



QUIDEL

Solana[®]

Technical Bulletin

HL7, LIS Interface Description

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 Solana Instrument and a Laboratory Information System (LIS).

The Solana Instrument implements an industry standard HL7 interface for use over Ethernet networks. The interface is designed to support unidirectional or bidirectional communications with Laboratory Information Systems (LIS). The LIS interface is built into the Solana instrument and requires minimal configuration to use.

The Physical Instrument connection is via Ethernet and the transport is via the Transmission Control Protocol/Internet Protocol (TCP/IP). The instrument has one standard Ethernet RJ-45 connector.

The interface is compliant with version 2.4 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.

Bidirectional Interface

Bidirectional use of the LIS interface means that the Solana Instrument can receive Orders for tests from an LIS system and send the results to the LIS system upon completion of those tests.

Implementation of a bidirectional interface requires two (2) interfaces be setup;

- One Interface from the LIS to the Solana for the transmission of Test Orders
- One from the Solana to the LIS for sending the Test Results

Solana Instrument	LIS System
Orders Interface ← Listening at Solana’s IP address and designated Port number (Listener Port) for LIS Order transmissions.	Orders Interface ← LIS Connects to Solana’s IP address and designated Port number (Listener Port) that’s setup to listen for 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).

Unidirectional Interface

Receiving test Orders is not a requirement for operation; Solana may be setup to send test results without implementing an Orders interface, thus unidirectional.

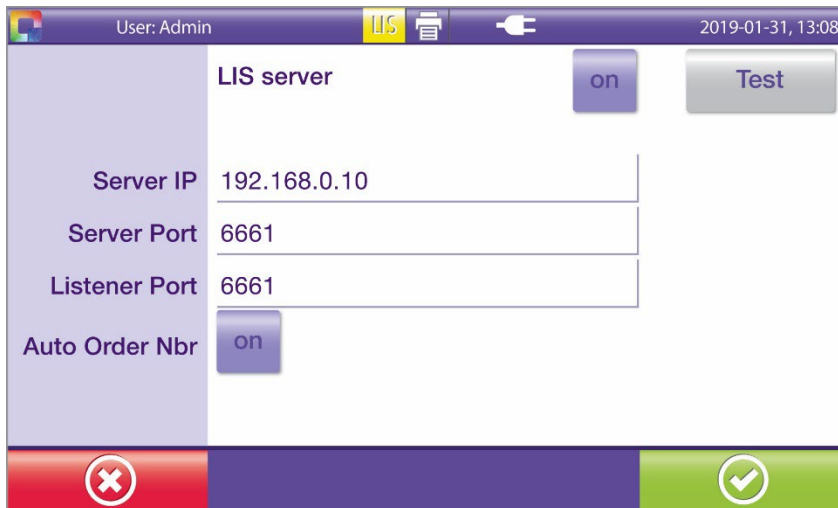
Implementation of a unidirectional interface requires one (1) interface be setup;

- One from the Solana to LIS for sending the Test Results

Solana 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).

LIS Interface Configuration

LIS Interface Setup Screen in Solana



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

The example “LIS Server” setup screen above is where the Result and the Order interfaces are configured.

- The “Server IP” field is for the IP Address of the LIS Server.
- The “Server Port” is the Port on which the LIS is listening for Test Results from the Solana
- The “Listener Port” is the Port on the Solana on which it will listen for Orders from the LIS. In the case of a unidirectional interface where the Orders interface is not implemented, set the Listener Port to the same value as the Server Port.

Note: The values in the screen example may vary for your specific configuration

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

If an Orders Interface is implemented, provide the LIS administrator with the “Listener Port” information from this setup screen and the IP address which has been assigned to this Solana instrument. Note, the Solana IP address is not the address shown in this example screen. The Solana’s Network Address is configured and viewed under the “Network Settings\LAN” settings screen in the Solana. Additional configuration detail for both Solana Network Address and LIS Server may be found in the Network Settings section in the Solana User Guide at: <http://www.guidel.com/molecular-diagnostics/solana-instrument>.

When configured with an Orders interface, the Solana will receive and store test orders sent from the LIS. During test operation, the Solana User will select and assign received Order numbers to the test samples from the list of Orders received. When the test measurements are complete, the results are forwarded to LIS over the Results Interface.

Note 1: In the v2.0.7 and higher software, the Patient ID must be assigned to the tube for the Order to match. If no Patient ID is entered for the tube, then the Solana will automatically assign a Patient ID of the tube number, e.g., “Tube 1”, “Tube 2”, etc. In the case where an Orders Interface is implemented, when an Order is selected or assigned to a tube from the Order number screen and a Patient ID is associated with that Order from the LIS, then the Patient ID in the Solana will be updated on the tube.

Note 2: When the Result message is generated referencing an LIS Order sent to the Solana, the PV1-2, Patient Class, from the original Order will be returned. Unless this value is U for unknown, the value may likely be incorrect as the patient may have moved since the time of the original Order send. Please ignore this value in the Result message.

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

Alternatively, if no Order number is assigned by the Solana User, then the LIS should use the Patient ID from the PID segment to place and result an Order for the reported test on this patient.

Note: Order number entry for each tube is checked by Solana prior to starting the test. The test will not start without an Order number entered for each tube. When workflow dictates that no Order number is assigned, then the Auto Order Nbr setting on the LIS Server settings screen should be set to On. The Result message will contain Order numbers automatically created and assigned by the Solana. These Order numbers should be ignored by the LIS.

The 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 resend is initiated when the connection to LIS is reestablished. The following message type is used to report results:

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

It is possible to send a Result for which no previous Order was received from the LIS. In that case, the Solana User will input the Order number manually while preparing the test.

Alternatively, if no Order number is assigned by the Solana User, then the LIS should use the Patient ID from the PID segment to place and result an Order for the reported test on this patient.

Note: Order number entry for each tube is checked by Solana prior to starting the test. The test will not start without an Order number entered for each tube. When workflow dictates that no Order number is assigned, then the Auto Order Nbr setting on the LIS Server settings screen should be set to On. The Result message will

contain Order numbers automatically created and assigned by the Solana. These Order numbers should be ignored by the LIS.

After the result is sent, the Solana 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.

The Test Results Message (The ORU Message)

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

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

- MSH Message Header
- PID Patient Identification
- PV1 Patient Visit Information
- 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 filled

2.1.1. 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: Solana
MSH-3.1	R	Instrument Serial Number	The Solana'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: 2.4
...	N		Not used

MSH Example

MSH|^~\&|Solana^15020027|Quidel|||20181121131908||ORU^R01|15428063489846|P|2.4

PID: Patient Identification Segment

Field	R/O/N	Name	Description
PID-1	O	Set ID – PID	Copied from Order, or if no Order exists: 1
PID-2	O	Patient ID	Copied from Order, or if no Order exists: Empty
PID-3	O	Patient identifier list	“Patient ID” sent by Solana
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: “----^----”
...	N		Not used

PID Example

PID|1||Patient10||---^---

PV1: Patient Visit Segment

Field	R/O/N	Name	Description
PV1-1	O	Set ID – PV1	Copied from Order, if no Order exists: 1
PV1-2	O	Patient class	Copied from Order, if no Order exists: U
...	N		Not used

PV1 Example

PV1|1|U

NOTE: When the Result message is generated referencing an LIS Order sent to the Solana, the PV1-2, Patient Class, from the original Order will be returned. Unless this value is U for unknown, the value may likely be incorrect as the patient may have moved since the time of the original Order send. Please ignore this value in the Result message.

ORC: Common Order Segment

Field	R/O/N	Name	Description
ORC-1	R	Order Control	"RE"
ORC-2	R	Placer Order Number	Order number sent by Solana
ORC-3	R	Filler Order Number	Order number sent by Solana
...	N		Not used

ORC Example

ORC|RE|15020027064701|15020027064701

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 e.g. "1234^TEST"
OBR-4.1	N	Identifier	Numerical Test Identifier
OBR-4.2	R	Test	Name of Test
OBR-5	N	Priority	Not used
OBR-6	N	Requested Date/Time	Not used
OBR-7	R	Observation Date/Time	Same as MSH-7
OBR-8	R	Observation End Date/Time	Same as MSH-7
...	N		Not used

OBR Example

OBR|1|15020027064701|15020027064701|^Influenza A+B|||20181121131908|20181121131908

OBX: Clinical Observations / Results Reporting

Field	R/O/N	Name	Description
OBX-1	N	Set ID – OBX	Empty
OBX-2	R	Value type	Always “ST”
OBX-3	R	Observation identifier	Name of Test
OBX-4	N	Observation sub-id	Empty
OBX-5	R	Observation value	Result value, text string for qualitative result, numerical value for quantitative result
OBX-6	O	Units	Empty for qualitative result, units for quantitative result
OBX-7	N	Reference range	Empty
OBX-8	N	Abnormal flags	Empty
OBX-9	N	Probability	Empty
OBX-10	N	Nature of abnormal test	Empty
OBX-11	R	Observation Result Status	Always “F”
OBX-12	N	Danger Code	Empty
OBX-13	N	Relevant Clinical Information	Empty
OBX-14	R	Specimen Received Date/Time	Same as MSH-7
OBX-15	N	Specimen Source	Empty
OBX-16	N	Ordering Provider	Empty
OBX-17	N	Order Callback Phone Number	Empty
OBX-18	R	Placer Field 1	Solana Serial Number
...	N		Not used

OBX Example

OBX|1|ST|InfluenzaB||positive|||||F|||20181121131908|||15020027

OBX|2|ST|InfluenzaA||negative|||||F|||20181121131908|||15020027

OBX note: there may be multiple OBX segments for tests that return more than one result.

LIS Transmission Acknowledgement

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

MSH Message Header

MSA Message Acknowledgement Type

If no positive acknowledgement is received, the Result is marked as “not transmitted” and transmission is retried.

MSH: Message Header Segment

Field R/O/N Name Description

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

Field	R/O/N	Name	Description
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 2.4
...	N		Not used

Transmission Acknowledgement Example

MSH|^~\&||Solana^15020027|Quidel|20190108134142||ACK|15469630785135|P|2.4

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 result
...	N	Not used	

MSA Acknowledgement Example

MSA|AA|15469630785135

Receiving orders from LIS – Functional Description

The Solana may receive an Order (an ORM Message) for the User to apply to a specific test tube. When the LIS Order has been assigned to a test tube and the results are available the result message referencing the specified Order will be sent to the LIS.

The following Order message is supported:

- ORM – general Order messages
- The following data is to be included in the message to create a unique Order in Solana:
 - ▶ Patient ID
 - ▶ Order No.
 - ▶ Test identifier

For each received Order an ACK message is sent automatically.

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
PV1 Patient Visit Information
ORC Common Order
OBR Observation Request

Any additional segments that comply with the message structure defined in HL7 2.4 may be received, but the content is ignored.

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 filled

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	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	N	Version ID	Version of standard used, shall be 2.4
...	N		Not used

MSH Example

MSH|^~\&|LIS|LIS|Solana|Quidel|20181106112236||ORM^O01|15428056991525||2.4

PID: Patient Identification Segment

Field	R/O/N	Name	Description
PID-1	O	Set ID – PID	
PID-2	O	Patient ID	Send Patient ID in PID 3.1
PID-3	R	Patient identifier list	Patient ID
PID-4	O	Alternate Patient ID	Alternate Patient AID
PID-5	O	Patient Name	Patient Name in the format “Lastname^Firstname”
...	N		Not used

PID Example

PID|||P0011^^^^MRT||Smith^John

PV1: Patient Visit Segment

Field	R/O/N	Name	Description
PV1-1	O	Set ID – PV1	Segment counter for repeated use
PV1-2	O	Patient class	Used to categorize patients (Emergency, Inpatient, Outpatient, ...)
...	N		Not used

PV1 Example

PV1|1|E

ORC: Common Order Segment

Field	R/O/N	Name	Description
ORC-1	R	Order Control	"NW" or "RE"
ORC-2	R	Placer Order Number	Order number sent by LIS
...	N		Not used

ORC Example

ORC|RE|15020027064701

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 e.g. "1234^TEST"
OBR-4.1	N	Identifier	Numerical Test Identifier
OBR-4.2	R	Test	Name of Test
...	N		Not used

OBR Example

OBR|1|||^Influenza A+B|||20181121131908|20181121131908

Note: The field OBR-4-2 defines the Test to be run on the instrument. The text in this field must exactly match the name of the Test as it appears in the instrument.

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

MSH: Message Header Segment

Field	R/O/N	Name	Description
MSH-1	R	Field separator	Always:
MSH-2	R	Encoding characters	Always: ^~\&
MSH-4	R	Sending Application	Always: Solana
MSH-5	R	Sending Facility	Always: Quidel
MSH-6	N	Receiving Application	Shall be used to identify the receiving system
MSH-7	N	Receiving Facility	Shall be used to identify the receiving system
MSH-8	R	Date / Time of message	Timestamp when the message has been created. Format: YYYYMMDDHHMMSS
MSH-9	N	Security	Empty
MSH-10	R	Message type	Always starts with: ACK
MSH-11	R	Message Control ID	Unique Number to identify the message
MSH-12	R	Processing ID	Always: P
MSH-13	R	Version ID	Always: 2.4
...	N		Not used

MSH ACK Example

MSH|^~\&|Solana|Quidel|20190108134142||ACK|15469630785135|P|2.4

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 result
...	N	Not used	

MSA Acknowledgement Example

MSA|AA|15469630785135

Examples

Order Transmission

MSH|^~\&|||20190106112236||ORM^O01|0011||2.4
PID||P0011^^^^MRT||Smith^John
PV1||E
ORC|NW|0000011
OBR|||01234^GAS

Order Received Acknowledgement

MSH|^~\&|Solana|Quidel||20190106112242||ACK^O01|14543173625293|P|2.4
MSA|AA|0011

Result

MSH|^~\&|Solana^15020027|Quidel||20190106114744||ORU^R01|14543174849305|P|2.4
PID||P0011^^^^MRT||Smith^John
PV1||E
ORC|RE|0000011|0000011
OBR|1|0000011|0000011|^GAS||20190106114744|20190106114744
OBX||ST|GAS||Negative||||F||20190106114744||15020027

Transmission Acknowledge

MSH|^~\&||Solana^15020027|Quidel|20190106114746||ACK|14543174849305|P|2.4
MSA|AA|14543174849305

Result Assay Panel Definition Table

The Table below outlines what Assay Panel information will be used in the OBR-4.2, Test, field and the OBX-3, Observation Identifier, field. The Method File Name is used in the OBR-4.2 field and the Analyte Name is used in the OBX-3 field except the Strep Comp Method File Name.

Long Name	Method File Name (OBR-4.2)	Analyte Names (OBX-3)	Observation Values (OBX-5)
Influenza	Influenza	InfluenzaA	Invalid, Negative, Positive
Influenza	Influenza	InfluenzaB	Invalid, Negative, Positive
Solana GAS	GAS	GAS	Invalid, Negative, Positive
Solana Trich	Trich	Trich	Invalid, Negative, Positive
Strep_Comp A	Strep Comp	Reference	***
Strep_Comp CG	Strep Comp	Target	***
Solana HSV VZV	HSV 1+2-VZV	HSV-1	Invalid, Negative, Positive
Solana HSV VZV	HSV 1+2-VZV	HSV-2	Invalid, Negative, Positive
Solana HSV VZV	HSV 1+2-VZV	VZV	Invalid, Negative, Positive
Solana C diff	C difficile	Cdiff	Invalid, Negative, Positive
Solana HSV 1+2	HSV 1+2	HSV-1	Invalid, Negative, Positive
Solana HSV 1+2	HSV 1+2	HSV-2	Invalid, Negative, Positive
Solana VZV	VZV	VZV	Invalid, Negative, Positive
Solana RSV+hMPV	RSV+hMPV	RSV	Invalid, Negative, Positive
Solana RSV+hMPV	RSV+hMPV	hMPV	Invalid, Negative, Positive
Solana RSV	RSV	RSV	Invalid, Negative, Positive
Solana SARS-CoV-2	SARS-CoV-2	SARS-CoV-2	Invalid, Negative, Positive
Solana hMPV	hMPV	hMPV	Invalid, Negative, Positive
Solana Bordetella	Bordetella	BP	Invalid, Negative, Positive
Solana Bordetella	Bordetella	BPP	Invalid, Negative, Positive

Note: The Strep Comp Test is performed in two sample tubes. The Analyte Name for the OBX-3 field in both cases will be two OBX segments for each tube, with each having an Analyte Name of 'Reference' and 'Target'. The 'Reference' OBX-5 Observation Values will be either 'Group CG tested' or 'Group A tested'. The 'Target' OBX-5 Values will be either 'CG Invalid', 'CG Negative', 'CG Positive', 'GAS Invalid', 'GAS Negative', or 'GAS Positive'.

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