>
```

Example B: Outgoing QC Message

The QC result generates two results; one for positive QC and one for negative QC as two cartridges were run.

```
H|\^&||Sofia^12345678|||||P|02.03.00|20190414065327<CR>
P|1|CASSER12|||||SITENAME<CR>
O|1|KITLOT12|Flu A+B||||JSmith||||Q<CR>
C|1||Read-Now Mode<CR>
R|1|^^^POS|passed||||F|||20190414061543<CR>
L|1|N<CR>
```

```
H|\^&||Sofia^12345678|||||P|02.03.00|20190414065739<CR>
P|1|CASSER12|||||SITENAME<CR>
O|1|KITLOT12|Flu A+B||||JSmith||||Q<CR>
C|1||Read-Now Mode<CR>
R|1|^^^NEG|passed||||F|||20190414062123<CR>
L|1|N<CR>
```

Example C: Outgoing Calibration Message

```
H|\^&||Sofia^12345678|||||P|02.03.00|20190414070819<CR>
P|1|CASSER12|||||SITENAME<CR>
O|1|CASLOT12|CB Cass||||JSmith||||C<CR>
R|1|^^^CB Cass|passed||||F|||20190414062839<CR>
L|1|N<CR>
```

LOW LEVEL ASTM MESSAGE EXAMPLES

Example D: Result message Example A with low level characters.

Sofia: <ENQ>

LIS: <ACK>

Sofia: <STX>1H|\^&||Sofia^12345678|||||P|02.03.00|20190414065327<CR><ETX>46<CR><LF>

LIS: <ACK>

Sofia: <STX>2P|1|PID1234|||||SITENAME<CR><ETX>DC<CR><LF>

LIS: <ACK>

Sofia: <STX>3O|1|SAM1234|Flu A+B||||JSmith||||P<CR><ETX>46<CR><LF>

LIS: <ACK>

Sofia: <STX>4C|1||Read-Now Mode<CR><ETX>AE<CR><LF>

LIS: <ACK>
Sofia: <STX>5R|1|^^^Flu A|negative||||F|||20190414064534<CR><ETX>9E<CR><LF>
LIS: <ACK>
Sofia: <STX>6R|2|^^^Flu B|negative||||F|||20190414064534<CR><ETX>A1<CR><LF>
LIS: <ACK>
Sofia: <STX>7L|1|N<CR><ETX>0A<CR><LF>
LIS: <ACK>
Sofia: <EOT>

Example E: QC Result message Example B with low level characters.

Sofia: <ENQ>
LIS: <ACK>
Sofia: <STX>1H|\^&|||Sofia^12345678|||||P|02.03.00|20190414065327<CR><ETX>46<CR><LF>
LIS: <ACK>
Sofia: <STX>2P|1|CASSER12|||||||||||||||||SITENAME<CR><ETX>59<CR><LF>
LIS: <ACK>
Sofia: <STX>3O|1|KITLOT12||Flu A+B|||||JSmith|||||Q<CR><ETX>D6<CR><LF>
LIS: <ACK>
Sofia: <STX>4C|1||Read-Now Mode<CR><ETX>AE<CR><LF>
LIS: <ACK>
Sofia: <STX>5R|1|^^^POS|passed||||F|||20190414061543<CR><ETX>32<CR><LF>
LIS: <ACK>
Sofia: <STX>6L|1|N<CR><ETX>09<CR><LF>
LIS: <ACK>
Sofia: <EOT>
Sofia: <ENQ>
LIS: <ACK>
Sofia: <STX>1H|\^&|||Sofia^12345678|||||P|02.03.00|20190414065739<CR><ETX>4D<CR><LF>
LIS: <ACK>
Sofia: <STX>2P|1|CASSER12|||||||||||||||||SITENAME<CR><ETX>59<CR><LF>
LIS: <ACK>
Sofia: <STX>3O|1|KITLOT12||Flu A+B|||||JSmith|||||Q<CR><ETX>D6<CR><LF>
LIS: <ACK>
Sofia: <STX>4C|1||Read-Now Mode<CR><ETX>AE<CR><LF>
LIS: <ACK>
Sofia: <STX>5R|1|^^^NEG|passed||||F|||20190414062123<CR><ETX>15<CR><LF>
LIS: <ACK>
Sofia: <STX>6L|1|N<CR><ETX>09<CR><LF>
LIS: <ACK>
Sofia: <EOT>

Example F: Calibration Result message Example C with low level characters.

Sofia: <ENQ>
LIS: <ACK>
Sofia: <STX>1H|\^&|||Sofia^12345678|||||P|02.03.00|20190414070819<CR><ETX>48<CR><LF>
LIS: <ACK>
Sofia: <STX>2P|1|CASSER12|||||||||||||||||SITENAME<CR><ETX>59<CR><LF>
LIS: <ACK>
Sofia: <STX>3O|1|CASLOT12||CB Cass|||||JSmith|||||C<CR><ETX>F1<CR><LF>
LIS: <ACK>
Sofia: <STX>4R|1|^^^CB Cass|passed||||F|||20190414062839<CR><ETX>77<CR><LF>
LIS: <ACK>
Sofia: <STX>5L|1|N<CR><ETX>08<CR><LF>
LIS: <ACK>
Sofia: <EOT>

Example G: Multiple Result messages.

The Sofia can send multiple messages during one communication phase. A low-level example of sending two messages during one session is shown below. Note how the Sofia must initiate each result transmission.

```
Sofia: <ENQ>
LIS: <ACK>
Sofia: <STX>1H|\^&|||Sofia^12345678|||||P|02.03.00|20190414071031<CR><ETX>3B<CR><LF>
LIS: <ACK>
Sofia: <STX>2P|1|PID1234|||||SITENAME<CR><ETX>DC<CR><LF>
LIS: <ACK>
Sofia: <STX>3O|1|SAM1234||Flu A+B|||||JSmith|||||P<CR><ETX>46<CR><LF>
LIS: <ACK>
Sofia: <STX>4C|1||Read-Now Mode<CR><ETX>AE<CR><LF>
LIS: <ACK>
Sofia: <STX>5R|1|^^^Flu A|negative|||||F|||||20190414064534<CR><ETX>9E<CR><LF>
LIS: <ACK>
Sofia: <STX>6R|2|^^^Flu B|negative|||||F|||||20190414064534<CR><ETX>A1<CR><LF>
LIS: <ACK>
Sofia: <STX>7L|1|N<CR><ETX>0A<CR><LF>
LIS: <ACK>
Sofia: <EOT>
Sofia: <ENQ>
LIS: <ACK>
Sofia: <STX>1H|\^&|||Sofia^12345678|||||P|02.03.00|20190414071231<CR><ETX>3D<CR><LF>
LIS: <ACK>
Sofia: <STX>2P|1|PID1236|||||SITENAME<CR><ETX>DE<CR><LF>
LIS: <ACK>
Sofia: <STX>3O|1|SAM1236||Flu A+B|||||JSmith|||||P<CR><ETX>48<CR><LF>
LIS: <ACK>
Sofia: <STX>4C|1||Read-Now Mode<CR><ETX>AE<CR><LF>
LIS: <ACK>
Sofia: <STX>5R|1|^^^Flu A|negative|||||F|||||20190414064734<CR><ETX>A0<CR><LF>
LIS: <ACK>
Sofia: <STX>6R|2|^^^Flu B|negative|||||F|||||20190414064734<CR><ETX>A3<CR><LF>
LIS: <ACK>
Sofia: <STX>7L|1|N<CR><ETX>0A<CR><LF>
LIS: <ACK>
Sofia: <EOT>
```

3. The Bi-directional (POCT1a) Interface – Functional Description

When the Test completes, a communication session is initiated to the LIS. If the transmission fails, the result is temporarily stored and can be resent. A Sofia user may resend results when the connection to the LIS is reestablished through the following:

From the Main Menu,
select Review Data
select Send Results
select Send Results to LIS
select one of the result options.

The following message format is used to report results:

- Sofia Serial Number
- Patient ID / Order No.
- Test identifier(s)

- Date and time of result reporting
- The analyte name and qualitative result(s)

After the connection has been established between the Sofia and the LIS, a conversation starts with the Hello message and ends with the Terminate message. During the conversation, Sofia 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 Sofia expects an ACK message from the LIS, otherwise the transfer will report as failed and the results will need to be resent.

Starting Conversation

A communication session (conversation) is always initiated by the Sofia.

The conversation has two phases:

1. Introduction.

See below a successful introduction sequence:

Sofia	LIS
HEL The Sofia initiates the conversation	
	ACK.R01
DST.R01 The Sofia sends its status to the LIS (always 0 not transmitted results).	
	ACK.R01
	DTV.R02 Set time
ACK.R01 Sofia sets the current time/date as sent by the DTV.R02 message	
	OPL.R01 Send Complete Operator List
ACK.R01 Sofia deletes the User DB, inserts the default supervisor, and adds the operator list as sent by the OPL.R01 messages	
	EOT.R01 End Operator List
	DTV.R01 Start continuous.
ACK.R01 The Sofia switches to LIS continuous phase.	

The introduction sequence starts if the Sofia intends to send results to LIS.

Note that the Sofia always declares a value of 0 not-transmitted results during the introduction and then switches to continuous mode.

2. LIS Continuous phase.

During this phase the Sofia will transmit, without any request from the LIS, new measurement results, or results stored in the Sofia to the LIS.

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

The continuous phase will be terminated by any of the conversation participants by sending a termination message.

The Sofia will send a termination message if the sending of the result/results is finished.

An Error Ack message is sent by the Sofia, if it gets invalid data. If the Sofia 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 Sofia, it transmits an ESC and an END message and disconnects from the LIS.

3.1. Introduction

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 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.

3.1.1. HEL.R01 – Hello Message

Field	Description	Example
HDR.control_id	A string guaranteed to uniquely identify this message throughout the conversation. Sofia implements this as an integer value.	"00001"
HDR.version_id	Version ID	Always: "POCT1"
HDR.creation_dttm	Sofia date and time when the message was sent.	"2017-08-11T10:17:03-00:00"
DEV.device_id	Sofia MAC	"00:20:4a:be:cf:a5"
DEV.serial_id	Sofia Serial Number	"00010387"

Field	Description	Example
DEV.manufacturer_name	The Sofia's corporate name	Always: "QUIDEL"
DEV.hw_version	The version number for the Sofia hardware	"00.03.01"
DEV.sw_version	The version number for the Sofia software	"02.03.01"
DEV.device_name	The model name for the Sofia	Always: "Sofia"
DCP.application_timeout	Sofia application timeout in seconds	Always: "100"
DSC.connection_profile_cd	CIC messaging profile that Sofia supports	Always: "CS"
DSC.topics_supported_cd	The message topics (beyond the minimum) supported.	Always: "DTV"
DSC.topics_supported_cd	The message topics (beyond the minimum) supported.	Always: "OP_LST_I"
DSC.directives_supported_cd	The Directive commands that Sofia supports	Always: "SET_TIME"
DSC.directives_supported_cd	The Directive commands that Sofia supports	Always: "START_CONTINUOUS"
DSC.max_message_sz	The max size message (in bytes) that Sofia can handle	Always: "1000"

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="2017-08-11T10:17:03-00:00"/>
```

```
  </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="Sofia"/>
```

```
  <DCP>
```

```
    <DCP.application_timeout V="100"/>
```

```
  </DCP>
```

```
  <DSC>
```

```
    <DSC.connection_profile_cd V="CS"/>
```

```
    <DSC.topics_supported_cd V="DTV"/>
```

```
    <DSC.topics_supported_cd V=" OP_LST_I"/>
```

```
    <DSC.directives_supported_cd V="SET_TIME"/>
```

```
    <DSC.directives_supported_cd V="START_CONTINUOUS"/>
```

```
    <DSC.max_message_sz V="1000"/>
```

```
  </DSC>
```

```
</DEV>
```

```
</HEL.R01>
```

3.1.2. ACK.R01 – Acknowledgement Message

Field	Description	Example
HDR.control_id	A string guaranteed to uniquely identify this message throughout the conversation.	"4011"

Field	Description	Example
HDR.version_id	Version ID	Always: "POCT1"
HDR.creation_dttm	LIS date and time when the message was sent.	"2018-05-20T08:21:50-00:00"
ACK.type_id	A code indicating whether the associated message was accepted (AA), in error (AE) or was rejected (AE).	"AA"
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="2018-05-20T08:21:50-00:00"/>
  </HDR>
  <ACK>
    <ACK.type_id V="AA"/>
    <ACK.control_id V="1"/>
  </ACK>
</ACK.R01>
```

3.1.3. 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	Sofia date and time when the message was sent.	"2017-05-20T08:56:22-00:00"
DST.status_dttm	The time from the Sofia that this status was observed.	"2017-05-20T08:56:22-00:00"
DST.new_observations_qty	The number of observations that Sofia will report. In Introduction, this value is always 0.	Always: "0"
DST.condition_cd	The current level of readiness of the Sofia.	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="2017-05-20T08:56:22-00:00" />
  </HDR>
  <DST>
    <DST.status_dttm V="2017-05-20T08:56:22-00:00" />
    <DST.new_observations_qty V="0" />
    <DST.condition_cd V="R" />
  </DST>
</DST.R01>
```

3.1.4. 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.	"2019-05-04T11:48:52+00:00"
DTV.command_cd	The Directive commands that Sofia supports to set the date and time, "SET_TIME".	Always: "SET_TIME"
TM.dttm	Observation Reviewer date-time stamp, conforming to the TS data type rules. Since Sofia does not address time zone, the time zone offset is always "+00:00"	"2019-05-04T11:48:51+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="2019-05-04T11:48:52+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>
```

3.1.5. OPL.R01 – Operator List Message

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	Sofia date and time when the message was sent.	"2019-05-04T11:48:54-05:00"
OPR.operator_id	The unique identifier for the operator.	"5010"
OPR.name	The name of the operator.	"Franklin"
ACC.method_cd	Sofia operators are granted permission to use all methods.	Always: "ALL"
ACC.permission_level_cd	The code that notates the Sofia access level of the operator. 4 = SUPERVISOR, 1 = USER	"1"
NTE.text	The Sofia 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="5010"/>
    <OPR.name V="Franklin"/>
    <ACC>
      <ACC.method_cd V="ALL"/>
      <ACC.permission_level_cd V="1"/>
    </ACC>
    <NTE>
      <NTE.text V="20"/>
    </NTE>
  </OPR>
  <OPR>
    .
  </OPR>
</OPL.R01>

```

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

Field	Description	Example
HDR.control_id	A string guaranteed to uniquely identify this message throughout the conversation.	"4015"
HDR.version_id	Version ID	Always: "POCT1"
HDR.creation_dttm	Sofia date and time when the message was sent.	"2019-05-04T11:52:54-05:00"
EOT.topic_cd	The code for the Topic that has just been completed.	Always: "OPL"

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>

```

3.1.7. 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	Sofia date and time when the message was sent.	"2019-05-04T11:53:54-05:00"
DTV.command_cd	The Directive commands that Sofia 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>

```

3.2. LIS Continuous

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.

3.2.1. OBS.R01 – Patient Test Observation Message

Field	Description	Example
HDR.control_id	A string guaranteed to uniquely identify this message throughout the conversation. Sofia implements this as an integer value.	"00027"
HDR.version_id	Version ID	Always: "POCT1"
HDR.creation_dttm	Sofia 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	Sofia 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 Sofia patient id entry.	"Y B1232"
OBS.observation_id	The analyte name from the Test Type File.	"Flu A"
OBS.qualitative_value	The qualitative result value from Sofia.	"negative"
OBS.method_cd	Sofia value determination, Measured "M", not Calculated "C".	Always: "M"
OPR.operator_id	Sofia Operator Name.	"Y B LAST"
ORD.universal_service_id	The assay long name from the Test Type File.	"Sofia Flu A+B"
ORD.order_id	Order Number from the Sofia.	"1232Y B"
RGT.name	The assay long name from the Test Type File.	"Sofia Flu A+B"
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.reason_cd V="NEW"/>
    <PT>
      <PT.patient_id V="Y B1232"/>
      <OBS>
        <OBS.observation_id V="Flu A" SN="QUIDEL"/>
        <OBS.qualitative_value V="negative"/>
        <OBS.method_cd V="M"/>
      </OBS>
      <OBS>
        <OBS.observation_id V="Flu B" SN="QUIDEL"/>
        <OBS.qualitative_value V="negative"/>
        <OBS.method_cd V="M"/>
      </OBS>
    </PT>
    <OPR>
      <OPR.operator_id V="Y B LAST"/>
    </OPR>
    <ORD>
      <ORD.universal_service_id V="Sofia Flu A+B"/>
      <ORD.order_id V="1232Y B" SN="QUIDEL"/>
    </ORD>
    <RGT>
      <RGT.name V="Sofia Flu A+B"/>
      <RGT.lot_number V="140403"/>
      <RGT.expiration_date V="2025-04-03"/>
    </RGT>
  </SVC>
</OBS.R01>

```

3.2.2. OBS.R02 – Non-Patient Test Observation Message

Field	Description	Example
HDR.control_id	A string guaranteed to uniquely identify this message throughout the conversation. Sofia implements this as an integer value.	"00027"
HDR.version_id	Version ID	Always: "POCT1"
HDR.creation_dttm	Sofia date and time when the message was sent.	"2019-02-22T11:02:44-00:00"
SVC.role_cd	For a Calibration test "CAL" and for a QC test "LQC".	"CAL"
SVC.observation_dttm	Sofia date and time when the test completed.	"2018-05-19T07:51:22-00:00"
SVC.reason_cd	Is the observation NEW or RES for resend?	"RES"

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"
OBS.qualitative_value	The qualitative result value from Sofia.	"passed"
OBS.method_cd	Sofia value determination, Measured "M", not Calculated "C".	Always: "M"
OPR.operator_id	Sofia Operator Name.	"Supervisor"
RGT.name	For a QC test, the assay long name from the Test Type File.	"Sofia Flu A+B"
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="2018-05-19T07:51:22-00:00"/>
```

```
    <SVC.reason_cd V="RES"/>
```

```
    <CTC>
```

```
      <CTC.name V="Calibration Result"/>
```

```
      <CTC.lot_number V="103533"/>
```

```
    </CTC>
```

```
    <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.R01>
```

3.2.3. ACK.R01 – Acknowledgement Message

Field	Description	Example
HDR.control_id	A string guaranteed to uniquely identify this message throughout the conversation.	"4011"

Field	Description	Example
HDR.version_id	Version ID	Always: "POCT1"
HDR.creation_dttm	Sofia date and time when the message was sent.	"2019-05-20T08:21:50-00:00"
ACK.type_id	A code indicating whether the associated message was accepted (AA), in error (AE) or was rejected (AE).	"AA"
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="2019-05-20T08:21:50-00:00"/>
  </HDR>
  <ACK>
    <ACK.type_id V="AA"/>
    <ACK.control_id V="1"/>
  </ACK>
</ACK.R01>
```

3.2.4. END.R01 – Terminate 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	Sofia date and time when the message was sent.	"2019-05-20T08:21:50-00:00"
TRM.reason_cd	The reason for terminating the conversation.	Always: "USR"

END.R01 Example

```
<?xml version="1.0" encoding="UTF-8"?>
<END.R01>
  <HDR>
    <HDR.control_id V="00002" />
    <HDR.version_id V="POCT1" />
    <HDR.creation_dttm V="2019-05-20T08:21:50-00:00" />
  </HDR>
  <TRM>
    <TRM.reason_cd V="USR" />
  </TRM>
</END.R01>
```

3.3. POCT1a Message Examples

Example A: Sofia initiating the conversation with LIS.

```
Sofia: <?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="Sofia"/>
  <DCP>
    <DCP.application_timeout V="100"/>
  </DCP>
  <DSC>
    <DSC.connection_profile_cd V="CS"/>
    <DSC.topics_supported_cd V="DTV"/>
    <DSC.topics_supported_cd V="OP_LST_I"/>
    <DSC.directives_supported_cd V="SET_TIME"/>
    <DSC.directives_supported_cd V="START_CONTINUOUS"/>
    <DSC.max_message_sz V="1000"/>
  </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>

```

Example B: Sofia sending status to LIS.

```

Sofia: <?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>

```

Example C: LIS DTV.R02 Set Time command to Sofia.

```

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>

```

```

Sofia: <?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>

```

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

```

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="陈"/>
            <ACC>
                <ACC.method_cd V="ALL"/>
                <ACC.permission_level_cd V="4"/>
            </ACC>
            <NTE>
                <NTE.text V="10"/>
            </NTE>
        </OPR>
    </OPL.R01>

```

```

</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>

```

Sofia: <?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="0" />
  </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>

```

Example E: LIS DTV.R01 Start Continuous command to Sofia.

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>

```

Sofia: <?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>

```

Example F: Sofia send an OBS.R01 patient result and OBS.R02 calibration result to LIS.

Sofia: <?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="IgM" SN="QUIDEL"/>
        <OBS.qualitative_value V="negative"/>
        <OBS.method_cd V="M"/>
    </OBS>
    <OBS>
        <OBS.observation_id V="IgG" 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="Sofia Lyme"/>
    <ORD.order_id V="225" SN="QUIDEL"/>
</ORD>

```

```

                <RGT>
                    <RGT.name V="Sofia Lyme"/>
                    <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>

Sofia: <?xml version="1.0" encoding="UTF-8"?>
<OBS.R02>
    <HDR>
        <HDR.control_id V="00007"/>
        <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"/>
            <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="8"/>
        <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="00007"/>
    </ACK>
</ACK.R01>

```

```

Sofia: <?xml version="1.0" encoding="UTF-8"?>
<END.R01>
    <HDR>
        <HDR.control_id V="00008" />
        <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="9"/>
        <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="00008"/>
    </ACK>
</ACK.R01>

```

4. Result Assay Panel Definition Table

The table below outlines what assay panel information will be used test name field (O-5 ASTM; ORD.universal_service_id POCT1a) and the analyte name field (R-3 ASTM;OBS.observation_id POCT1a). The Short Name is used in the test name field and the Analyte Name is used in the observation id (analyte name) field.

Long Name	Short Name	Analyte Name	Lower Limit	Upper Limit	Scale	Observation Values
Sofia Flu A+B	Flu A+B	Flu A				Invalid, Negative, Positive
Sofia Flu A+B	Flu A+B	Flu B				Invalid, Negative, Positive
Sofia Lyme	Lyme	IgG				Invalid, Negative, Positive
Sofia Lyme	Lyme	IgM				Invalid, Negative, Positive
Sofia RSV	RSV	RSV				Invalid, Negative, Positive
Sofia Strep A+	Strep A+	Strep A+				Invalid, Negative, Positive
Sofia Strep A	Strep A	Strep A				Invalid, Negative, Positive
Sofia Urine hCG	hCG (U)	hCG				Invalid, Negative, Positive
Sofia Strep pneumo	S. pneumo	S. pneumo				Invalid, Negative, Positive

Long Name	Short Name	Analyte Name	Lower Limit	Upper Limit	Scale	Observation Values
Sofia Legionella	Legion	Legion				Invalid, Negative, Positive
Sofia VitD Serum	VitD Srm	VitD	< 10	> 100	1	10.0 - 100.0

If you have any questions regarding the use of this product, please contact Quidel 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 Quidel 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) 0 1800 200441 (toll free)	emeatechnicalsupport@quidel.com
Austria	+43 316 231239	
France	0 (805) 371674	
Germany	+49 (0) 7154 1593912	
Netherlands	0 800 0224198	
Switzerland	0 800 554864	
United Kingdom	0 800 3688248	
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
China	0400 920 9366 or +86 021 3217 8300	chinatechnicalservice@quidel.com

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