cobas® liat system

Host Interface Manual HL7
Publication version 11.3
Software versions 3.4 & 3.5

VV-07717-12

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US Publication information

Edition notice

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Intended use

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Feedback

This document was created by Roche Diagnostics GmbH. (operator manual content) and the Roche Diagnostics Engineering Operations department. Direct questions or concerns regarding the contents of this document :

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Document availability

This document is available on the Roche Diagnostics USA website at navifyportal.roche.com.

OS-00176-11

Application Code Number (ACN) Disclaimer for US Customers

Due to the increasing complexity of laboratories and the increase in types of tests being run, it is critical to use unique host download codes for each test when mapping codes on your Laboratory Information System (LIS). It is also strongly recommended to use alpha or alphanumeric codes on your LIS. If unique LIS test codes are not used when mapping on the LIS, this could cause a test result from one test to be reported for a different test.

Required actions when using this host interface manual:

- ***Ensure that the LIS test codes mapped to your LIS are unique for each test.***
- ***Always identify the instrument source of the results on your LIS.***
- ***Please disregard any application code numbers in this host interface manual. Refer to the appropriate method sheet, package insert or application code numbers document for the most current application code number information.***

OS-00176-11

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APPROVED FOR USE IN THE US

Publication information

Publication version	Software version	Revision date	Change description
3.0	2.0	December 2014	Software version.
4.0	2.1	December 2015	First publication in Roche user documentation format.
5.0	2.1.1	February 2016	Software update. Branding, address, and intended use updates.
6.0	3.0	June 2016	Software update. Edition notice updated. Approvals section updated.
6.1	3.1	May 2017	Software update. Secure communications Observation (test) names updated so as to include the script used to process them, e.g.: Influenza A (FABA)
7.0	3.2	February 2018	Minor corrections. • NB: In field NTE-3, Tube ID, Tube=<tube_id>, contains only the tube ID, without the serial number. • Minor terminology corrections • Correction to supported workflows.
7.1	3.2	April 2020	New functionality: • Assay SARS-CoV-2 (SCFA) added • Removal of MRSA assay-related information
8.0	3.3	Feb 2020	Corrections: • Terminology of communication protocols corrected (HL7 and POCT1-A) • Connectivity item **Server**: fully qualified names are supported. • Removal of MRSA assay-related information • Support of patient verification workflow
8.1	3.3	July 2020	New functionality: • Assay SARS-CoV-2(SCFA) added • Example for SARS-CoV-2 (SCFA) added
8.2	3.3	February 2021	• Added information about Ethernet configuration and speed Corrections: • Description of non-acknowledged messages in 'Sending results to the LIS' • MSH field numbering in HL7 Result message details • MSH field numbering in HL7 Acknowledgment message details • A second example for NTE.3 added in HL7 Result message details • Software version and tube data updated in communications examples
8.3	3.3	May 2021	New functionality: • Assay SARS-CoV-2 (COVA) added • Example for SARS-CoV-2 (COVA) added
9.0	3.3 patch 1	February 2021	Update for software version 3.3 patch 1. New functionality: • Detected Ct values (per target) are reported for valid positive results • Invalid results and information about aborted runs are now sent • AutoRelease replaces AutoSend

Revision history

Publication version	Software version	Revision date	Change description
9.1	3.3 patch 1	May 2021	New functionality: • Assay SARS-CoV-2 (COVA) added • Example for SARS-CoV-2 (COVA) added What is new in publication version 9.2 (10)
9.2	3.3 patch 1	September 2021	Minor updates for SME review. What is new in publication version 9.2 (10)
10.0	3.4	August 2022	Update for software version 3.4. What is new in publication version 10.0 (10)
11.0	3.4 & 3.5	October 2023	Update to include software version 3.5. What is new in publication version 11.0 (11)
11.1	3.4 & 3.5	June 2024	Added new assay **cobas**® **liat** SARS-CoV-2, Influenza A/B & RSV nucleic acid test (CFRA). What is new in publication version 11.1 (11)
11.2	3.4 & 3.5	December 2024	Added new assays **cobas**® **liat** CT/NG/MG nucleic acid test (CNMA) and **cobas**® **liat** CT/NG nucleic acid test (CNDA). What is new in publication version 11.2 (12)
11.3	3.4 & 3.5	May 2025	Added new assays **cobas**® **liat** SARS-CoV-2/Flu v2 nucleic acid test (SF2A) and **cobas**® **liat** SARS-CoV-2 v2 nucleic acid test (CV2A). What is new in publication version 11.3 (12)

Revision history

Edition notice

This publication is intended for Host Interface programmers and the Roche Service and Support organization of the **cobas**® **liat** analyzer.

Every effort has been made to ensure that all the information contained in this publication is correct at the time of publishing. However, the manufacturer of this product may need to update the publication information as output of product surveillance activities, leading to a new version of this publication.

Where to find information

The **cobas**® **liat** system **User Guide** contains all information about the product, including the following:

- Safety
- Installation
- Routine operation
- Maintenance and calibration
- Troubleshooting information
- Configuration information
- Background information
- Approvals
- Contact addresses

The **cobas® liat Quick Start Guide** is intended as a reference during the **cobas® liat** analyzer setup.

The **cobas® liat Cleaning Tool Guide** is intended as an instruction for using the **cobas® liat** cleaning tool with the **cobas® liat** analyzer.

The **cobas® liat Advanced Tools Guide** is intended as reference for performing various functions, including archiving data and syncing assay tube lots between **cobas® liat** analyzers.

The **cobas® liat** System **Host Interface Manual HL7** contains all necessary information about the HL7 interface.

The **cobas® liat** System **Host Interface Manual POCT1-A (DML)** contains all necessary information about the DML interface.

The **cobas® liat** System **User Assistance** is the online help version of the **cobas® liat** System **User Guide**.

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⚠ General attention

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- Pay particular attention to all safety notices.
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- Do not use the software in a way that is not described in this publication.
- Store all publications in a safe and easily retrievable place.

⚠ Incident reporting

- Inform your Roche representative and your local competent authority about any serious incidents which may occur when using this product.

Images

The screenshots and hardware images in this publication have been added exclusively for illustration purposes. Configurable and variable data in screenshots, such as tests, results, or path names visible therein must not be used for laboratory purposes.

Example communication messages

Any software version, build number and variable data included in the example communication messages is for illustration purposes only. It might not match what is actually transmitted by the analyzer or host.

Warranty

Any customer modification to the analyzer and the use of unauthorized assay tubes or accessories renders the warranty null and void.

Do not open the **cobas® liat** analyzer, change a component or install unauthorized software.

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Support If you have any further questions, please contact your Roche Support representative with the system information collected as described in the Troubleshooting chapter in the **cobas**® **liat** system **User Guide**.

Feedback Every effort has been made to ensure that this publication fulfills the intended use. All feedback on any aspect of this publication is welcome and is considered during updates. Contact your local Roche Service representative, should you have any such feedback.

In the U.S., call the following number: 1-800-800-5973.

Table of contents

Preface

Intended use

Refer to the **cobas® liat** system User Guide.

Symbols and abbreviations

Product names

Except where the context clearly indicated otherwise, the following product names and descriptors are used.

Product name	Descriptor
cobas® liat analyzer	analyzer
cobas® liat assay tube	assay tube

Product names

Symbols used in the publication

Symbol	Explanation
•	List item
	Cross-refrence to related topics containing further information.
	Tip. Extra information on correct use or useful hints.
	Start of a task or cross-reference to a task.
	Extra information within a task
	Figure. Used in figure titles and cross-references to figures.
	Table. Used in table titles and cross-references to tables.

Symbols used in the publication

Abbreviations

The following abbreviations are used.

Abbreviation	Definition
CLSI	Clinical and Laboratory Standards Institute
Ct	Threshold cycle
DML	Device Messaging Layer
HIS	Hospital information system
HL7	Health Level 7 An organization that provides connectivity standards for the healthcare industry. http://www.hl7.org/

Abbreviations used in this publication

Abbreviation	Definition
IHE	Integrating Healthcare Enterprises An organization that provides implementation guidelines for connectivity standards in the healthcare environment.
IVD	In vitro diagnostic
LIS	Laboratory information system
LPOCT	Laboratory Point Of Care Testing IHE profile covering diagnostic tests performed at the point of care in a healthcare institution
MAC	Media Access Control. Typically referred to as MAC Address, a unique identifier assigned to a wired or wireless network interface controller used to identify a connected device.
NCCLS	National Committee for Clinical Laboratory Standards
POCT	Point of Care Testing. Diagnostic testing performed near or at the patient care facility or bedside.
UTC/GMT	Universal Time Coordinated / Greenwich Mean Time
UTF-8	Unicode (or Universal Coded Character Set) Transformation Format – 8-bit. A character encoding capable of encoding all possible characters.
UUID	Universally unique identifier. A 128-bit number used to identify information in computer systems.

Abbreviations used in this publication

Supporting documents

This document makes references to or assumes familiarity with the information contained in the following documents.

Name	Type	Description
[1] HL7 implementation guide	External	HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1. http://www.hl7.org/
[2] User Guide	Internal	**cobas**® **liat** system User Guide
[3] IHE Laboratory (LAB)Technical Framework, Volume 2b	External	IHE Laboratory (LAB) Technical Framework, Volume 2b, IHE International, Inc. Accessed: https://www.ihe.net/uploadedFiles/Documents/Laboratory/IHE_LAB_TF_Rev6.0_Vol2b_FT_2015-07-14.pdf

Supporting documents and citations

What is new in publication version 9.2

Text removed

The section "About the analyzer functions" was removed.

HL7 Result message details

The MSH-11 Version field description was corrected.

HL7 Result message details (27)

The NTE-3 Comment field description and remarks were corrected.

HL7 Result message details (27)

Example HL7 result messages

The example CDFA result message was corrected.

Generic example result message (31)

HL7 Acknowledgment message details

The MSH-11 Version field description was corrected.

HL7 acknowledgment message details (32)

Minor corrections to text and formatting

Edition notice (3)

Abbreviations (8)

About the POCT1-A communication standard (13)

What is new in publication version 10.0

Influenza A (FABA)

Added notes that assay Influenza A (FABA) is no longer supported.

Observations (23)

Universal service identifier (24)

Universal service identifier

Added "Liat SARS-CoV-2" to the Values for universal_service_id (OBR-4) table.

Universal service identifier (24)

HL7 Result message details	Removed PatientVerificationFailureIgnored from NTE-3. HL7 Result message details (27)
Non-supported characters	Added new table with additional characters. Non-supported characters (30)

What is new in publication version 11.0

New branding	The cover page, the colors, and the fonts were updated. The product names, descriptors, and publication names were updated. The pictures of the analyzer and the screenshots were updated accordingly. Product names (8)
Observations	Added Script name column to "Observation ID's and script names used by the analyzer" table and resorted rows. Observation ID's and script names used by the analyzer (OBX-3) (24)
Example message logs	Replaced assay specific examples with generic examples. Example HL7 result messages (31)
Minor changes	Updated Publication information. Updated descriptions for OBR-4 and OBX-5 segments in HL7 Result message details. Changed field values for ERR segments in HL7 Acknowledgment message details. HL7 Result message details (27) HL7 acknowledgment message details (32)

What is new in publication version 11.1

New assays	Added new assay **cobas® liat** SARS-CoV-2, Influenza A/B & RSV nucleic acid test (CFRA). Observation ID's and script names used by the analyzer (OBX-3) (24) Values for universal_service_id (OBR-4) (25)

Minor changes

The footnote in the HL7 result segment details table was updated.

HL7 result segment details (27)

Corrected error in message example 2.

Example HL7 acknowledgment messages (34)

What is new in publication version 11.2

New assays

Added new assays **cobas**® **liat** CT/NG/MG nucleic acid test (CNMA) and **cobas**® **liat** CT/NG nucleic acid test (CNDA).

Observation ID's and script names used by the analyzer (OBX-3) (24)

Values for universal_service_id (OBR-4) (25)

What is new in publication version 11.3

New assays

Added new assays **cobas**® **liat** SARS-CoV-2/Flu v2 nucleic acid test (SF2A) and **cobas**® **liat** SARS-CoV-2 v2 nucleic acid test (CV2A).

Observation ID's and script names used by the analyzer (OBX-3) (24)

Values for universal_service_id (OBR-4) (25)

About the POCT1-A communication standard

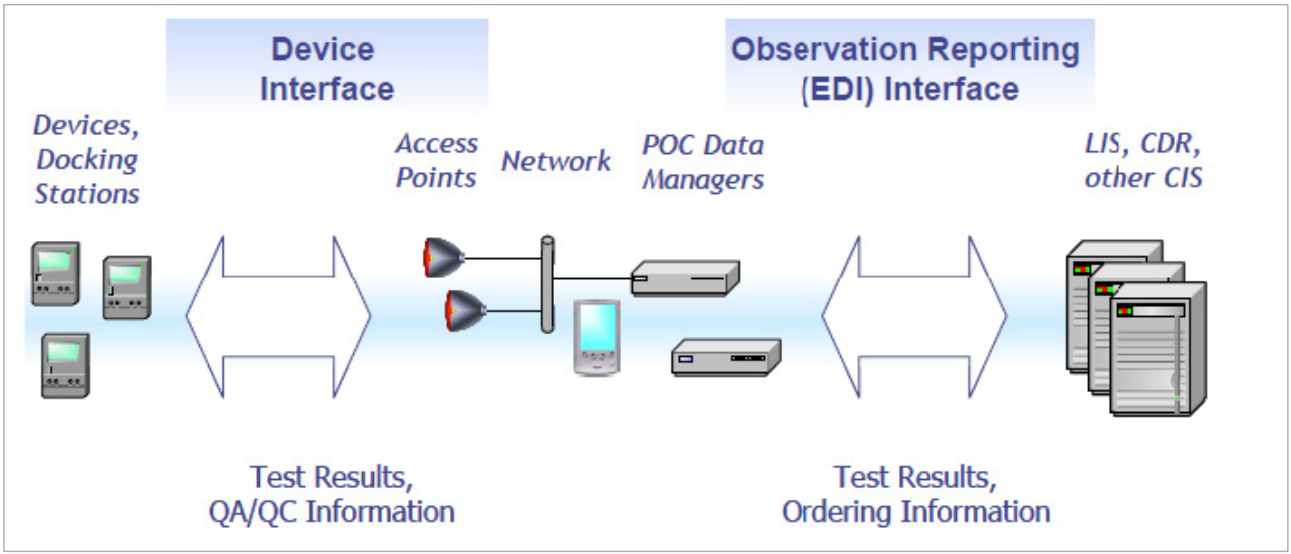
The analyzer provides connectivity for transferring patient results to a customer's laboratory information system (LIS), a hospital information system (HIS) or Point-Of-Care (POC) Management System.

The analyzer is a POCT device for Molecular Diagnostics and it implements a widely used communication standard for POCT called POCT1-A standard, which was published by the CLSI (formerly NCCLS).

The POCT1-A standard describes 2 types of communication interfaces for the data exchange:

- *Device Interface:* controls the flow of information between POC devices and Observation Reviewers.
- *Observation Reporting Interface:* describes messaging between Observation Reviewers and Observation Recipients (Hospital or Laboratory Information System) based on HL7 version 2.5.1. messages. For the **cobas® liat**, this interface is used to send test results from the analyzer to the HIS or LIS.

This publication only describes the HL7 protocol (Observation Reporting Interface). For information about the device interface, refer to the **cobas® liat** system **Host Interface Manual POCT1-A (DML)**.



Overview of POCT1-A interfaces

As the analyzer supports both communication interfaces, it can alternatively connect directly to a host without a data manager in between.

About connectivity

For connectivity related information, refer to the **cobas® liat** system **User Guide**, chapter **Connectivity**, which covers the following topics:

- How to connect the analyzer manually to the network
- How to connect the analyzer to the Roche remote service
- How to connect the analyzer to a host system
- Conceptual information about security, monitoring host connectivity, and data exchange with a LIS
- How to define and configure network resources
- How to use the share lot folder
- How to configure the share lot function

Secure certification validation

The analyzer uses TCP/IP based communication with the LIS through a wired LAN connection. The TCP/IP stack handles most of the lower-level communication protocol.

The analyzer can establish a secure connection with LIS hosts that support the Transport Layer Security (TLS) protocol version 1.2. TLS is enabled by default.

TLS is enabled by default.

The secure communications server's certificate needed for establishing the secure TLS v1.2 connection shall be manually acknowledged on the analyzer by the Administrator. This acknowledgment just needs to be done once, prior to the first secure connection to the LIS. All upcoming secure connections will “remember” this first manual Acknowledgment, and will use the stored value to verify the identity of the LIS host.

If the certificate or the LIS host itself changes (i.e. a different server), all the analyzers within the customer premises shall re-validate the new host certificate.

Ethernet connection

The Ethernet connection does not need to be configured. The **cobas® liat** system is capable of communicating at 10/100 Mbps, at full or half duplex. The highest common speed between the connected devices is used.

Workflows

In this section

About workflows

The analyzer can send HL7 messages directly to a remote host. Unlike the POCT1-A protocol, which requires a "Hello" and "End" protocol, HL7 message just need to have the correct structure.

For more information regarding HL7 messages refer to the [1] HL7 implementation guide. (*HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health*, Release 1. http://www.hl7.org/)

The analyzer is able to send patient test results.

The analyzer also sends an Acknowledgment message.

Note that the **cobas® liat** analyzer is a client, the host is the server. The analyzer establishes a connection before sending result messages. When the host has acknowledged the message, the analyzer closes the network connection. The host has to return to the listening state.

Communication scenarios

Results can be released automatically or manually.

The following table shows the communication scenarios as they are currently supported by the analyzer.

Name	Description
Auto release results	The analyzer releases patient results automatically after measurement. Released results are automatically sent to the host.
Release results manually	The user chooses patient results that are stored on the analyzer and releases them. The released results are automatically sent to the host.

Supported communication scenarios

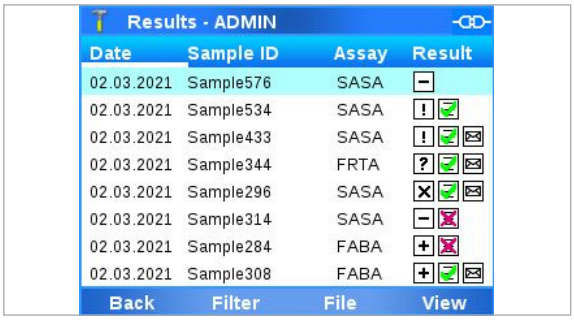
Sending results to the LIS

Releasing results manually

The analyzer can generate valid, invalid, and indeterminate results. All released results are sent, including invalid results and information about aborted runs.

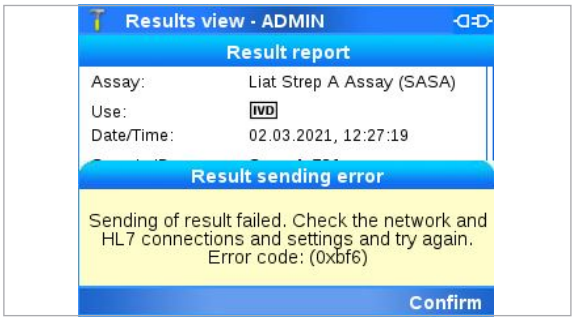
How the operator releases results manually

The operator can release or reject each result with the “Approval” option from the **Result report** screen or the **Results** screen. Released results are then sent automatically. Rejected results cannot be sent to a LIS.



An icon on the right-hand column of the **Results** screen shows the sending status of the result. No icon means that the result has not been sent.

To send a result the operator releases a result on the analyzer. The result is then sent to a LIS host. The host (e.g. HL7) stores the result and sends back an acknowledgment. The result is marked as “sent to host and acknowledged” on the screen (white envelope icon).

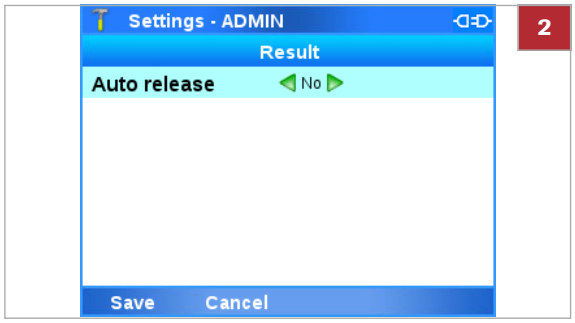


When the host encounters an error, the acknowledgment contains information about the error condition. Each time the sending of a result is triggered (automatically or manually), the analyzer makes up to 3 attempts to send. If all attempts fail, an error message is displayed on the analyzer.

No envelope icon is shown if the result is not sent by the analyzer, or if sending fails.

Results can only be marked and released individually. Releasing multiple results is not supported.

For information on performing assays, refer to the [2] **cobas® liat** system User Guide.



To configure manual release of results

1 On the **Main** screen, choose **Settings > System > Result settings**. Choose the **Select** button.
➔ The **Result** screen is displayed.

2 Choose the **Auto release** item, then choose the **No** value to disable automatic release of results.

3 Choose the **Save** button.

Releasing results automatically

The **Auto release** option allows the analyzer to automatically release results and send them to the host once the results are generated. Indeterminate, or invalid results, and information about aborted runs, are also sent to the host.

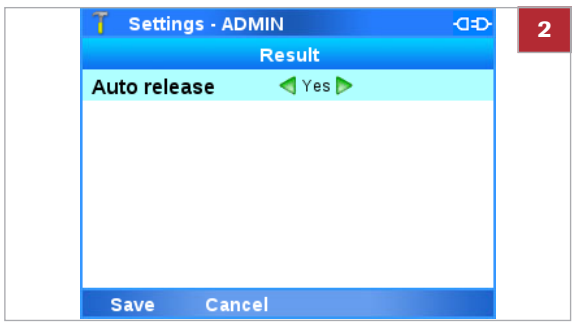
When the analyzer completes a run, it automatically releases the results, which are then sent to the host. The host processes and stores the received results and sends back an acknowledgment so that the analyzer can mark the results as “acknowledged by host” without manually releasing them.

When the host encounters an error, the acknowledgment contains information about the error condition. Each time the sending of a result is triggered (automatically or manually), the analyzer makes up to 3 attempts to send. If all attempts fail, an error message is displayed on the analyzer.

No envelope icon is shown if the result is not sent by the analyzer, or if sending fails.

To configure automatic release of results

1 On the **Main** screen, choose **Settings > System > Result settings**. Choose the **Select** button.
➔ The **Result** screen is displayed.



2 Choose the **Auto release** item, then choose the **Yes** value to disable automatic release of results.

3 Choose the **Save** button.

HL7 Protocol

In this section

Message types

The analyzer sends and accepts messages according to the HL7 Version 2.5.1 standard. These are text-based messages consisting of segments and fields.

Test result report

The test result report is sent by the analyzer. The definition follows the IHE's "LPOCT" profile definition[(a)], which provides guidance for the implementation of the observation reporting (HL7) interface.

ORU^R30:	`MSH`		Message Header
	`PID`		Patient Identification
	`ORC`		Common Order Information
	`OBR`		Observation Request
	`NTE`		Comment for result
	`{`		
		`OBX`	Observation result related to OBR
		`NTE`	Comment for observation

(a) IHE Technical Framework LAB TF-2b, chapter 3.32 "Accepted Observation Set (LAB-32)"

	OBX	Observation result interpretation
	OBX	Ct value
}		

With {} = repeatable segment

Acknowledgment

When the host processes the ORU^R30 message it responds with an ACK^R33 message of the following structure:

ACK^R33:	MSH		Message Header
	MSA		Message Acknowledgment
	[ERR]	Error	Common Order Information

With [] = optional segment

Observations

The observation ID in OBX-3 consists of two parts.

- The result type, for example, influenza A
- The script name that was used for processing and detection, for example FRTA.

These are combined in the observation ID, with the script name in brackets. For example:

```
Influenza A (FRTA)
```

The observation id is a component of the observation messages (ORU^R30).

The **cobas® liat** system and associated assays are not commercially available in all markets. Please check with local Regulatory affiliate for regulatory status.

Script name	OBS.observation_id: result type (script name)	Description
CDFA	Cdiff (CDFA)	*Clostridium difficile* (*C. difficile*)
CFRA	Influenza A (CFRA)	Influenza assay run, type A
CFRA	Influenza B (CFRA)	Influenza assay run, type B
CFRA	RSV (CFRA)	Respiratory syncytial virus
CFRA	SARS-CoV-2 (CFRA)	Severe acute respiratory syndrome coronavirus 2
CNDA	CT (CNDA)	*Chlamydia trachomatis (C. trachomatis)*
CNDA	NG (CNDA)	*Neisseria gonorrhoeae (N. gonorrhoeae)*
CNMA	CT (CNMA)	*Chlamydia trachomatis (C. trachomatis)*
CNMA	MG (CNMA)	*Mycoplasma genitalium (M. genitalium)*
CNMA	NG (CNMA)	*Neisseria gonorrhoeae (N. gonorrhoeae)*
COVA	SARS-CoV-2 (COVA)	Severe acute respiratory syndrome coronavirus 2
CV2A	SARS-CoV-2 (CV2A)	Severe acute respiratory syndrome coronavirus 2
FABA	Influenza A (FABA)[(a)]	Influenza assay run, type A
FABA	Influenza B (FABA)[(a)]	Influenza assay run, type B
FRTA	Influenza A (FRTA)	Influenza assay run, type A
FRTA	Influenza B (FRTA)	Influenza assay run, type B
FRTA	RSV (FRTA)	Respiratory syncytial virus
SASA	Strep A (SASA)	Strep assay run, type A (Group A *Streptococcus*)
SCFA	Influenza A (SCFA)	Influenza assay run, type A
SCFA	Influenza B (SCFA)	Influenza assay run, type B
SCFA	SARS-CoV-2 (SCFA)	Severe acute respiratory syndrome coronavirus 2
SF2A	Influenza A (SF2A)	Influenza assay run, type A
SF2A	Influenza B (SF2A)	Influenza assay run, type B
SF2A	SARS-CoV-2 (SF2A)	Severe acute respiratory syndrome coronavirus 2

Observation ID's and script names used by the analyzer (OBX-3)

(a) Influenza assay is no longer supported from software version 3.4 onwards, but migrated results may be available from software version 3.3

Observation ID for Ct value

When sending the Ct value, the observation ID has this format:

`[Target]^[Target] ([Assay-short-name])``^99_ROC^S_OTHER^Other Supplemental^IHE LPOCT`

[Target] and **[Assay-short-name]** are variables, and the rest of the string is fixed.

Universal service identifier

The universal service in OBR-4 of the observation message (ORU^R20) identifies the assay.

The **cobas® liat** system and associated assays are not commercially available in all markets. Please check with local Regulatory affiliate for regulatory status.

OBR-4: universal service id
Cdiff
Liat CT/NG
Liat CT/NG/MG
Liat Flu/RSV Assay
Liat Influenza Assay(a)
Liat SARS-CoV-2
Liat SARS-CoV-2 v2
Liat SARS-CoV-2/Flu
Liat SARS-CoV-2/Flu v2
Liat SARS-CoV-2/Flu/RSV
Liat Strep A Assay

Values for universal_service_id (OBR-4)

(a) Influenza assay is no longer supported from software version 3.4 onwards, but migrated results may be available from software version 3.3

Minimal layer protocol

The test result message and the acknowledgment are transmitted over TCP/IP using the MLLP or LLP protocol as defined by HL7. This is a simple data framing protocol without any handshake or checksum calculation.

With the particular message content shown as DATA and

<VT>: ASCII "Vertical Tabulator" 0x0B

<FS>: ASCII "File Separator" 0x1C

<CR>: ASCII "Carriage Return" 0x0D

The analyzer always acts as the TCP/IP client. The host can listen on any port but the host's IP address and port must be configured in the analyzer's settings.

HL7 result report message

In this section

HL7 Result message details

Segment	Field	Field name	Data: data type, description or example	Remark
MSH	-	Field separator	|	Fixed text
MSH	1	Encoding characters	^~\&	fixed text
MSH	2	Sending Application	cobas Liat	Fixed text (config.)
MSH	3	Sending Facility	Roche	Fixed text (config.)
MSH	4	Receiving Application	Host	Fixed text (config.)
MSH	5	Receiving Facility	Healthcare Provider	Fixed text (config.)
MSH	6	Date/Time of message	Message Time in UTC	in UTC[a]
MSH	8	Message Type	ORU^R30^ORU_R30	Fixed text
MSH	9	Message Control ID	UUID	
MSH	10	Processing ID	P	Fixed text
MSH	11	Version	2.5	Fixed text
MSH	17	Character Set	UNICODE UTF-8	Fixed text
PID	3	Patient ID List	Patient / Sample ID	
PID	5	Patient Name	unknown	Fixed text
PID	8	Administrative Sex	U	Fixed text
PID	12	Country Code	Country Code	Always empty
ORC	1	Order Control	NW	Fixed text
OBR	4	Universal Service ID	Assay code for request	Assay code for request. For supported values, follow the link. Universal service identifier (24)
OBR	11	Specimen Action Code	O	Fixed text
OBR	25	Order Result Status	F	Fixed text
OBR	32	Principal Result Interpreter	Approver	Manually-sent results: login name of the approver. Auto-send results: empty.
OBR	34	Technician	User	Login name of the user that performed the result.

HL7 result segment details

Segment	Field	Field name	Data: data type, description or example	Remark
NTE	3	Comment	Run no. Device S/N> Version Tube TubeExp TubeLot	Semi-colon-separate list of values. Syntax: Run = <value>; Device = <value>; Version = <value>; Tube = <value>; TubeExp = <value>; TubeLot = <value> For example: `Run=89;Device=M1-E-00301;Version=3.4.0.xxxx;Tube=00002;TubeExp=2023-01-31;TubeLot=00121A`
OBX	2	Value Type	`NM`	Fixed text. Shows that the first occurrence of the OBX record contains the numerical result.
OBX	3	Observation Identifier	Assay Code	Assay for result. Supported values: Observations (23) e.g.: `Strep A (Assay)` etc. If the run was aborted, a single “Unknown Target” is reported. The assay short name is always appended after it, e.g.: `Unknown Target (SCFA)`
OBX	5	Observation value	Result Value	
OBX	6	Units	Unit of measurement	
OBX	11	Result Status	F	Fixed text
OBX	16	Responsible Observer	User	Identical to OBR-34
OBX	18	Equipment Instance ID	MAC Address	
OBX	19	Date/Time of analysis	Analysis Date Time	In UTC[(a)]
NTE	1	Set ID	`1`	Fixed text
NTE	3	Comment	Use	If the run was aborted, either of the following is appended: • `Aborted by User` • `Aborted by System` • `Aborted by Script`
OBX	2	Value Type	`ST`	Fixed text. Shows that the second occurrence of the OBX record has a text string as the result value.
OBX	3	Observation Identifier	Assay	Assay for result. Supported values: Observations (23) If the run was aborted, a single “Unknown Target” is reported. The assay short name is always appended after it, e.g.: `Unknown Target (SCFA)`
OBX	5	Observation value	Interpretation	Textual interpretation of the result. This is either: • `Detected` • `Not detected` • `Aborted` • `Indeterminate` • `Invalid`

HL7 result segment details

Segment	Field	Field name	Data: data type, description or example	Remark
OBX	11	Result Status	`F`	Fixed text
OBX	2	Value Type	`NM`	Fixed text. Shows that the third occurrence of the OBX record has a numerical value as the result value.
OBX	3	Observation Identifier	Assay	Assay for result. Supported values: Observations (23) Additional formatting for Ct value: Observation ID for Ct value (24) If the run was aborted, a single “Unknown Target” is reported. The assay short name is always appended after it, e.g.: `Unknown Target (SCFA)`
OBX	5	Ct value	Decimal number or empty string `""`	The decimal number can contain any number of decimal places. Example of a reported (empty) Ct value: `OBX||NM|Influenza B^Influenza B (SCFA)^99_ROC^S_OTHER^Other Supplemental^IHE LPOCT||""||||||F`
OBX	11	Result Status	`F`	Fixed text

HL7 result segment details

(a) The Date/Time format is YYYYMMDDhhmmss+/-TTTT
with YYYY: year; MM: month; DD: day; hh: hour; mm: minute; ss: second; +/- TTTT: UTC/GMT time zone, including a + or - identifier.

The analyzer supports alphanumeric sample or patient IDs. Some hosts might encounter problems when receiving non-numeric IDs.

Ct values

Ct values are reported in an OBX segment for every valid, positive target result or control. For example, the SCFA assay contains 3 additional OBX segments, one for “SARS-COV-2”, one for “Influenza A” and a last one for “Influenza B”.

For negative, invalid, or indeterminate target results, or aborted runs, an empty string "" is sent.

Information about aborted runs

If a run was aborted, a single observation with the identifier "Unknown Target" is reported with a note segment (NTE) to indicate the abort reason.

Generic example aborted run (32)

Invalid sample results

Whenever an assay run is invalid, all its targets are reported with an observation value of `Invalid`. Invalid external control assay runs are able to report valid target results.

Generic example invalid assay run (32)

Non-supported characters

The following characters cannot be transmitted via HL7. Do not use these characters in sample ID or a user ID.

Character	Hex value	Description
[NUL]	00	Null
[SOH]	01	Start of heading
[STX]	02	Start of text
[ETX]	03	End of text
[EOT]	04	End of transmission
[ENQ]	05	Enquiry
[ACK]	06	Acknowledge
[BEL]	07	Bell
[BS]	08	Backspace
[HT]	09	Horizontal tab
[LF]	0A	Line feed
[VT]	0B	Vertical tab
[FF]	0C	Form feed
[CR]	0D	Carriage return
[SO]	0E	Shift out
[SI]	0F	Shift in
[DLE]	10	Data link escape
[DC1]	11	Device control 1
[DC2]	12	Device control 2
[DC3]	13	Device control 3
[DC4]	14	Device control 4
[NAK]	15	Negative acknowledge
[SYN]	16	Synchronous idle
[ETB]	17	End of transmission block
[CAN]	18	Cancel
[EM]	19	End of medium
[SUB]	1A	Substitute
[ESC]	1B	Escape
[FS]	1C	Field separator
[GS]	1D	Group separator
[RS]	1E	Record separator
[US]	1F	Unit separator
[Space]	20	Space
&	26	Ampersand
;	3B	Semicolon
\	5C	Backslash
^	5E	Caret / circumflex
|	7C	Vertical bar
~	7E	Tilde
[DEL]	7F	Delete

Non-supported characters

Example HL7 result messages

This section shows example result messages sent from the **cobas® liat** analyzer to the host.

The **cobas® liat** system and associated assays are not commercially available in all markets. Please check with local Regulatory affiliate for regulatory status.

The result message structure is identical for every assay. Some values in the structure will change depending on which assay is used. In these examples, the following placeholders are used to mark values that will change based on the assay used:

OBX-3: observation id	Description
Target 1 (TEST)	Generic example assay, target 1
Target 2 (TEST)	Generic example assay, target 2

Placeholders for OBX-3: observation id

OBR-4: universal service id
Liat Generic Assay

Placeholder for OBR-4: universal service id

Other values in the examples are for information purposes only, and will be different to the observed values. For example, timestamps, serial numbers or version numbers.

Note: Some segments like MSH are long and are displayed in line-wrapped format.

Generic example result message

```
MSH|^~\&|cobas Liat|Roche|Host|Healthcare Provider|20200301131214+0100||ORU^R30^ORU_R30|898e9e28-
992b-40f1-bea8-558085ea958b|P|2.5||||||UNICODE UTF-8
PID|||PAT030||unknown|||U
ORC|NW
OBR||||Liat Generic Assay|||||||O|||||||||||||||F|||||||N/A||ADMIN
NTE|||Run=00003;Device=M1-E-00345;Version=3.5.0.xxxx;Tube=00003;TubeExp=2030-01-31;TubeLot=20126A
OBX||NM|Target 1 (TEST)||0|0|||||F|||||ADMIN||f8:dc:7a:07:3c:22|20200301131200+0100
NTE|1||EUA/IVD
OBX||ST|Target 1 (TEST)||Detected||||||F
OBX||NM|Target 1^Target 1 (TEST)^99_ROC^S_OTHER^Other Supplemental^IHE LPOCT||29.7783202283394||||||
F
OBX||NM|Target 2 (TEST)||0|0|||||F|||||ADMIN||f8:dc:7a:07:3c:22|20200301131200+0100
NTE|1||EUA/IVD
OBX||ST|Target 2 (TEST)||Not Detected||||||F
OBX||NM|Target 2^Target 2 (TEST)^99_ROC^S_OTHER^Other Supplemental^IHE LPOCT||""||||||F
```

Generic example aborted run

```
MSH|^~\&|cobas Liat|Roche|Host|Healthcare Provider|20201110162058+0100||ORU^R30^ORU_R30|8b5fd9fb2eee
-4687-8828-69b313f5bdfd|P|2.5||||||UNICODE UTF-8
PID|||PAT040||unknown|||U
ORC|NW
OBR||||Liat Generic Assay|||||||O|||||||||||||||F|||||||System||ADMIN
NTE|||Run=00007;Device=M1-E-13405;Version=3.5.0.xxxx;Tube=00003;TubeExp=2030-01-31;TubeLot=20126A
OBX||NM|Unknown Target (TEST)||0|0|||||F|||||ADMIN||f8:dc:7a:0b:cf:33|20201110162051+0100
NTE|1||EUA/IVD; Aborted by User
OBX||ST|Unknown Target (TEST)||Aborted||||||F
OBX||NM|Unknown Target^Unknown Target (TEST)^99_ROC^S_OTHER^Other Supplemental^IHE LPOCT||""||||||F
```

Generic example invalid assay run

```
MSH|^~\&|cobas Liat|Roche|Host|Healthcare Provider|20201110173156+0100||ORU^R30^ORU_R30|e71f2574-
2b94-4393-9e0c-8bcef16c3c0d|P|2.5||||||UNICODE UTF-8
PID|||PAT050||unknown|||U
ORC|NW
OBR||||Liat Generic Assay|||||||O|||||||||||||||F|||||||System||ADMIN
NTE|||Run=00014;Device=M1-E-13405;Version=3.5.0.xxxx;Tube=00003;TubeExp=2030-01-31;TubeLot=20126A
OBX||NM|Target 1 (TEST)||0|0|||||F|||||ADMIN||f8:dc:7a:0b:cf:33|20201110173143+0100
NTE|1||EUA/IVD
OBX||ST|Target 1 (TEST)||Invalid||||||F
OBX||NM|Target 1^Target 1 (TEST)^99_ROC^S_OTHER^Other Supplemental^IHE LPOCT||""||||||F
OBX||NM|Target 2 (TEST)||0|0|||||F|||||ADMIN||f8:dc:7a:0b:cf:33|20201110173143+0100
NTE|1||EUA/IVD
OBX||ST|Target 2 (TEST)||Invalid||||||F
OBX||NM|Target 2^Target 2 (TEST)^99_ROC^S_OTHER^Other Supplemental^IHE LPOCT||""||||||F
```

HL7 acknowledgment message

In this section

HL7 acknowledgment message details

Upon reception of the ORU^R30 result message the host processes the message and answers with an acknowledgment message ACK^R33. Depending on the processing status, the host sends an appropriate acknowledgment code and where applicable also a detailed error message.

Code	Meaning	Comment
AA	Application Acknowledge	Result stored and processed by host
AE	Application Error	Host failed to store and process result
AR	Application Reject	Syntax error in message or message incomplete

HL7 acknowledgment codes

If the host sends back an AE or AR, send also an ERR segment populated with detailed error information.

Segment	Field	Field name	Data	Remark
MSH	-	Field separator	|	Only this is supported
MSH	1	Encoding characters	^~\&	Only this is supported
MSH	2	Sending Application		Optional
MSH	3	Sending Facility		Optional
MSH	4	Receiving Application		Optional
MSH	5	Receiving Facility		Optional
MSH	6	Date/Time of message		In UTC[(a)]
MSH	8	Message Type	ACK^R33^ACK	Fixed text
MSH	9	Message Control ID	UUID	
MSH	10	Processing ID	P	Fixed text
MSH	11	Version	2.5	Fixed text
MSH	17	Character Set	UNICODE UTF-8	Fixed text
MSA	1	Acknowledgment Code	AA, AE or AR	
MSA	2	Message Control Id	UUID	UUID that has been previously send to host
ERR	3	HL7 Error Code	*HL7_Error_Code^Error_Text*	Host needs to provide error code according to HL7 table 0357 and a host specific error information in form of a free text. Error codes according to HL7 table 0357 (33)
ERR	4	Severity	E	Fixed text

HL7 acknowledgment segment details

(a) See HL7 Result message details (27)

Error codes according to HL7 table 0357

Error code	Meaning
101	Required field missing
102	Data type error
103	Table value not found
200	Unsupported message type
201	Unsupported event code
202	Unsupported processing id
203	Unsupported version id
204	Unknown key identifier
205	Duplicate key identifier
206	Application record locked
207	Application internal error

HL7 table 0357 - error codes

Example HL7 acknowledgment messages

Here are some examples for a HL7 acknowledgment messages sent back from the host to the analyzer as a response to a received HL7 result message.

Some Segments like the MSH line are too long and are displayed in line-wrapped format.

Example 1 The host accepted the result message and processed the result.

```
MSH|^~\&|Host|Healthcare Provider|cobas Liat|Roche|20140716195357+0000||ACK^R33^ACK|E6BDAFD0-E22B-
485B-B124-A26174D4434D|P|2.5||||||UNICODE UTF-8
MSA|AA|25fdc862-9a41-45b5-a710-7579038fe168
```

Example 2 The host rejected the received result message due to a duplicate key.

```
MSH|^~\&|Host|Healthcare Provider|cobas Liat|Roche|20140716195357+0000||ACK^R33^ACK|E6BDAFD0-E22B-
485B-B124-A26174D4434D|P|2.5||||||UNICODE UTF-8
MSA|AR|612b7a6b-8190-4c09-9de6-9a5b01228587
ERR|||205|E
```

Example 3 The host rejected the received result message due to an unknown key.

```
MSH|^~\&|Host|Healthcare Provider|cobas Liat|Roche|20140716195357+0000||ACK^R33^ACK|E6BDAFD0-E22B-
485B-B124-A26174D4434D|P|2.5||||||UNICODE UTF-8
MSA|AE|612b7a6b-8190-4c09-9de6-9a5b01228587
ERR|||204|E
```