

cobas[®] pure integrated solutions

Simplicity meets Excellence

Host Interface Manual

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Software version 01-03 and higher



Publication information

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Revision history

Edition notice

This publication is intended for operators of **cobas® pure** integrated solutions.

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 **User Assistance** contains all information about the product, including the following:

- Routine operation
- Maintenance
- Safety
- Troubleshooting information
- Configuration information
- Background information, for example, about analytical principles

The **Safety Guide** contains important safety information. You must read the Safety Guide before operating the system.

The **User Guide** focuses on routine operation and maintenance. The chapters are organized according to the normal operation workflow.

The **Quick Reference Guide** gives a brief introduction to important routine tasks and daily maintenance.

The **cobas®** e-library provides access to important updates, Method Sheets, Value Sheets, and other important documents from Roche.

The PC manufacturer's manual contains all information about the control unit hardware.

The original version of this document is in English. All translations of this document have been translated from the original version in English. You can find the original and translated versions of this document at:

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Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU.

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Directive (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances.

Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonization of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.

Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006

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- IEC 61010-1

- IEC 61010-2-101

The instrument complies with the emission and immunity requirements described in standard IEC 61326-2-6/EN 61326-2-6.

Contact addresses – software



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Distributed in USA by	Roche Diagnostics 9115 Hague Road Indianapolis, Indiana, USA
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Contact addresses – instrument

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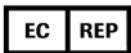
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New roles and responsibilities



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1. Connection Overview

1.1. Overview

An automatic analyzer performs data communication over the Ethernet connection of a control unit computer. The communication interface specifications between this analyzer and the host consist of a three-layer structure as shown in the figure below. This section describes the specifications for the application layer. The communication protocol used in the HL7 (Health Level Seven) channel is compliant with the HL7 standards version 2.5.

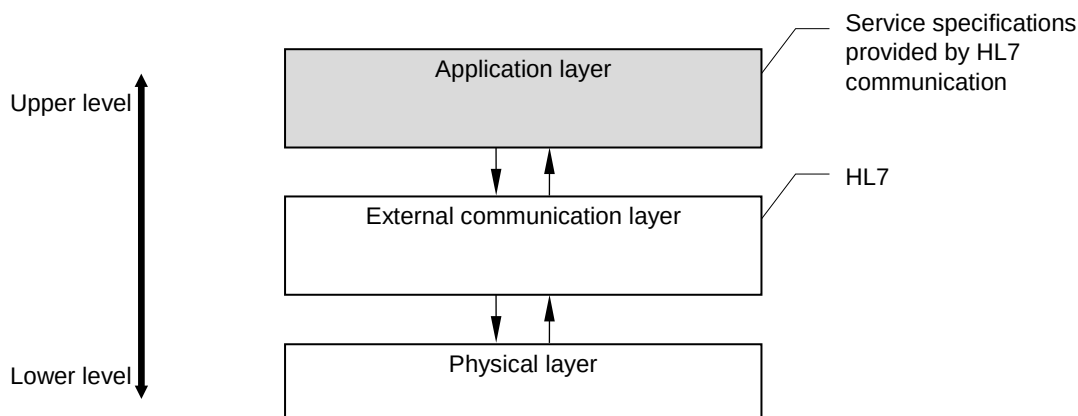


Figure 1.1-1. HOST Communication Process Layers

1.2. About cobas e flow tests

1.2.1. Introducing the cobas e flow test

This chapter gives a general introduction to the **cobas e** flow test feature.

Only the **cobas e** 402 module supports **cobas e** flow tests.

1.2.2. What is a cobas e flow test

The **cobas e** 402 module supports **cobas e** flow tests to improve the turnaround time and minimize the error rate.

A **cobas e** flow test consists of a pre-defined group of tests, known as “embedded tests”. These tests are combined into a sequence or set of sequences connected by a decision-making algorithm.

Therefore, the operator does not need to order each test individually, or assess the results of each test to decide which test to order next. Instead, the operator orders just one **cobas e** flow test. The system orders the tests, and automatically assesses each result to decide on which tests to order next.

Roche Diagnostics provides the full definition of the **cobas e** flow test package.

The definition is not editable, and embedded tests cannot be ordered separately.

To obtain a **cobas e** flow test, download them from the **HOST**.

The following items also have to be installed to be able to run the **cobas e** flow test on the **cobas e** 402 module:

- All required embedded tests on the control unit
- All required calibrators and QC materials on the control unit before running embedded tests

For more information on obtaining and installing **cobas e** flow tests, see the **cobas® pure** User Guide.

1.2.2.1. **cobas e** flow test results

Each **cobas e** flow test provides a main result and potentially one or more subresults. Depending on the embedded test results during execution, a **cobas e** flow test can report different result types, units, and/or a different number of subresults.

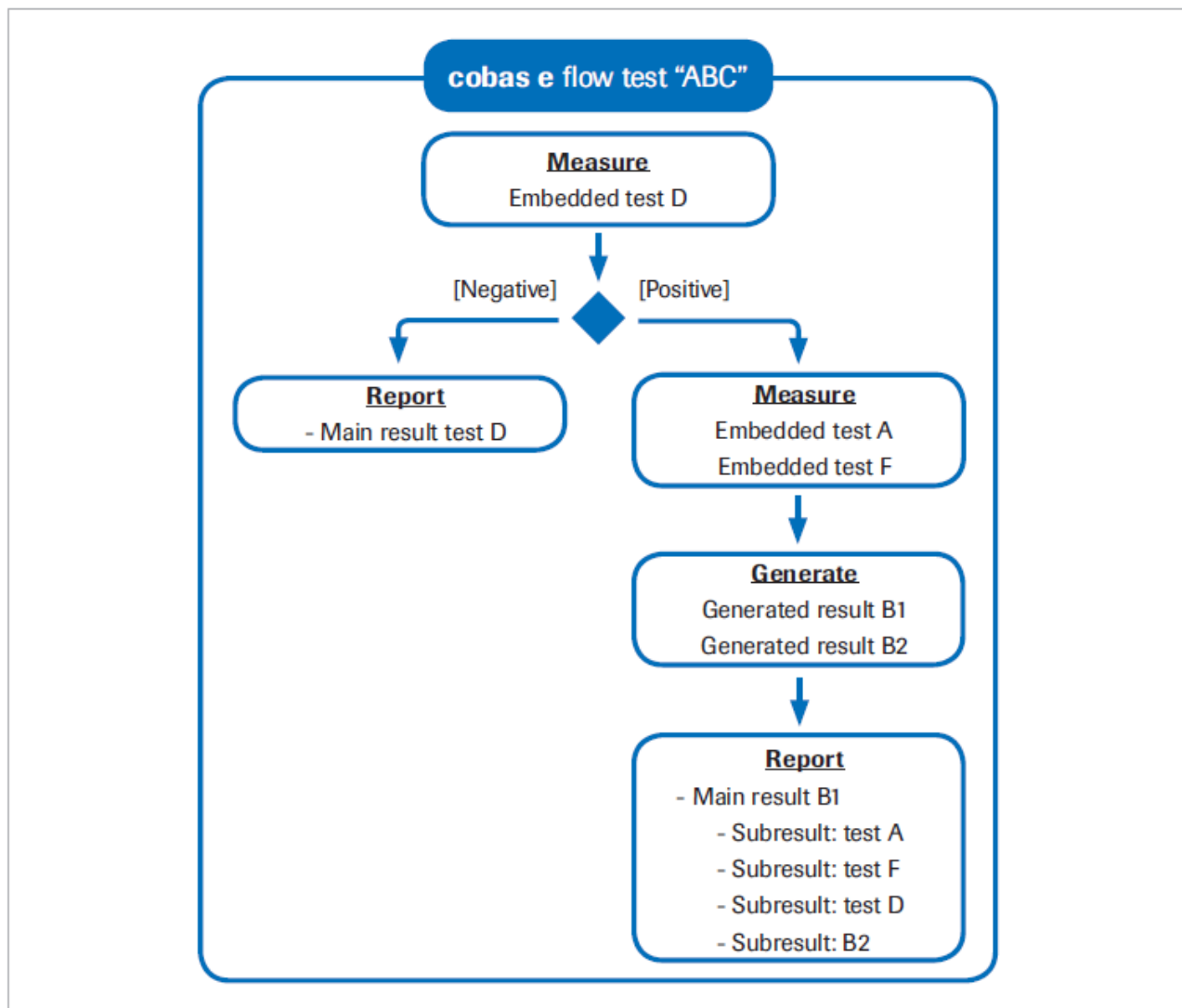


Figure 1-2 **cobas e** flow test

The main and subresults of a **cobas e** flow test can be:

- A measured result of one of its embedded tests
- A generated result of a **cobas e** flow test

Subresults provide additional information for the user. Therefore, they can be reported to host systems as supplementary information, for example, for the following reasons:

- Traceability
- Archiving of results
- Troubleshooting

The following diagram shows an example for a successfully processed **cobas e** flow test “HIV Duo” with its main and subresults:

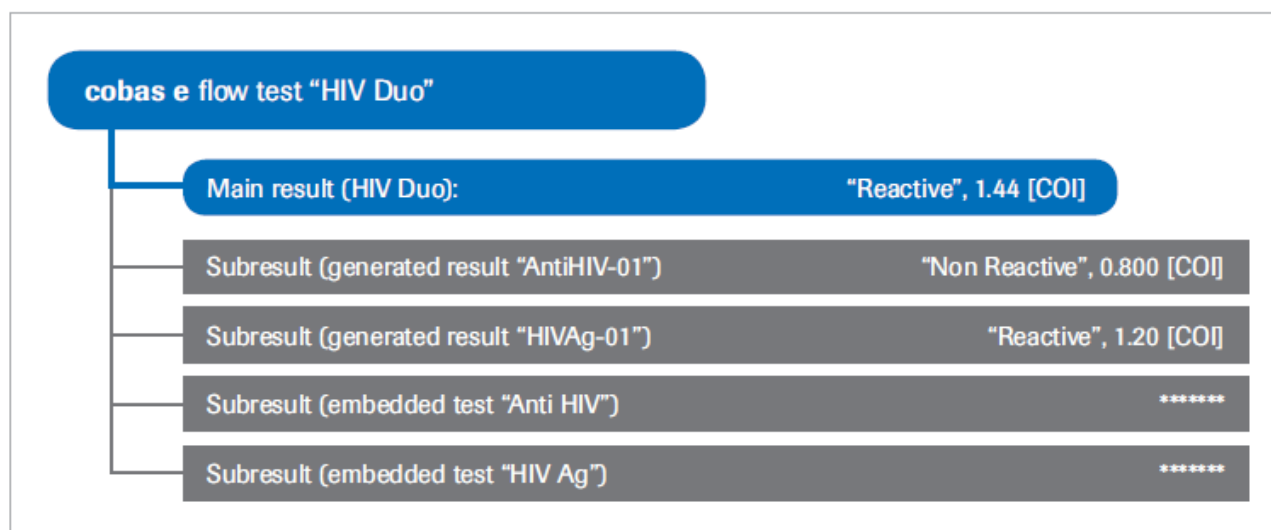


Figure 1-3 cobas e flow test – successfully processed

The definition of the **cobas e** flow test specifies the units and type of the main result, as well as the units, number, and types of any subresults. The definition is not configurable.

Notice:

Only specified subresults are reported

Subresult values are reported only if the **cobas e** flow test, as defined by Roche Diagnostics, calls for them to be reported. Otherwise, they are suppressed.

The following table shows all possible result types of **cobas e** flow test main or subresults including their units:

Result type	Example [unit]
A <i>quantitative</i> value as result of a measured embedded test	2.33 [U/mL]
A <i>qualitative</i> value derived from the measured results	"Repeatedly reactive" (without any unit)
A <i>qualitative</i> value derived from the measured results, plus a corresponding <i>quantitative</i> value as COI (Cut-off index)	"Non Reactive", 1.20 [COI]
A <i>qualitative</i> value derived from the measured results, plus a corresponding <i>quantitative</i> value	"Avidity High", 65 [%]
A <i>quantitative</i> value as result of a measured embedded test, plus a corresponding <i>qualitative</i> value	3.12 [mmol/L], "Non Reactive"

Result types returned by **cobas e** flow tests

Table 1-1 cobas e flow test – possible result types

Note: The *qualitative/quantitative* and *quantitative/qualitative* result types are only available for **cobas e** flow tests.

Notice:

Perform calibration and QC tests separately from the cobas e flow test

To use **cobas e** flow tests, be sure to calibrate and perform QC on all embedded tests and tests involved in the **cobas e** flow test.

1.2.2.2. Generic data alarm

When data alarms or errors occur during the measurement of embedded tests, cobas® pure control unit flags the **cobas e** flow test main result with a generic data alarm “**eFlow.E**”. The specific data alarm is visible in the result message of the embedded test.

1.2.2.3. Cancellation

An error in an embedded test may stop the processing of the **cobas e** flow test. For example, if there is a sample short error, no numeric result value can be determined. In this case, the system cancels any further actions, and marks the **cobas e** flow test with the data alarm “**eFlow.E**”. Any available test results or subresults are reported to the host.

After solving the problem, the operator has to reorder the **cobas e** flow test from the host.

1.2.3. QC for cobas e flow test

In order to ensure the accuracy and quality of patient results, the system validates the results against the status of their corresponding QC results.

The control unit of **cobas® pure** calculates the calculated QC value which is used in **cobas e** flow tests.

A calculated QC is a result calculated by a defined formula. It is needed as a combined QC result for **cobas e** flow tests.

For QC of a **cobas e** flow test, the following types of QC results are considered:

- Single QC
- Calculated QC

1.2.3.1. Single QC definition

Single QC means a single QC result for each measured embedded test.

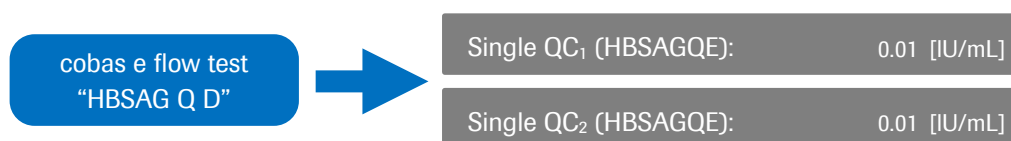


Figure 1-4 cobas e flow test – single QC

1.2.3.2. Calculated QC definition

Calculated QC means QC results for "linked tests" or "linked kits" within a **cobas e** flow test. This is provided by Roche Diagnostics

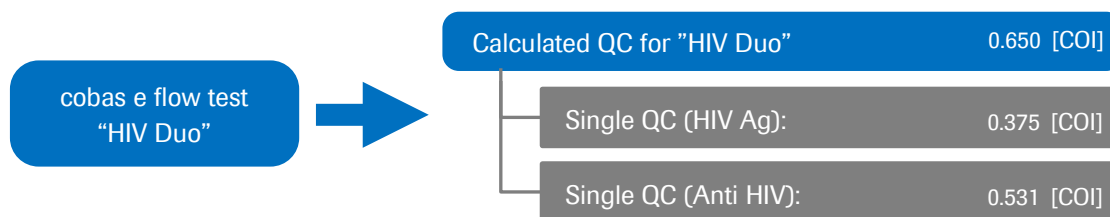


Figure 1-5 **cobas e** flow test – calculated QC

For details of linked tests and linked kits, see the next section.

Calculated QC for linked tests or linked kits

A **cobas e** flow test may measure multiple embedded tests during its execution. The embedded tests can be specified as a set of combined embedded tests (linked tests) or combined **cobas e** packs (linked kits). Therefore, there are dependencies between embedded tests or **cobas e** packs. The definition of the linked tests or linked kit forces the instrument to measure the tests in a certain order of pipetting.

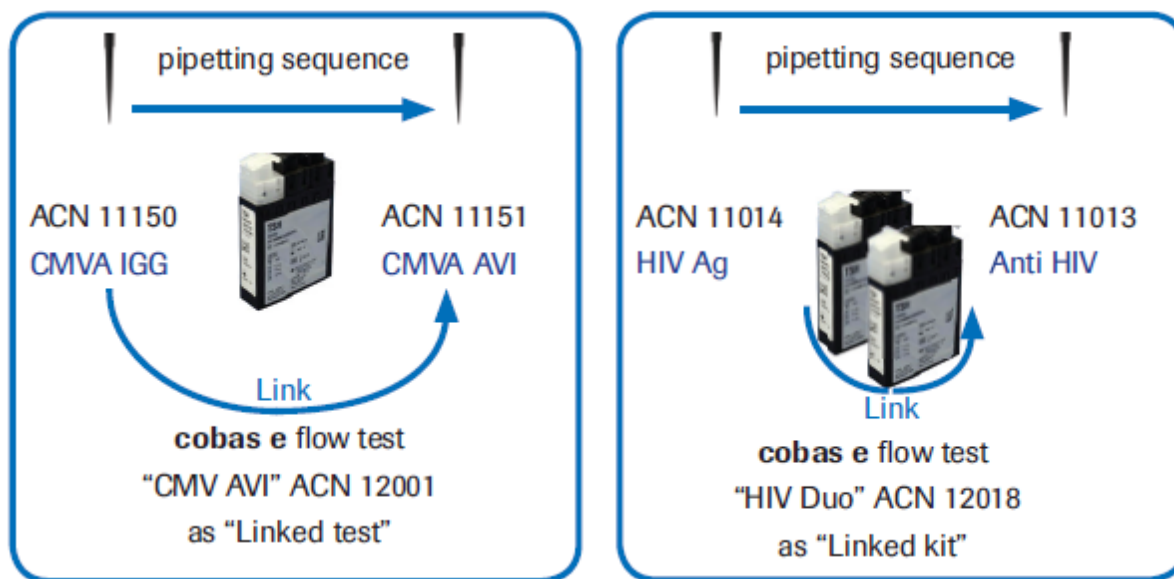


Figure 1-6 **cobas e** flow test – linked test and linked kit

The **cobas® pure** control unit can generate a calculated QC result using a pre-defined formula based on a specific **cobas e** flow test. The calculated result is based on the single QC results of the embedded tests in the **cobas e** flow test. When a **cobas e** flow test is installed on the **cobas® pure** control unit, the calculated QC functionality is automatically installed and enabled with it.

However, not all **cobas e** flow tests have a calculated QC value. There is only at most one formula for calculated QC per **cobas e** flow test.

The following example shows calculated QCs for the **cobas e** flow test “HIV Duo” on a **cobas e** 402 module:

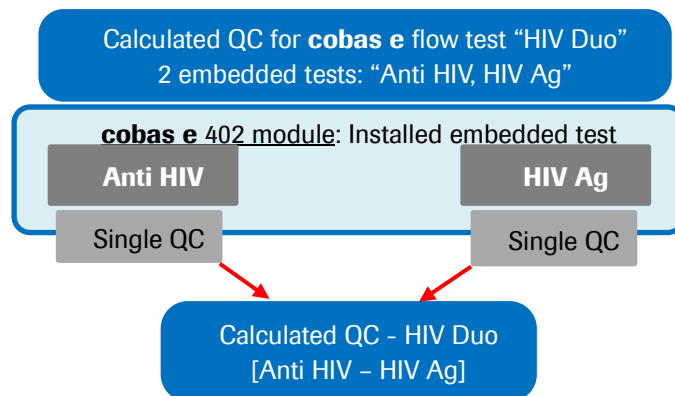


Figure 1-7 – cobas e flow test – calculated QCs

The following diagram shows an example result of a calculated QC including its corresponding single QC result values.

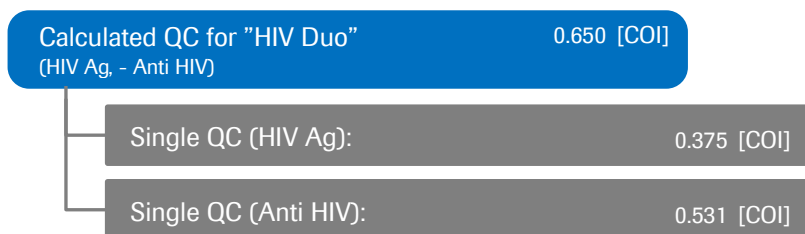


Figure 1-8 cobas e flow test – calculated QC with single QC result values

For each measurement of linked tests or embedded tests referred to linked kits during the **cobas e** flow test execution, the appropriate calculated QC result must be used for **cobas e** flow test validation.

For each QC result that is used by an embedded test in the **cobas e** flow test, the **cobas® pure** control unit performs a calculation taking into account the following components:

- QC material

Note:

If one or both of the measured QC results of the embedded tests are marked with the status Error, the calculated final QC result is marked with the status Error as well.

1.2.3.3. About QC result validation of a cobas e flow test result

In order to validate **cobas e** flow test results (if configured), the system considers all relevant QC results (single QC measurements as well as calculated QCs). The following diagram shows which QC results are relevant to validate a **cobas e** flow test.

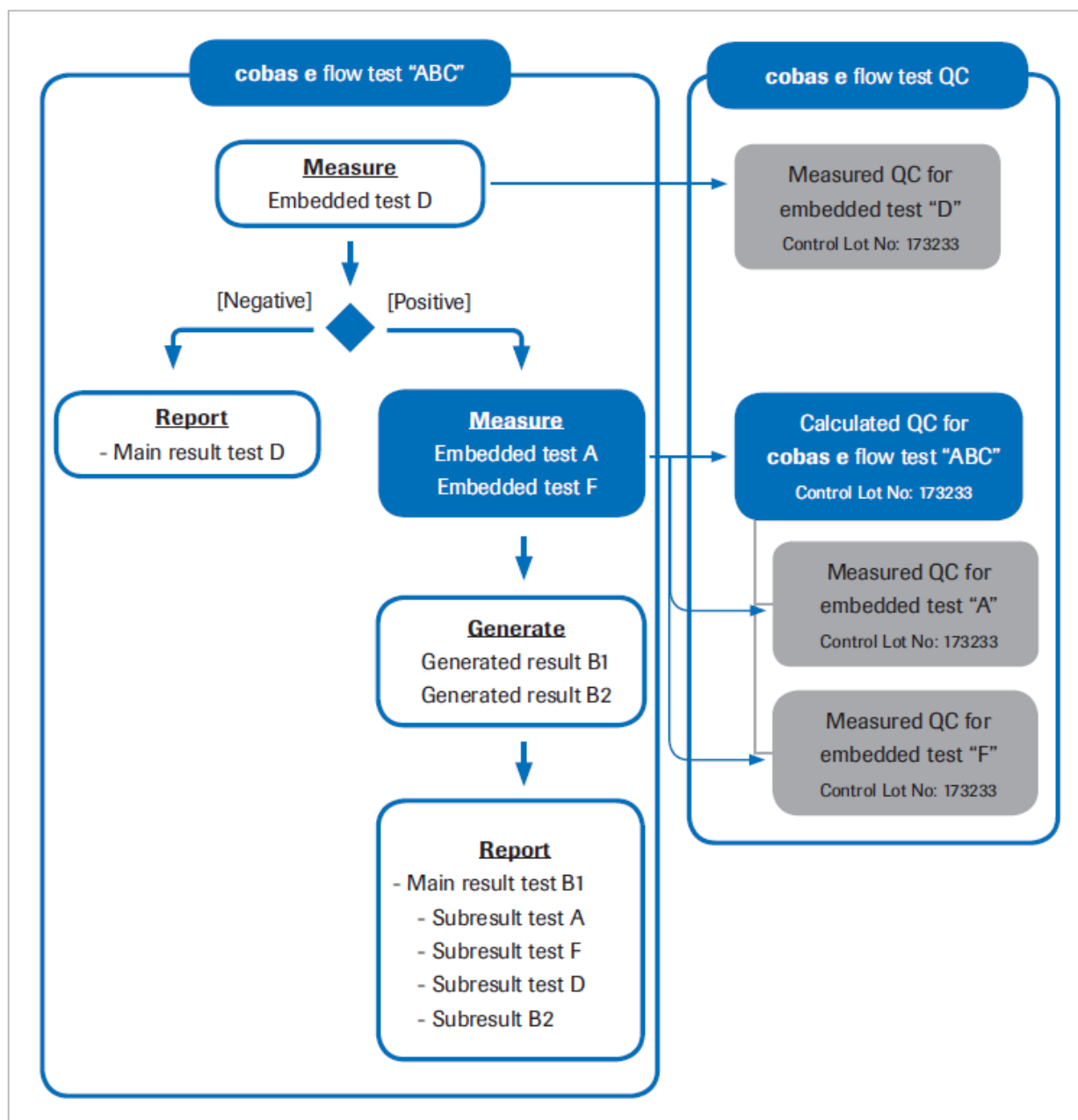


Figure 1-9 cobas e flow test – QC result validation

The diagram below shows the relevant calculated QC results and single QC results for a particular example **cobas e** flow test result.

Note:

The diagram represents the logical structure of the message, rather than the actual physical structure.

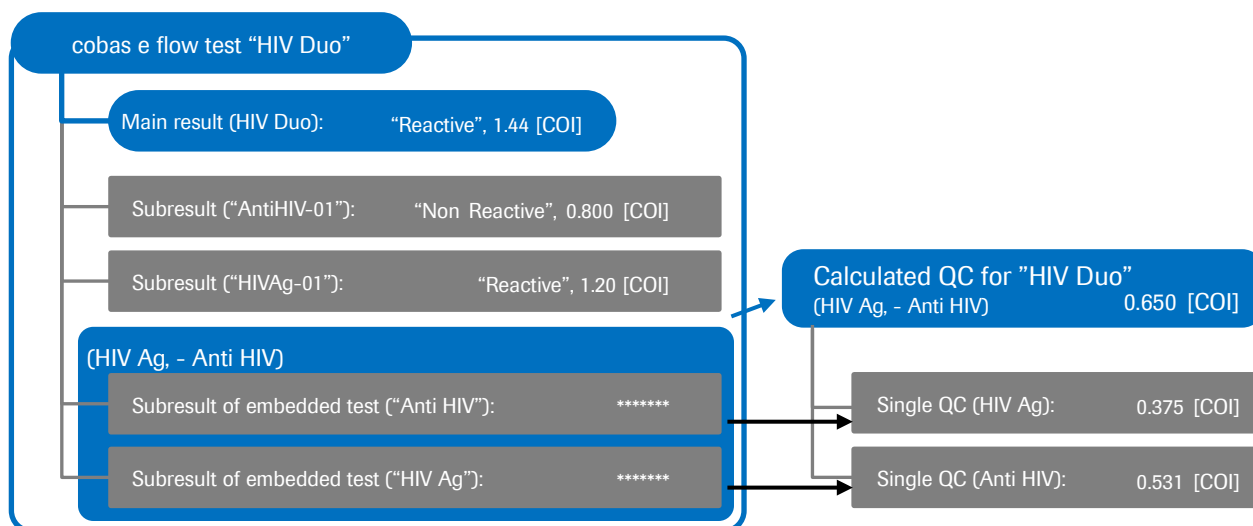


Figure 1-10 cobas e flow test – relevant calculated QC results

Each measurement of linked tests or embedded tests referred to linked kits needs to be validated against the appropriate calculated and single QC results. The following diagram shows an example for the **cobas e** flow test “HIV Duo R (duplicate repeat)” and its calculated QC results. In order to simplify the diagram, only a part of the subresults and only one control level is shown.

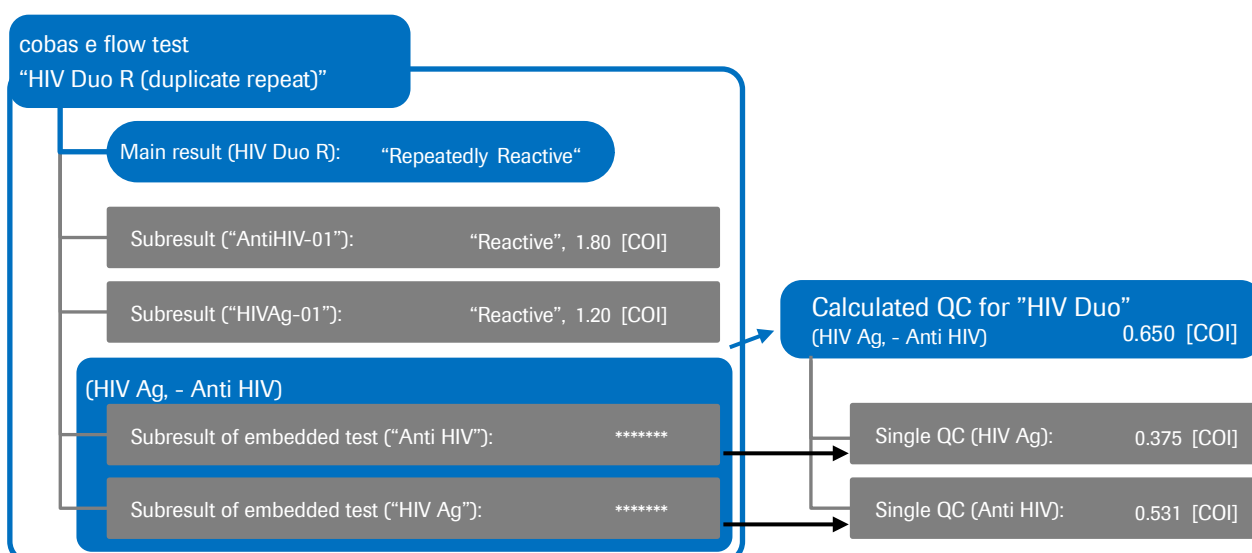


Figure 1-11 cobas e flow test – calculated QC results

1.2.4. About repeat, rerun and reflex tests with cobas e flow

This section describes the general definitions of terms “repeat, rerun, and reflex”, and how they can be used with **cobas e** flow tests

1.2.4.1. Repeat, rerun and reflex tests

You can repeat a test in 2 different ways.

- Repeat test: Repeats the measurement of the same test under the same conditions.
- Rerun test: Reruns the same test with a different dilution. It is also possible to trigger a test order according to the result from another test.
- Reflex test: Uses the result of one test to order another test.

1.2.4.2. cobas e flow test rules

- You can repeat the whole **cobas e** flow test manually.
- You cannot repeat an embedded test of a **cobas e** flow test.
- You cannot order a rerun with different dilutions for a **cobas e** flow test or its embedded tests.
- A test can trigger a **cobas e** flow test as a reflex test

1.2.4.3. Manual and automatic

The following table shows which options can be ordered manually, and which options can be triggered automatically for **cobas e** flow tests.

	cobas® pure CU manual	cobas® pure CU automatic	HOST
Repeat	Yes	No	Yes
Rerun	No	No	No
Reflex	Yes	No	Yes

Table 1-2 Manual and automatically triggered options

Note:

Automatic rerun for e flows is always OFF

1.3. Protocol Overview

The communication protocol between the **cobas® pure** and HOST is based on HL7.

The user can select either a server or a client as the role of the **cobas® pure** on the Ethernet communication.

(1) When the role of the **cobas® pure** is selected as client:

The user needs to set the IP address of the HOST and the TCP port number, local IP Address of **cobas® pure** is set by GUI.

IP addresses will be validated (IP format) during user entry.

(Default: 162.132.241.105)

Any host IP address shall be configured.

The host port no. shall be configured.

(Default: 54000)

(2) When the role of the **cobas® pure** is selected as server:

The user needs to set the TCP port number. The local IP address of **cobas® pure** is set.

The local IP Address of CU shall be configured from 162.132.241.105 to 162.132.241.107, but not limited to this IP range.

IP addresses will be validated (IP format) during user entry.

(Default: 162.132.241.105)

The local IP Address of **cobas® pure** shall be configured. IP addresses will be validated (IP format) during user entry.

(Default: 162.132.241.105)

The local port no. shall be configured.

(Default: 54000)

2. HOST Communication Functionality Specification

2.1. Realtime Communication

The Realtime Communication is a handshake protocol that the messages of the test order and test result between **cobas® pure** and HOST in the sequential procedure from the loading a rack into the **cobas® pure** to the output of the test result. The relation of available real time communication function and sample class (Routine/STAT/Manual-Rerun/ QC (Control)/ Calib) for samples by **cobas® pure** and HOST are shown in Table 2.1-1 Realtime Communication Functions for sample measurement. The communication type that is available on the **cobas® pure** and HOST is different by the communication protocol.

Table 2.1-1 Realtime Communication Functions for sample measurement

	Message type	Sent by	Patient samples			Control	Calibration
			Routine	Manual rerun	STAT		
1	Test selection information inquiry	cobas® pure	0	0	0	-	-
2	Test selection information response	HOST	0	0	0	-	-
3	Result Report	cobas® pure	0	0	0	0	0
4	Test selection information inquiry for automatic rerun	cobas® pure	0	-	0	-	-
5	Test selection information response for automatic rerun	HOST	0	-	0	-	-
6	Result Report for automatic rerun	cobas® pure	0	-	0	-	-

(0: Available)

The table below shows the realtime communication function except for the sample measurement.

Table 2.1-2 Realtime Communication Functions except for sample measurement

	Message type	Sent by
1	Instrument status update	cobas® pure
2	Inventory status update	cobas® pure

2.1.1. Test selection information inquiry of patient sample

When the **cobas® pure** detects a rack with patient samples, it sends the test selection information inquiry to the HOST sample by a sample according to the test selection inquiry setting of the system.

The **cobas® pure** sends the test selection information inquiry to the HOST in the ascending order of the position of the detected sample on the rack.

After the **cobas® pure** sends the test selection information inquiry to the HOST, it waits for the test selection inquiry response (test orders) from the HOST until the specified time of “Test Selection Timeout” in the system setting is expired.

When the timeout occurs, a system alarm is issued on the **cobas® pure**. When **cobas® pure** receives the response from the HOST within the specified period or the timeout occurs without the test order from the HOST, the **cobas® pure** sends the test selection information inquiry of the sample on the next position of the rack to the HOST. If there is no further sample detected on that rack, the next rack will be processed.

2.1.2. Test selection information response of patient sample

The **cobas® pure** starts the test measurement of the sample by using the sample information that is received from the HOST.

If the **cobas® pure** sends the inquiry of a registered sample to the HOST, it merges the test measurement of the ordered tests and the test orders received from the HOST. When the **cobas® pure** inquires the sample that its test order is already registered, **cobas® pure** merges the test selection information from the HOST with the already registered test orders.

If there is a deletion indication for the registered test information, the **cobas® pure** deletes the indicated test orders.

2.1.2.1. Ordering Sample Index (SI2 formerly known as Serum Index)

The host shall send only the application codes for L, H, and I. With this, only L, H, and I results are sent back to the host.

Sample Type	ACN L	ACN H	ACN I
Ser/pl	29112	29113	29114
Urine	29132	29133	29134
CSF	29122	29123	29124

Table 2-3 Sample Index

Note:

If the ACN for SI2 is sent to the instrument as well, the result of absorption for SI2 is sent in addition. The ACN numbers might be subject to change. You can verify the ACNs with the current method sheet for SI2 and sample index applications provided in the library of the system.

2.1.2.2. Ordering HbA1c

The host shall send only the ratio ACNs (either % or mmol/mol)

Sample Type	ACN Ratio %	ACN Ration mmol/mol
Whole blood	20662	20667
Hemolysate	20665	20666

Table 2-4 Ordering HbA1c

Note:

The ACN numbers might be subject to change. You can verify the ACNs with the current method sheet for HbA1c and A1CX3 provided in the library of the system.

2.1.3. Result report

When the results of patient samples, control samples or calibration are created, the **cobas® pure** sends the test results to the HOST according to the system setting.

The user can specify the timing of sending the test result to the HOST and its transmission unit on the system setting of the **cobas® pure**. (For details, see section “2.6.6”) The **cobas® pure** does not send the test which has neither a result nor a data flag to the HOST. (e.g., masked test).

The **cobas® pure** does not send the test result of the patient sample with data alarm that is specified on the block upload by the user to the HOST.

The **cobas® pure** only sends the results of sample index to the HOST. The test, which is defined and used, for sample index measurement is not sent to the HOST.

The **cobas® pure** sends the test result of the supplemented test for %HbA1c (Hb and HbA1c test) to the HOST according to the Host Settings of the system.

The main result together with all defined subresults including flags and alarms is forwarded to the connected HOST according to the design of the **cobas e** flow test according to the Host Settings of the system.

If the number of measuring results, Formulas, Variables and Linkage Records which are sent to HOST is over 200, system alarm occurs, and system does not send the results to HOST.

2.1.3.1. Test result with absorbance data/ raw data

cobas® pure does not send the absorbance data or raw data with the test result to the HOST in real time.

Note:

The effective signal, effective voltage, effective current and PMT spike value are included in result data (not raw data).

2.1.4. Test selection information inquiry for automatic rerun

When the automatic rerun mode is available, the **cobas® pure** will send the available test results to the HOST, then the **cobas® pure** sends the test selection information inquiry for automatic rerun to the HOST according to the Host Settings of the system.

The user can set the condition for the automatic rerun test selection information inquiry of patient sample to HOST on the system setting of the **cobas® pure**.

For abnormal samples (sample short or sample clot etc.) the **cobas® pure** does not send a test selection information inquiry for automatic rerun.

After the **cobas® pure** sends the test selection information inquiry for automatic rerun to the HOST, the **cobas® pure** waits for the response from the HOST by the specified period of timeout.

When the timeout occurs, a system alarm is raised on the **cobas® pure**.

2.1.5. Test selection information response for automatic rerun

The **cobas® pure** starts the test measurement for the automatic rerun test selection information inquiry by using the received sample information from the HOST.

If the test order has been already registered for the sample which the **cobas® pure** inquires, the **cobas® pure** merges both test orders and starts the test measurement.

If the received test order from the HOST is the same like the already registered test order, the already registered test order is overwritten with the test order from the HOST.

If there is a delete order of test order in the received test order from the HOST, the **cobas® pure** deletes the specified test order from the sample.

In addition, the **cobas® pure** continues the test measurement if there is an automatic rerun order.

If there is no rerun order of the sample, the **cobas® pure** finishes the test measurements of the corresponding sample.

2.1.5.1. Reflex Run

The new test order can be added to the sample as automatic rerun order from the HOST.

2.1.6. Result Report for automatic rerun

The user can specify the timing of sending the test result to the HOST and its transmission unit on the system setting of the **cobas® pure**.

For automatic rerun test results of the patient sample, the **cobas® pure** sends the test results to the HOST according to the system setting.

The other specification is same as the result report for the first run (Refer to section 2.1.3).

2.1.7. Instrument status update

If the system setting is available, the **cobas® pure** sends the instrument status to the HOST in real time.

The **cobas® pure** sends the system status to the HOST in the following cases.

- When the instrument status changes.
- When the connection of **cobas® pure** and HOST is established.

2.1.8. Inventory status update

When the system setting is available, the **cobas® pure** sends the availability of the tests that are registered on the **cobas® pure** to the HOST.

The availability of all tests is sent to the HOST in the following cases:

- When the instrument status changes from Standby to Operation.
- When the connection of **cobas® pure** and HOST is established.

The availability of assays is sent to the HOST separately in the following case:

When the Instrument status is Operation and the availability of the corresponding assay has changed.

The conditions that a system judges the test is available or unavailable are as follows:

[General test] System recognizes the following mask cause is changed.

- Test masking
 - No test assigned / Test masking / Reagent specific masking
- Reagent masking
- Calibration masking
- Patient mask by QC

[cobas e flow test] System recognizes the situation is changed as follows:

- The **cobas e** flow test is installed or not.
- The **cobas e** flow test is masked or not.
- All embedded tests are installed or not.

2.2. Batch Communication

The batch communication is an operation method to send messages of the test order and test result to the HOST or **cobas® pure** unidirectional.

The communication types for sample measurement between **cobas® pure** and HOST are shown in Table 2.2-1
Batch communication functions for sample measurement.

Table 2.2-1 Batch communication functions for sample measurement

Message type	Sent by	Patient sample		Control	Calibration
		Routine	STAT		
Test selection information reception	HOST	0	0/-*	0	0
Test result report	cobas® pure	0	0	0	0
Test order report	cobas® pure	0	0	-	-
Test order or result request	cobas® pure	0	0	-	-
Sending of Absorbance data and Raw data	cobas® pure	0	0	0	0

(0: Available)

* STAT samples are not allowed in Sequence mode for Batch communication.

The table below shows the batch communication function except for the sample measurement.

Table 2.2-2 Batch communication functions except for sample measurement

	Message type	Sent by
1	Test masking request	HOST
2	Reagent masking request of patient sample	HOST

2.2.1. Test selection information reception

The HOST must wait until it receives an Acknowledgement Message for the current test order from **cobas® pure** before it can send test order(s) for the next sample. See also section 3.1.2.

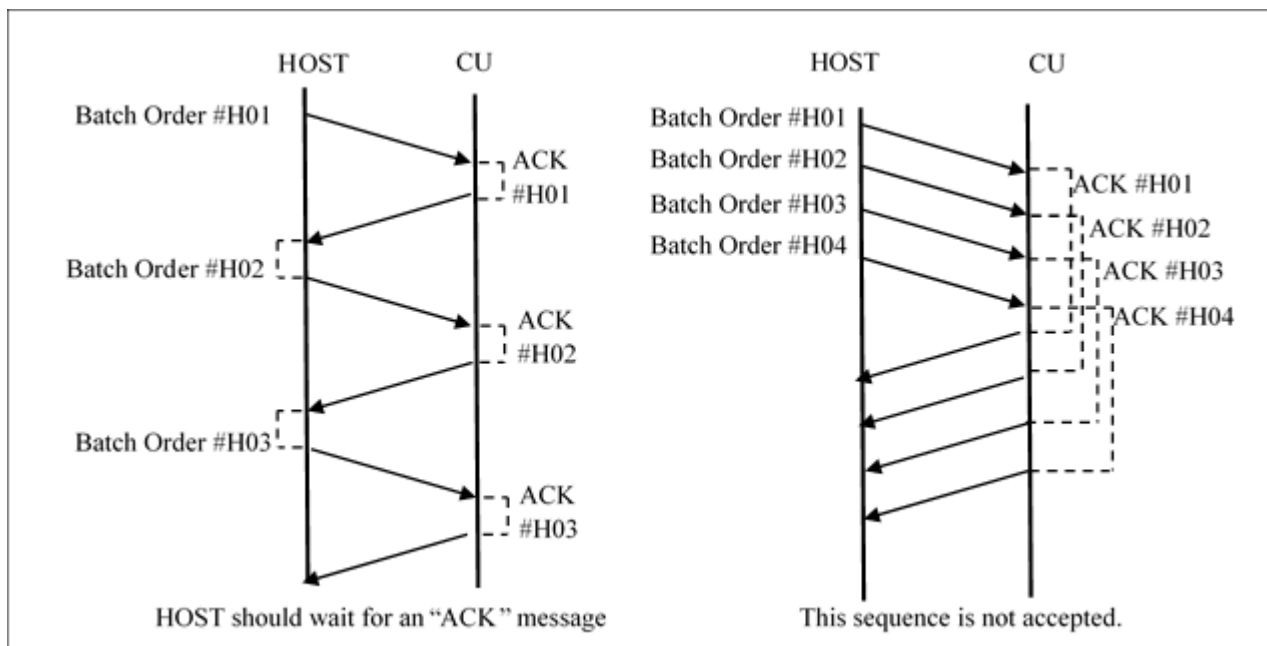


Figure 2.2 1 an example of host message structure

2.2.1.1. Test selection information reception for the patient sample

The **cobas® pure** can receive the test orders for patient samples from the HOST.

If the received test orders from the HOST are the same as the test orders that have already been registered, the **cobas® pure** overwrites the already registered test orders with the received test orders from the HOST.

If there is a delete order of test order in the received test orders from the HOST, the **cobas® pure** deletes the specified test order from the sample order.

If the test order from the HOST includes an ACN which is not installed on the system, it will be ignored and the rest of the tests will be performed normally.

2.2.1.2. Test selection information reception for control sample

The **cobas® pure** can receive the test orders for control sample measurement from the HOST.

The details refer to section 2.5

2.2.1.3. Test selection information reception for calibrator

The **cobas® pure** can receive the test orders for calibration measurement from the HOST.

The details refer to section 2.4

2.2.2. Test result report

2.2.2.1. Test result of patient sample and control sample

The user can specify the condition of the test order to be sent to the HOST for the patient sample and the control sample that are selected on the Result screen.

The available condition for users is shown in Table 2.2-3 Condition for sending the batch result

Table 2.2-3 Condition for sending the batch result

Condition	Notes
Run Type (for patient samples only)	The user can select one of the following conditions: ➤ 1st The test order with the 1st run result is sent to the HOST. ➤ Rerun The test order with the rerun test result is sent to the HOST. (The test order without rerun test result is not sent to the HOST.) ➤ Selected When there is a 1st run result only, this result is sent to HOST. When there is a 1st run result and a rerun result, the chosen test result is sent to the HOST. For the test order with a 1st run result, a rerun test result, and the one with the data alarm specified on the block upload, the other without the data alarm that is not specified on the block upload is sent.
Test HOST Status	The user can select one of the following conditions: ➤ All The test result that the Test HOST Status is “not sent to HOST” or “sent to HOST” is sent to HOST. ➤ Not sent to HOST The test result that the Test HOST Status is “NOT sent to HOST” is sent to HOST.
Ignore “Block upload” setting Former “Review by exception”	The user can select the option for sending results with block upload alarm. Default is not selected. ➤ The option is available The results that are attached data alarm defined by “Block upload” are sent to HOST. ➤ The option is not available The results that are attached data alarm defined by “Block upload” are not sent to HOST.

Note: If the number of measuring results, Formulas, Variables and Linkage Records which are sent to the HOST is over 200, a system alarm occurs, and the system does not send the results to the HOST.

2.2.2.2. Calibration result sending

The user can send the test result of the calibration results that are specified on the Calibration screen to the HOST. There are two ways to send the calibration results to the HOST. The absorbance data (only 2 wavelength) for **c** 303 is sent to HOST. The raw data for ISE and **e** 402 is not sent to HOST.

- Only specified test results
- All test results of on-board reagent packs

2.2.3. Test order or result request of patient sample

The **cobas® pure** can send the test order of a patient sample by a sample, corresponding to request from HOST. The test order information is sent to HOST according to the following query:

- Query for all results and orders
All the ordered tests (including measured test and not measured test) are sent to HOST.
- Query only for final results
The final result is sent to HOST (e.g., when the first test and rerun test measurement is performed and this query is received from HOST, only the rerun test is sent to HOST.).
- Query only for open orders
The tests, which are not measured including masked test, are sent to HOST.

2.2.4. Sending of absorbance data for photometric and raw data for immunoassay

2.2.4.1. Sending of patient sample and control sample data

The user can send the absorbance data for photometric and raw data for immunoassay of the specified test order for patient samples and the control samples that are selected on the Sample & QC Result screen.

The details refer to Table 2.2-4 Sending of data sending in batch

Table 2.2-4 Sending of data sending in batch

	Absorbance data	Raw data
Photometric assay for c 303	0 (2 wavelengths of calibrator)	-
Immunoassay for e 402	-	0 (Including data point)
ISE test	-	-

(0: Available)

2.2.5. Sending of calibration data

The user can send the calibration data on the Calibration screen. The details refer to Table 2.2-5 Calibration data sending in batch

Table 2.2-5 Calibration data sending in batch

	Calibration result	Absorbance data	Raw data
Photometric assay for c 303	0	0 (2 wavelengths of calibrator)	-
Immunoassay for e 402	0	-	-
ISE test	0	-	-

(0: Available)

2.2.6. Test masking request

The HOST can request the registration and releasing of mask as the test masking request to the **cobas® pure**. In case of **cobas** e flow test, the test masking requests are accepted when zero is set.

2.2.7. Masking request of patient sample for reagent pack

The HOST can request the registration and releasing of mask as the masking request of the patient sample for the reagent pack to the **cobas® pure**.

2.2.8. Instrument status update request

The HOST can request the instrument status update to the **cobas® pure**.

2.2.9. Inventory status update request

The HOST can request the inventory status update to the **cobas® pure**.

2.2.10. Instrument status update

When the **cobas® pure** receives the instrument status update request, it sends the instrument status to HOST. Detail information describe in chapter 2.1.7 Instrument status update.

2.2.11. Inventory status update

When the **cobas® pure** receives the inventory status update request, it sends the inventory status to HOST. Detail information describe in chapter 2.1.8 Inventory status update.

2.3. Operation of Patient samples

2.3.1. 3rd run onward

cobas® pure can receive the 2nd onward rerun order for the same assay.

The sample that is registered on the **cobas® pure** is tested for one test order up to the 2nd run (1st run/automatic rerun).

However, the user may decide that the 3rd and 4th test are needed by the result of the 1st run and the rerun test. For handling this, the **cobas® pure** can receive the 2nd onward rerun order for the same assay.

The registration method of the 2nd and following rerun order for the same assay is shown as below:

- Test order registration by real time communication
The 2nd and the following rerun is ordered from HOST as response for the sample inquiry that is reloaded as manual rerun sample.
- Test order registration by batch communication
The 2nd and the following rerun are ordered from the HOST by the batch communication.

2.3.2. Sample with barcode read error inquiry in ID mode

The HOST can order the tests by the arbitrary ID for the sample without barcode label or with barcode read error.

In sample ID mode, the **cobas® pure** sends the test selection information inquiry of the sample with barcode read error with “*” as sample ID to the HOST according to the Host Settings of the system setting.

The HOST can add the arbitrary sample ID to the inquiry for sample with barcode read error and send the response of the test order information. When the **cobas® pure** receives the test order from the HOST, the **cobas® pure** performs the test measurement of the sample with barcode read error by the sample ID that is received from the HOST and outputs the test result.

2.3.3. Inquiry of sample without sample type in ID mode

The HOST can order the test by indicating the sample type to the sample which is not defined the type sample. **cobas® pure** handles samples on the none rack as undefined type sample.

In sample ID mode, **cobas® pure** sends the test selection information inquiry of the undefined type sample with “none” as sample type to the HOST. The HOST replies the test order with the sample type for the inquiry of the sample without sample type from the **cobas® pure**. When the **cobas® pure** receives the test order, the

instrument performs the test measurement of the sample by the sample type that is received from the HOST and outputs the test result. The **cobas® pure** also uses the sample type that is received from the HOST for the inquiry of the automatic rerun for the HOST.

2.3.4. Setting of sample container type from HOST

The HOST can specify the sample container type as a test order of a sample.

The setting of sample container type that HOST can specify is shown in Table 2.3-1 Setting of sample container type

Table 2.3-1 Setting of sample container type

Setting by	Descriptions
Blank	The sample container type is not specified by HOST. In this case, the system defines the sample container type by the "rack assignment" and "height detection".
SC	The system handles it as standard tube.
MC	The system handles it as micro cup.
NST0	The system handles it as non-standard tube.
FBT1	The system handles it as FBT1 tube.
FBT2	The system handles it as FBT2 tube.
FBT3	The system handles it as FBT3 tube.

2.3.4.1. Setting of sample container type at real time order registration

The HOST can specify the sample container type for a test selection information inquiry from the **cobas® pure** and sends the response of a test order of a sample.

The **cobas® pure** defines the sample container type by the container that is specified by HOST and the sample container information that is recognized by the system.

The available container types for HOST depend on the type of rack used for samples.

The details are shown below.

- Standard tube rack

For the sample on Standard tube rack, the relation between sample container type specified by HOST and sample container information recognized by **cobas® pure** is shown in Table 2.3-2 Sample container for Standard tube rack.

If the HOST specifies the sample container type of special tube, the **cobas® pure** handles the test order as message error and does not register the received test order information.

- Non-standard rack

The tube type is defined only by the rack range by system.

For the samples on Non-standard Tube rack, the relation of sample container type specified by HOST and sample container information recognized by system and sample container shape defined by **cobas® pure** is shown in Table 2.3-3 Sample container for Non-standard tube rack.

If the HOST specifies the sample container type as a different non-standard tube, the **cobas® pure** handles the test order as message error and does not register the received test order information.

- Mixed (Standard and Non-standard) Tube rack

Standard and Non-standard tubes can be installed randomly in the standard rack range with None sample type.

The Host can specify the tube type for each sample on mixed tube rack.

For samples on mixed tube rack, the relation between sample container type specified by the host and sample container information recognized by **cobas® pure** is shown in Table 2.3-4 Sample container for Mixed tube rack.

Table 2.3-2 Sample container for Standard tube rack

		Sample container shape to be recognized by system				
		Sample cup	75mm tube	CupOn75mm tube	100mm tube	CupOn100mm tube
Sample container type to be specified from HOST	Blank	Standard cup	75mm tube	CupOn75mm tube	100mm tube	CupOn100mm tube
	SC	Standard cup	75mm tube	CupOn75mm tube	100mm tube	CupOn100mm tube
	MC	Micro cup	75mm tube	MicroCupOn 75mm tube	100mm tube	MicroCupOn100mm tube
	NST0	Message error	Message error	Message error	Message error	Message error
	FBT1	Message error	Message error	Message error	Message error	Message error
	FBT2	Message error	Message error	Message error	Message error	Message error
	FBT3	Message error	Message error	Message error	Message error	Message error

Table 2.3-3 Sample container for non-standard tube rack

		Sample container shape to be recognized by system			
		NST	FBT1	FBT2	FBT3
Sample container type to be specified from HOST	Blank	NST	FBT1	FBT2	FBT3
	SC	NST	FBT1	FBT2	FBT3
	MC	NST	FBT1	FBT2	FBT3
	NST0	NST	Message error	Message error	Message error
	FBT1	Message error	FBT1	Message error	Message error
	FBT2	Message error	Message error	FBT2	Message error
	FBT3	Message error	Message error	Message error	FBT3

Table 2.3-4 Sample container for Mixed tube rack

		Sample container shape to be recognized by system				
		Sample cup	75mm tube	CupOn75mm tube	100mm tube	CupOn100mm tube
Sample container type to be specified from HOST	Blank	Standard cup	75mm tube	CupOn75mm tube	100mm tube	CupOn100mm tube
	SC	Standard cup	75mm tube	CupOn75mm tube	100mm tube	CupOn100mm tube
	MC	Micro cup	75mm tube	MicroCupOn 75mm tube	100mm tube	MicroCupOn100mm tube
	NST0	NST	NST	NST	NST	NST
	FBT1	FBT1	FBT1	FBT1	FBT1	FBT1
	FBT2	FBT2	FBT2	FBT2	FBT2	FBT2
	FBT3	FBT3	FBT3	FBT3	FBT3	FBT3

The HOST cannot specify the sample container type to the test order information for the automatic rerun test selection information inquiry from the **cobas® pure**.

When the HOST specifies the sample container type in the test information for the automatic rerun, the **cobas® pure** ignores the received sample container type.

2.3.4.2. Setting of sample container type at batch order registration

The HOST can specify the following as the sample container type of the test order that is indicated in batch:

- Blank
- SC
- MC

When the HOST specifies the sample container type except the “MC” container type for the test selection information of the new sample, the **cobas® pure** registers the received sample container type as “SC” to the sample information.

When the HOST sends the test order in batch for the sample that is being measured, the **cobas® pure** ignores the received sample container type (the system does not update the sample container type.).

When the HOST sends the test order in batch for the sample that the measurement is completed, the **cobas® pure** updates the sample container type as below:

- When the HOST specifies the sample container type as “SC” or “MC”, **cobas® pure** registers the received sample container type to the sample information.
- When the HOST specifies the sample container type except the “SC” or “MC”, **cobas® pure** does not update the sample container type.

2.3.4.3. Sample container type to be sent to HOST

cobas® pure sends the sample container type as a part of test result information to the HOST. The sample container type to be sent to the **cobas® pure** is defined according to the sample container shape. The relation of the sample container shape and the sample container type to be sent by the **cobas® pure** is shown in Table 2.3-5 Sample container type to be sent to HOST.

Table 2.3-5 Sample container type to be sent to HOST

Sample container shape	Sample container type
Standard cup	SC
Micro cup	MC
75mm tube	Blank
CupOn75mm tube	SC
MicroCupOn75mm tube	MC
100mm tube	Blank
CupOn100mm tube	SC
MicroCupOn100mm tube	MC
NST	NST0
FBT1	FBT1
FBT2	FBT2
FBT3	FBT3

2.3.5. Replicate measurement

The HOST can send the order of the replicate measurement for the patient sample.

When multiple duplicated test orders are specified in the test selection that is received from the HOST, the **cobas® pure** judges to receive the replicate measurement order.

When the HOST sends the order of the replicate measurement, the pipetting volume of the duplicated test orders should be the same. Different test counts are possible to be ordered by HOST. For ISE test (Na, K, Cl), it must be the same test count.

Only one sample index test (L, H and I) can be ordered to the sample which registered the other replicated orders. Replicate measurement order for **cobas e flow** is not allowed.

The HOST cannot send the order of the replicate measurement as automatic rerun test.

When the sample that the multiple duplicated tests are ordered tests is loaded into system, **cobas® pure** does not send the test selection information inquiry to the HOST.

2.4. Operation of Calibration

HOST sends the following information as key information for calibration order:

- Application code
- Module (Serial No.)
- Reagent information (container code, lot, sequence)
- Calibration method

The system judges the following as error case:

- There is no reagent on the specified module.
- There is no calibration parameter.
- The calibration method is not correct.
- In case of ISE, tests which are available in test assignment screen are not ordered in same time.

Note:

If the calibrator parameter is not installed, the calibration request is accepted, but the calibration is not performed.

When the measurement condition is not satisfied, this calibration measurement is not performed.

2.5. Operation of control samples

HOST sends the following information as key information for QC order:

- Module (Serial No.)
- Application code
- Reagent information (container code, lot, sequence)
- Control material code

cobas e flow test cannot be requested for QC measurement from HOST.

The system judges the following as error case:

- There is no reagent on the specified module.
- There is no control parameter.

When the measurement condition is not satisfied, this control measurement is not performed.

2.6. Settings for HOST Function

The user can set the HOST communication settings on the setting screen of the **cobas® pure**.

The user logged on as Administrator can change the settings.

When the instrument status is Standby, the setting can be changed.

2.6.1. Communication

The user can set the identifier of the **cobas® pure** (system) and HOST and the communication method to be used by the **cobas® pure** for communication with the HOST.

The screenshot displays the 'Host Settings' window with the 'Communication' tab selected. The 'General' section includes input fields for 'Instrument Name' and 'Host Name', a checkbox for 'Automatic Session Recovery', and a 'CU Role' dropdown menu currently set to 'Server'. The 'Instrument Upload' section contains two checkboxes: 'Instrument Status Update' and 'Inventory Status Update'. Below these are two main configuration boxes: 'Instrument' and 'LIS'. The 'Instrument' box has an 'IP V4' dropdown set to 'Other' and a 'Port' dropdown set to '54000'. The 'LIS' box has an 'IP V4' dropdown set to 'Other' and a 'Port' dropdown set to '65535'. A line labeled 'Roche Firewall' connects the two boxes. At the bottom right are 'Save' and 'Cancel' buttons.

Figure 2-3 Host Settings – Communication tab

The user can change the settings when the HOST communication setting is OFF.

The communication settings that can be defined by users are described below.

(1) Instrument Name

The user can set the instrument name to be used for the communication message between **cobas® pure** and HOST.

(2) Instrument ID

The user can set the instrument ID to be used for the communication message between **cobas® pure** and HOST.

(3) HOST Name

The user can set the HOST name to be used for the communication message between **cobas® pure** and HOST.

(4) HOST ID

The user can set the HOST ID to be used for the communication message between **cobas® pure** and HOST.

(5) Automatic Session Recovery

The user can select whether to disconnect or automatically reconnect the connection of **cobas® pure** and HOST when a communication error occurs.

(6) CU Role (Client / Server)

The user can change the connection role of the **cobas® pure** as client or server

(7) Instrument – IP V4

The user can select the IP address of Instrument on drop down menu from the following.
162.132.241.105 (default setting)

162.132.241.106

162.132.241.107

Other (if “Other” is selected, 4 field to input IP address are appeared, “172.18.38.XX” is protected)

(8) Instrument – Port

When **cobas® pure** role is selected as Server, the user needs to select the port number of instrument.

The user can select the port on drop down menu from the following.

54000 (default setting) / 54001 / 54002 / 54003 / 54004 / 54005 / 54006 / 54007 / 54008 / 54009 /

Other (if “Other” is selected, field to input Port is appeared)

(9) LIS – IP V4

When **cobas® pure** role is selected as Client, user needs to select the IP address of LIS.

The user can input the IP address of LIS on edit box.

(10) LIS – Port

When **cobas® pure** role is selected as Client, the user needs to select the port number of LIS.

The user can select the port on drop down menu from the following.

54000 (default setting) / 54001 / 54002 / 54003 / 54004 / 54005 / 54006 / 54007 / 54008 / 54009 /

Other (if “Other” is selected, field to input Port is appeared)

(11) Instrument Information Upload Setting

The user can select whether to send the instrument information to HOST.

For details, see section 2.6.20.

2.6.2. Instrument Information Upload Setting

The user can set the followings for the Instrument Information to be sent by the cobas pure to the HOST.

(1) Instrument status update

(2) Inventory status update

The details are described below.

2.6.2.1. Instrument Status Update

The user can set the availability of the function that the instrument status is sent from **cobas® pure** to the HOST in real time.

The system sends instrument status information to HOST at the following timing.

- When the instrument is power up with HOST connection is ON.
- When communication between instrument and HOST is established.
- When the instrument status changes.

2.6.2.2. Inventory Status Update

The user can set the availability of the function that the availability of tests is sent from the **cobas® pure** to the HOST in real time.

The system sends inventory status information to HOST at the following timing.

- When the instrument is power up with HOST connection is ON.
- When communication between instrument and HOST is established.
- When the instrument status changes from Stand By to Preparation.

2.6.3. Result Components Settings

The user can configure the following result components to be sent for test result messages from **cobas® pure** to the host.

- (1) Result Value of Photometric Qualitative Test
- (2) Original Data Upload
- (3) Custom Host Code for Formulas and Variables
- (4) Result Message for Quantitative Immunoassays
- (5) Result Message only for Qualitative Immunology Tests
- (6) Subresult of **cobas** e flow Tests
- (7) Host Code by Reported lab Unit for **cobas** e flow Tests

Host Settings

Communication **Result Components** Host Code Test Selection Inquiry

Send to Host

- ☐ Result Value of Photometric Qualitative Tests
- ☐ Original Data Upload
- ☐ Custom Host Codes for Formulas and Variables
- ☐ Result Message for Quantitative Immunoassays
- ☐ Result Message only for Qualitative Immunology Tests
- ☐ Subresults of cobas e flow Tests
- ☐ Host Code by Reported Lab Unit for cobas e flow Tests

Save Cancel

2.6.3.1. Result Value of Photometric Qualitative Test

The user can set the qualitative test result and whether to send the test value to the HOST or not as the clinical chemistry qualitative assay result.

This setting is applied to when the test result of patient sample is sent to the HOST.

- Selecting ON
The qualitative test result and test value are sent to the HOST as test result of qualitative assay.
- Selecting OFF
The qualitative test result is sent to the HOST as test result of qualitative assay.

2.6.3.2. Original Data Upload

In addition to the ordered HbA1c (NGSP value (%) / IFCC value (mmol/mol)), the user can set whether the supplemented test (Hb and HbA1c) measurement results are also sent to the HOST.

In addition to the ordered formula calculated test, the user can set whether the supplemented test measurement results are also sent to the Host.

- Selecting ON
The supplemented test measurement results are sent to the HOST.
- Selecting OFF
The supplemented test measurement results are not sent to the HOST.

This setting is applied to when the test result of patient and QC sample is sent to the HOST.

2.6.3.3. Custom Host Codes for Formulas and Variables

The user can select the subresult Host code which is defined by user or default subresult Host code. The subresult is the formula or the variable, which are defined as reportable test in **cobas e** flow test. This setting is applied to when the test result of the "Subresults of **cobas e** flow tests" is ON.

- Selecting ON
A custom Host code for subresult, which was set in Host code setting, is sent to the HOST.
When a custom Host code for subresult was not defined, a default character string is sent to the HOST.
- Selecting OFF
Always a default character string of a subresult is sent to the HOST.

2.6.3.4. Result Message for Quantitative Immunoassays

The user can set the test value and whether to send the qualitative test result (Result Message) to the HOST or not as the quantitative immunoassay result.

This setting is applied to when the test result of patient sample and control sample is sent to the HOST.

- Selecting ON
The test value and qualitative test result are sent to the HOST as test result of quantitative assay.
[*] When the following case, space is set for the qualitative test result.
(a) When the qualitative determination cannot be performed because the data alarm is added to the test result etc.
(b) When the test order that the qualitative determination is not performed in the analytical parameter
- Selecting OFF
The test value is sent to the HOST as test result of quantitative assay.

2.6.3.5. Result Message only for Qualitative Immunology Tests

The user can set the qualitative test result and whether to send the Cut off index to the HOST or not as the qualitative immunoassay result.

This setting is applied to when the test result of patient sample is sent to the HOST.

- Selecting ON
The qualitative test result is sent to the HOST as test result of qualitative assay.
- Selecting OFF
The qualitative test result and Cut off index are sent to the HOST as test result of qualitative assay.

2.6.3.6. Subresults of cobas e flow Tests

The user can set whether to send the reported subresult of **cobas e** flow test to the HOST or not.

This setting is applied to when the test result of patient sample is sent to the HOST.

- Selecting ON
The reported subresults of **cobas e** flow test are sent to the HOST.
- Selecting OFF
The reported subresults of **cobas e** flow test are not sent to the HOST.

2.6.3.7. Host Code by Reported Lab Unit for cobas e flow Tests

The user can assign a Host code of a **cobas e** flow test for different reported lab units.

This setting is applied to when the test result of patient sample is sent to the HOST.

- Selecting ON
A Host code, which is selected, by the application code of **cobas e** flow test and the unit of test item

which is assigned as main result is sent to the HOST.

- Selecting OFF

A Host code which is selected by the application code and unit of **cobas e** flow test is sent to the HOST.

2.6.4. Host Code

The code between **cobas® pure** and HOST communication to identify the test orders may be different from the application codes used in the instrument. Therefore, the user can set the code which is used between **cobas® pure** and the HOST instead of the application code in the **cobas® pure**. User can set two kinds of host code setting below.

Test	Unit	ACN	Host Code
AHBC2 R	COI	12014	12014
AHBS 2	IU/L	10138	10138
AHCV 2	COI	10104	10104
AHCV2 E	COI	11104	11104
AHCV2 R	COI	12010	12010
AHCV2 R	COI	12010	12010
AHIV	COI	11013	11013
AST	U/L	20228	20228
ASTP	U/L	20220	20220
CA2	mmol/L	20340	20340
CHOL2S	mmol/L	20410	20410

Figure 2-5 Host Settings - Host Code

- Main Host Codes

The user can assign one host code for normal test except for **cobas e** flow test. For **cobas e** flow test, Host code can be assigned for each different reported lab units.

- Host Codes setting for **cobas e** flow subresults

For **cobas e** flow test results, the user can set the host code for every formula or variable, which is reported as a subresult within **cobas e** flow test.

2.6.5. Test Selection Inquiry

The user can set the following for the test order inquiry of patient sample that is sent from the **cobas® pure** to the HOST in real time communication:

- (1) Enable Test Selection Inquiry
- (2) Timeout for Inquiry
- (3) Inquiry for Automatic Rerun
- (4) Inquiry for Manual Rerun
- (5) Always inquiry for test selection on STAT & routine samples (First Run Only)
- (6) Inquiry in Case of Barcode Read Error

Figure 2-6 Host Settings - Test Selection Inquiry

The details are described below.

The user can change the setting when the HOST communication setting is OFF on the Start screen.

2.6.5.1. Enable Test Selection Inquiry

When the user enables this function, the **cobas® pure** sends the test selection inquiry of patient sample to the HOST.

- Selecting ON
cobas® pure sends the test inquiry of the 1st loaded patient sample to the HOST.
- Selecting OFF
cobas® pure does not send the test inquiry of the loaded patient sample to the HOST.

During sending the test selection information inquiry to the HOST, when the test result of other sample is ready to be sent to the HOST, the **cobas® pure** does not send the test result but waits for the response from the HOST for the inquiry. The waited test result is sent to the HOST after the response from the HOST for the test selection information inquiry is received or the inquiry timeout occurs. During sending the test selection information inquiry to the HOST, the **cobas® pure** does not send the Instrument status or the Inventory status to the HOST.

2.6.5.2. Timeout for Inquiry

The user can set how long to wait the response from the HOST for the test selection information inquiry for the specified period of time in real time communication.

After the **cobas® pure** sends the test selection information inquiry to the HOST, the **cobas® pure** waits the response from the HOST for the specified period of time. (The unit of time to be set for the Timeout Interval is the second. upper limit of the Timeout is 300 seconds). Default interval is 18 seconds.

If the **cobas® pure** does not receive the test order information from the HOST within the specified time, the system alarm occurs on the **cobas® pure** and it releases the wait status for the corresponding sample.

2.6.5.3. Inquiry for Automatic Rerun

The user can set whether to send the test selection information inquiry of automatic rerun from the **cobas® pure** in real time communication.

- Selecting ON

The **cobas® pure** sends the test selection information inquiry of automatic rerun to the HOST.

- Selecting OFF

The **cobas® pure** does not send the test selection information inquiry of automatic rerun to the HOST.
(The automatic rerun operation of the corresponding sample is started without waiting of the response from the HOST.)

2.6.5.4. Inquiry for Manual Rerun

The user can set whether to send the test selection information inquiry of manual rerun from the **cobas® pure** in real time communication.

- Selecting ON

The **cobas® pure** sends the test inquiry of the loaded patient sample as manual rerun to the HOST.

- Selecting OFF

The **cobas® pure** does not send the test inquiry of the loaded patient sample as manual rerun to the HOST.

2.6.5.5. Always inquiry for test selection on STAT & routine samples (First Run Only)

The user can set whether to always send the test selection information inquiry from the **cobas® pure** in real time communication.

- Selecting ON

The **cobas® pure** sends the test inquiry to the HOST regardless of sample with or without test order.

- Selecting OFF

The **cobas® pure** sends the test inquiry to the HOST if the loaded sample is without test orders.

If the sample that the test order is already registered is loaded, the **cobas® pure** does not send the test inquiry to the HOST.

2.6.5.6. Inquiry in case of Barcode Read Error

The user can set whether to send the test selection information inquiry of the sample with sample ID read error from the **cobas® pure** in real time communication.

This setting is applied when the barcode setting of the patient sample is the sample ID mode.

- Selecting ON

If the sample barcode read of the loaded sample is failed, the **cobas® pure** sends the test selection information inquiry of the sample with “*” as sample ID to the HOST.

- Selecting OFF

If the sample barcode read of the loaded sample is failed, the **cobas® pure** does not send the test selection information inquiry to the HOST.

2.6.6. Result Upload Setting

The user can set the followings for the timing to send the test selection information inquiry from the **cobas® pure** in realtime communication:

- (1) Routine Samples
- (2) STAT Samples
- (3) QC
- (4) Calibration
- (5) As Soon As Setting

Figure 2-7 Result Upload

The sending timing that can be selected on Routine Samples/ STAT Samples/ Control Samples/ Calibration Results is shown in Table 2.6-1 Sending timing in result upload setting.

Table 2.6-1 Sending timing in result upload setting

Test orders	Sample (O: available)				Descriptions
	R	S	Q	C	
By Sample	O	O	O	-	In the case of routine and STAT samples, the test result will be sent at a timing that depends upon both the As Soon As Setting, and whether there is a rerun order of for requested item or not. Refer to Table 2.1-1 for detailed information.
By Test	O	O	O	O	It is sent when each test result of test orders of the corresponding round is ready. *
No Upload	O	O	O	O	The test result is not sent in real time communication.

(O: Available)

* In case several tests are ready at the same time (e.g. sample contains requests for Sample Index, where results are held back until the last Sample Index result is available or e.g. **cobas e** flows, where the Main result and sub-results are ready together), these results will be sent together in one message.

Table 2.6-2 List of sending timing (As Soon As Setting)

Test order	As soon As	Result transmission	Automatic rerun inquiry
By Sample	On	When all test items which can lead to rerun are ready	When all test items which can lead to rerun were sent to host
	Off	When all test items are ready	When all test items were sent to host
By Test	On	One upload after each test result is available	When all results which can lead to rerun were sent to host
	Off	One upload after each test result is available	When all test items were sent to host

2.6.7. Sample Type with Sample Barcode

The user can use sample barcode including sample type the only specified rack range. The determined sample type out of the sample barcode information will be then included in the test selection inquiry (QPD-10).

This setting is applied when the barcode setting of the patient sample is the sample ID mode.

Set the rack range information for “22 Barcode” on the Rack Range screen.

Sample Type	Routine	Rerun	STAT
9 AmniF	0 - 0	0 - 0	0 - 0
10 Stool	0 - 0	0 - 0	0 - 0
11 Plasma	50181 - 50183	0 - 0	0 - 0
12 Serum	50184 - 50185	0 - 0	0 - 0
21 None	50186 - 50190	0 - 0	0 - 0
22 Barcode	50191 - 50200	0 - 0	0 - 0

Figure 2-8 “22 Barcode” on the Rack Range Screen

Set the Sample Type Encoding in Barcode information on the Barcode Reading screen.

Position	Last	Digits	2
Ser/Pl	41	Hemoly	05
Urine	13	AmniF	12
CSF	08	Stool	98
Suprnt	07	Plasma	22
Others	09	Serum	44
WB	55		
OraFlu	87		

Figure 2-9 Sample Type Encoding on the Barcode Reading Screen

Table 2.6-2 Sample Type Encoding in Barcode information

Item	Description	comment
Position	Select the position of sample type information in sample barcode. ➤ "First" ➤ "Last"	
Digit	Select the character length of sample type information in sample barcode. ➤ "1" ➤ "2" ➤ "3"	Maximum character length of sample barcode is 22 the same as standard sample barcode.
Ser/Pl	Enter the sample information value for Ser/Pl.	Only numerical value can be used for sample
Urine	Enter the sample information value for Urine.	

CSF	Enter the sample information value for CSF.	type information. Max.: Number of digits selected in Digits.
Suprnt	Enter the sample information value for Suprnt.	
Others	Enter the sample information value for Others.	
WB	Enter the sample information value for WB.	
OraFlu	Enter the sample information value for OraFlu.	
Hemoly	Enter the sample information value for Hemoly.	
AmniF	Enter the sample information value for AmniF.	
Stool	Enter the sample information value for Stool.	
Plasma	Enter the sample information value for Plasma.	
Serum	Enter the sample information value for Serum.	

2.7. Communication Start/Stop

The user can set the start and stop of HOST communication.

When the “On Line” is selected, the communication is available and the “Off Line” is selected, the communication is not available. Changing the communication status is available regardless of the instrument status.

Table 2.7-1 shows the difference in TCP/IP connection by **cobas® pure** role.

cobas® pure detects a communication error and closes a connection, when the message (reply from HOST) is timeout.

Table 2.7-1 Communication of TCP/IP

cobas® pure Role / Situation	Server	Client
Selected the “On Line”	The cobas® pure opens a TCP/IP port and waits a connection from the HOST.	The cobas® pure goes to connect with the HOST.
Selected the “Off Line”	The cobas® pure closes a connection.	

2.8. Block Upload

The user can specify the exception data alarm from the list of the data alarm that is attached to the patient sample.

cobas® pure does not send the test result of the patient sample with Data Alarm that is specified for Block Upload by the user to the HOST. If the tests A and B are measured for the routine sample and the Exception Alarm is attached to only test A, the **cobas® pure** sends the test B result only as a test result of routine sample to the HOST.

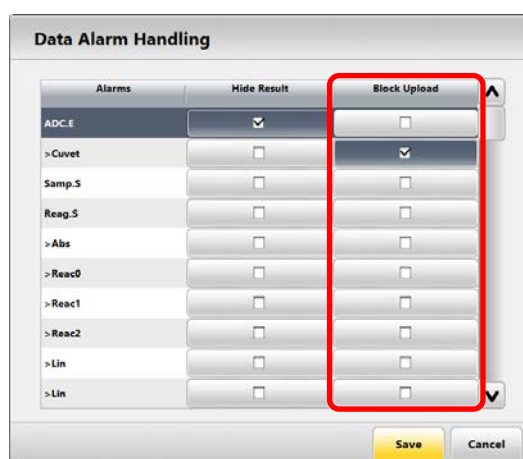


Figure 2-10 Data Alarm Handling

The results that are attached data alarm defined by "Block Upload" can be sent to HOST by batch.
For detail of the way, see section 2.2.2.1.

2.9. Hide Result

The user can specify the result suppression from the list of the data alarm that is attached to the patient sample. Results with specified data alarms are output with asterisk instead of the numeric values. Suppressed result with asterisks is sent to HOST. Result suppression is applied to patient and Roche control sample results.

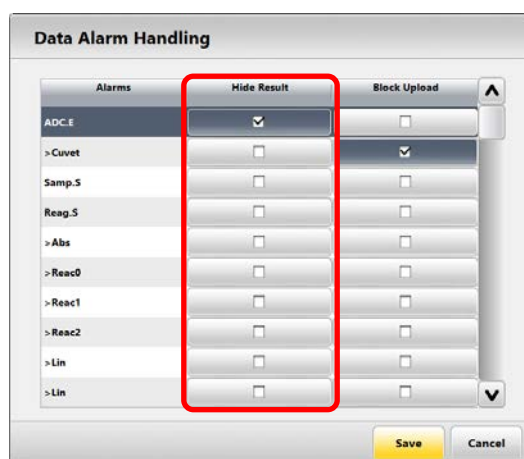


Figure 2-11 Data Alarm Handling

2.10. UNICODE

The HOST can use the UNICODE UTF-8 characters for information on the message. The size of UNICODE character is 4 byte or less. If this size is exceeded, the system alarm is issued and this host message is not accepted.

2.11. HOST Communication trace

This function applies to all host communications. When this function is enabled, the content of the communication with the host can be stored at the analyzer. The Communication Trace report can be printed from the global Print screen. This report can be used as an analysis tool if a problem occurs.

In case that "Period" is selected on the screen, the range from start to end is inputted. The log information is outputted according to the range. In case that "Minutes" is selected, the start data/time is inputted. The log information is outputted at the range of one minutes from the defined date /time.

The system manages up to 20 days of trace information.

Table 2.11-1 Host communication trace

Item	Descriptions
File Name	Log file name which describes the communication trace information.
Communication Date	The date of communication. year / month /day (The order of printing of a date follows a setup of Date Format item of a screen.)
Communication Time	Time of communication. Hour : minute : second : millisecond
Event	Transmit/receive event. Transmit : "Send"

	Receive : "Receive" Alarm : "Error"
Size(Byte)	Transmit/receive text size. Output blank when "Event" is "Error".
Code	Output code when an alarm occur with "Error" event. Alarm code : XX-YYY-ZZZZZZ X : Module type Y : Alarm code Z : Alarm sub code Output code when a retry occur with "Error" event. Retry code : NNNN N : consistent number Output blank when "Event" is "Send" or "Receive".
Data	When "Period" is selected from Data Selection, type of communication transmit/receive text outputs. When "Minute" is selected from Data Selection, type of communication transmit/receive text outputs. When the alarm occur for value of Direction, the alarm name outputs.

Data Range: 2016/4/10 10:00 - 2016/4/11 10:00

Communication Date/Time		Size(Byte)	Code	Data
File Name : TRACE_H_20160410.log				
2016/04/10	10:15:323	Receive	146	ACK^R22^ACK
2016/04/10	12:56:180	Send	263	Q8P^WOS^Q8P_Q11
2016/04/10	15:21:324	Error	17-126-000025-1	Abnormal Text from Data Manager

3. Host Communication Message Specification

3.1. Communication type

The communication types provided between **cobas® pure** and host are defined as shown in Table 3.1-1.

Table 3.1-1 Communication Types

No	Function	Message type	Communication direction	Remarks
1	Test selection inquiry/receive (real time)	QBP^Q11^QBP_Q11	cobas pure-->	
		RSP^K11^RSP_K11	<-- HOST	
		OML^O33^OML_O33	<-- HOST	
		ORL^O34^ORL_O42	cobas pure -->	
2	Test selection information receive (batch)	OML^O33^OML_O33	<-- HOST	
		ORL^O34^ORL_O42	cobas pure -->	
3	Measurement results upload (Patient/QC)	OUL^R22^OUL_R22	cobas pure -->	Patient/QC result report
		ACK^R22^ACK	<-- HOST	
4	Measurement results upload (Calibration)	OUL^R23^OUL_R23	cobas pure -->	Calibration Result (real time, batch)
		ACK^R23^ACK	<-- HOST	
5	Instrument Status Upload	ESU^U01^ESU_U01	cobas pure -->	
		ACK^U01^ACK	<-- HOST	
6	Measurement results send request /Measurement results send Order request /Send of ordered tests on Instrument (batch)	QBP^Q11^QBP_Q11	<-- HOST	QDP includes type of Request
		OUL^R22^OUL_R22	cobas pure -->	
		ACK^R22^ACK	<-- HOST	
7	Inventory Status Update	INU^U05^INU_U05	cobas pure -->	Test availability for all tests is sent everytime
		ACK^U05^ACK	<-- HOST	
8	Test Masking Request	EAC^U07^EAC_U07	<-- HOST	
		ACK^U07^ACK	cobas pure -->	
9	Calibration request (batch)	OML^O33^OML_O33	<-- HOST	
		ORL^O34^ORL_O42	cobas pure -->	
10	QC request (batch)	OML^O33^OML_O33	<-- HOST	
		ORL^O34^ORL_O42	cobas pure -->	
11	Inventory Status Request	INR^U14^INR_U14	<-- HOST	ROC-03 Request
		INU^U05^INU_U05	cobas pure -->	ROC-04 Request
12	Instrument Status Request	ESR^U02^ESR_U02	<-- HOST	ROC-01 Request
		ESU^U01^ESU_U01	cobas pure -->	ROC-02 Request

3.1.1. Message structure and sequence for test selection inquiry/Test selection receive (real time)

Message structure and communication sequence for test selection inquiry/test selection receive (real time) is described below.

QBP^Q11^QBP_Q11 [cobas pure -> HOST]

Segment	Meaning	Comment
MSH	Message header	
QPD	Query Parameter Definition	
RCP	Response Control Parameter	

RSP^K11^RSP_K11 [HOST-> cobas pure]

Segment	Meaning	Comment
MSH	Message header	
MSA	Message Acknowledgement	
[ERR]	Error	If MSA-1 is not equal to AA otherwise prohibited
QAK	Query Acknowledgement	
QPD	Query Parameter Definition	

OML^O33^OML_O33 [HOST -> cobas pure] Test Order Submission

Segment	Meaning	Repeat Max	Comment
MSH	Message header		
[	--- Patient begin		Not used for Sequence Number Mode.
PID	Patient Identifier		
]	--- Patient end		
	--- Specimen begin		
SPM	Specimen		
SAC	Specimen Container Detail Segment		
{	--- Order begin	N	N=0 – 200
ORC	Common Order		
	--- Timing begin		
TQ1	Timing Quantity		
	--- Timing End		
	--- Observation Request begin		
OBR	Observation Request		
[TCD]	Test code detail		In the case of a request including an unknown ACN, the request for the sample is reject. The analysis is performed excluding the masked ACN.
	--- Observation Request end		
}	--- ORDER end		
	--- Specimen End		

OML^O33^OML_O33 [HOST -> cobas pure] Negative Query Response

Segment	Meaning	Repeat Max	Comment
MSH	Message header		
SPM	Specimen		
SAC	Specimen Container Detail Segment		
ORC	Common Order		

ORL^O34^ORL_O42 [cobas pure -> HOST] Response to a submission of Test orders

Segment	Meaning	Comment
MSH	Message header	
MSA	Message Acknowledgement	Even if unknown test items are included in the test order, "AA" is set.
[ERR] ¹	Error	If MSA-1 is not equal to AA otherwise prohibited
[	--- Patient Begin	Not used for Sequence Number Mode.
PID	Patient Identification	Must be the same as in incoming OML^O33
]	--- Patient end	
{		
SPM	Specimen	Must be the same as in incoming OML^O33
SAC	Specimen Container	Must be the same as in incoming OML^O33
{		
ORC	Common order	Must be the same as in incoming OML^O33
}		
}		

¹: If ERR segment is present, usage of response group (PID, SPM, SAC, ORC) is prohibited.

{ }: repeat segment

[]: optional segment

ORL^O34^ORL_O42 [cobas pure -> HOST] (Ack of a negative Query Response)

Segment	Meaning	Comment
MSH	Message header	
MSA	Message Acknowledgement	Even if unknown test items are included in the test order, "AA" is set.
[ERR]	Error	If MSA-1 is not equal to AA otherwise prohibited

[]: optional segment

3.1.2. Message structure and sequence for test selection receive (batch)

Message structure and communication sequence for test selection receive (batch) is described as below.

OML^O33^OML_O33 [HOST -> cobas pure] Test Order Submission

Segment	Meaning	Repeat Max	Comment
MSH	Message header		
[	--- Patient begin		Not used for Sequence Number Mode.
PID	Patient Identifier		
]	--- Patient end		
	--- Specimen begin		
SPM	Specimen		
SAC	Specimen Container Detail Segment		
{	--- Order begin	N	N=0 – 200
ORC	Common Order		
	--- Timing begin		
TQ1	Timing Quantity		
	--- Timing End		
	--- Observation Request begin		
OBR	Observation Request		
[TCD]	Test code detail		
	--- Observation Request end		
}	--- ORDER end		
	--- Specimen End		

{ }: repeat segment

[]: optional segment

ORL^O34^ORL_O42 [cobas pure -> HOST]

Segment	Meaning	Comment
MSH	Message header	
MSA	Message Acknowledgement	Even if unknown test items are included in the test order, "AA" is set.
[ERR] ¹	Error	If MSA-1 is not equal to AA otherwise prohibited
	--- Response begin	
[	--- Patient begin	Not used for Sequence Number Mode.
PID	Patient Identification	Must be the same as in incoming OML^O33
]	--- Patient end	
	--- Specimen begin	
SPM	Specimen	Must be the same as in incoming OML^O33
SAC	Specimen Container	Must be the same as in

		incoming OML^O33
	--- Order begin	
{		
ORC	Common order	Must be the same as in incoming OML^O33
}		
	--- Order end	
	--- Specimen end	
	---Response end	

¹: If ERR segment is present, usage of response group (PID, SPM, SAC, ORC) is prohibited.

{ }: repeat segment

[]: optional segment

3.1.3. Message structure and sequence for test results upload (Patient/QC)

Message structure and communication sequence for test results upload (Patient/QC) is described as below.

OUL^R22^OUL_R22 [cobas pure-> HOST] Real time/ Batch upload of sample/QC results

Segment	Meaning	Repeat Max	Comment
MSH	Message header		
[	--- Patient begin		Not used for Sequence Number Mode and for QC results
PID	Patient Identification		
]	--- Patient end		
	--- Specimen begin		
SPM	Specimen information		
	--- Container begin		
SAC	Container information		
	--- Container end		
{	QC specimen begin		Not used for patient sample results
INV	QC specimen information		
}	QC specimen end		
{	--- ORDER begin		
OBR	Observation Order		
ORC	Common Order		
	--- Timing Begin		
TQ1	Timing/Quantity		
	--- Timing end		
	--- RESULT begin		
See the table below: Measured Test Results/ cobas e flow Patient			Either: - "Measured Test Results (embedded)

Result/ Calculated QC Result/ cobas e flow variables and formulas/ Linkage Record			and regular Results for Patient and QC)" or - "eFlow Patient Result" or - "Calculated QC Result"
	--- RESULT end		
}	--- ORDER end		
	Specimen end		

Measured Test Results (embedded and regular Results for Patient and QC):

{	--- Measured Test RESULT begin		
OBX	Observation Result	2	The contents depend on the sample (OBX-2 = "NM" and OBX-2="CE" are always set.)
TCD	Test Code Detail		Dilution and Repeat Information (TCD is sent only once per measured test)
{INV}	Substance Identifier (e.g., reagents used for testing)		Traceability information
{OBX}	Additional data for Observation Result	n	One for: - Pipetting Time, - Calibration ID Optional: - Data Points (PMT, EFS, EFV, EFC) (if transmission requested) - Raw Data (PMT, EFS, EFV, EFC) (if transmission requested) For Patient Results only: - TR_TECHNICALLIMIT (if defined) - TR_REPEATLIMIT (if defined) - TR_EXPECTEDVALUES (if defined) - QC TID - QC STATE For QC (depending on Symmetric/Asymmetric): - QC UPPER - QC LOWER - QC TARGET

			- QC_SD_RANGE n= 1 – 200 (200 is the absolute maximum of OBX Records in one Order block)
}	Measured Test RESULT end		

eFlow Patient Result:

{	--- cobas e flow RESULT begin		
OBX	Main Result (see “Measured Test Results (embedded and regular Results for Patient and QC)”) or e flow variables and formulas (see “ cobas e flow variables and formulas”)	4	Must exist always (cobas e flow result) Two record is fixed. (OBX-2 = “NM” and OBX-2=“CE”) Additionally, QC TID and QC status is attached. (OBX-2 = “EI” and OBX3.1=“ QCTID”, and OBX-2=“CE” and OBX3.1=“ QCSTATUS”)
{	--- cobas e flow SUB RESULTS begin		Depends on checkmark (Send Sub results to HOST)
[e flow variables and formulas]			Optional for detail see “ cobas e flow variables and formulas”
[Embedded Test Results]			Optional for detail see “Measured Test Results (embedded and regular Results for Patient and QC)”
[Linkage Records]			Optional for detail see “Linkage Record” (for “Linked Kit” and “Linked Test”)
}	--- cobas e flow SUB RESULTS end		
}	--- cobas e flow RESULT end		

Calculated QC Result:

{	--- Calculated QC RESULT begin		
OBX	Observation Result	2	The contents depend on the sample. (OBX-2 = “NM” and OBX-2=“CE” are always set.)
{INV}	Substance Identifier (e.g., reagents used for testing)		Traceability information (Linked Kit and Linked Test)
{OBX}	Additional data for Observation Result	2	One for: - Pipetting Time - Combination ID
{	--- Calculated QC: Single measured QC RESULT begin		
[Embedded Test QC Results]			Optional for detail see “Measured Test Results (embedded and regular Results for Patient and QC)”
}	--- Calculated QC: Single measured QC RESULT end		
}	--- Calculated QC RESULT end		

cobas e flow variables and formulas:

{	--- cobas e flow variable and formulas RESULT begin		
OBX	Observation Result	2	The contents depend on the sample. (OBX-2 = "NM" and OBX-2="CE" are always set.)
}	--- cobas e flow variable and formulas RESULT end		

Linkage Record:

{	--- Linkage Record begin		
OBX	Linkage Information	2	These two records are always set (OBX-2 = "NM" and OBX-2="CE") and OBX-5,OBX-6 is "" null (double quote double quote)
{INV}	Substance Identifier (e.g., reagents used for testing)		Traceability information
{OBX}	Additional data for Linkage Information	n	One for: - Pipetting Time, - Combination ID n= 1 – 200 (200 is the absolute maximum of OBX Records in one Order block)
	--- Linkage Record end		

ACK^R22^ACK [HOST-> cobas pure]

Segment	Meaning	Comment
MSH	Message header	
MSA	Message Acknowledgement	
{[ERR]}	Error Segment	If MSA-1 != AA

{ }: repeat segment

[]: optional segment

3.1.4. Message structure and sequence for test results upload (Calibration)

Message structure and communication sequence for test results upload (Calibration) is described below.

OUL^R23^OUL_R23 [cobas pure-> HOST]

Segment	Meaning	Repeat Max	Comment
MSH	Message header		
{	--- SPECIMEN begin	n	For each transmitted level, this structure is repeated. n=1 - 6
SPM	Specimen information		
OBX	Curve Parameters		OBX-5 is empty for cobas pure
	--- Container begin		
SAC	Specimen Container		
{	--- ORDER begin		
OBR	Observation Order		For each level the same information is transmitted
ORC	Common order		For each level the same information is transmitted
{	--- RESULT begin		
OBX	Observation Result		
{[INV]}	Information about used reagents, etc.		
}	--- RESULT end		
}	--- ORDER end		
	---Container end		
}	---SPECIMEN end		

{ }: repeat segment

[]: optional segment

ACK^R23^ACK [HOST-> cobas pure]

Segment	Meaning	Comment
MSH	Message header	
MSA	Message Acknowledgement	
{[ERR]}	Error Segment	If MSA-1 != AA

{ }: repeat segment

[]: optional segment

3.1.5. Message structure and sequence for instrument status upload

Message structure and communication sequence for instrument status upload is described below.

ESU^U01^ESU_U01 [cobas pure-> HOST]

Segment	Meaning	Comment
MSH	Message header	
EQU	Equipment Detail Segment	

ACK^U01^ACK [HOST-> cobas pure]

Segment	Meaning	Comment
MSH	Message header	
MSA	Message Acknowledgement	
{{ERR}}	Error Segment	If MSA-1 != AA

{ }: repeat segment

[]: optional segment

3.1.6. Message structure and sequence for test results send request /test results send (batch)

Message structure and communication sequence for test results send request /test results send (batch) is described below.

QBP^Q11^QBP_Q11[HOST -> cobas pure]

Segment	Meaning	Comment
MSH	Message header	
QPD	Query Parameter Definition Segment	QPD-1 = defines type of query
RCP	Response Control Parameter Segment	

OUL^R22^OUL_R22 [cobas pure-> HOST]

Segment	Meaning	Repeat Max	Comment
MSH	Message header		
	--- SPECIMEN begin		
[	--- Patient begin		Not used for Sequence Number Mode.
PID	Patient Identification		
]	--- Patient end		
SPM	Specimen information		
SAC	Container information		
{	--- ORDER begin		
OBR	Observation Order		
ORC	Common Order		
TQ1	Timing/Quantity		
{	--- RESULT begin	n	n= 1 - 200
OBX	Observation Result		The content depends on the sample.
TCD	Test Code Detail		Dilution and Repeat Information
{[INV]}	Substance Identifier (e.g., reagents used for testing)		Traceability information
}	--- RESULT end		
}	--- ORDER end		

{ }: repeat segment

[]: optional segment

3.1.7. Message structure and sequence for inventory status update

Message structure and communication sequence for inventory status update is described below.

INU^U05^INU_U05 [cobas pure-> HOST]

Segment	Meaning	Repeat Max	Comment
MSH	Message header		ROC-04
EQU	Equipment Detail Segment		
{INV}	Inventory Detail Segment	1000	cobas pure sends INV segments which are corresponding to the registered application parameter.

ACK^U05^ACK [HOST-> cobas pure]

Segment	Meaning	Comment
MSH	Message header	
MSA	Message Acknowledgement	
{[ERR]}	Error Segment	If MSA-1 != AA

{ }: repeat segment

[]: optional segment

3.1.8. Message structure and sequence for masking request

Message structure and communication sequence for test masking request or reagent patient manual mask is described below.

EAC^U07^EAC_U07 [HOST ->cobas pure]

Segment	Meaning	Repeat Max	Comment
MSH	Message header		
EQU	Equipment Detail Segment		
{ECD}	Equipment Command Segment	1000	Only one reagent masking per message is allowed. ECD segments shall be processed in the order they occur in the message; in case of any contradictions, the later ECD segment shall be considered.

ACK^U07^ACK [cobas pure -> HOST]

Segment	Meaning	Comment
MSH	Message header	
MSA	Message Acknowledgement	If unknown test items are included, "AE" is set.
{[ERR]}	Error Segment	If MSA-1 != AA

{ }: repeat segment

[]: optional segment

3.1.9. Message structure and sequence for calibration request

Message structure and communication sequence for calibration request is described below.

OML^O33^OML_O33 [HOST-> cobas® pure]

Segment	Meaning	Repeat Max	Comment
MSH			
SPM			
SAC			To identify reagent by - Reagent Container Code, - Lot number and - Reagent Sequence Number
ORC			
{	--- ORDER BEGIN		
OBR			Application Code, Calibration Method
OBX			To identify the used module and submodule
}	--- ORDER END		

ORL^O34^ORL_O42 [HOST-> cobas pure]

Segment	Meaning	Comment
MSH	Message header	
MSA	Message Acknowledgement	Even if unknown test items are included in the order, "AA" is set.
[ERR]1	Error	If MSA-1 is not equal to AA otherwise prohibited
SPM	Specimen	Must be the same as in incoming OML^O33
SAC	Specimen Container	Must be the same as in incoming OML^O33
{		
ORC	Common order	Must be the same as in incoming OML^O33
}		

¹: If ERR segment is present, usage of response group (PID, SPM, SAC, ORC) is prohibited.

{ }: repeat segment

[]: optional segment

3.1.10. Message structure and sequence for QC request

Message structure and communication sequence for QC request is described below.

OML^O33^OML_O33 [HOST -> cobas pure] Test Order Submission

Segment	Meaning	Repeat Max	Comment
MSH	Message header		
SPM	Specimen		SPM-11-1 = "Q" SPM-2 Control material code
SAC	Specimen Container Detail Segment		To identify reagent by -Reagent Container Code, -lot number and -Reagent Sequence Number
ORC	Common Order		
[[	--- ORDER begin	n	n= 0 - 200
OBR	Observation Request		Application Code
OBX			To identify the used module and submodule
]]	--- ORDER end		

ORL^O34^ORL_O42 [cobas pure -> HOST]

Segment	Meaning	Comment
MSH	Message header	
MSA	Message Acknowledgement	Even if unknown test items are included in the order, "AA" is set.
[ERR]1	Error	If MSA-1 is not equal to AA otherwise prohibited
SPM	Specimen	Must be the same as in incoming OML^O33
SAC	Specimen Container	Must be the same as in incoming OML^O33
ORC	Common order	Must be the same as in incoming OML^O33

¹: If ERR segment is present, usage of response group (PID, SPM, SAC, ORC) is prohibited.

{ }: repeat segment

[]: optional segment

3.1.11. Message structure and sequence for inventory status request

Message structure and communication sequence for inventory status update request is described below.

INR^U14^INR_U14 [HOST -> cobas pure]

Segment	Meaning	Repeat Max	Comment
MSH	Message header		ROC-03
EQU	Equipment Detail Segment		

INR^U5^INR_U05 [HOST -> cobas pure]

Segment	Meaning	Repeat Max	Comment
MSH	Message header		
EQU	Equipment Detail Segment		
{INV}	Inventory Detail Segment	1000	cobas pure sends INV segments, which are corresponding to the registered application parameter.

INU^U05^INU_U05 [HOST -> cobas pure]

Segment	Meaning	Comment
MSH	Message header	
MSA	Message Acknowledgment	
[ERR]	Error	If MSA-1 != AA

{ }: repeat segment

[]: optional segment

3.1.12. Message structure and sequence for instrument status request

Message structure and communication sequence for instrument status update request is described below.

ESR^U02^ESR_U02 [HOST -> cobas pure]

Segment	Meaning	Repeat Max	Comment
MSH	Message header		
EQU	Equipment Detail Segment		

ESU^U01^ESU_U01 [HOST -> cobas pure]

Segment	Meaning	Repeat Max	Comment
MSH	Message header		
EQU	Equipment Detail Segment		

INU^U05^INU_U05 [HOST -> cobas pure]

Segment	Meaning	Comment
MSH	Message header	
MSA	Message Acknowledgment	
[ERR]	Error	If MSA-1 != AA

{ }: repeat segment
[]: optional segment

3.2. HL7 Syntax

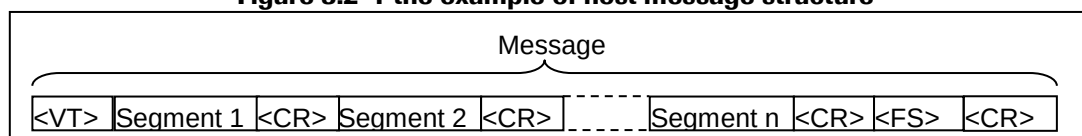
This describes the structure of messages transferred using HL7. Test selection, measurement values, and other data are exchanged between the automatic analyzer and host, but all of this exchanged data follows the HL7 syntax.

3.2.1. Message structure

One HL7 message shall consist of a series of multiple segments that starts with <VT> and ends with <FS><CR>. The segment part shall be divided by <CR> (0x0D). The Start Block character, <VT>, shall be (0x0B). The End of Message character, <FS><CR> (0x1C 0x0D), shall consist of 2 bytes.

This diagram shows the example of message structure.

Figure 3.2-1 the example of host message structure



Only UNICODE UTF-8 characters shall be used for each segment.

When the special character is included in host message, the character is converted to the escape sequence.

(Refer to

)

Target	Conversion rule
Field separator	→ \F\
Component separator	^ → \S\
Subcomponent separator	& → \T\
Repeating separator	~ → \R\ (*)
Escape character	\ → \E\

Table 3.2-1 Special character convert list '~' is not used for the sample barcode.

3.2.2. Segment Type

The segment types are shown in Table 3.2-2.

No	Abbreviation	Name
1	ECD	Equipment Command Segment
2	EQU	Equipment Detail Segment
3	INV	Inventory Detail Segment
4	MSA	Message Acknowledgment Segment
5	MSH	Message Header Segment
6	NTE	Comment Segment
7	OBR	Observation Request Segment
8	OBX	Observation/Result Segment
9	PID	Patient Identification Segment
10	QPD	Query Parameter Definition Segment
11	RCP	Response Control Parameter Segment
12	SAC	Specimen Container Detail Segment
13	SPM	Specimen Segment
14	TCD	Test Code Detail Segment
15	TQ1	Timing/Quantity Segment
16	ORC	Common Order
17	ERR	Error Segment

Table 3.2-2 Segment Types

3.2.3. Definition Value

The definitions, which are used in each segment, are described in following tables.

State Value[EQU-3.1]	State Description[EQU-3.2]	Description
PU	POWERED_UP	Powered up
IN	INITIALIZING	Initializing
ID	IDLE	Idle (Standby)
OP	NORMAL_OPERATION	Normal operation
ES	E_STOPPED	E-stopped

Table 3.2-3 EQU-3

Instrument state	State Value	Instrument state description	Description
------------------	-------------	------------------------------	-------------

[EQU-3.4]	[EQU-3.1]	[EQU-3.5]	
1	PU	Power up	Power up
2	IN	Initialize	Initialize
3	ID	Stand by	Stand by
4	OP	Stop	Stop
5	ES	Emergency stop	Emergency stop
6	OP	Preparation	Preparation
7	OP	Operation	Operation
8	OP	Rack supply complete	Rack supply complete
9	OP	Rack collection complete	Rack collection complete
10	OP	Rack supply complete (restart disabled)	Rack supply complete (Restart disabled)
11	OP	Rack collection complete (restart disabled)	Rack collection complete (Restart disabled)
13	OP	S.Stop	S.Stop
14	OP	TM with rack supply	TM with rack supply
15	OP	TM without rack supply	TM without rack supply
16	OP	Reagent registration	Reagent registration
17	OP	Pipe	Pipe
18	OP	Powerup pipe	Powerup pipe
19	OP	Startup pipe	Startup pipe
20	OP	Reconnection	Reconnection
21	ID	Shutdown	Shutdown
22	OP	Pipe interrupted	Pipe interrupted
26	OP	Rack Reception	Rack Reception
30	OP	Post Operation	Post Operation
31	OP	Conditioning	Conditioning
32	OP	Rack Reception (Database Backup)	Rack Reception (Database Backup)
33	OP	Rack Reception (Sample Backup)	Rack Reception (Sample Backup)
34	OP	Sample Backup	Sample Backup
35	OP	Partial Reset	Partial Reset
36	OP	Rack Reception (Exchange)	Rack Reception (Exchange)
37	OP	RS.Stop	RS.Stop
38	OP	Rack Reception (Reagent Registration)	Rack Reception (Reagent Registration)
39	OP	Rack Reception (CBM)	Rack Reception (CBM)

Table 3.2-4 EQU-3

3rd OBX-18 repetition of Submodule [OBX-18-1]

Module type	Result type	Submodule [OBX-18-1]
c 303	Routine / STAT	1
	Formula calculated test for Routine/STAT	1
	QC	1
	Formula calculated test for QC	1
	Calibration	1
ISE	Routine / STAT	1
	Formula calculated test for Routine/STAT	1
	QC	1
	Formula calculated test for QC	1
	Calibration	1
c 303 and ISE	Formula calculated test for Routine/STAT	1
	Formula calculated test for QC	1
e 402	Routine / STAT	1

Formula calculated test for Routine/STAT	1
QC	1
Formula calculated test for QC	1
Calibration	1
cobas e flow(main) embedded test	1
cobas e flow(sub) embedded test	1
cobas e flow(main) variables and formulas	0
cobas e flow(sub) variables and formulas	0
Linkage Records	0
Calculated QC	0
cobas e flow is aborted	0

Error code [ERR-3]

Value	Description	Comment	Code Set
ERR-3^1	ERR-3^2 & MSA-3	-	ERR3^3
100	Segment sequence error	Error: The message segments were not in the proper order, or required segments are missing	HL70357
101	Required field missing	Error: A required field is missing from a segment	HL70357
102	Data type error	Error: The field contained data of the wrong data type, e.g. an NM field contained "FOO".	HL70357
103	Table value not found	Error: A field of data type ID or IS was compared against the corresponding table, and no match was found.	HL70357
200	Unsupported message type	Rejection: The Message Type is not supported.	HL70357
201	Unsupported event code	Rejection: The Event Code is not supported.	HL70357
202	Unsupported processing id	Rejection: The Processing ID is not supported.	HL70357
203	Unsupported version ID	Rejection: The Version ID is not supported.	HL70357
204	Unknown key identifier	Rejection: The ID of the patient, order, etc., was not found. Used for transactions other than additions, e.g. transfer of a nonexistent patient.	HL70357
207	Application internal error	Some application error occurs e.g. Application code is unknown. Dilution is not applicable to measure.	HL70357

Message Type [MSH-9]

Definition	Description
QBP^Q11^QBP_Q11	Test selection inquiry, Test result and order query, Calibration and QC Request
OML^O33^OML_O33	Test selection information receive
OUL^R22^OUL_R22	Measurement results of Patient/QC upload, Answer to Result and Order Query
EAC^U07^EAC_U07	Test Masking Request, Database Reset
OUL^R23^OUL_R23	Calibration Result
ESU^U01^ESU_U01	Equipment Status Message

INU^U05^INU_U05	Inventory Update Message
ACK^R22^ACK	Acknowledge to Result upload message
ACK^R23^ACK	Acknowledge to Calibration Result Message
ACK^U01^ACK	Acknowledge to Equipment Status Message
ACK^U05^ACK	Acknowledge to Inventory Update Message
INR^U14^INR_U14	Inventory Request
ESR^U02^ESR_U02	Equipment Status Request

Sample Type [SPM-4] [QPD-10]

Definition	Description	Coding
SERPLAS	Serum / Plasma	99ROC
UR	Urine	HL70487
CSF	Cerebrospinal Fluid	HL70487
SUPN	Supernatant	99ROC
FLD	Other fluids	HL70487
WB	Whole blood	HL70487
SAL	Oral fluids (Saliva)	HL70487
HEML	Hemolysate	99ROC
AMN	Amniotic fluid	HL70487
PROC_STL	Processed stool	99ROC
PLAS	Plasm (Not supported by e 402 module)	HL70487
SER	Serum (Not supported by e 402 module)	HL70487
ORH	Other (used for calibrator only)	HL70487
"" (HL7 NULL – i.e. the value is known to be non-existent)	No specimen assigned, used for “None Rack”. (This shall be used in QPD-10 or in SPM-4 for negative query response of a sample that is not known by HOST.)	

Sample Container Type [QPD-11] [SPM-27]

Definition	Description	Coding
SC	Standard cup	99ROC
MC	Micro cup	99ROC
NST0	Non-standard tube	99ROC
FBT1	False bottom tube 1	99ROC
FBT2	False bottom tube 2	99ROC
FBT3	False bottom tube 3	99ROC
<Empty>	Unknown cup type If the host sends no container	

Qualitative result code for cobas photometric and ISE tests [OBX-5]

Definition	Description	Comment	Coding
-2	Measurement values $\leq$ Limit 1		99ROC
-1	Criterion Limit 1 $<$ Measurement value $\leq$ Criterion Limit 2		99ROC
0	Criterion Limit 2 $<$ Measurement value $\leq$ Criterion Limit 3		99ROC
1	Criterion Limit 3 $<$ Measurement value $\leq$ Criterion Limit 4		99ROC
2	Criterion Limit 4 $<$ Measurement value $\leq$ Criterion Limit 5		99ROC
3	Measurement value $>$ Limit 5		99ROC

Qualitative result code for cobas immuno tests [OBX-5]

Definition	Result Message	Comment	Coding
-1	non reac.	-	99ROC
0	border	-	99ROC
1	reac.	-	99ROC
2	n.a.	for future use	99ROC
3	n.a.	for future use	99ROC
4	gray-zone	-	99ROC
5	indeterminate	-	99ROC
6	above measuring range	-	99ROC
7	below measuring range	-	99ROC
8	result between LoB and LoD	-	99ROC
9	result between LoD and LoQ	-	99ROC
10	result between LoB and LoQ	-	99ROC
11	close to medical decision point	-	99ROC
12	close to medical decision point 1	-	99ROC
13	close to medical decision point 2	-	99ROC
14	close to medical decision point 3	-	99ROC
15	Avidity high	-	99ROC
16	Avidity low	-	99ROC
17	confirmatory test possible	-	99ROC
18	confirmatory test recommended	-	99ROC
19	confirmation recommended	-	99ROC
20	NAT-testing recommended	-	99ROC
21	PCR recommended	-	99ROC
22	repeat in duplicate recommended	-	99ROC
23	retesting recommended	-	99ROC
24	limited precision	-	99ROC
25	dilution automatically or manually	-	99ROC
26	dilution recommended	-	99ROC
27	manual dilution recommended	-	99ROC
28	additional diagnostic testing recommended	-	99ROC
29	follow up sample recommended	-	99ROC
30	Confirmed non-reactive	-	99ROC
31	Confirmed positive	-	99ROC
32	Confirmation not valid	-	99ROC
33	Intermediate	-	99ROC
34	Repeatedly reactive	-	99ROC
35	Repeatedly reactive, investigated using an independent neutralization test	-	99ROC
36	acute	-	99ROC

37	early recovery	-	99ROC
38	chronic infection	-	99ROC
39	recovered infection	-	99ROC
40	Avidity medium	-	99ROC
41	acute	-	99ROC
42	late-acute	-	99ROC
43	remote	-	99ROC
44	persisting IgM	-	99ROC
45	antibody titer protective	-	99ROC
46	immunocomplex detectable	-	99ROC
47	Neutralization positive	-	99ROC
48	equivocal	-	99ROC
49	Immunity likely	-	99ROC
50	Immunity unlikely	-	99ROC
51	Immunity unlikely - (Re)Vaccination might be considered	-	99ROC
52	Immunity questionable – Blot recommended	-	99ROC
53	risk score "high"	-	99ROC
54	risk score "low"	-	99ROC
55	risk score "borderline" + (follow up sample recommended)	-	99ROC
56	no risk calculation possible	-	99ROC
57	no avidity calculation possible	-	99ROC
58	invalid	-	99ROC
59	below dilution range	-	99ROC
60	no reliable avidity score	-	99ROC
61	Avidity gray-zone	-	99ROC
62	Avidity borderline	-	99ROC
63	avidity determination failed	-	99ROC
64	no avidity determination possible, IgG titer too low	-	99ROC
65	confirmed reactive	-	99ROC
66	confirmed negative	-	99ROC
67	error, multiflow aborted	-	99ROC
68	inconsistent result in multiflow	-	99ROC
69	implausible	-	99ROC
70	risk "high"	-	99ROC
71	risk "low"	-	99ROC
72	risk "borderline"	-	99ROC
73	No avidity determination possible - IgG titer too high	-	99ROC
74	Analyte concentration too low	-	99ROC
75	Analyte concentration too high	-	99ROC
76	Logical cobas e flow error - invalid result calculation	-	99ROC
77	Error after avidity triggered dilution	-	99ROC
78	Error after analyte triggered dilution	-	99ROC
79	Below measuring range - retesting without dilution recommended	-	99ROC
80	Retesting without dilution recommended	-	99ROC
81	No confirmation testing possible - insufficient analyte	-	99ROC
82	Antigen test positive, antibody test negative	-	99ROC
83	Antigen test positive, antibody test positive	-	99ROC
84	Antigen test negative, antibody test positive	-	99ROC
85	Antigen test negative, antibody test negative	-	99ROC
86	No calculation possible	-	99ROC
87	No score calculation possible	-	99ROC
88	Seronegative	-	99ROC
89	Early phase of infection	-	99ROC

90	Acute phase of infection	-	99ROC
91	Transient phase of infection	-	99ROC
92	Late phase of infection	-	99ROC
93	Past infection	-	99ROC
94	Isolated IgG reactivity observed	-	99ROC
95	Isolated IgM reactivity observed	-	99ROC
96	Uncertain serologic status	-	99ROC
97	Reactivated infection	-	99ROC
98	Non-primary infection	-	99ROC
99	Reactivated or non-primary infection	-	99ROC
100	Reactivated or persisting IgM titer	-	99ROC
101	Presumed seronegative	-	99ROC
102	Presumed early phase of infection	-	99ROC
103	Presumed acute phase of infection	-	99ROC
104	Presumed transient phase of infection	-	99ROC
105	Presumed late phase of infection	-	99ROC
106	Presumed past infection	-	99ROC
107	Presumed reactivated infection	-	99ROC
108	Presumed non-primary infection	-	99ROC
109	Presumed reactivated or non-primary infection	-	99ROC
110	Reactivated or persisting IgM titer likely	-	99ROC
111	May indicate a seronegative status	-	99ROC
112	May indicate an early phase of infection	-	99ROC
113	May indicate an acute phase of infection	-	99ROC
114	May indicate a transient phase of infection	-	99ROC
115	May indicate a late phase of infection	-	99ROC
116	May indicate a past infection	-	99ROC
117	May indicate a reactivated infection	-	99ROC
118	May indicate a non-primary infection	-	99ROC
119	May indicate a reactivated or a non-primary infection	-	99ROC
120	May indicate a reactivated or persisting IgM titer	-	99ROC

Abnormal flags [OBX-8 for patient result]

Definition	Description	Coding
H	Above high normal value	HL70078
N	Normal	HL70078
L	Below low normal value	HL70078
Other data alarms	Refer to Data Alarm list	99ROC
SUP	For embedded test which are not to be reported	99ROC

Data Alarm list [OBX-8]

Alarm No.	Name	Meaning	Output character X: can be output		
			Text	PRN	SCR
0	(No Alarm)	-	-		
1	ADC abnormal	[Photometric] The ADC value of the primary or secondary wavelength is zero (in monochromatic measurement, the primary wavelength only). [ISE] The system cannot read the ADC data properly. [Immunology] The ADC data is abnormal.	ADC.E	X	X
2	ABS Cell blank abnormal	The cell blank value used for measurement exceeds or less than the reference value by more than 0.1Abs.	>Cuvet	X	X
3	Sample short	Before sample aspiration, the liquid level cannot be detected in the sample container. 1) Sample short was detected. 2) No sample was placed.	Samp.S	X	X
4	Reagent short	The liquid level cannot be detected in the reagent container. Detected foam or air aspiration as liquid level.	Reag.S	X	X
5	ABS over	The absorbance value to be used for calculation after cell blank correction exceeded 3.3. (Check is done for each wavelength)	>Abs	X	X
7	Reaction limit over	In a rate assay, the main wavelength absorbance in measure points exceeds the specified reaction limit value (the value after the automatic correction). Depending on the number of measure points within the limit, there are three types: [1] All measure points exceed the reaction limit.	>Reac0	X	X
8	Reaction limit over (2nd ..)	[2] The second and subsequent points exceed the reaction limit.	>Reac1	X	X
9	Reaction limit over (3rd ..)	[3] The third and subsequent points exceed the reaction limit.	>Reac2	X	X
10	Linearity abnormal 1	In rate assay, the reaction linearity exceeds the specified limit value. There are two types of checks depending on the number of measure points: [1] When there are 9 or more measure points for c 303.	>Lin	X	X
11	Linearity abnormal 2	[2] When there are 4-8 measure points for c 303.	>Lin	X	X
12	S1ABS abnormal	During calibration, expected absorbance is outside the S1 Abs Limit.	S1A.E	X	X
13	DUPLICATE error	[Photometric] The difference between the first and second measurement (absorbance) of a calibrator is outside the specified range.	Dup.E	X	X
14	STANDARD error	1) During photometric calibration, any one of the following alarms was encountered: ADC abnormal, cell blank abnormal, sample short, sample air bubble, sample clot, reagent short, absorbance over, reaction limit over, linearity abnormal, duplicate error, calculation not possible, standard 1 absorbance abnormal, Stop mixing, Mixing current low.	Std.E	X	X

		2) During calibration, calculation was disabled. 3) During nonlinear calibration, an extreme value appeared.			
15	SENSITIVITY error	Sensitivity is checked for linear (2 to 6 points) or nonlinear calibration.	Sens.E	X	X
16	CALIB error	The current calibrator concentration value differs from predefined limits. 1. Std (3) compensator concentration value (relative check) The actual Std (3) concentration differs more than $\pm x$ mmol/L from the previous one. 2. Std(3) absolute check Limit low < current Std(3) compensator concentration value < Limit high	Cal.E	X	X
17	SD limit error	During nonlinear or multipoint linear calibration, the SD value was larger than the specified SD limit.	SD.E	X	X
18	ISE Noise error	1. The fluctuation in electromotive force exceeds the following value (When this data alarm is attached to the one of ISE tests, the system attaches the data alarm to the other ISE tests): Na: 0.7 mV K: 1.0 mV Cl: 0.8 mV 2. The electromotive force of ISE internal standard shifts in the minus direction more than -0.7mV from the previous value at the same time for all electrodes (Na, K and Cl)	ISE.N	X	X
19	ISE Voltage Level error	During measurement of internal reference, the mean of the EMF values was not within the following ranges (Internal standard solution): Na: -90.0 to -10 mV K: -90.0 to -10 mV Cl: 80.0 to 160 mV When this data alarm is attached to the one of ISE test, the system attaches the data alarm to the all of ISE tests.	ISE.E	X	X
20	Slope abnormal	The slope value was not within the following ranges. Na: UU-VV mV/dec K: WW-XX mV/dec Cl: YY-ZZ mV/dec (UU, VV, WW, XX, YY, ZZ are defined in application parameters.)	Slop.E	X	X
22	IS concentration abnormal	The concentration of the Internal Standard solution (ISE IS) was not within the following ranges Na: UU-VV mmol/L, K: WW-XX mmol/L Cl: YY-ZZ mmol/L (UU, VV, WW, XX, YY, ZZ are defined in application parameters.) The deviation from previous IS value was not within the following value. Na: +/- AA mmol/L, K: +/- BB mmol/L,	IStd.E	X	X

		CI: +/- CC mmol/L, (AA, BB, CC are defined in application parameters.)			
26	Technical Limit over (upper)	[Photometric/ISE] The concentration exceeds the specified technical limit range. [Immunology] The concentration exceeds the measuring range.	>Test	X	X
27	Technical Limit over (lower)	[Photometric/ISE] The concentration is below the specified technical limit range. [Immunology] The concentration is below the measuring range.	<Test	X	X
28	Random error	When the interval of N (run size) QC measurements (same material code, same control lot and same test) is greater than 4 SD N (run size) is selected by user. (Values: 2-10, default: 2)	R4SD	X	X
30	Systematic Error (2-2S)	The values of two consecutive QC measurements exceed ± 2 SD.	S2-2Sw	X	X
32	Systematic Error (4-1S)	The values of four consecutive QC measurements exceed ± 1 SD.	S4-1Sw	X	X
34	Systematic Error (10x)	The values of 10 consecutive QC measurements are on one side of the mean.	S10Xw	X	X
35	QC error (3SD)	The value of one QC measurement exceeds ± 3 SD.	Q3SD	X	X
37	Calculation test error	A data alarm has occurred for the test needed in the calculation.	ClcT.E	X	X
38	Overflow	Display is not possible because the output figure exceeds the defined number of digits.	Over.E	X	X
39	Calculation not possible	1) The denominator becomes zero in calculation. 2) An overflow occurred in logarithmic or exponential calculation. 3) Result was left blank.	Calc.?	X	X
40	Outside of expected value (upper)	Outside of expected value (upper)	H	X	X
41	Outside of expected value (lower)	Outside of expected value (lower)	L	X	X
43	Calibration result abnormal (Sample Flag)	No calibration data or previous calibration data used. This alarm is attached to routine/rerun/STAT/control samples.	Cal.E	X	X
44	Repeat limit over (upper)	The quantitative result exceeds the upper limit of the specified repeat limit range. Effective when "Repeat Limit Check" is ON. Auto rerun ON/OFF is depending on the setting.	>Rept	X	X
45	Repeat limit over (lower)	The quantitative result falls below the lower limit of the specified repeat limit range. Effective when "Repeat Limit Check" is ON. Auto rerun ON/OFF is depending on the setting.	<Rept	X	X
46	ABS maximum over (nonLin curve)	1) The absorbance of a sample is found equal or greater than the theoretical maximum absorbance	Samp.?	X	X

		in ascending calibration curve. 2) The absorbance of a sample is found equal or less than the theoretical minimum absorbance in descending calibration curve.			
47	Calibration result invalid	Result was generated with an invalid transferred calibration.	Cal.I	X	X
48	QC range over (upper)	The QC result exceeds the upper limit of the specified QC range.	QCHigh	X	X
49	QC range over (lower)	The QC result falls below the lower limit of the specified QC range.	QCLow	X	X
51	Response(ISE) abnormal 1	The A Factor is outside the following limits: Na: A > 0.154 K: A > 0.107 Cl: A > 0.330	Rsp1.E	X	X
52	Response(ISE) abnormal 2	The A Factor is outside the following limits: Na: A > 0.232 K: A > 0.160 Cl: A > 0.490	Rsp2.E	X	X
59	Stop mixing	The supersonic wave output for stirring has not been done.	MIXSTP	X	X
60	Mixing current low	Mixing current is lower than its standard.	MIXLOW	X	X
61	Sample height abnormal	During sample pipetting of whole blood, it detects liquid level over the height of 57 mm from the bottom of the sample tube.	Samp.V	X	X
68	Sample air bubble	Air bubble is detected in the sample when the sample is aspirated.	Samp.B	X	X
69	Reagent hovering	The reagent probe hovers over the reaction disk (over reagent / dilution / pretreatment).	Reag.H	X	X
70	Reagent film detection	The reagent probe detects a film on the reagent (reagent / dilution / pretreatment).	Reag.F	X	X
71	Potential carry over	The signal level of this sample is low (a carryover may have occurred).	CarOvr	X	X
72	Sample clot	The specified volume of sample is not aspirated: Clogging or sample short was detected in the sample probe.	Samp.C	X	X
73	Carry over detergent short	Shortage of detergent for reagent carryover evasion is detected. Detected foam or air aspiration as liquid level.	Det.S	X	X
74	Reagent disk temperature	Reagent disk temperature is out of range	Reag.T	X	X
75	Incubator temperature	Incubator temperature is out of range.	Inc.T	X	X
76	System reagent temperature	ProCell/CleanCell temperature is out of range.	SysR.T	X	X
77	Cell temperature	Measuring cell temperature is out of range.	Cell.T	X	X
83	Sample carry over for modules	After pipetting at C module, appended test (Reflex) is required sample carry over wash.	Samp.O	X	X
86	Sample LLD abnormal	The sample probe does not start LLD or LLD is not completed (because of dirt on the tip etc.)	SLLD.E	X	X
87	Sample LLD noise	The sample probe did not detect the liquid surface properly because of air bubbles on the sample or static electricity.	SLLD.N	X	X
90	QC error (2SD)	The value of one QC measurement exceeds ± 2 SD.	Q2SD	X	X
91	Systematic error (7T)	Seven control measurements trend in the same direction.	7Tw	X	X

92	Washing buffer SS temperature	The separation station temperature of PreClean (former washing buffer, WB) is out of range.	WBSS.T	X	X
93	Washing buffer temperature	PreClean temperature is out of range.	WB.T	X	X
99	Current range over (operation)	The measuring cell current is out of range in the determination cycle during operation.	>Curr	X	X
100	Low level signal	The effective signal of test is lower than the specified lower limit value.	<SigL	X	X
101	Reagent Expired Date	The alarm indicates that an expired reagent was used; the test result is not guaranteed.	ReagEx	X	X
102	QC error	There is an error related to QC.	QCErr	X	X
103	Sample index interference lipemia	The lipemia value exceeds the specified limit value.	>I.L	X	X
104	Sample index interference hemolysis	The hemolysis value exceeds the specified limit value.	>I.H	X	X
105	Sample index interference icteric	The icteric value exceeds the specified limit value.	>I.I	X	X
106	Sample index interference lipemia / hemolysis	Both of the lipemia value and hemolysis value exceed the specified limit value.	>I.LH	X	X
107	Sample index interference lipemia / icteric	Both of the lipemia value and icteric value exceed the specified limit value.	>I.LI	X	X
108	Sample index interference hemolysis / icteric	Both of the hemolysis value and icteric value exceed the specified limit value.	>I.HI	X	X
109	Sample index interference lipemia / hemolysis / icteric	All of lipemia, hemolysis and icteric values exceed the specified limit value.	>I.LHI	X	X
110	Sample Index Measurement not performed.	Sample index measurement could not be performed	na.LHI	X	X
112	On board stability, limit over on R.Rotor and ISE reagents.	On board stability limit was exceeded on Reagent Rotor and ISE reagents	OBS.RR	X	X
114	Kinetic unstable	Detected by Kinetic unstable check.	>Kin	X	X
115	Kinetic unstable 1	Detected by Kinetic unstable check.	>Kin1	X	X
116	Kinetic unstable 2	Detected by Kinetic unstable check.	>Kin2	X	X
117	Kinetic unstable 3	Detected by Kinetic unstable check.	>Kin3	X	X
118	cobas e flow error (main result)	Sub result that was measured in cobas e flow has data alarm except QCErr and HU.	eflowE	X	X
119	Higher uncertainty	Result value is higher than the Technical Limit Low and lower than the Uncertainty Limit High.	HU	X	X
120	Expired ISE electrode	The alarm indicates that an expired electrode was used; the test result is not guaranteed.	ElecEx	X	X
121	High Dose Hook Effect Check	Detected by High Dose Hook Effect Check	Hook	X	X
122	Kinetic Roughness Check	Detected by Kinetic Roughness Check	Rough	X	X
123	On board stability limit over on ISE electrodes	On board stability time and or count was exceeded on ISE electrodes	OBS.EL	X	X

125	Sample probe pressure abnormal	During checking pressure of the flow path after sample pipetting of whole blood, abnormality is detected.	SASP.A	X	X
126	cobas e flow warning (main result)	When Higher Uncertainty flag is attached to a Sub Result, this data alarm is attached to the Main Result.	eflowW	X	X

Calibration alarm flags [OBX-8 for calibration result]

Definition	Description	Target	Coding
NoCalib (no use)	No calibration available.	c 303 , ISE, e 402	99ROC
LotCalib	Lot calibration result is generated.	c 303 , e 402	99ROC
ContainerCalib	Cassette calibration result is generated.	c 303 , ISE, e 402	99ROC
InheritedLotCalib	This calibration result is inherited when the lot calibration is success.	c 303 , e 402	99ROC
InheritedItemCalib	Used for upload of newest calibration data.	c 303	99ROC
RejectedCalib	Calibration was rejected by operator, and the previous calibration state is used.	c 303 , e 402	99ROC
FailedCalib	Calibration failure	c 303 , ISE, e 402	99ROC
AutoCalib	Calibration result is calculated without measurement.	c 303	99ROC

Result status [OBX-11 for patient]

Definition	Description
F	First run result, or QC result or calibration result
C	Corrected result (Rerun result)
X	Observation is failed, no results are available. The error code shall be specified as an interpretation flag in OBX-8. Used for any types of tests without result and for canceled e flows.
R	Result validation is not yet performed or has failed. Those results shall not be considered final and reported upstream. Used only for upload of measured embedded tests with result of an e flow that is canceled.
V	(cobas e flow tests only) A measured embedded test result which has been promoted to the main result of a cobas e flow test
B	(cobas e flow tests only) Additional record - a linkage record, used to link the result to a calculated QC result

Data Code [OBX-3]

Definition	Description
EFS	Effective signal
EFV	Effective voltage
EFC	Effective current
PMT	PMT spike
ABS	Absorbance data
RCV	Result check value

Calibration Method [OBX-17 for calibration result]

Definition	Description
1PointA	Calibration method for the correction of calibration according to application parameter by 1point measurement.
1PointB	Calibration method for the correction of calibration according to application parameter by 1point measurement.
2Point	Calibration method for the correction of calibration according to application parameter by 2point measurement.
Full	Full calibration
AutoCal	Calibration method for the tests of using AutoCal reagents

Calibration result type [OBX-17 for calibration result]

Definition	Description
LinearRegression	regression line (2-6 calibrator setpoints)
LinearSlope	combination of a single low calibrator and a given calibration curve slope
Spline	polynomial of 3 rd order for smoothed setpoint to setpoint connection (2-6 setpoints)
LineGraph	algorithm with linear setpoint to setpoint connection (2-6 setpoints)
RCM1	classic Rodbard algorithm (4-6 calibrator setpoints)
RCM2	combination of 2 algorithms for increasing and decreasing curves (4-6 setpoints)
RCM3	Leo/Euler algorithm especially for CRP assay using DUREL concept (5-6 setpoints)
RCM4	Rodbard algorithm with shift especially for HbA1c assay (5-6 setpoints)
RCM5	Sigmoid algorithm especially for HbA1c assay (4-6 setpoints)

Calibration Level [OBX-17 for calibration result]

Definition	Description
Level1	Chemistry standard(1) or ISE Low or immunoassay level1
Level2	Chemistry standard(2) or ISE High or immunoassay Level2
Level3	Chemistry standard(3) or ISE Calib or immunoassay Level3
Level4	Chemistry standard(4) or immunoassay Level4
Level5	Chemistry standard(5) or immunoassay Level5
Level6	Chemistry standard(6)

Bottle Type [INV-2 for QC/Calibration result]

Definition	Description
CURRENT	Current Reagent
STANDBY	Standby Reagent

Reagent Type [INV-3]

Definition	Description
R1	Reagent 1 used (c 303)
R2	Reagent 2 used (c 303)
R3	Reagent 3 used (c 303)
SPR	Special reagent (c 303)
ASY	Assay (e 402)
IS	Internal standard solution (ISE)
DIL	Diluent (ISE)
REF	Reference solution (ISE)

KIT	Linked Kit ID for linkage between calculated QC result and cobas e flow result
PRC	Procell (e 402)

3.2.4. Field attributes within segments

The attributes of the fields comprising the segments are defined in the definition table.

This explains how to read the segment definition table.

The details refer to Table 3.2-3.

Table 3.2-3 Explanation about attribute name

No.	Attribute name	Description
1	Field (Field)	Field position. Order where the target field appears in the record.
2	Name (Element name)	Name of target field
3	Mandatory (OPT)	Indicates that this field is mandatory within the segment. If "R" does not appear for Mandatory, the fields are defined in HL7 but can be omitted. R = mandatory O = optional Empty = not used, has to be empty
4	Comments (Comments)	Field description
5	Type (DT)	Fields have one of the type names shown below. - ST: Character string (up to 200 characters) - NM: Numerical value A "+" or "-" sign is added to the beginning, and if no sign is added, it is treated as "+". If no decimal point is included, the value is treated as an integer. The placement of "0" before numbers and "0" after numbers with a decimal point is allowed. - TS: Time Stamp: Time stamp. The format is different for each segment. Details refer to each section below. - DTM: Time Stamp with time zone. Time stamp. This is a character string where DT and TM plus the time zone are joined together. The format is YYYYMMDDHHMMSSQZZzz (Q is sign of time zone ("+" or "-"), ZZ hours of the time zone offset ("00" to "12", zz Minutes of the time zone offset ("00" or "30"). i.e. "20160715235901-0330" (15 of July 2016, 23:59:01, Newfoundland Standard Time) used in MSH-7 only. -ID: Coded values for HL7 tables. This data type is defined when the definition value in HL7 rule is used. -TX: Text Data (Up to 64Kbyte) -EI: Entity identifier It defines a given entity within a specified series of identifiers. This data type is used for Message profile ID. The details refer to section below. -IS: Coded value for user-defined tables -CE: Coded element This data type consists of the following components: identifier (ST); text (ST); name of coding system (ID); -CWE: Coded with Exceptions -ERL: Error Location This indicates where the abnormal information is set. For more details, refer to section 2.3.4.5 -MSG: Message Type For the list of message types, refer to section 2.2 -VID: Version Identifier HL7 version is set to this data type. -PT: Processing type This data type consists of the following components: Processing ID (ID) and Version ID (VID). -OG: Observation Grouper -XCN: Composite ID Number and Name for Persons This data type is used for the operator ID for observer in this system. -NA: Numeric Array

		-CX: Extended composite ID with check digit This data type is used for patient ID in this system. -XPN: Extended person name This data type is used for the patient name (First name, last name, initial and other patient information related patient name). -SN: Structured numeric Structured numeric include intervals ($^0-^1$), ratios ($^1/^2$ or $^1:^2$), inequalities ($<^10$), or categorical results (2^+). This data type is used for pre-dilution or dilution ratio expression in this system. The details refer to SAC or TCD segment. -EIP: Entity Identifier Pair Basically this data type consists of Placer (order user) and Filter (measurement user). Placer is only used in this system.
6	Maximum length (LEN)	Maximum number of valid characters excluding the escape character of the target field.

3.2.4.1. Equipment Command Segment (ECD)

The host shall use the Equipment Command Segment to instruct the **cobas® pure** what masking to perform. The data structure is shown in Table 3.2-4.

Table 3.2-4 Field attribute for ECD segment

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
ECD-0	Field Type	R		ST	3	'ECD' fixed
ECD-1	Reference command number	R		NM	16	Sequence Number starting with 1
ECD-2	Instruction	R		ST	250	The instruction specifying masking or unmasking. -
ECD-2.1	Command Code	R		ST	250	The instruction specifying masking or unmasking either - "MASK" or - "UNMASK" - "DBRESET"
ECD-2.2	Field contains no data					
ECD-2.3	Name Space	R		ID	12	Fixed "99ROC"
ECD-3	Field contains no data.					
ECD-4	Field contains no data.					
ECD-5	command parameter	R		TX	65536	This field shall specify the parameters of the command. MaskType~TestCode~ModulType~ModuleSerial~Submodul~ReagentCode~ReagentLot~ReagentSequenceNumber
ECD-5 ₍₁₎	Mask Type	O		TX	1	Either: - "P" for Patient masking, (mask only patient result measurement, Calibration and QC are still run. - "T" for Test masking (masks every measurement) - "R" for Reagent masking For ECD-2 = " UNMASK " only "R" is allowed.
ECD-5 ₍₂₎	Test code	O		TX	5	Test code (ACN) only valid for Mask Type "P" and "T" else empty

ECD-5 ₍₃₎	Module Type	R		TX	4	Either - e 402 - c 303 or - ISE
ECD-5 ₍₄₎	Module Serial Number	O		TX	8	Serial Number of Module
ECD-5 ₍₅₎	Submodule Identifier	O		TX	1	Either - 0 - 1 - 2 Empty for masking/unmasking of cobas e flow or for Mask Type "R". "0" and "2" are not used, because e 402 has only one MC.
ECD-5 ₍₆₎	Reagent Code	O		TX		Reagent Code for Mask Type "R" or empty else
ECD-5 ₍₇₎	Reagent Lot	O		TX		Reagent Lot for Mask Type "R" or empty else
ECD-5 ₍₈₎	Reagent Sequence No	O		TX		Reagent Sequence Number for Mask Type "R" or empty else

3.2.4.2. Equipment Detail Segment (EQU)

The equipment detail segment shall contain the data necessary to identify and maintain the equipment that is being used throughout the Laboratory Automation System.

The data structure is shown in Table 3.2-5.

Table 3.2-5 Field attribute for EQU segment

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments																		
EQU-0	Field Type	R	R	ST	3	'EQU' fixed																		
EQU-1	Identifier for The equipment.	R		EI	427	This is the identifier from an institution's master list of equipment. Fixed value "1".																		
			R	EI		Takes the format of OBX- 18[EQU1.1^EQU1.2~EQU1.1^EQU1.2[~EQU1.1^EQU1.2] 3 rd repetition is only used if the transferred information is submodule specific. Else not used.																		
EQU-1.1	Entity Identifier		R	ST	50	<table><tr><th colspan="2">1st EQU-1 repetition</th><th colspan="2">2nd EQU-1 repetition</th><th colspan="2">3rd EQU-1 repetition</th></tr><tr><th>EQU - 1.1</th><th>EQU - 1.2</th><th>EQU - 1.1</th><th>EQU - 1.2</th><th>EQU - 1.1</th><th>EQU - 1.2</th></tr><tr><td>Module type 0 fixed</td><td>Manufact urer ID Should be defined. Preferred: ROCHE</td><td>Module serialNo or cobas® pure serial number</td><td>Manufa cturer ID same as first EQU-1.2</td><td>Submod ule ID 0 fixed</td><td>Manufa cturer ID Same as first EQU-1.2</td></tr></table>	1 st EQU-1 repetition		2 nd EQU-1 repetition		3 rd EQU-1 repetition		EQU - 1.1	EQU - 1.2	EQU - 1.1	EQU - 1.2	EQU - 1.1	EQU - 1.2	Module type 0 fixed	Manufact urer ID Should be defined. Preferred: ROCHE	Module serialNo or cobas® pure serial number	Manufa cturer ID same as first EQU-1.2	Submod ule ID 0 fixed	Manufa cturer ID Same as first EQU-1.2
1 st EQU-1 repetition		2 nd EQU-1 repetition		3 rd EQU-1 repetition																				
EQU - 1.1	EQU - 1.2	EQU - 1.1	EQU - 1.2	EQU - 1.1	EQU - 1.2																			
Module type 0 fixed	Manufact urer ID Should be defined. Preferred: ROCHE	Module serialNo or cobas® pure serial number	Manufa cturer ID same as first EQU-1.2	Submod ule ID 0 fixed	Manufa cturer ID Same as first EQU-1.2																			
EQU-1.2	Namespace ID		R	IS	20																			
EQU-2	Event Date/Time	R	R	DT	26	The transmission date/time presented in YYYYMMDDhhmmss format																		

EQU-3	Instrument status		R	CE	250	Contains a state value defined by the HL7 protocol, and an additional state value defined by the instrument. <i>State value^State description^Coding system^Instrument state^Instrument state description^Instrument coding system</i>
EQU-3.1				ST	(2)	<i>State value</i> Instrument state value. Values in this field are defined by the HL7 protocol and based on LECIS. Definition refers to section 3.2.3.
EQU-3.2				ST	(16)	<i>State description</i> Description of current instrument state. Definition refers to section 3.2.3.
EQU-3.3				ID	(5)	<i>Coding system</i> State value coding system '99LECIS' fixed.
EQU-3.4				ST	(2)	<i>Instrument state</i> Instrument-defined state value Definition refers to section 3.2.3.
EQU-3.5				ST	(50)	<i>Instrument state description</i> Description of instrument-defined state value. Definition refers to section 3.2.3
EQU-3.6				ID	(7)	<i>Instrument coding system</i> Coding system of instrument-defined state value. '99HITACHI' fixed.

3.2.4.3. Inventory Detail Segment (INV)

cobas® pure shall use the Inventory Detail Segment to communicate the availability of a test or **cobas e** flow test to the host. Within an equipment inventory update message, an INV segment shall be sent for each test installed on **cobas® pure**.

The data structure is shown in Table 3.2-6.

Table 3.2-6 Field attribute for INV segment (used in Status/Inventory Upload)

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
INV-0	Field Type		R	ST	3	'INV' fixed
INV-1	Test Identifiers		R	CE	250	Test code or application code. Identifies the test or analyte this segment relates to.
INV-1.1	Identifier		R	ST	20	Test code defaults to the ACN
INV-1.2	Field is empty					
INV-1.3	Coding system		R	ID	12	Fixed "99ROC"
INV-2	Test status		R	CE	250	Test status. Specifies whether the test is masked (unavailable) or unmasked (available). In the case of cobas e flow tests, the all embedded tests which are defined in cobas e flow file is available
INV-2.1	Identifier		R	ST	20	Either - "OK" available - "NW" not available warning
INV-2.2	Field is empty					
INV-2.3	Coding system		R	ID	12	Fixed "HL70383"

cobas® pure shall use the substance identifier segment to identify the reagents used in a test, when sending a result report message to the host. The data structure is shown in Table 3.2-7 and Table 3.2-8.

Table 3.2-7 Field attribute for INV segment (placed after an OBX segment)

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
INV-0	Field Type		R	ST	3	'INV' fixed
INV-1	Substance Identifier		R	CE	250	Reagent Code
INV-2	Substance Status		R	CE		Bottle type (Standby/Current)
INV-2 ₍₁₎	Substance status		R	CE		Fixed "OK^HL70383"
INV-2 ₍₂₎	Standby Current bottle type		R	CE		- "STANDBY^99ROC" - "CURRENT^99ROC"
INV-3	Reagent Type		R	CE		
INV-3.1	Reagent Type		R	ST	3	Reagent type. The definitions refer to section 3.2.3.
INV -4	Reagent Sequence No		R	CE		Either: -Serial number of the reagent used - Linked Kit ID if INV-3.1 = "KIT"
INV-5	Container Carrier Identifier		R	CE	2	Disk(1 Fixed)
INV-6	Position		R	CE	2	Either: -Reagent Position on Disk - 1 if Reagent type is (IS,DIL or ,REF) - "" null (double quote double quote) if INV-3.1=KIT
INV-12	Expiry		R	TS	1	Expiration date/time Format: YYYYMMDD If precision is only year and month DD is set to the final day of the month. If INV-3.1=KIT Then expiration date: based on the reagent from the involved embedded tests (all e packs in the KIT have the same expiration date).
INV-15	Field contains no data.					
INV -16	Reagent Lot No		R	ST	20	Lot number of the reagent used.

Table 3.2-8 Field attribute for INV segment (QC result)

Field	Element Name	OPT (From HOST)		OPT (From cobas pure)	DT	LEN	Comments
INV-0	Field Type			R	ST	3	'INV' fixed
INV-1	Substance Identifier			R	CE	250	
INV- 1.1	Control Code			R	ST	22	Control material code
INV- 1.2	Control Name			R	ST	20	Control Name
INV- 1.3	Coding system			R	ID	12	Fixed "99ROC"
INV-2	Substance Status			R	CE	250	
INV- 2.1	Identifier			R	ST	20	Fixed "OK"

INV-2.2	Field is empty						
INV-2.3	Coding system			R	ID	12	Fixed "HL703843"
INV-3	Substance Type			R	CE	250	
INV-3.1	Identifier			R	ST	20	Fixed "CO"
INV-3.2	Field is empty						
INV-3.3	Coding system			R	ID	12	Fixed "HL70384"
INV-4	Inventory container ID			R	CE	250	
INV-4.1	Bottle Count number			R	NM	80	Bottle count number
INV-4.2	Field is empty						
INV-4.3	Coding system			R	ID	12	Fixed "99ROC"

3.2.4.4. Message Acknowledgment Segment (MSA)

The MSA segment shall contain information sent while acknowledging another message.

The data structure is shown in Table 3.2-9.

Table 3.2-9 Field attribute for MSA segment

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
MSA-0	Field Type	R	R	ST	3	'MSA' fixed
MSA-1	Acknowledgment Code	R	R	ID	2	For all other response messages: 'AA': Application Accept. This acknowledges the message is valid and was successfully processed. 'AR': Application reject (the request message could not be parsed at all or contains wrong values in MSH-9, MSH-11, MSH-12 or MSH-21) 'AE': Application Error. (any other error in the message, or an internal system error)
MSA-2	Message Control ID	R	R	ST	20	Message Control ID, from MSH-10 segment of the message that cobas® pure is acknowledging.

3.2.4.5. Error Segment (ERR)

The ERR segment shall contain information sent due to a negative acknowledge of another message.

The data structure is shown in Table 3.2-10.

Table 3.2-10 Field attribute for ERR segment

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
ERR-0	Field Type	R	R	ST	3	'ERR' fixed
ERR-1	Field contains no data					
ERR-2	Error location	O	O	ERL	18	See example after the table
ERR-2.1	Segment ID	R	R	ST	3	Name of the segment where the error was discovered, e.g. "SPM"
ERR-2.2	Segment sequence	R	R	NM	2	Sequence number of the segment where the error was discovered
ERR-2.3	Field number	O	O	NM	2	Sequence number of the segment field where the error was discovered, one-based
ERR-2.4	Field repetition	O	O	NM	2	Repetition number of the segment field where the error was discovered, one-based
ERR-2.5	Component number	O	O	NM	2	Sequence number of the field component where the error was discovered, one-based
ERR-2.6	Sub-component number	O	O	NM	2	Sequence number of the sub-component where the error was discovered, one-based
ERR-3	Error Code	R	R	CWE	250	
ERR-3.1	Identifier	R	R	ST	20	Value from the table HL70357
ERR-3.2	Text	O	O	ST	199	
ERR-3.3	Coding system	R	R	ID	12	Fixed "HL70357"
ERR-4	Severity	R	R	ID	1	Fixed "E" (error)

ERR-5	Vendor defined error code	O	O	CWE	250	Can be ignored
ERR-5.1	Identifier	R	R	ST	20	Vendor defined code (e.g. to enrich the standard code from ERR-3) Can be empty
ERR-5.2	Text	O	O	ST	199	Can be empty
ERR-5.3	Coding system	R	R	ID	12	Fixed "99ROC"
ERR-6	Field contains no data					
ERR-7	Field contains no data					
ERR-8	User message	O	O	TX	250	Can be ignored

3.2.4.6. Message Header Segment (MSH)

The MSH segment shall contain information sent while acknowledging another message. This segment occurs at the beginning of every message.

The data structure is shown in Table 3.2-11, Table 3.2-12, Table 3.2-13, Table 3.2-14, Table 3.2-15, Table 3.2-16, Table 3.2-17, Table 3.2-18, Table 3.2-19, Table 3.2-20, and Table 3.2-21.

Table 3.2-11 Field attribute for MSH segment QBP^Q11^QBP_Q11

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
MSH-0	Field Type	R	R	ST	3	'MSH' fixed
MSH-1	Field Separator	R	R	SI	1	' ' fixed
MSH-2	Encoding Characters	R	R	ST	4	'^~\&' fixed
MSH-3	Sending application		R	IS	30	Instrument name as defined in Host Settings on cobas® pure
MSH-4	Field contains no data.					
MSH-5	Receiving application		R	IS	30	Host name as defined in Host Settings on cobas® pure
MSH-6	Field contains no data.					
MSH-7	Date/Time Of Message	R	R	DT M	26	YYYYMMDDHHMMSSQZZzz Time zone is included
MSH-8	Field contains no data					
MSH-9	Message Type	R	R	MSG	15	fixed "QBP^Q11^QBP_Q11"
MSH-10	Message Control	R	R	ST	50	Message Control ID that uniquely identifies the message, for example, a sequence number or GUID string
MSH-11	Processing ID	R	R	PT	3	
MSH-11.1	Processing ID	R	R	ID	1	Fixed "P"
MSH-12	Version ID	R	R	VID	60	'2.5.1' fixed
MSH-13	Field contains no data.					
MSH-14	Field contains no data.					
MSH-15	Accept Acknowledgement Type.	R	R	ID	2	Fixed "NE"

MSH-16	Application Acknowledgment Type	R	R	ST	2	Fixed "AL"	
MSH-17	Field contains no data.						
MSH-18	Character Set	R	R	ID	16	'UNICODE UTF-8' fixed	
MSH-21	Message profile ID			EI	427	1 st MSH-21 repetition	
MSH-21.1	Entity ID		R	ST	50	MSH-21-1	MSH-21-2
						"LAB-27R"	"ROCHE"
MSH-21.2	Namespace ID		R	IS	20	If used from host: empty	

Table 3.2-12 Field attribute for MSH segment –RSP^K11^RSP_K11

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments				
MSH-0	Field Type	R	R	ST	3	'MSH' fixed				
MSH-1	Field Separator	R	R	SI	1	' ' fixed				
MSH-2	Encoding Characters	R	R	ST	4	'^~\&' fixed				
MSH-3	Sending application		R	IS	20	Should be a copy of MSH-5 of QBP^Q11				
MSH-4	Sending Facility					Should be a copy of MSH-6 of QBP^Q11				
MSH-5	Receiving Application		R	IS	20	Should be a copy of MSH-3 of QBP^Q11				
MSH-6	Receiving Facility					Should be a copy of MSH-4 of QBP^Q11				
MSH-7	Date/Time Of Message	R	R	DTM	26	YYYYMMDDHHMMSSQZZzz Including Time zone				
MSH-8	Field contains no data									
MSH-9	Message Type	R	R	MSG	15	fixed "RSP^K11^RSP_K11"				
MSH-10	Message Control	R	R	ST	50	Message Control ID that uniquely identifies the message, for example, a sequence number or GUID string				
MSH-11	Processing ID	R	R	PT	3					
MSH-11.1	Processing ID	R	R	ID	ID	Fixed "P"				
MSH-12	Version ID	O	R	VID	60	'2.5.1' fixed				
MSH-13	Field contains no data.									
MSH-14	Field contains no data.									
MSH-15	Field contains no data.									
MSH-16	Field contains no data.									
MSH-17	Field contains no data.									
MSH-18	Character Set	R	R	ID	16	'UNICODE UTF-8' fixed				
MSH-21	Message profile ID			EI	427	1st MSH-21 repetition <table><tr><td>MSH-21-1</td><td>MSH-21-2</td></tr><tr><td>"LAB-27R"</td><td>"ROCHE"</td></tr></table>	MSH-21-1	MSH-21-2	"LAB-27R"	"ROCHE"
MSH-21-1	MSH-21-2									
"LAB-27R"	"ROCHE"									
MSH-21.1	Entity ID	R	R	ST	50					
MSH-21.2	Namespace ID	R	R	IS	20					

Table 3.2-13 Field attribute for MSH segment OML^O33^OML_O33

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments	
MSH-0	Field Type	R	R	ST	3	'MSH' fixed	
MSH-1	Field Separator	R	R	SI	1	' ' fixed	
MSH-2	Encoding Characters	R	R	ST	4	'^~\&' fixed	
MSH-3	Sending identifier	O		IS	20	if sent used only for tracing information	
MSH-4	Sending Facility					if sent used only for tracing information	
MSH-5	Receiving identifier	O		IS	20	if sent used only for tracing information	
MSH-6	Receiving Facility					if sent used only for tracing information	
MSH-7	Date/Time Of Message	R	R	DTM	26	YYYYMMDDHHMMSSQZZz	
MSH-8	Field contains no data						
MSH-9	Message Type	R	R	MSG	15	fixed "OML^O33^OML_O33"	
MSH-10	Message Control	R	R	ST	50	Message Control ID that uniquely identifies the message, for example, a sequence number or GUID string	
MSH-11	Processing ID	R	R	PT	3		
MSH-11.1	Processing ID	R	R	ID	ID	Fixed "P"	
MSH-12	Version ID	O	R	VID	60	'2.5.1' fixed	
MSH-13	Field contains no data.						
MSH-14	Field contains no data.						
MSH-15	Accept Acknowledgement Type.	R	R	ID		Fixed "NE"	
MSH-16	Application Acknowledgment Type	R	R	ID		Fixed "AL"	
MSH-17	Field contains no data.						
MSH-18	Character Set	R	R	ID	16	'UNICODE UTF-8' fixed	
MSH-21	Message profile ID	R		EI	427	MSH-21-1	MSH-21-2
MSH-21.1	Entity ID	R		ST	50	"LAB-28R"	"ROCHE"
MSH-21.2	Namespace ID	R		IS	20	Empty if send from Instrument	

Table 3.2-14 Field attribute for MSH segment ORL^O34^ORL_O42

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments						
MSH-0	Field Type	R	R	ST	3	'MSH' fixed						
MSH-1	Field Separator	R	R	SI	1	' ' fixed						
MSH-2	Encoding Characters	R	R	ST	4	'^~\&' fixed						
MSH-3	Sending identifier	O		IS	20	Instrument name as defined in Host Settings on cobas® pure						
MSH-4	Sending Facility					Should be a copy of MSH-6 of OML^O33						
MSH-5	Receiving identifier	O		IS	20	Host name as defined in Host Settings on cobas® pure						
MSH-6	Receiving Facility					Should be a copy of MSH-4 of OML^O33						
MSH-7	Date/Time Of Message	R	R	DTM	26	YYYYMMDDHHMMSSQZZz						
MSH-8	Field contains no data											
MSH-9	Message Type	R	R	MSG	15	fixed "ORL^O34^ORL_O42"						
MSH-10	Message Control	R	R	ST	50	Message Control ID that uniquely identifies the message, for example, a sequence number or GUID string						
MSH-11	Processing ID	R	R	PT	3							
MSH-11.1	Processing ID	R	R	ID	ID	Fixed "P"						
MSH-12	Version ID	O	R	VID	60	'2.5.1' fixed						
MSH-13	Field contains no data.											
MSH-14	Field contains no data.											
MSH-15	Field contains no data.											
MSH-16	Field contains no data.											
MSH-17	Field contains no data.											
MSH-18	Character Set	R	R	ID	16	'UNICODE UTF-8' fixed						
MSH-21	Message profile ID			EI	427	Empty if send from Instrument						
MSH-21.1	Entity ID	R		ST	50	<table><tr><td colspan="2">1st MSH-21 repetition</td></tr><tr><td>MSH-21-1</td><td>MSH-21-2</td></tr><tr><td>"LAB-28R"</td><td>"ROCHE"</td></tr></table>	1 st MSH-21 repetition		MSH-21-1	MSH-21-2	"LAB-28R"	"ROCHE"
1 st MSH-21 repetition												
MSH-21-1	MSH-21-2											
"LAB-28R"	"ROCHE"											
MSH-21.2	Namespace ID	R		IS	20							

Table 3.2-15 Field attribute for MSH segment OUL^R22^OUL_R22

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments						
MSH-0	Field Type	R	R	ST	3	'MSH' fixed						
MSH-1	Field Separator	R	R	SI	1	' ' fixed						
MSH-2	Encoding Characters	R	R	ST	4	'^~\&' fixed						
MSH-3	Sending identifier	O		IS	20	Instrument name as defined in Host Settings on cobas® pure						
MSH-4	Sending Facility											
MSH-5	Receiving identifier	O		IS	20	Host name as defined in Host Settings on cobas® pure						
MSH-6	Receiving Facility											
MSH-7	Date/Time Of Message	R	R	DTM	26	YYYYMMDDHHMMSSQZZzz						
MSH-8	Field contains no data											
MSH-9	Message Type	R	R	MSG	15	fixed "OUL^R22^OUL_R22"						
MSH-10	Message Control	R	R	ST	50	Message Control ID that uniquely identifies the message, for example, a sequence number or GUID string						
MSH-11	Processing ID	R	R	PT	3							
MSH-11.1	Processing ID	R	R	ID	ID	Fixed "P"						
MSH-12	Version ID	R	R	VID	60	'2.5.1' fixed						
MSH-13	Field contains no data.											
MSH-14	Field contains no data.											
MSH-15	Accept Acknowledgement Type.	R	R	ID		Fixed "NE"						
MSH-16	Application Acknowledgment Type	R	R	ID		Fixed "AL"						
MSH-17	Field contains no data.											
MSH-18	Character Set	R	R	ID	16	'UNICODE UTF-8' fixed						
MSH-21	Message profile ID			EI	427	<table><tr><th colspan="2">1st MSH-21 repetition</th></tr><tr><th>MSH-21-1</th><th>MSH-21-2</th></tr><tr><td>"LAB-29"</td><td>"IHE"</td></tr></table>	1 st MSH-21 repetition		MSH-21-1	MSH-21-2	"LAB-29"	"IHE"
1 st MSH-21 repetition												
MSH-21-1	MSH-21-2											
"LAB-29"	"IHE"											
MSH-21.1	Entity ID	R	R	ST	50							
MSH-21.2	Namespace ID	R	R	IS	20							

Table 3.2-16 Field attribute for MSH segment OUL^R23^OUL_R23

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments	
MSH-0	Field Type	R	R	ST	3	'MSH' fixed	
MSH-1	Field Separator	R	R	SI	1	' ' fixed	
MSH-2	Encoding Characters	R	R	ST	4	'^~\&' fixed	
MSH-3	Sending identifier	O		IS	20	Instrument name as defined in Host Settings on cobas® pure	
MSH-4	Sending Facility						
MSH-5	Receiving identifier	O		IS	20	Host name as defined in Host Settings on cobas® pure	
MSH-6	Receiving Facility						
MSH-7	Date/Time Of Message	R	R	DTM	26	YYYYMMDDHHMMSSQZZzz	
MSH-8	Field contains no data						
MSH-9	Message Type	R	R	MSG	15	fixed "OUL^R23^OUL_R23"	
MSH-10	Message Control	R	R	ST	50	Message Control ID that uniquely identifies the message, for example, a sequence number or GUID string	
MSH-11	Processing ID	R	R	PT	3		
MSH-11.1	Processing ID	R	R	ID	ID	Fixed "P"	
MSH-12	Version ID	R	R	VID	60	'2.5.1' fixed	
MSH-13	Field contains no data.						
MSH-14	Field contains no data.						
MSH-15	Accept Acknowledgement Type.	R	R	ID		Fixed "NE"	
MSH-16	Application Acknowledgment Type	R	R	ID		Fixed "AL"	
MSH-17	Field contains no data.						
MSH-18	Character Set	R	R	ID	16	'UNICODE UTF-8' fixed	
MSH-21	Message profile ID			EI	427	1 st MSH-21 repetition	
MSH-21.1	Entity ID	R	R	ST	50	MSH-21-1	MSH-21-2
MSH-21.2	Namespace ID	R	R	IS	20	"LAB-29C"	"ROCHE"

Table 3.2-17 Field attribute for MSH segment ESR^U02^ESR_U02

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments							
MSH-0	Field Type	R	R	ST	3	'MSH' fixed							
MSH-1	Field Separator	R	R	SI	1	' ' fixed							
MSH-2	Encoding Characters	R	R	ST	4	'^~\&' fixed							
MSH-3	Sending identifier	O		IS	20	if sent used only for tracing information							
MSH-4	Sending Facility					if sent used only for tracing information							
MSH-5	Receiving identifier	O		IS	20	if sent used only for tracing information							
MSH-6	Receiving Facility					if sent used only for tracing information							
MSH-7	Date/Time Of Message	R	R	DTM	26	YYYYMMDDHHMMSSQZZz							
MSH-8	Field contains no data												
MSH-9	Message Type	R	R	MSG	15	fixed "ESR^U02^ESR_U02"							
MSH-10	Message Control	R	R	ST	50	Message Control ID that uniquely identifies the message, for example, a sequence number or GUID string							
MSH-11	Processing ID	R	R	PT	3								
MSH-11.1	Processing ID	R	R	ID	ID	Fixed "P"							
MSH-12	Version ID	R	R	VID	60	'2.5.1' fixed							
MSH-13	Field contains no data.												
MSH-14	Field contains no data.												
MSH-15	Accept Acknowledgement Type.	R	R	ID		Fixed "NE"							
MSH-16	Application Acknowledgment Type	R	R	ID		Fixed "AL"							
MSH-17	Field contains no data.												
MSH-18	Character Set	R	R	ID	16	'UNICODE UTF-8' fixed							
MSH-21	Message profile ID			EI	427	<table><tr><th colspan="2">1st MSH-21 repetition</th></tr><tr><th>MSH-21-1</th><th>MSH-21-2</th></tr><tr><td>"ROC-01"</td><td>"ROCHE"</td></tr></table>		1 st MSH-21 repetition		MSH-21-1	MSH-21-2	"ROC-01"	"ROCHE"
1 st MSH-21 repetition													
MSH-21-1	MSH-21-2												
"ROC-01"	"ROCHE"												
MSH-21.1	Entity ID	R	R	ST	50								
MSH-21.2	Namespace ID	R	R	IS	20								

Table 3.2-18 Field attribute for MSH segment ESU^U01^ESU_U01

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments							
MSH-0	Field Type	R	R	ST	3	'MSH' fixed							
MSH-1	Field Separator	R	R	SI	1	' ' fixed							
MSH-2	Encoding Characters	R	R	ST	4	'^~\&' fixed							
MSH-3	Sending identifier	O		IS	20	Instrument name as defined in Host Settings on cobas® pure							
MSH-4	Sending Facility												
MSH-5	Receiving identifier	O		IS	20	Host name as defined in Host Settings on cobas® pure							
MSH-6	Receiving Facility												
MSH-7	Date/Time Of Message	R	R	DTM	26	YYYYMMDDHHMMSSQZZzz							
MSH-8	Field contains no data												
MSH-9	Message Type	R	R	MSG	15	fixed “ESU^U01^ESU_U01”							
MSH-10	Message Control	R	R	ST	50	Message Control ID that uniquely identifies the message, for example, a sequence number or GUID string							
MSH-11	Processing ID	R	R	PT	3								
MSH-11.1	Processing ID	R	R	ID	ID	Fixed “P”							
MSH-12	Version ID	R	R	VID	60	‘2.5.1’ fixed							
MSH-13	Field contains no data.												
MSH-14	Field contains no data.												
MSH-15	Accept Acknowledgement Type.	R	R	ID		Fixed “NE”							
MSH-16	Application Acknowledgment Type	R	R	ID		In case of “Instrument Status Update”: Fixed “AL” In case of “Instrument Status Request”: Fixed “NE”							
MSH-17	Field contains no data.												
MSH-18	Character Set	R	R	ID	16	‘UNICODE UTF-8’ fixed							
MSH-21	Message profile ID			EI	427	<table><tr><th colspan="2">1st MSH-21 repetition</th></tr><tr><th>MSH-21-1</th><th>MSH-21-2</th></tr><tr><td>“ROC-02”</td><td>“ROCHE”</td></tr></table>		1 st MSH-21 repetition		MSH-21-1	MSH-21-2	“ROC-02”	“ROCHE”
1 st MSH-21 repetition													
MSH-21-1	MSH-21-2												
“ROC-02”	“ROCHE”												
MSH-21.1	Entity ID	R	R	ST	50								
MSH-21.2	Namespace ID	R	R	IS	20								

Table 3.2-19 Field attribute for MSH segment INR^U14^INR_U14

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments							
MSH-0	Field Type	R	R	ST	3	'MSH' fixed							
MSH-1	Field Separator	R	R	SI	1	' ' fixed							
MSH-2	Encoding Characters	R	R	ST	4	'^~\&' fixed							
MSH-3	Sending identifier	O		IS	20	if sent used only for tracing information							
MSH-4	Sending Facility					if sent used only for tracing information							
MSH-5	Receiving identifier	O		IS	20	if sent used only for tracing information							
MSH-6	Receiving Facility					if sent used only for tracing information							
MSH-7	Date/Time Of Message	R	R	DTM	26	YYYYMMDDHHMMSSQZZz							
MSH-8	Field contains no data												
MSH-9	Message Type	R	R	MSG	15	fixed “ INR^U14^INR_U14”							
MSH-10	Message Control	R	R	ST	50	Message Control ID that uniquely identifies the message, for example, a sequence number or GUID string							
MSH-11	Processing ID	R	R	PT	3								
MSH-11.1	Processing ID	R	R	ID	ID	Fixed “P”							
MSH-12	Version ID	R	R	VID	60	'2.5.1' fixed							
MSH-13	Field contains no data.												
MSH-14	Field contains no data.												
MSH-15	Accept Acknowledgement Type.	R	R	ID		Fixed “NE”							
MSH-16	Application Acknowledgment Type	R	R	ID		Fixed “AL”							
MSH-17	Field contains no data.												
MSH-18	Character Set	R	R	ID	16	'UNICODE UTF-8' fixed							
MSH-21	Message profile ID			EI	427	<table><tr><th colspan="2">1st MSH-21 repetition</th></tr><tr><th>MSH-21-1</th><th>MSH-21-2</th></tr><tr><td>“ROC-03”</td><td>“ROCHE”</td></tr></table>		1 st MSH-21 repetition		MSH-21-1	MSH-21-2	“ROC-03”	“ROCHE”
1 st MSH-21 repetition													
MSH-21-1	MSH-21-2												
“ROC-03”	“ROCHE”												
MSH-21.1	Entity ID	R	R	ST	50								
MSH-21.2	Namespace ID	R	R	IS	20								

Table 3.2-20 Field attribute for MSH segment INU^U05^INU_U05

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments							
MSH-0	Field Type	R	R	ST	3	'MSH' fixed							
MSH-1	Field Separator	R	R	SI	1	' ' fixed							
MSH-2	Encoding Characters	R	R	ST	4	'^~\&' fixed							
MSH-3	Sending identifier	O		IS	20	Instrument name as defined in Host Settings on cobas® pure							
MSH-4	Sending Facility												
MSH-5	Receiving identifier	O		IS	20	Host name as defined in Host Settings on cobas® pure							
MSH-6	Receiving Facility												
MSH-7	Date/Time Of Message	R	R	DTM	26	YYYYMMDDHHMMSSQZzz							
MSH-8	Field contains no data												
MSH-9	Message Type	R	R	MSG	15	fixed “ INU^U05^INU_U05”							
MSH-10	Message Control	R	R	ST	50	Message Control ID that uniquely identifies the message, for example, a sequence number or GUID string							
MSH-11	Processing ID	R	R	PT	3								
MSH-11.1	Processing ID	R	R	ID	ID	Fixed “P”							
MSH-12	Version ID	R	R	VID	60	‘2.5.1’ fixed							
MSH-13	Field contains no data.												
MSH-14	Field contains no data.												
MSH-15	Accept Acknowledgement Type.	R	R	ID		Fixed “NE”							
MSH-16	Application Acknowledgment Type	R	R	ID		In case of “Inventory Status Update”: Fixed “AL” In case of “Inventory Status Request”: Fixed “NE”							
MSH-17	Field contains no data.												
MSH-18	Character Set	R	R	ID	16	‘UNICODE UTF-8’ fixed							
MSH-21	Message profile ID			EI	427	<table><tr><th colspan="2">1st MSH-21 repetition</th></tr><tr><th>MSH-21-1</th><th>MSH-21-2</th></tr><tr><td>“ROC-04”</td><td>“ROCHE”</td></tr></table>		1 st MSH-21 repetition		MSH-21-1	MSH-21-2	“ROC-04”	“ROCHE”
1 st MSH-21 repetition													
MSH-21-1	MSH-21-2												
“ROC-04”	“ROCHE”												
MSH-21.1	Entity ID	R	R	ST	50								
MSH-21.2	Namespace ID	R	R	IS	20								

Table 3.2-21 Field attribute for MSH segment ACK^<varies>^ACK (the middle component must correspond to MSH-9-2 of the acknowledged message)

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
MSH-0	Field Type	R	R	ST	3	'MSH' fixed
MSH-1	Field Separator	R	R	SI	1	' ' fixed
MSH-2	Encoding Characters	R	R	ST	4	'^~\&' fixed
MSH-3	Sending identifier	O		IS	20	Instrument name as defined in Host Settings on cobas® pure
MSH-4	Sending Facility					Should be a copy of MSH-6 of the acknowledged message
MSH-5	Receiving identifier	O		IS	20	Host name as defined in Host Settings on cobas® pure
MSH-6	Receiving Facility					Should be a copy of MSH-4 of the acknowledged message
MSH-7	Date/Time Of Message	R	R	DTM	26	YYYYMMDDHHMMSSQZZzz
MSH-8	Field contains no data					
MSH-9	Message Type	R	R	MSG	15	
MSH-9.1	Message Code	R	R	IS	3	Fixed "ACK"
MSH-9.2	Trigger event	R	R	IS	3	Copy of MSH-9.2 of the message being acknowledged
MSH-9.3	Message structure	R	R	IS	3	Fixed ACK
MSH-10	Message Control	R	R	ST	50	Message Control ID that uniquely identifies the message, for example, a sequence number or GUID string
MSH-11	Processing ID	R	R	PT	3	
MSH-11.1	Processing ID	R	R	ID	ID	Fixed "P"
MSH-12	Version ID	O	R	VID	60	'2.5.1' fixed
MSH-13	Field contains no data.					
MSH-14	Field contains no data.					
MSH-15	Field contains no data.					
MSH-16	Field contains no data.					
MSH-17	Field contains no data.					
MSH-18	Character Set	O	R	ID	16	'UNICODE UTF-8' fixed
MSH-21	Message profile ID			EI	427	Should be a copy of MSH-21 of the message being acknowledged

3.2.4.7. Observation Request Segment (OBR)

cobas® pure shall use the observation request segment in a result report message or a test selection upload message. The host shall use the observation request segment in a test selection download message.

An OBR shall be created for every normal test and every **cobas e** flow test. For a normal test, there shall be several OBX segments for the OBR. For a **cobas e** flow test, there shall be one OBR segment, which has **several** OBX segments for the **cobas e** flow main result, and OBX segments for each associated embedded test with raw data and reported variables.

The data structure is shown in Table 3.2-22.

Table 3.2-22 Field attribute for OBR segment

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
OBR-0	Field Type	R	R	ST	3	'OBR' fixed
OBR-1	SetID	O	R	NM	4	The first segment is 1, then increments by 1 for each subsequent OBR segment.
OBR-2	Placer order number	R	R	EI	50	-
OBR-2.1	Entity identifier	R	R	ST	50	Either: - "" null (double quote double quote) if order is created on Instrument directly - Order ID from HOST
OBR-3	Field contains no data.					
OBR-4	Universal service identifier	R	R	CE	250	
OBR-4.1	Identifier	R	R	ST	20	Test code defaults to the ACN
OBR-4.2	Text	R	R	ST	199	Fixed empty
OBR-4.3	Coding system	R	R	ID	12	Fixed "99ROC"
OBR-5	Field contains no data.					
OBR-6	Field contains no data.					
OBR-7	Field contains no data.					
OBR-8	Field contains no data.					
OBR-9	Field contains no data.					
OBR-10	Field contains no data.					
OBR-11	Specimen action code	R	R	ST	1	- "G" Test is/was added as a reflex test else prohibited Note: When the orders which was set G to OBR-11 are received from HOST and cobas® pure send the result to HOST, cobas® pure set G to OBR-11 of the corresponding result.

OBR-46	Placer Supplemental Service Information	O	O	CE	250	Only used for Calibration Request to transmit the calibration method.
OBR-46.1	Calibration Method	R		ST	20	Calibration Method, "Full" can be used.
OBR-46.2	Field contains no data					
OBR-46.3	Coding System	R		ID	20	Fixed "99ROC"

3.2.4.8. Observation/Result Segment (OBX)

cobas® pure shall use the observation request segment in a result report message.

The data structure is shown in Table 3.2-23, Table 3.2-24, Table 3.2-25, Table 3.2-26, Table 3.2-27 and Table 3.2-28.

(1) For patient results

Table 3.2-23 Field attribute for OBX segment (patient results)

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
OBX-0	Field Type		R	ST	3	'OBX' fixed
OBX-1	SetID		R	NM	4	The first segment is 1, then increments by 1 for each subsequent OBX segment. Reset is done by new OBR-Segment
OBX-2	Value type		R	ID	3	Either: - NM for numeric results - CE for Qualitative results and QC State - ST for Target Ranges - EI for Calibration ID and QC TID - DTM for Pipetting Time - "" null (doublequote doublequote) for Results where OBX-5 and OBX-6 are empty
OBX-3	Observation Identifier		R	CE	250	The test code. (Observation identifier or Application code.) This identifies the test or analyte which this message relates to. A cobas e flow test can contain an internally-calculated formula result. Therefore, in the case that variable or formula is a subresult of a cobas e flow test, this field can contain the name of this variable or formula. This field can also contain the host code assigned to this variable or formula. cobas e flow tests with different units for the main result may contain here the host code assigned for this unit.

OBX-3.1	Identifier		R	ST	20	For Result uploads this defaults to the ACN In case that the variable or formula is a subresult of cobas eflow, this is set as defaults to the Variable or Formula Name or the host code defined for the variable or formula. eflows with different units for the main result may contain here the host code assigned for this unit. “TR_TECHNICALLIMIT”, “TR_REPEATLIMIT”, “TR_EXPECTEDVALUES” are used to transfer Technical limit, repeat limit and expected values. “PT” for transfer of Pipetting Time “CalibrationID” for transfer of CalibrationID for this measurement “QCTID” for transfer of QC ID for this measurement. “QCSTATE” for transfer of QC State for this measurement “CombID” for Linkage Information between calculated QC result and e flow result for this measurement.
OBX-3.2	Text		R	ST	199	If OBX-3.1 is “PT” “Pipetting Time” If OBX-3.1 is “CalibrationID” “CalibrationID” If OBX-3.1 is “QCTID” “QC Test ID” If OBX-3.1 is “QCSTATE” “QC Status” else equal to OBX-3.1. If OBX-3.1 is “CombID” “Measurement Cell Test Combination ID”
OBX-3.3	Coding system		R	ID	12	Fixed “99ROC”
OBX-3.4	Alternate Identifier		O	ST	20	- Empty for Results. - “S_OTHER” else
OBX-3.5	Alternate Text		O	ST	199	- “Other Supplemental” if OBX-3.4 is S_OTHER -
OBX-3.6	Alternate coding system		O	ID	12	- Fixed “IHELAW”
OBX-4	Observation Sub-ID (Run number)		R	OG	20	Fixed “1”
OBX-5 if OBX-2 is NM						
OBX-5	Observation Result		R	NM	16	Either: - Numeric Result Value “*****” for suppressed results
OBX-5 If OBX-2 is “ST”						
OBX-5	Observation Result		R	ST	200	If OBX-3.1 is starting with “TR_TECHNICALLIMIT” the Technical limit is transmitted If OBX-3.1 is starting with “TR_REPEATLIMIT” the Repeat limit is transmitted If OBX-3.1 is starting with “TR_EXPECTEDVALUES” the Expected values are transmitted
OBX-5 if OBX-2 is EI						
OBX-5	Observation Result		R	EI	200	CalibrationID if OBX-3.1 = “CalibrationID” QC Test ID if OBX-3.1 = “QCTID”. Multiple QC IDs can be provided, separated by “~”. Measurement Cell Test Combination ID, if OBX-3.1 = “CombID”

OBX-5 if OBX-2 is CE						
OBX-5	Observation Result		R	CE	65536	Either: - Qualitative Results - "*****" for suppressed results - QC Status if OBX-3.1 = "QCSTATE"
OBX-5.1	Identifier		R	ID	12	- One of the codes defined in table "Qualitative result code for cobas tests" - "*****" for suppressed results - If OBX-3.1 is "QCSTATE" either ➤ 0 (invalid) ➤ 1 (success) ➤ 2 (fail)
OBX-5.2	Not used		O			
OBX-5.3	Coding System		R	ID	12	Fixed "99ROC"
OBX-5 if OBX-2 is DTM						
OBX-5	Observation Result		R	DTM	65536	Pipetting time in "YYYYMMDDhhmmss" Format If this OBX is a part of a Linkage Record of e flow Then pipetting time of the first measured embedded test.
OBX-5 if OBX-2 is empty						
OBX-5	Observation Result		R		65536	Fixed entry "''" null (doublequote doublequote)
OBX-6	Unit		O	CE	250	Required if OBX-2 is - NM - NA Else prohibited
OBX-6.1	Identifier		R	ST	20	Units of measurement used for measuring the result <u>For photometric raw data</u> , this shows ABS. <u>For result check value</u> , this shows RCV <u>For a raw data/data point result (for Immuno Tests)</u> , this shows COUNT. <u>For qualitative cobas e flow test results</u> , no value is sent in this field.
OBX-6.2	Empty Field					
OBX-6.3	Coding System		R	ID	12	Fixed "99ROC"
OBX-7	Empty Field					
OBX-8	Interpretation flags		R	CWE	250	Data alarms are placed here and also codes that identifies if the result is normal or abnormal. i.e. "76^System reagent temperature^99ROC~H^HL70078~HU^99ROC" The Interpretation flags needs to be ordered by the priority of the flags, most important first, and least important last. If the field size is not sufficient, The least important alarms should be cut. When no flags are applicable, the HL7 NULL value quotequote (""") must be placed here.
OBX-8.1	Flag identifier		R	ID	3	When no flags are applicable, the HL7 NULL value quotequote (""") must be placed here.
OBX-8.2	Text		O	ST		Can be empty
OBX-8.3	Coding system		C	ID	12	Either - "HL70078" for the data alarms defined in HL7 0078 - "99ROC" for the specified data alarms of cobas® pure - Empty if OBX-8.1 is HL7 NULL value quotequote (""")
OBX-9	Field contains no data.					

OBX-10	Field contains no data.																							
OBX-11	Result status		R	ID	1	Result status The definition refer to section 3.2.3.																		
OBX-12	Field contains no data.																							
OBX-13	Field contains no data.																							
OBX-14	Field contains no data.																							
OBX-15	Field contains no data.																							
OBX-16	Responsible observer		R	XCN	25																			
OBX-16.1	Observer		R	ST	25	First repetition -- User name of the logged in user Second repetition – fixed “REALTIME” if sent automatically (or as response to a Result Query), fixed “BATCH” if sent manually. Examples: “Klauspeter~BATCH”, “Krankenschwester~REALTIME”.																		
OBX-17	Field contains no data.																							
OBX-18	Measurement unit ID		R	EI	427	OBX18.1^OBX18.2~OBX18.1^OBX18.2[~OBX18.1^OBX18.2]																		
OBX-18.1	Entity Identifier		R	ST	50	<table><tr><th colspan="2">1st OBX-18 repetition</th><th colspan="2">2nd OBX-18 repetition</th><th colspan="2">3rd OBX-18 repetition (used only if the result could be mapped onto sub-module)</th></tr><tr><th>OBX-18-1</th><th>OBX-18-2</th><th>OBX-18-1</th><th>OBX-18-2</th><th>OBX-18-1</th><th>OBX-18-2</th></tr><tr><td>Module type (e402, c303, ISE) or empty if result cannot be mapped to Instrument (Sample short etc.)</td><td>Manufacturer ID: fixed “ROCHE”</td><td>Module serial № or cobas® pure serial number</td><td>Manufacturer ID same as first OBX-18.2</td><td>Definition refers to section 3.2.3.</td><td>Manufacturer ID same as first OBX-18.2</td></tr></table>	1 st OBX-18 repetition		2 nd OBX-18 repetition		3 rd OBX-18 repetition (used only if the result could be mapped onto sub-module)		OBX-18-1	OBX-18-2	OBX-18-1	OBX-18-2	OBX-18-1	OBX-18-2	Module type (e402, c303, ISE) or empty if result cannot be mapped to Instrument (Sample short etc.)	Manufacturer ID: fixed “ROCHE”	Module serial № or cobas® pure serial number	Manufacturer ID same as first OBX-18.2	Definition refers to section 3.2.3.	Manufacturer ID same as first OBX-18.2
1 st OBX-18 repetition		2 nd OBX-18 repetition		3 rd OBX-18 repetition (used only if the result could be mapped onto sub-module)																				
OBX-18-1	OBX-18-2	OBX-18-1	OBX-18-2	OBX-18-1	OBX-18-2																			
Module type (e402, c303, ISE) or empty if result cannot be mapped to Instrument (Sample short etc.)	Manufacturer ID: fixed “ROCHE”	Module serial № or cobas® pure serial number	Manufacturer ID same as first OBX-18.2	Definition refers to section 3.2.3.	Manufacturer ID same as first OBX-18.2																			
OBX-18.2	Namespace ID		R	IS	20																			
OBX-19	Analysis date time		R	TS	14	Time at which the result became available or at which the observation failed. If OBX-11 = “B” or (OBX-3.1 = “PT” or “CombID” or “QCTID”), then measurement time of the last measured embedded test.																		
OBX-19.1	Timestamp		R	DTM	14	String in format YYYYMMDDhhmmss																		
OBX-29	Observation Type		R	ID	4	Fixed “RSLT” (observation result)																		

(2) For QC results

Table 3.2-24 Field attribute for OBX segment (QC results)

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
OBX-0	Field Type		R	ST	3	'OBX' fixed
OBX-1	SetID		R	SI	4	The first segment is 1, then increments by 1 for each subsequent OBX segment. Reset is done by new OBR-Segment
OBX-2	Value type		R	ID	3	Either: - NM for numeric results and "QC_TARGET", "QC_LOWER", "QC_UPPER", "QC_SD_RANGE" - DTM for Pipetting Time - EI for CalibrationID - CE for QC Status - "" null (doublequote doublequote) for Results where OBX-5 and OBX-6 are empty
OBX-3	Observation Identifier		R	CE	250	The test code. (Observation identifier or Application code.) This identifies the test or analyte, which this message relates to. QC_TARGET, QC_LOWER, QC_UPPER or QC_SD_RANGE for transfer of QC Target, lower, upper and SD range If QC_SD_RANGE is transferred QC_TARGET must also be set, but QC_LOWER and QC_UPPER are not allowed to transfer. QC_UPPER and QC_LOWER must be transferred together, QC_TARGET is optional. QC_TARGET must be transferred either - With QC_SD_RANGE or - QC_UPPER and QC_LOWER
OBX-3.1	Identifier		R	ST	20	Test code of used test: QC_TARGET, QC_LOWER, QC_UPPER or QC_SD_RANGE" for transfer of QC ranges "PT" for transfer of Pipetting Time "CalibrationID" for transfer of CalibrationID for this measurement "CombID" for Linkage Information between calculated QC result and e flow result for this measurement.
OBX-3.2	Text		R	ST	199	If OBX-3.1 is "PT" "Pipetting_Time" If OBX-3.1 is "CalibrationID" "CalibrationID" If OBX-3.1 is "CombID" "Measurement Cell Test Combination ID" else equal to OBX-3.1
OBX-3.3	Coding system		R	ID	12	Fixed "99ROC"
OBX-3.4	Alternate Identifier		O	ST	20	- Empty for Results. - "S_OTHER" for Pipetting time (OBX-3.1 is PT) or QC_TARGET, QC_LOWER, QC_UPPER or QC_SD_RANGE or CalibrationID
OBX-3.5	Alternate Text		O	ST	199	- "Other Supplemental" if OBX-3.4 is S_OTHER
OBX-3.6	Alternate coding system		O	ID	12	- Fixed "IHELAW"

OBX-4	Observation Sub-ID (Run number)		R	ST	20	Fixed "1"
OBX-5	Observation Result		R	According to OBX-2	65536	If OBX-2 is NM: Numeric Result Value or used QC lower limit (OBX-3.1 is QC_LOWER), used QC upper limit (OBX-3.1 is QC_UPPER), used QC Target Value (OBX-3.1 is QC_TARGET) or used QC SD Range (OBX-3.1 is QC_SD_RANGE) If OBX-2 is EI CalibrationID and OBX-3.1 = "CalibrationID" the calibrationID If OBX-2 is empty fixed entry "" null (doublequote doublequote) If OBX-2 is DTM the pipetting time in "YYYYMMDDhhmmss" Format If OBX-2 is DTM and this OBX is a part of a Linkage Record of a flow then pipetting time of the first measured QC result of the involved embedded test in the calculated QC. Measurement Cell Test Combination ID, if OBX-3.1 = "CombID"
OBX-6	Unit		O	CE	250	Required if OBX-2 is - NM - NA Else prohibited
OBX-6.1	Identifier		R	ST	20	Units of measurement used for measuring the result
OBX-6.2	Empty Field					
OBX-6.3	Coding System		R	ID	12	Fixed "99ROC"
OBX-7	Empty Field					
OBX-8	Interpretation flag		R	CWE	250	Data alarms are placed here and also codes that identifies if the result is normal or abnormal. i.e. "76^System reagent temperature^99ROC~HH^HL70078~HU^99ROC" The Interpretation flags needs to be ordered by the priority of the flags, most important first, and least important last. If the field size is not sufficient The least important alarms should be cut. When no flags are applicable, the HL7 NULL value quotequote ("") must be placed here.
OBX-8.1	Flag identifier		R	ID	3	i.e. H, N, L as defined in HL70078 or other abnormal flags as defined in 99ROC. When no flags are applicable, the HL7 NULL value quotequote ("") must be placed here.
OBX-8.2	Text		O	ST		Might be empty
OBX-8.3	Name space		C	ID	12	Either - "HL70078" for the data alarms defined in HL7 0078 - "99ROC" for the specified data alarms of cobas pure - Empty if OBX-8.1 is HL7 NULL value quotequote ("")
OBX-9	Field contains no data.					
OBX-10	Field contains no data.					
OBX-11	Result status		R	ID	1	Result status The definition refer to section 3.2.3.
OBX-12	Field contains no data.					
OBX-13	Field contains no data.					

OBX-14	Field contains no data.																							
OBX-15	Field contains no data.																							
OBX-16	Responsible observer		R	XCN	25																			
OBX-16.1	Observer		R	ST	25	First repetition -- User name of the logged in user Second repetition – fixed “REALTIME” if sent automatically (or as response to a Result Query), fixed “BATCH” if sent manually. Examples: “Klauspeter~BATCH”, “Krankenschwester~REALTIME”.																		
OBX-17	Field contains no data.																							
OBX-18	Measurement unit ID		R	EI	427	OBX18.1^OBX18.2~ OBX18.1^OBX18.2[~OBX18.1^OBX18.2]																		
OBX-18.1	Entity Identifier		R	ST	50	<table><tr><th colspan="2">1st OBX-18 repetition</th><th colspan="2">2nd OBX-18 repetition</th><th colspan="2">3rd OBX-18 repetition (only for measured QC, not for calculated QC)</th></tr><tr><th>OBX-18-1</th><th>OBX-18-2</th><th>OBX-18-1</th><th>OBX-18-2</th><th>OBX-18-1</th><th>OBX-18-2</th></tr><tr><td>Module type (e402, c303, ISE) or empty if result cannot be mapped to Instrument (Sample short etc.)</td><td>Manufacturer ID Should be defined. Preferred: ROCHE</td><td>Module serial N^o or cobas[®] pure serial number</td><td>Manufacturer ID same as first OBX-18.2</td><td>Definition refers to section 3.2.3.</td><td>Manufacturer ID same as first OBX-18.2</td></tr></table>	1 st OBX-18 repetition		2 nd OBX-18 repetition		3 rd OBX-18 repetition (only for measured QC, not for calculated QC)		OBX-18-1	OBX-18-2	OBX-18-1	OBX-18-2	OBX-18-1	OBX-18-2	Module type (e402, c303, ISE) or empty if result cannot be mapped to Instrument (Sample short etc.)	Manufacturer ID Should be defined. Preferred: ROCHE	Module serial N ^o or cobas [®] pure serial number	Manufacturer ID same as first OBX-18.2	Definition refers to section 3.2.3.	Manufacturer ID same as first OBX-18.2
1 st OBX-18 repetition		2 nd OBX-18 repetition		3 rd OBX-18 repetition (only for measured QC, not for calculated QC)																				
OBX-18-1	OBX-18-2	OBX-18-1	OBX-18-2	OBX-18-1	OBX-18-2																			
Module type (e402, c303, ISE) or empty if result cannot be mapped to Instrument (Sample short etc.)	Manufacturer ID Should be defined. Preferred: ROCHE	Module serial N ^o or cobas [®] pure serial number	Manufacturer ID same as first OBX-18.2	Definition refers to section 3.2.3.	Manufacturer ID same as first OBX-18.2																			
OBX-18.2	Namespace ID		R	IS	20																			
OBX-19	Analysis date time		R	TS	14	Time at which the result became available or at which the QC observation failed. If this OBX is a part of a Linkage Record of e flow then measurement time of the last measured QC result of the involved embedded test in the calculated QC.																		
OBX-19.1	Timestamp		R	DTM	14	String in format YYYYMMDDhhmmss																		
OBX-21	Observation Instance Identifier		R	EI		QC TID																		
OBX-29	Observation Type		R	ID	4	Fixed “RSLT” (observation result)																		

(3) For raw data/data point upload for patient/QC result

Table 3.2-25 Field attribute for OBX segment for raw data/data point uploads (for patient/QC results)

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
OBX-0	Field Type		R	ST	3	'OBX' fixed
OBX-1	SetID		R	NM	4	The first segment is 1, then increments by 1 for each subsequent OBX segment. Reset is done by new OBR-Segment
OBX-2	Value type		R	ID	3	Either: - NM for raw data - NA for data point/abs/RCV values - "" null (doublequote doublequote) for Results where OBX-5 and OBX-6 are empty
OBX-3	Observation Identifier		R	CE	250	The test code. (Observation identifier or Application code.) This identifies the test or analyte, which this message relates to. A cobas e flow test can contain an internally-calculated formula result. Therefore, in the case that variable or formula is a subresult of a cobas e flow test, this field can contain the name of this variable or formula. This field can also contain the host code assigned to this variable or formula. *) cobas e flow test cannot be requested for QC measurement from HOST.
OBX-3.1	Identifier		R	ST	20	For Upload of Raw Data/data points/Abs/RCV values the Identifier defaults to: - ACN+"_EFS" - ACN+"_EFV" - ACN+"_EFC" - ACN+"_PMT" - ACN+"_ABS" - ACN+"_RCV"
OBX-3.2	Text		R	ST	199	Equal to OBX-3.1.
OBX-3.3	Coding system		R	ID	12	Fixed "99ROC"
OBX-3.4	Alternate Identifier		O	ST	20	- "S_RAW" for Raw Data - "S_GRAPH" for Data points/Abs/RCV values
OBX-3.5	Alternate Text		O	ST	199	- "Raw Supplemental" if OBX-3.4 is S_RAW - "Supplemental Graph" if OBX-3.4 is S_GRAPH
OBX-3.6	Alternate coding system		O	ID	12	- Fixed "IHELAW"
OBX-4	Observation Sub-ID (Run number)		R	OG	20	Fixed "1"
OBX-5 if OBX-2 is "NA"						
OBX-5 for photometric raw data (c 303)						
OBX-5	Observation Result		R	NM	16	Raw Data Value

OBX-5 if OBX-2 is "NA" and OBX-3.1 is ACN + "_ABS"						
OBX-5	Observation Result		R	NA	65536	Hint: Only numeric values are allowed, the separator would be for Datatype NA the ^ and the ~ ΔABSValue WaveLengthCategory 1: Main wave length 2: Sub wave length 0: Other Each wave length (e.g. 340nm -> 340) ΔABSValue^WaveLengthCategory1^WaveLengthCategory2~WaveLength1^WaveLength2~CellBlankValue1WaveLength1^CellBlankValue2WaveLength1^...^CellBlankValueNWaveLength1~CellBlankValue1WaveLength2^CellBlankValue2WaveLength2^...^CellBlankValueNWaveLength2~AbsValue1WaveLength1^AbsValue2WaveLength1^.....^AbsValueNWaveLength1~AbsValue1WaveLength2^AbsValue2WaveLength2^.....^AbsValueNWaveLength2
OBX-5 if OBX-2 is "NA" and OBX-3.1 is ACN + "_RCV"						
OBX-5	Observation Result		R	NA	65536	ReactionLimitCheckValue~LinearityCheck~HighDoseHookEffectCheck~KineticUnstableCheck~KineticRoughnessCheck -KineticUnstableCheck The components of Kinetic Unstable Check take the following values and are separated by "^" : CalcResultPriority1^CalcResultPriority2^CalcResultPriority3^CalcResultPriority4^CalcResultPriority5^CalcResultPriority6^CalcResultPriority7^CalcResultPriority8^CalcResultPriority9^CalcResultPriority10 -KineticRoughnessCheck The components of Kinetic Roughness Check take the following values and are separated by "^" : SD1^SD2^SD3
OBX-5 for immuno raw data (e402) and OBX-2 is NM and OBX-3.1 is ACN + "_EFS" or ACN+ "_EFV" or ACN+ "_EFC" or ACN+ "_PMT"						
OBX-5	Observation Result		R	NM	16	Raw Data Value
OBX-5 for immuno data point upload (e402) if OBX-2 is "NA" and OBX-3.1 is ACN + "_EFS" or ACN+ "_EFV" or ACN+ "_EFC"						
OBX-5	Observation Result		R	NA	65536	For immunoassay data point results (Effective signal, Effective Voltage, Effective Current), the components take the following values: (If the value of OBX-3.1 ends with EFS, EFV, EFC) -Data point values (Max. 200) separated by ^ (DataPointValue1^DataPointValue2^...^DataPointValue200) Notes: Data point values is sent to HOST only when raw data batch sending is done)
OBX-6	Unit		R	CE	250	
OBX-6.1	Identifier		R	ST	20	Units of measurement used for measuring the result For photometric raw data, this shows ABS. For result check value, this shows RCV For a raw data/data point result (for Immuno Tests), this shows COUNT.
OBX-6.2	Empty Field					
OBX-6.3	Coding System		R	ID	12	Fixed "99ROC"
OBX-7	Empty Field					

OBX-8	Interpretation flags		R	CWE	250	Data alarms are placed here and also codes that identifies if the result is normal or abnormal. i.e. "76^System reagent temperature^99ROC~HH^HL70078~HU^99ROC" The Interpretation flags needs to be ordered by the priority of the flags, most important first, and least important last. If the field size is not sufficient, The least important alarms should be cut. When no flags are applicable, the HL7 NULL value quotequote ("") must be placed here.
OBX-8.1	Flag identifier		R	ID	3	
OBX-8.2	Text		O	ST		Can be empty
OBX-8.3	Coding system		C	ID	12	Either - "HL70078" for the data alarms defined in HL70078 - "99ROC" for the specified data alarms of cobas® pure - Empty if OBX-8.1 is HL7 NULL value quotequote ("")
OBX-9	Field contains no data.					
OBX-10	Field contains no data.					
OBX-11	Result status		R	ID	1	Result status The definition refer to section 3.2.3.
OBX-12	Field contains no data.					
OBX-13	Field contains no data.					
OBX-14	Field contains no data.					
OBX-15	Field contains no data.					
OBX-16	Responsible observer		R	XCN	25	
OBX-16.1	Observer		R	ST	25	First repetition -- User name of the logged in user Second repetition - fixed "REALTIME" if sent automatically (or as response to a Result Query), fixed "BATCH" if sent manually. Examples: "Klauspeter~BATCH", "Krankenschwester~REALTIME".
OBX-17	Field contains no data.					

OBX-18	Measure ment unit ID		R	EI	427	OBX18.1^OBX18.2~OBX18.1^OBX18.2[~OBX18.1^OBX18.2]																							
OBX-18.1	Entity Identifier		R	ST	50	<table><tr><th colspan="2">1st OBX-18 repetition</th><th colspan="2">2nd OBX-18 repetition</th><th colspan="2">3rd OBX-18 repetition (used only if the result could be mapped onto sub-module)</th></tr><tr><th>OBX-18-1</th><th>OBX-18-2</th><th>OBX-18-1</th><th>OBX-18-2</th><th>OBX-18-1</th><th>OBX-18-2</th></tr><tr><td>Module type (e402, c303, ISE) or empty if result cannot be mapped to Instrume nt (Sample short etc.)</td><td>Manufact urer ID: fixed "ROCHE"</td><td>Modul e serial N^o or cobas ® pure serial numbe r</td><td>Manufac turer ID same as first OBX- 18.2</td><td>Definiti on refers to section 3.2.3.</td><td>Manuf acture r ID same as first OBX- 18.2</td></tr></table>						1 st OBX-18 repetition		2 nd OBX-18 repetition		3 rd OBX-18 repetition (used only if the result could be mapped onto sub-module)		OBX-18-1	OBX-18-2	OBX-18-1	OBX-18-2	OBX-18-1	OBX-18-2	Module type (e402, c303, ISE) or empty if result cannot be mapped to Instrume nt (Sample short etc.)	Manufact urer ID: fixed "ROCHE"	Modul e serial N ^o or cobas ® pure serial numbe r	Manufac turer ID same as first OBX- 18.2	Definiti on refers to section 3.2.3.	Manuf acture r ID same as first OBX- 18.2
1 st OBX-18 repetition		2 nd OBX-18 repetition		3 rd OBX-18 repetition (used only if the result could be mapped onto sub-module)																									
OBX-18-1	OBX-18-2	OBX-18-1	OBX-18-2	OBX-18-1	OBX-18-2																								
Module type (e402, c303, ISE) or empty if result cannot be mapped to Instrume nt (Sample short etc.)	Manufact urer ID: fixed "ROCHE"	Modul e serial N ^o or cobas ® pure serial numbe r	Manufac turer ID same as first OBX- 18.2	Definiti on refers to section 3.2.3.	Manuf acture r ID same as first OBX- 18.2																								
OBX-18.2	Namespa ce ID		R	IS	20																								
OBX-19	Analysis date time		R	TS	14	Time at which the result became available or at which the observation failed.																							
OBX-19.1	Timestam p		R	DTM	14	String in format YYYYMMDDhhmmss																							
OBX-29	Observati on Type		R	ID	4	Fixed "RSLT" (observation result)																							

(4) For calibration results

Table 3.2-26 Field attribute for OBX segment (Calibration result)

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
OBX-0	Field Type		R	ST	3	'OBX' fixed
OBX-1	SetID		R	SI	4	The first segment is 1, then increments by 1 for each subsequent OBX segment.
OBX-2	Value type		R	ID	3	Either: - fixed "DTM" for Pipetting Time - fixed "ST" for Calibration Result of e402 - fixed NA for Calibration Results of c303 and ISE - empty if OBX-4 is "CURVE"
OBX-3	Observation Identifier		R	CE	250	The test code. (Observation identifier or Application code.) This identifies the test or analyte, which this message relates to.
OBX-3.1	Identifier		R	ST	20	Test code of used test "PT" for transfer of Pipetting Time
OBX-3.2	Text		R	ST	199	If OBX-3.1 is "PT" "Pipetting Time" else equal to OBX-3.1

OBX-3.3	Coding system		R	ID	12	Fixed "99ROC"
OBX-3.4	Alternate Identifier		O	ST	20	- "S_OTHER" for Pipetting time (OBX-3.1 is PT) - Else empty
OBX-3.5	Alternate Text		O	ST	199	- "Other Supplemental" if OBX-3.4 is S_OTHER - Else empty
OBX-3.6	Alternate coding system		O	ID	12	Fixed "IHELAW" if OBX-3.4 is not empty Else empty
OBX-4	Observation Sub-ID (Run number)		R	ST	20	Either - Fixed "Curve" for Curve Parameters in OBX-5 Fixed "Signal" for Signals and target values in OBX-5
OBX-5	Result Value		R	ST	65536	If OBX-4 = "Curve" then this field is empty. If OBX-4="Signal" the Signals and target values Hint: To separate the signal, calibration factors, units, , flags and target values etc. use "~"
OBX-5 for photometric check result value (c 303) if OBX-2 is NA and OBX-4 is <u>Signal</u> Format is the following: <i>StandarddeviationvalueData~STD1AbsorbanceValue~STD2AbsorbanceValue~STD3AbsorbanceValue~STD4AbsorbanceValue~STD5AbsorbanceValue~STD6AbsorbanceValue~CalibrationFactor~CalibrationTargetValues</i>						
OBX-5 ₍₁₎	Standard deviation value data		R	NM		Standard deviation value data
OBX-5 ₍₂₎	STD1Absorbance value		R	NM		Absorbance values in STD1, (number types). Format: <i>Absorbance^FirstAbsorbance^FirstInitialAbsorbance^SecondAbsorbance^SecondInitialAbsorbance</i>
OBX-5 ₍₃₎	STD2Absorbance value		R	NM		Absorbance values in STD2, (number types). Format: <i>Absorbance^FirstAbsorbance^FirstInitialAbsorbance^SecondAbsorbance^SecondInitialAbsorbance</i>
OBX-5 ₍₄₎	STD3Absorbance value		R	NM		Absorbance values in STD3, (number types). Format: <i>Absorbance^FirstAbsorbance^FirstInitialAbsorbance^SecondAbsorbance^SecondInitialAbsorbance</i>
OBX-5 ₍₅₎	STD4Absorbance value		R	NM		Absorbance values in STD4, (number types). Format: <i>Absorbance^FirstAbsorbance^FirstInitialAbsorbance^SecondAbsorbance^SecondInitialAbsorbance</i>
OBX-5 ₍₆₎	STD5Absorbance value		R	NM		Absorbance values in STD5, (number types). Format: <i>Absorbance^FirstAbsorbance^FirstInitialAbsorbance^SecondAbsorbance^SecondInitialAbsorbance</i>
OBX-5 ₍₇₎	STD6Absorbance value		R	NM		Absorbance values in STD6, (number types). Format: <i>Absorbance^FirstAbsorbance^FirstInitialAbsorbance^SecondAbsorbance^SecondInitialAbsorbance</i>

OBX-5 ⁽⁸⁾	Calibration Factor		R	NM		KFactor^P1^P2^P3^P4^P5^S1ABS^S2ABS^S3ABS^S4ABS^S5ABS^S6ABS^Intercept^2PIntercept^1P/2PSlops In case of calibration result for line graph and Spline: S1ABS, S2ABS, S3ABS, S4ABS, S5ABS and S6ABS are set. In case of calibration result for RCM1,2,5: P1,P2, P3 and P4 are set. In case of calibration result for RCM3,4: P1,P2,P3,P4 and P5 are set. In case of linear regression and linear slop: Intercept and KFactor are set. 2P Intercept is set when classic 2 point calibration is performed. 1P/2P intercept is sent when classic1 point A, classic 1 point B and classic 2 point calibration is performed.
OBX-5.9 ⁽⁹⁾	Calibration target values		R	NM		Calibration target values TargetValueSTD1^TargetValueSTD2^TargetValueSTD3^TargetValueSTD4^TargetValueSTD5^TargetValueSTD6
OBX-5 if OBX-2 is "DTM" and OBX-3.1 is "PT_"						
OBX-5	Pipetting time		R	DTM		First pipetting time ~Second pipetting time~Third pipetting time The pipetting time in "YYYYMMDDhhmmss" Format. Pipetting Times are separated by "~"
OBX-5 for ISE calibration result if OBX-2 is NA and OBX-4 is Signal						
Format: CalibrationResult~DataAlarm						
OBX-5 ⁽¹⁾	Data		R	NA		Calibration result IS EMF^Low EMF^High EMF^Calib. EMF^Slope for Display^IS Conc^Calib Conc^Carryover^Slope for calculation^Compensate
OBX-5 ⁽²⁾	Data Alarm		R	NA		Data alarm number is set to each field. IS EMF Data Alarm^Low EMF Data Alarm ^High EMF Data Alarm ^Calib EMF Data Alarm ^ Slope for Display Data Alarm ^IS Conc Data Alarm ^Calib Conc Data Alarm ^Carryover Data Alarm ^ Slope for calculation Data Alarm^Compensate Data Alarm
OBX-5 for immunoassay calibration result (e 402)						
(values are separated by "~" i.e. Valid~true~true~...)						
OBX-5 ⁽¹⁾	Result Status		R	ST		- Valid - Invalid This field is used for qualitative and quantitative result.
OBX-5 ⁽²⁾	MissingValue		R	ST		- true (if violation) - false (if no violation) This field is used for qualitative and quantitative result.
OBX-5 ⁽³⁾	MinSignal		R	ST		- true (if violation) - false (if no violation) This field is used for qualitative and quantitative result.
OBX-5 ⁽⁴⁾	MaxSignal		R	ST		- true (if violation) - false (if no violation) This field is used for qualitative and quantitative result.
OBX-5 ⁽⁵⁾	CalibratorFactor		R	ST		Decimal value This field is used for quantitative result.
OBX-5 ⁽⁶⁾	Deviation		R	ST		- true (if violation) - false (if no violation) This field is used for qualitative and quantitative result.

OBX-5 ₍₇₎	Slope		R	ST		- true (if violation) - false (if no violation) This field is used for qualitative result.
OBX-5 ₍₈₎	MinAccept Diff		R	ST		- true (if violation) - false (if no violation) This field is used for quantitative result.
OBX-5 ₍₉₎	SystemError		R	ST		- true (if violation) - false (if no violation) This field is used for qualitative and quantitative result.
OBX-5 ₍₁₀₎	Signal value 1		R	ST		<i>SignalVal1</i> This field is used for qualitative and quantitative result.
OBX-5 ₍₁₁₎	Signal value 2		R	ST		<i>SignalVal2</i> This field is used for qualitative and quantitative result.
OBX-5 ₍₁₂₎	TargetValue Level 1		O	ST		Target Value for Level 1(for quantitative tests). Might be empty
OBX-5 ₍₁₃₎	TargetValue Level 2		O	ST		Target Value for Level 2(for quantitative tests). Might be empty
OBX-5 ₍₁₄₎	TargetValue Level 3		O	ST		Target Value for Level 3(for quantitative tests). Might be empty
OBX-5 ₍₁₅₎	TargetValue Level 4		O	ST		Target Value for Level 4(for quantitative tests). Might be empty
OBX-5 ₍₁₆₎	TargetValue Level 5		O	ST		Target Value for Level 5(for quantitative tests). Might be empty
OBX-5 ₍₁₇₎	Unit		O	ST		Unit
OBX-5 ₍₁₈₎	CUTOff		O	ST		CUT off (for qualitative tests).
OBX-5 ₍₁₉₎	BorderLine AreaUpper Limit		O	ST		BorderLineAreaUpperLimit (for qualitative tests)
OBX-5 ₍₂₀₎	BorderLine AreaLower Limit		O	ST		BorderLineAreaLowerLimit Used for qualitative tests).
OBX-6	unit		R	ST		<u>Unit</u> Required if OBX-2 is - NM - NA Else prohibited
OBX-6.1	Identifier		R	ST	20	Units of measurement used for the result
OBX-6.2	Empty Field					
OBX-6.3	Coding System		R	ID	12	Fixed "99ROC"
OBX-7	Field contains no data.					
OBX-8	Calibration alarm flags.		R	ST	250	If OBX-4.1 = "Curve" the Data Alarms When no alarms are applicable or when OBX-4-1 is not "Curve", the HL7 NULL value quotequote ("") must be placed here.
OBX-8.1	Flag identifier		R	ID	3	The definition refer to section 3.2.3
OBX-8.2	Text		O	ST		Might be empty
OBX-8.3	Name space		C	ID	12	Either - "HL70078" for the data alarms defined in HL7 0078 - "99ROC" for the specified data alarms of cobas® pure - Empty if OBX-8.1 is HL7 NULL value quotequote ("")

OBX-9	Field contains no data.																													
OBX-10	Field contains no data.																													
OBX-11	Field contains no data.		R	ST	1	Fixed "F"																								
OBX-12	Field contains no data.																													
OBX-13	Field contains no data.																													
OBX-14	Field contains no data.																													
OBX-15	Field contains no data.																													
OBX-16	Responsible observer		R	XCN	25																									
OBX-16.1	Observer		R	ST	25	First repetition -- User name of the logged in user Second repetition – fixed "REALTIME" if sent automatically (or as response to a Result Query), fixed "BATCH" if sent manually. Examples: "Klauspeter~BATCH", "Krankenschwester~REALTIME".																								
OBX-17	Observation method		O	CE	250	1 st repetition calibration method, 2 nd repetition calibration result type 3 rd repetition Calibration level The definition refer to section 3.2.3 i.e. Full~Linear~Level1																								
OBX-18	Measurement unit ID		R	EI	427	<table><tr><th colspan="2">1st OBX-18 repetition</th><th colspan="2">2nd OBX-18 repetition</th><th colspan="2">3rd OBX-18 repetitions</th></tr><tr><th>OBX-18-1</th><th>OBX-18-2</th><th>OBX-18-1</th><th>OBX-18-2</th><th>OBX-18-1</th><th>OBX-18-2</th></tr><tr><td>Module type (e402, c303, ISE) or empty if result at cannot be mapped to Instrument (Sample short etc.)</td><td>Manufacturer ID Should be defined. Preferred: ROCHE</td><td>Module serial N° or cobas® pure serial number</td><td>Manufacturer ID same as first OBX-18.2</td><td>Definition refers to section 3.2.3.</td><td>Manufacturer ID same as first OBX-18.2</td></tr><tr><td colspan="6">.</td></tr></table>	1 st OBX-18 repetition		2 nd OBX-18 repetition		3 rd OBX-18 repetitions		OBX-18-1	OBX-18-2	OBX-18-1	OBX-18-2	OBX-18-1	OBX-18-2	Module type (e402, c303, ISE) or empty if result at cannot be mapped to Instrument (Sample short etc.)	Manufacturer ID Should be defined. Preferred: ROCHE	Module serial N° or cobas® pure serial number	Manufacturer ID same as first OBX-18.2	Definition refers to section 3.2.3.	Manufacturer ID same as first OBX-18.2	.					
1 st OBX-18 repetition		2 nd OBX-18 repetition		3 rd OBX-18 repetitions																										
OBX-18-1	OBX-18-2	OBX-18-1	OBX-18-2	OBX-18-1	OBX-18-2																									
Module type (e402, c303, ISE) or empty if result at cannot be mapped to Instrument (Sample short etc.)	Manufacturer ID Should be defined. Preferred: ROCHE	Module serial N° or cobas® pure serial number	Manufacturer ID same as first OBX-18.2	Definition refers to section 3.2.3.	Manufacturer ID same as first OBX-18.2																									
.																														
OBX-18.1	Entity Identifier		R	ST	50																									
OBX-18.2	Namespace ID		R	IS	20																									
OBX-19	Result time		R	TS	26	Time at which result is available.																								
OBX-21	Calibration ID		R	EI		Calibration Identifier must be unique for all calibrations (i.e. GUID) and is only sent if OBX-4 = "CURVE"																								

Table 3.2-27 Field attribute for OBX segment (calibration raw data – only used for photometric calibrations)

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
OBX-0	Field Type		R	ST	3	'OBX' fixed
OBX-1	SetID		R	NM	4	The first segment is 1, then increments by 1 for each subsequent OBX segment. Reset is done by new OBR-Segment
OBX-2	Value type		R	ID	3	Fixed "NA" (numeric array)
OBX-3	Observation Identifier		R	CE	250	The test code. (Observation identifier or Application code.) This identifies the test or analyte, which this message relates to.
OBX-3.1	Identifier		R	ST	20	For Upload of ABS/RCV values the Identifier defaults to: ACN+"_ABS" ACN+"_RCV"
OBX-3.2	Text		R	ST	199	Equal to OBX-3.1.
OBX-3.3	Coding system		R	ID	12	Fixed "99ROC"
OBX-3.4	Alternate Identifier		O	ST	20	fixed "S_GRAPH" for ABS/RCV values
OBX-3.5	Alternate Text		O	ST	199	fixed "Supplemental Graph" if OBX-3.4 is S_GRAPH
OBX-3.6	Alternate coding system		O	ID	12	Fixed "IHELAW"
OBX-4	Observation Sub-ID (Run number)		R	OG	20	
OBX-4.1	Run Number		R	ST	20	Fixed "1"
OBX-4.2	Group ID		R	NM	5	Fixed "1"
OBX-4.3	Pipetting Number		O	NM	5	Pipetting number either: - 1 or 2 - Empty if OBX-3.1 is ACN+"_RCV" <i>PipettingNumber</i> means as below: <i>1: First pipetting</i> <i>2: Second pipetting</i>

OBX-5 for photometric raw data (c303) and OBX-3.1 is ACN + "_ABS"						
OBX-5	Observation Result		R	NA	65536	Hint: Only numeric values are allowed, the separator would be for Datatype NA the ^ and the ~ ΔABSValue Wavelength Each wave length (e.g. 340nm -> 340) WaveLengthCategory 1: Main wave length 2: Sub wave length 0: Other Each wave length (e.g. 340nm -> 340) ΔABSValue^WaveLengthCategory1^WaveLengthCategory2~WaveLength1^WaveLength2~CellBlankValue1WaveLength1^CellBlankValue2WaveLength1^...^CellBlankValueNWaveLength1~CellBlankValue1WaveLength2^CellBlankValue2WaveLength2^...^CellBlankValueNWaveLength2~AbsValue1WaveLength1^AbsValue2WaveLength1^.....^AbsValueNWaveLength1~AbsValue1WaveLength2^AbsValue2WaveLength2^.....^AbsValueNWaveLength2
OBX-5 for photometric raw data (c303) and OBX-3.1 is ACN + "_RCV"						
OBX-5	Observation Result		R	NA	65536	SDLimitCheck
OBX-6	Field contains no data.					
OBX-7	Field contains no data.					
OBX-8	Field contains no data.					
OBX-9	Field contains no data.					
OBX-10	Field contains no data.					
OBX-11	Field contains no data.		R	ST	1	Fixed "F"
OBX-12	Field contains no data.					
OBX-13	Field contains no data.					
OBX-14	Field contains no data.					
OBX-15	Field contains no data.					
OBX-16	Responsible observer		R	XCN	25	
OBX-16.1	Observer		R	ST	25	First repetition -- User name of the logged in user Second repetition – fixed "REALTIME" if sent automatically (or as response to a Result Query), fixed "BATCH" if sent manually. Examples: "Klauspeter~BATCH", "Krankenschwester~REALTIME".

OBX-17	Observation method		O	CE	250	1 st repetition calibration method, 2 nd repetition calibration result type 3 rd repetition Calibration level The definition refers to section 2.4.3 i.e. Full~Linear Level1					
OBX-18	Measurement unit ID		R	EI	427	OBX18.1^OBX18.2~ OBX18.1^OBX18.2~OBX18.1^OBX18.2 .					
						1 st OBX-18 repetition		2 nd OBX-18 repetition		3 rd OBX-18 repetitions	
						OBX-18-1	OBX-18-2	OBX-18-1	OBX-18-2	OBX-18-1	OBX-18-2
						Module type (e 402, c 303, ISE) or empty if result at cannot be mapped to Instrument (Sample short etc.)	Manufacturer ID Should be defined. Preferred: ROCHE	Module serial N° or cobas® pure serial number	Manufacturer ID same as first OBX-18.2	Definition refers to section 3.2.3.	Manufacturer ID same as first OBX-18.2
OBX-19	Result time		R	TS	26	Time at which result is available.					
OBX-21	Field contains no data.										

Table 3.2-28 Field attribute for OBX segment for QC/Calibration request to identify module/submodule

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments					
OBX-0	Field Type		R	ST	3	'OBX' fixed					
OBX-1	SetID		R	NM	4	The first segment is 1, then increments by 1 for each subsequent OBX segment. Reset is done by new OBR-Segment					
OBX-2	Value type		R	ID	3	Fixed "EI" (Entity Identifier)					
OBX-3	Observation Identifier		R	CE	250	The test code. (Observation identifier or Application code.) This identifies the test or analyte, which this message relates to.					
OBX-3.1	Identifier		R	ST	20	Fixed "74720-4"					
OBX-3.2	Text		R	ST	199	Fixed "Device Name"					
OBX-3.3	Coding system		R	ID	12	Fixed "LN"					
OBX-4	Field contains no data.										
OBX-5	Observation Result		R	EI	65536	Device Identifier OB5.1^OBX5.2~ OBX5.1^OBX5.2~OBX5.1^OBX5.2 i.e. e402^ROCHE~1234-56^ROCHE~1^ROCHE					
						1 st OBX-5 repetition		2 nd OBX-5 repetition		3rd OBX-5 repetitions	
						OBX-5-1	OBX-5-2	OBX-5-1	OBX-5-2	OBX-5-1	OBX-5-2
						Module type (e402, c303, ISE)	Manufacturer ID should be defined. Preferred: ROCHE	Module Serial № or cobas® pure serial number	Manufacturer ID same as first OBX-5.2	Submodule ID 1 or 2, 0 (zero) otherwise.	Manufacturer ID same as first OBX-5.2
OBX-6	Field contains no data.										
OBX-7	Field contains no data.										
OBX-8	Field contains no data.										
OBX-9	Field contains no data.										
OBX-10	Field contains no data.										
OBX-11	Observation Result Status.		R	ST	1	Fixed "O"					

3.2.4.9. Patient Identification Segment (PID)

cobas® pure shall use the patient identification segment to send patient information in a Result Report message. The host shall use the patient identification segment to send patient information in a test selection download message.

The data structure is shown in Table 3.2-29.

Table 3.2-29 Field attribute for PID segment

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
PID-0	Field Type	R	R	ST	3	'PID' fixed
PID -1						
PID -2						
PID -3	Patient ID	R	R	CX	278	PID-3-1: Patient ID
PID-3.1	Patient ID	R	R	ST	50	Patient ID
PID -4	Field contains no data.					
PID -5	Patient legal name	R	R	XP	250	Only the name type code is allowed.
PID -5.7	Name type code	R	R	ID	1	fixed to "U" for unspecified name (all other components empty)
PID -6	Field contains no data.					
PID -7	Date of birth. Patient age shall be calculated based on this value and under consideration of the sample registration date.	O	O	TS	26	Date in YYYYMMDD format
PID -8	Administrative Sex of patient	O	O	IS	1	Sex of patient - M Male - F Female - U Unknown. Any other value defaults to unknown, and is returned to the host as U.

3.2.4.10. Query Parameter Definition Segment (QPD) for test selection inquiry

cobas® pure shall use the query parameter segment in an inquiry for a test selection to give details of the sample. The data structure is shown in Table 3.2-30, Table 3.2-31.

Table 3.2-30 Field attribute for QPD segment for a test selection inquiry in Barcode Mode

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
QPD-0	Field Type		R	ST	3	'QPD' fixed
QPD -1	Message Name		R	ST	250	Query Name
QPD-1.1	Identifier		R	ST	20	Either: - "INIBAR" for Initial query - "RRRBAR" for RRR queries (Repeat Rerun Reflex)
QPD-1.2	Field contains no data.					
QPD-1.3	Coding system		R	ID	12	Fixed "99ROC"
QPD -2	Query Tag		R	ST	32	Query tag to identify the query. A GUID should be used
QPD -3	Container ID		R	EI	256	Contains the Sample ID.
QPD -3.1	Entity identifier		R	ST		Either: - "*****" (22 asterisks) in case of Barcode Read Error. - Sample ID (else)
QPD -4	Rack ID		R	ST	80	Rack ID
QPD -5	Position No		R	NA	80	Position of Sample on Rack (1-5)
QPD -6	Field contains no data.					
QPD -7	Field contains no data.					
QPD -8	Field contains no data.					
QPD -9	Field contains no data.					
QPD -10	Sample Type		R	CE	256	Sample Type i.e. SERPLAS^^99ROC Definition refer to section 3.2.3
QPD -11	Sample container type		R	CE	256	Sample container type. Definition refer to section 3.2.3 i.e. SC^^99ROC Note: If the host sends no container type value, cobas® pure decides the sample container type based on the instrument logic.
QPD -12	Priority		R	ST	256	Code indicating the original priority of the rack. - S STAT - R Routine

Table 3.2-31 Field attribute for QPD segment for a test selection inquiry Query in Sequence Mode

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
QPD-0	Field Type		R	ST	3	'QPD' fixed
QPD -1	Message Name		R	ST	250	Query Name
QPD-1.1	Identifier		R	ST	20	Either: - "INISEQ" for Initial query - "RRRSEQ" for RRR queries (Repeat Rerun Reflex)
QPD-1.2	Test		R	ST	199	
QPD-1.3	Coding system		R	ID	12	Fixed "99ROC"
QPD -2	Query Tag		R	ST	32	Query tag to identify the query. A GUID should be used
QPD -3	Container ID		R	EI	256	Contains the Sequence Number
QPD -3.1	Entity identifier		R	ST		Sequence Number
QPD -4	Rack ID		R	ST	80	Rack ID
QPD -5	Position No		R	NA	80	Position of Sample on Rack (1-5)
QPD -6	Field contains no data.					
QPD -7	Field contains no data.					
QPD -8	Field contains no data.					
QPD -9	Field contains no data.					
QPD -10	Sample Type		R	CE	256	Sample Type i.e. SERPLAS^^99ROC Definition refer to section 3.2.3
QPD -11	Sample container type		R	CE	256	Sample container type. Definition refer to section 3.2.3 i.e. SC^^99ROC Note: If the host sends no container type value, cobas® pure decides the sample container type based on the instrument logic.
QPD -12	Priority		R	ST	256	Code indicating the priority. - S STAT - R Routine

3.2.4.11. Query Parameter Definition Segment (QPD) for a result and order query

The host uses the query parameter segment (QPD) in a result query to inquire for the measurement results for a given sample.

The data structure is shown in Table 3.2-32 and Table 3.2-33.

Table 3.2-32 Field attribute for QPD segment for a result and order query Sample ID Mode

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
QPD-0	Field Type	R		ST	3	'QPD' fixed
QPD -1	Message Name	R		ST	250	
QPD-1.1	Identifier	R		ST	20	Fixed "REQSID"
QPD-1.2	Text	R		ST	199	Fixed "Query Sample Mode"
QPD-1.3	Coding system	R		ID	12	Fixed "99ROC"
QPD -2	Query Tag	R		ST	32	Query tag to identify the query. A GUID should be used
QPD -3	Sample Identifier.	R				Sample Identifier
QPD -3.1	Entity identifier	R				Sample ID
QPD -4	Field contains no data.					
QPD -5	Field contains no data.					
QPD -6	Field contains no data.					
QPD -7	Field contains no data.					
QPD -8	Field contains no data.					
QPD -9	Field contains no data.					
QPD -10	Sample Type	R		CE	256	Sample Type i.e. SERPLAS^ ^99ROC Definition refer to section 3.2.3
QPD -11	Field contains no data.					.
QPD -12	Priority	R		ST	256	Code indicating the priority. - S STAT - R Routine
QPD -13	Query kind	O		ST	256	.A one-character code. - "A" Query for all results and orders - "F" Query only for Final results - "O" Query only for open orders - Empty defaults to "A"

Table 3.2-33 Field attribute for QPD segment for a result and order query Sequence Mode

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
QPD-0	Field Type	R		ST	3	'QPD' fixed
QPD -1	Message Name	R		ST	250	
QPD-1.1	Identifier	R		ST	20	Fixed "REQSEQ"
QPD-1.2	Text	R		ST	199	Fixed "Query Sequence Mode"
QPD-1.3	Coding system	R		ID	12	Fixed "99ROC"
QPD -2	Query Tag	R		ST	32	Query tag to identify the query. A GUID should be used
QPD -3	Sample Identifier.	R				Sequence Identifier
QPD -3.1	Entity identifier	R				Sequence Number
QPD -4	Field contains no data.					
QPD -5	Field contains no data.					
QPD -6	Field contains no data.					
QPD -7	Field contains no data.					
QPD -8	Field contains no data.					
QPD -9	Field contains no data.					
QPD -10	Sample Type	R		CE	256	Sample Type i.e. SERPLAS^ ^99ROC Definition refer to section 3.2.3
QPD -11	Field contains no data.					
QPD -12	Priority	R		ST	256	Code indicating the priority. - S STAT - R Routine
QPD -13	Query kind	O		ST	256	One-character code - "A" Query for all results and orders - "F" Query only for Final results - "O" Query only for open orders - Empty defaults to "A"

3.2.4.12. Response Control Parameter Segment (RCP)

cobas® pure and the host shall use the response control parameter segment (RCP) with a query message (test selection inquiry, result query, order query) to specify the priority of the message.

The data structure is shown in Table 3.2-34.

Table 3.2-34 Field attribute for RCP segment

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
RCP-0	Field Type	R	R	ST	3	'RCP' fixed
RCP -1	Query priority	R	R	ST	1	Query priority (immediate), fixed string I
RCP -2	Query limited request	O	R	NM	10	Query limited request, fixed value 1
RCP -3	Response modality	O	R	ST	250	Response modality, fixed character value "R^HL70394"

3.2.4.13. Specimen Container Detail Segment (SAC)

cobas® pure shall use the specimen container detail (SAC) segment to identify the location of the sample's container in a result report or in a test selection request message.

The data structure is shown in Table 3.2-35, Table 3.2-36, Table 3.2-37, and Table 3.2-38.

Table 3.2-35 Field attribute for SAC segment (Sample Request/Upload)

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
SAC-0	Field Type	R	R	ST	3	'SAC fixed
SAC -1	Field contains no data.					
SAC -2	Field contains no data.					
SAC -3	Patient sample Information Calibration information	R	R	EI:	80	
SAC-3.1	Sample ID/Sequence Number	O	O	ST	22	If SAC-3.2 is "BARCODE" the Sample ID of the Sample If SAC-3.2 is "SEQUENCE" the Sequence Number of the Sample
SAC-3.2	Type	O	O	ST	10	Either: - Fixed "BARCODE" for Barcodes in SAC-3.1 or - Fixed "SEQUENCE" for Sequence Number in SAC-3.1 or
SAC -4	Field contains no data.					
SAC -5	Field contains no data.					
SAC -6	Field contains no data.					
SAC -7	Field contains no data.					
SAC -8	Field contains no data.					
SAC -9	Field contains no data.					
SAC -10	Rack ID	O	O	EI	80	Rack barcode ID

						In case of OML^O33^OML_O33 (realtime), this data must be set. In case of OML^O33^OML_O33 (batch), this data must be empty.
SAC -11	Position No	O	O	NA	80	Position on rack (1-5) In case of OML^O33^OML_O33 (realtime), this data must be set. In case of OML^O33^OML_O33 (batch), this data must be empty.
SAC-29	Pre-Dilution Code	O	O	SN	10	Either: - “^1^: ^1” or empty for a not pre-diluted sample or - “^1^+” for a pre-diluted sample

Table 3.2-36 SAC-10/SAC-11 optional condition

Sample Recognition Mode	Sample Identification	Rerun Rack Allocation	Sample Barcode Read Status	Sample Type	Rack ID / Position No. information
Sample ID Mode	Routine / STAT	-	Successful / Manual Registration	Mixed Sample Type	Not omissible
				Others	Omissible
			Failed	Mixed Sample Type	Not omissible
				Others	Not omissible
Sequence Number Mode	Routine	-	-	Mixed Sample Type	Omissible
	STAT	-	-	Mixed Sample Type	Not omissible
	Manual Rerun	Yes	-	Mixed Sample Type	Omissible
		No	-	Mixed Sample Type	Not omissible

Table 3.2-37 Field attribute for SAC segment (QC/Calibration Upload)

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
SAC-0	Field Type	R	R	ST	3	'SAC fixed
SAC -1	Field contains no data.					
SAC -2	Field contains no data.					
SAC -3	Patient sample Information Calibration information	R	R	El:	80	
SAC-3.1	Sample ID/Sequence Number	O	O	ST	22	If SAC-3.2 is “CALIBRATOR” the calibrator code If SAC-3.2 is “CONTROL” the control material code
SAC-3.2	Type	O	O	ST	10	Either: - Fixed “CALIBRATOR” for Calibrator Code in SAC-3.1 or - Fixed “CONTROL” for control material code in SAC-3.1
SAC -4	Field contains no data.					
SAC -5	Field contains no data.					
SAC -6	Field contains no data.					
SAC -7	Field contains no data.					
SAC -8	Field contains no data.					

SAC -9	Field contains no data.					Fixed "Lot^^99ROC"
SAC -10	Lot Number	0	0	El	80	Lot number
SAC -11	Position No	0	0	NM	80	Bottle Count Number

Table 3.2-38 Field attribute for SAC segment for QC/Calibration Request

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
SAC-0	Field Type	R	R	ST	3	'SAC fixed
SAC -1	Field contains no data.					
SAC -2	Field contains no data.					
SAC -3	Reagent Container Code	R	R	EI:	80	Reagent Container Code
SAC -4	Field contains no data.					
SAC -5	Field contains no data.					
SAC -6	Field contains no data.					
SAC -7	Field contains no data.					
SAC -8	Field contains no data.					
SAC -9	Field contains no data.					Fixed "Lot^ ^99ROC"
SAC -10	Lot Number	O	O	EI	80	Lot number
SAC -11	Position No	O	O	NM	80	Bottle Count Number

3.2.4.14. Specimen Segment (SPM)

cobas® pure uses the specimen segment to send information about the specimen in a Result Report message, and in a test selection upload message. The host uses the specimen segment to send information about the specimen in a test selection download message.

The data structure is shown in Table 3.2-39, Table 3.2-40 and Table 3.2-41.

(1) SPM in test selections, patient results and quality control results

Table 3.2-39 Field attribute for SPM segment for test selections, patient results and quality control results

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
SPM-0	Field Type	R	R	ST	3	'SPM' fixed
SPM -1	Sequence number.	R	R			Fixed "1"
SPM-2 for patient sample						
SPM -2	Patient sample Information	R	R	EIP:	80	Patient results when using sample IDs (default) For Patient Results, the number or alphanumeric string read from sample's barcode, (string of max. 22 characters padding not allowed). Note this is a simple string field in this situation.
SPM-2.1	Placer assigned specimen ID	R	R	EI		i.e. 4711&BARCODE

SPM -2.1.1	Sample ID/Sequence Number	R	R	ST	22	If SPM-2.1.2 is "BARCODE" the Sample ID of the Sample If SPM-2.1.2 is "SEQUENCE" the Sequence Number of the Sample
SPM -2.1.2	Type	R	R	IS	10	Either: - Fixed "BARCODE" for Barcodes in SPM-2.1 or - Fixed "SEQUENCE" for Sequence Number in SPM-2.1
SPM-2 for control sample						
SPM -2	Control sample Information	R	R	EIP	80	Control Identifier (Control Code, Control Name,
SPM-2.1	Placer assigned specimen ID	R	R	EI		i.e. 301&CONTROL
SPM -2.1.1	Control Code	R	R	ST	22	Control material Code
SPM -2.1.2	Type	R	R	IS	10	Fixed "CONTROL" for Controls in SPM-2.1
SPM -3	Field contains no data.					
SPM -4	Specimen Type	R	R	CWE	250	Specimen Type according to table "Sample Type" in 3.2.3 If QC Sample this is either - "" null (Double quote double quote) (for ISE & c303) - Specimen Type according to table "Sample Type" in section 3.2.3.
SPM-4.1	Identifier	R	R	ST	20	Specimen Type according to table "Sample Type" in section 3.2.3
SPM-4.2	Text	O	O	ST	199	Empty
SPM-4.3	Coding system id	R	R	ID	12	If no ISE or c303 QC Sample either - "HL70487" - "99ROC"
SPM-5	Field contains no data.					
SPM-6	Field contains no data.					
SPM-7	Field contains no data.					
SPM-8	Field contains no data.					
SPM-9	Field contains no data.					
SPM-10	Field contains no data.					
SPM-11	Specimen role	R	R	CWE	250	Specimen role. This is a code that identifies what purpose the specimen is used for.
SPM-11.1	Identifier	R	R	ST	20	Either - P for Patient Sample - Q for QC - U only when ORC-1 equals to "DC", i.e. when the specimen is unknown and/or there are no orders for it ("negative query response")
SPM-11.2	Field contains no data					

SPM-11.3	Coding system	R	R	ID	12	Fixed "HL70369"
SPM-12	Field contains no data.					
SPM-13	Field contains no data.					
SPM-14	Comment	O	O	ST	250	Specimen description in format: <u>C1~C2~C3~C4~C5</u> - C1 Sample Comment 1. String with up to 30 characters - C2 Sample Comment 2. String with up to 25 characters - C3 Sample Comment 3. String with up to 20 characters - C4 Sample Comment 4. String with up to 15 characters - C5 Sample Comment 5. String with up to 10 characters These comments are visible on the control unit.
SPM-15	Field contains no data.					
SPM-16	Field contains no data.					
SPM-17	Specimen collection date / time	O	O	TS	26	Specimen collection date / time. (YYYYMMDDHHMMSS)
SPM-18	Field contains no data					
SPM-19	Expiration date time		O	TS	26	Expiration date of control (YYYYMMDD, DD is set to the final day of the month.)
SPM-20	Field contains no data.					
SPM-21	Field contains no data.					
SPM-22	Field contains no data.					
SPM-23	Field contains no data.					
SPM -24	Specimen Condition		O	CWE	250	Either: "PSCO^^99ROC" (potential sample carry over) or empty Note: "#" in screen corresponds to "PSCO^^99ROC" "b" or "empty " in screen corresponds to empty
SPM-25	Field contains no data.					
SPM-26	Field contains no data.					
SPM -27	Container type	O	R		250	Container type. Definition refers to section 3.2.3 i.e. SC^^99ROC

(2) SPM in calibration results

Table 3.2-40 Field attribute for SPM segment for calibration result

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
SPM-0	Field Type		R	ST	3	'SPM' fixed
SPM -1	Field contains no data.					
SPM -2	Calibrator information		R	EIP:	80	
SPM-2.1	Placer assigned specimen ID		R	EI		i.e. 901&CALIBRATOR
SPM-2.1.1	Calibrator Identifier		R	ST	22	The calibrator code
SPM-2.1.2	Type		R	IS	10	Fixed "CALIBRATOR" for Calibrator Code in SAC- 2.1
SPM -3	Field contains no data.					
SPM -4	Specimen Type		R	CWE	250	Specimen Type Must be according to HL70487
SPM-4.1	Identifier		R	ST	20	Fixed "ORH" for Calibrators
SPM-4.2	Text		O	ST	199	Empty
SPM-4.3	Coding system		R	ID	12	Fixed "HL70487"
SPM-5	Field contains no data.					
SPM-6	Field contains no data.					
SPM-7	Field contains no data.					
SPM-8	Field contains no data.					
SPM-9	Field contains no data.					
SPM-10	Field contains no data.					
SPM-11	Specimen role		R	CWE	250	Specimen role. This is a code that identifies what purpose the specimen is used for.
SPM-11.1	Identifier		R	ST	20	Fixed "C" for Calibrator
SPM-11.2	Field contains no data					
SPM-11.3	Coding system		R	ID	12	HL70369
SPM-19	Expiration date time		O	TS	26	Expiration date of control (YYYYMMDD, DD defaults is set to the final day of the month.)

(3) SPM in QC/calibration request

Table 3.2-41 Field attribute for SPM segment for QC/calibration request

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
SPM-0	Field Type	R		ST	3	'SPM' fixed
SPM -1	Field contains no data.					
SPM -2	Specimen information	R		EID	80	Material code
SPM -3	Field contains no data.					
SPM -4	Specimen Type	R		CWE	250	
SPM-4.1	Identifier	R		ST	20	For Calibrator: Fixed "ORH" If QC Sample this is either - "" null (Double quote double quote) (for ISE & c303) Specimen Type according to table "Sample Type" in section 3.2.3
SPM-4.2	Text	O		ST	199	Empty
SPM-4.3	Coding system id	R		ID	12	If SPM-4.1 is not "" null Sample either - "HL70487" - "99ROC" According to table Sample Type in section 3.2.3
SPM-5	Field contains no data.					
SPM-6	Field contains no data.					
SPM-7	Field contains no data.					
SPM-8	Field contains no data.					
SPM-9	Field contains no data.					
SPM-10	Field contains no data.					
SPM-11	Specimen role	R		CWE	250	Specimen role. This is a code that identifies what purpose the specimen is used for.
SPM-11.1	Identifier	R		ST	20	Either Fixed "C" for Calibrator or Fixed "Q" for QC
SPM-11.2	Field contains no data					
SPM-11.3	Coding system	R		ID	12	HL70369

3.2.4.15. Test Code Detail Segment (TCD)

cobas® pure shall use the test code detail segment in result report message to give dilution factors.

The data structure is shown in Table 3.2-42.

Table 3.2-42 Field attribute for TCD segment

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
TCD-0	Field Type	R	R	ST	3	'TCD' fixed
TCD-1	Universal service identifier	R	R	CE	250	Should correspond to OBX-3.
TCD-1.1	Identifier	R	R	ST	20	Test code defaults to the ACN
TCD-1.2	Text	R	R	ST	199	Fixed empty
TCD-1.3	Coding system	R	R	ID	12	Fixed "99ROC"
TCD-2	Auto-dilution factor	O	O	SN	20	For photometric test, the pipetting volume and dilution ratio is as follows. ➤ Normal ➤ Increase ➤ Decrease ➤ 1:3 ➤ 1:5 ➤ 1:10 ➤ 1:20 ➤ 1:50 For HbA1c test, the pipetting volume and dilution ratio is as follows. ➤ Normal ➤ Increase ➤ Decrease For ISE test, the pipetting volume and dilution ratio is as follows. ➤ Normal ➤ Increase ➤ Decrease For immunology test, the pipetting volume and dilution ratio is as follows. ➤ Normal * ➤ Decrease * ➤ 1:1 ➤ 1:1.1 ➤ 1:2 ➤ 1:5 ➤ 1:10 ➤ 1:20 ➤ 1:30 ➤ 1:50 ➤ 1:100 ➤ 1:400 ➤ 1:900 ➤ 1:27000 * It is analyzed at the dilution ratio according to the dilution ratio setting defined in the application parameter, and it is displayed by the dilution ratio.

						Example: ^1^:^5 –diluted, dilution factor 1 to 5 ^1^:^1 – not diluted Empty – not diluted ^1^+ diluted, factor unknown ^1^- concentrated, factor unknown
TCD-2.1	Empty					
TCD-2.2	Num1	R	R	NM	1	Fixed “1”
TCD-2.3	Separator/Suffix	R	R	ST	1	“:” (colon) – numeric dilution factor is provided in TCD-2.4 “+” – dilution factor must be determined by the instrument “-” – concentration factor must be determined by the instrument
TCD-2.4	Dilution factor	O	O	NM	15	Positive number if TCD-2.3 = “:”, otherwise prohibited

3.2.4.16. Common Order Segment (ORC)

cobas® pure shall use the common order segment to determine what to do with the ordered test
The data structure is shown in Table 3.2-43, Table 3.2-44 and Table 3.2-45.

Table 3.2-43 Field attribute for ORC segment for OML^O33

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
ORC-0	Field Type	R	R	ST	3	‘ORC’ fixed
ORC-1	Order control	R	R	ST	250	For OML_O33 Either: “NW” – New order “CA” Order cancellation “DC” Discontinue - when no orders are available for sample
ORC-9	Transaction date/time	R	R	TS	14	If Answer to Test Selection Request from host empty.
ORC-9.1	Timestamp	R	R	DTM	14	YYYYMMDDhhmmss

Table 3.2-44 Field attribute for ORC segment for ORL^34^ORL_O42

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
ORC-0	Field Type	R	R	ST	3	‘ORC’ fixed
ORC-1	Order control	R	R	ST	250	If ORC-1 in OML_O33 is NW either “OK” – order accepted “UA” – unable to accept (including the case that the unknown test items are ordered.) If ORC-1 in OML_O33 is CA either “CR” – canceled as requested “UC” – unable to cancel (including the case that the unknown test items are ordered.)
ORC-5	Order status		R	ID	2	Either: “SC” in process scheduled “IP” in process unspecified “CA” order is canceled “CM” order is completed (No use)

Table 3.2-45 Field attribute for ORC segment for OUL_R22 and OUL_R23

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
ORC-0	Field Type	R	R	ST	3	'ORC' fixed
ORC-1	Order control	R	R	ST	250	Fixed "SC"
ORC-5	Order status		R	ID	2	Either: "A" some but not all results available "CM" order is completed

The following table shows correspondence of ORC fields in request and response messages:

ORC-1 in the incoming OML^033	Possible values of ORC-1 in ORL^034	Possible values of ORC-5 in ORL^034
Fixed "NW" (new order)	Fixed "OK" (order accepted)	Fixed "SC" (in process, scheduled) Fixed "IP" (in process, unspecified)
	Fixed "UA" (unable to accept)	Fixed "CA" (canceled)
Fixed "CA" (cancel order)	Fixed "CR" (canceled as requested)	Fixed "CA" (canceled)
	Fixed "UC" (unable to cancel)	Fixed "IP" (in process, unspecified) Fixed "CM" (completed)

3.2.4.17. Query Acknowledge Segment (QAK)

cobas® pure uses this segment in a test selection acknowledge to acknowledge the test selection inquiry. The data structure is shown in Table 3.2-46.

Table 3.2-46 Field attribute for QAK segment

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
QAK-0	Field Type	R	R	ST	3	'QAK' fixed
QAK -1	Query tag	R	R	ST	32	Copy of QPD-2 from request message
QAK -2	Query response status	R	R	ID	2	One of: "OK" – no errors "AR" – Query is rejected "AE" – Query is accepted, but its processing has failed
QAK -3	Message query name.	R	R	CE	250	Copy of QPD-1 from request message
QAK -3.1	Identifier	R	R	ST	20	Copy of QPD-1.1 from request message
QAK -3.2	Text	R	R	ST	199	Copy of QPD-1.2 from request message
QAK -3.3	Coding system	R	R	ID	12	Copy of QPD-1.3 from request message

3.2.4.18. Timing/Quantity Segment (TQ1)

cobas® pure uses this segment in a test selection message (optionally) and in a result report message. The host uses this segment in a test selection messages (optionally).

The data structure is shown in Table 3.2-47.

Table 3.2-47 Field attribute for TQ1 segment

Field	Element Name	OPT (From HOST)	OPT (From cobas pure)	DT	LEN	Comments
TQ1-0	Field Type	R	R	ST	3	'TQ1' fixed
TQ1 -1	Field contains no data					
TQ1 -2	Field contains no data.					-
TQ1 -3	Field contains no data.					
TQ1 -4	Field contains no data.					
TQ1 -5	Field contains no data.					
TQ1 -6	Field contains no data.					
TQ1 -7	Field contains no data.					
TQ1 -8	Field contains no data.					
TQ1 -9	Priority	R	R	CWE	250	Priority -
TQ1 -9.1	Priority	R	R	ST	1	Priority - S STAT sample. STAT samples must be placed on a STAT rack. Not available in Test Order Submission (OML^O33^OML O33 (batch)) if SPM-2.1.2 is "SEQUENCE" - R Routine sample (default) CS Change Priority sample (routine sample with STAT priority by Urgent Analysis function). "CS" only available in Test Order Submission (OML^O33^OML_O33 (realtime))
TQ1 -9.2	Field contains no data.					
TQ1 -9.3	Coding system	R	R	ID	12	- Fixed "HL70485"

3.3. Example Messages

The table indicates the sending result data by executing the several action.

Table 3.3-1 Result send data list by batch

Sample	Action 1	Action 2	Result send data				
			Send data	Conc.	Photometry (Reaction Data)	Immunoassay (Raw Data)	ISE (Raw Data)
Patient, QC	Open "Sample & QC Result" Screen Select sample Execute "Send To HOST" (Condition: All/Not Sent To HOST, 1st/Rerun/Selected)	Result	All test items of selected sample	Yes	N/A	N/A	N/A
		Reaction Monitor	Selected test item of selected sample	Yes	2 wavelength reaction data	-	-
		Raw	Selected test item of selected sample	Yes	-	Immuno Raw Data	-
Patient, QC	Open "Reaction Monitor" Screen Execute "Send To HOST"	-	Selected test item of selected sample	Yes	2 wavelength reaction data	-	-
Calib	Open Calibration "Results" Screen Select test item Execute "Send To HOST"	-	Selected test item	Yes	2 wavelength reaction data	-	-

Table 3.3-2 Result send data list by Realtime

Sample	Conc.	Photometry (Reaction Data)	Immunoassay (Raw Data)	ISE(Raw Data)
Patient	Yes	N/A	N/A	N/A
QC	Yes	N/A	N/A	N/A
Calib	Yes	N/A	N/A	N/A

3.3.1. OML_033 Message from host with test order

Application Code: 20630

Sample ID: 2022101

```
MSH|^~\&|Host||cobasPure||20221216145008+0200||OML^033^OML_033|5194fe1c-89fc-4de9-8|P|2.5.1|||NE|AL||UNICODE UTF-8||LAB-28R^ROCHE
PID||000008||^U||20000101|F
SPM|1|2022101&BARCODE|SERPLAS^99ROC||||P^HL70369||||20221216145008|||||||SC^99ROC
SAC||2022101^BARCODE||||50005|1
ORC|NW||||20221216145008
TQ1|||||R^HL70485
OBR|1|2022101||20630^99ROC
TCD|20630^99ROC
```

3.3.2. ORL_042 Response from cobas pure to a submission of order

Sample ID: 2022101

```
MSH|^~\&|cobas pure||Host||20221216145001+0900||ORL^034^ORL_042|926|P|2.5.1|||UNICODE UTF-8
MSA|AA|5194fe1c-89fc-4de9-8
PID||000008||^U||20000101|F
SPM|1|2022101&BARCODE|SERPLAS^99ROC||||P^HL70369||||20221216145008|||||||SC^99ROC
SAC||2022101^BARCODE||||50005|1
ORC|OK|||SC
```


3.3.3. OUL_R22 Message for test results upload

Application Code: 20630

Sample ID 2022101

Patient Result Upload Quantitative 5.2 mmol/L

```
MSH|^~\&|cobas pure||Host||20221216150149+0900||OUL^R22^OUL_R22|945|P|2.5.1||NE|AL||UN
ICODE UTF-8||LAB-29^IHE
PID|||000008||^U||20000101|F
SPM|1|2022101&BARCODE||SERPLAS^^99ROC||||P^HL70369||~||20221216145008||||PS
CO^^99ROC||SC^^99ROC
SAC||2022101^BARCODE||||50005|1|||||^1^:~1
OBR|1|2022101|20630^^99ROC||||G
ORC|SC|||CM
TQ1|||||R^HL70485
OBX|1|NM|20630^20630^99ROC^^IHELAW|1|5.2|mmol/L^^99ROC||27^^99ROC||F|||yapk2~REALTI
ME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216150149|||||RSLT
OBX|2|CE|20630^20630^99ROC^^IHELAW|1|^99ROC||27^^99ROC||F|||yapk2~REALTIME||c303^
ROCHE~MC02-03^ROCHE~1^ROCHE|20221216150149|||||RSLT
TCD|20630^^99ROC|^1^:~1
INV|2063001|OK^^HL70383~CURRENT^^99ROC|R1|1408|1|1||||20230531||614042
INV|2063001|OK^^HL70383~CURRENT^^99ROC|R3|1408|1|1||||20230531||614042
OBX|3|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20221216145113||
27^^99ROC||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216150149||||
||RSLT
OBX|4|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|732||27
^^99ROC||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216150149||||
||RSLT
OBX|5|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2416~2412||27^^99R
OC||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216150149|||||RSL
T
OBX|6|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|1^^99ROC||27^^99R
OC||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216150149|||||RSL
T
OBX|7|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
0.110 - 41.6||27^^99ROC||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221
216150149|||||RSLT
OBX|8|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|-99999
99 - 9999999||27^^99ROC||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221
216150149|||||RSLT
OBX|9|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
-9999999 - 9999999||27^^99ROC||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE
|20221216150149|||||RSLT
```

3.3.4. OUL_R22 Message for test results upload with serum index

Application Code: 20630

Sample ID 2022105

Patient Result Upload Quantitative 13.3mmol/L

```
MSH|^~\&|cobas pure||Host||20221216150205+0900||OUL^R22^OUL_R22|946|P|2.5.1||NE|AL||UN
ICODE UTF-8||LAB-29^IHE
PID|||000008||^U||20000101|F
SPM|1|2022105&BARCODE||SERPLAS^^99ROC||||P^HL70369||~||20221216145010||||PS
CO^^99ROC||SC^^99ROC
SAC||2022105^BARCODE||||50005|2|||||^1^:~1
```

```

OBR|1|2022105||20630^^99ROC|||||G
ORC|SC|||CM
TQ1||||||R^^HL70485
OBX|1|NM|20630^20630^99ROC^^IHELAW|1|13.3|mmol/L^^99ROC||104^^99ROC|||F||||yapk2~REAL
TIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216150205|||||||RSLT
OBX|2|CE|20630^20630^99ROC^^IHELAW|1|^99ROC|||104^^99ROC|||F||||yapk2~REALTIME||c303
^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216150205|||||||RSLT
TCD|20630^^99ROC|^1^:^1
INV|2063001|OK^^HL70383~CURRENT^^99ROC|R1|1408|1|1|||||20230531|||614042
INV|2063001|OK^^HL70383~CURRENT^^99ROC|R3|1408|1|1|||||20230531|||614042
OBX|3|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20221216145129|||
104^^99ROC|||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216150205|||||
||||RSLT
OBX|4|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|732|||10
4^^99ROC|||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216150205|||||
||RSLT
OBX|5|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2416~2412|||104^^99
ROC|||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216150205|||||||RS
LT
OBX|6|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|1^^99ROC|||104^^99
ROC|||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216150205|||||||RS
LT
OBX|7|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
0.110 - 41.6|||104^^99ROC|||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|2022
1216150205|||||||RSLT
OBX|8|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|-99999
99 - 9999999|||104^^99ROC|||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|2022
1216150205|||||||RSLT
OBX|9|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
-9999999 - 9999999|||104^^99ROC|||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCH
E|20221216150205|||||||RSLT

```

3.3.5. OUL_R22 Upload Message - Sample Index Measurement Ser/PI L

Application Code: 29112

Sample ID 2022105

```

MSH|^~\&|cobas pure||Host||20221216145501+0900||OUL^R22^OUL_R22|940|P|2.5.1|||NE|AL|UN
ICODE UTF-8||LAB-29^IHE
PID|||000008||^U||20000101|F
SPM|1|2022105&BARCODE||SERPLAS^^99ROC|||||P^^HL70369|||~|20221216145010|||||PS
CO^^99ROC||SC^^99ROC
SAC|||2022105^BARCODE|||||50005|2|||||||1^:1
OBR|1|2022105||29112^^99ROC|||||G
ORC|SC|||CM
TQ1||||||R^^HL70485
OBX|1|NM|29112^29112^99ROC^^IHELAW|1|46|Index^^99ROC||N^^HL70078|||F||||yapk2~REALTIM
E||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216145501|||||||RSLT
OBX|2|CE|29112^29112^99ROC^^IHELAW|1|^99ROC|||N^^HL70078|||F||||yapk2~REALTIME||c303
^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216145501|||||||RSLT
TCD|29112^^99ROC|^1^:1
INV|2911001|OK^^HL70383~CURRENT^^99ROC|R1|2042|1|40|||||20230531|||587813
OBX|3|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20221216145121|||
N^^HL70078|||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216145501|||||
||||RSLT
OBX|4|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|723|||N^

```

```

^HL70078|||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216145501|||||
||RSLT
OBX|5|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|||N^HL70078|||F||
||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216145501|||||||RSLT
OBX|6|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|0^99ROC|||N^HL70
078|||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216145501|||||||RS
LT
OBX|7|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
- |||N^HL70078|||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|2022121614550
1|||||||RSLT
OBX|8|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1| - |||
N^HL70078|||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216145501||||
||||RSLT
OBX|9|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
- |||N^HL70078|||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|2022121614550
1|||||||RSLT

```

3.3.6. OUL_R22 Upload Message - Sample Index Measurement Ser/PI H

Application Code: 29113

Sample ID 2022105

```

MSH|^~\&|cobas pure||Host||20221216145502+0900||OUL^R22^OUL_R22|941|P|2.5.1|||NE|AL||UN
ICODE UTF-8|||LAB-29^IHE
PID|||000008||^U||20000101|F
SPM|1|2022105&BARCODE||SERPLAS^99ROC|||||P^HL70369|||~|20221216145010|||||PS
CO^99ROC||SC^99ROC
SAC|||2022105^BARCODE|||||50005|2|||||||1^:1
OBR|1|2022105||29113^99ROC|||||G
ORC|SC|||CM
TQ1||||||R^HL70485
OBX|1|NM|29113^29113^99ROC^^IHELAW|1|1576|Index^99ROC||N^HL70078|||F||||yapk2~REALT
IME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216145501|||||||RSLT
OBX|2|CE|29113^29113^99ROC^^IHELAW|1|^99ROC||N^HL70078|||F||||yapk2~REALTIME||c303
^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216145501|||||||RSLT
TCD|29113^99ROC|^1^:1
INV|2911001|OK^HL70383~CURRENT^99ROC|R1|2042|1|40|||||20230531|||587813
OBX|3|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20221216145121|||
N^HL70078|||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216145501||||
||||RSLT
OBX|4|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|723||N^
HL70078|||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216145501|||||
||RSLT
OBX|5|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|||N^HL70078|||F||
||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216145501|||||||RSLT
OBX|6|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|0^99ROC|||N^HL70
078|||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216145501|||||||RS
LT
OBX|7|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
- |||N^HL70078|||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|2022121614550
1|||||||RSLT
OBX|8|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1| - |||
N^HL70078|||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216145501||||
||||RSLT
OBX|9|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
- |||N^HL70078|||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|2022121614550

```

1|||||||RSLT

3.3.7. OUL_R22 Upload Message - Sample Index Measurement Ser/PI I

Application Code: 29114

Sample ID 2022105

```
MSH|^~\&|cobas pure||Host||20221216145502+0900||OUL^R22^OUL_R22|942|P|2.5.1||NE|AL||UN
ICODE UTF-8||LAB-29^IHE
PID|||000008||^U||20000101|F
SPM|1|2022105&BARCODE||SERPLAS^^99ROC||||P^HL70369||~|20221216145010||||PS
CO^^99ROC||SC^^99ROC
SAC||2022105^BARCODE||||50005|2|||||^1^:^1
OBR|1|2022105|29114^^99ROC||||G
ORC|SC|||CM
TQ1|||||R^HL70485
OBX|1|NM|29114^29114^99ROC^^IHELAW|1|0|Index^^99ROC|N^HL70078||F|||yapk2~REALTIME
|c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216145501|||||RSLT
OBX|2|CE|29114^29114^99ROC^^IHELAW|1|^99ROC||N^HL70078||F|||yapk2~REALTIME|c303
^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216145501|||||RSLT
TCD|29114^^99ROC|^1^:^1
INV|2911001|OK^HL70383~CURRENT^^99ROC|R1|2042|1|40||||20230531||587813
OBX|3|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20221216145121||
N^HL70078||F|||yapk2~REALTIME|c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216145501||||
||||RSLT
OBX|4|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|723||N^
^HL70078||F|||yapk2~REALTIME|c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216145501||||
||||RSLT
OBX|5|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1||N^HL70078||F||
||yapk2~REALTIME|c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216145501|||||RSLT
OBX|6|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|0^^99ROC||N^HL70
078||F|||yapk2~REALTIME|c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216145501|||||RS
LT
OBX|7|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
- ||N^HL70078||F|||yapk2~REALTIME|c303^ROCHE~MC02-03^ROCHE~1^ROCHE|2022121614550
1|||||RSLT
OBX|8|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1| - ||
N^HL70078||F|||yapk2~REALTIME|c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216145501||||
||||RSLT
OBX|9|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
- ||N^HL70078||F|||yapk2~REALTIME|c303^ROCHE~MC02-03^ROCHE~1^ROCHE|2022121614550
1|||||RSLT
```

3.3.8. OML_O33 from host with test orders (ISE)

ACN: 29070 | 29080 | 29090

Sample ID: 2022100

```
MSH|^~\&|Host||cobasPure||20221216145012+0200||OML^O33^OML_O33|26abf995-9c67-4524-a|P|2
.5.1|||NE|AL||UNICODE UTF-8|||LAB-28R^ROCHE
PID|||000008||^U||20000101|F
SPM|1|2022100&BARCODE||SERPLAS^^99ROC|||||P^HL70369|||||20221216145012|||||||SC^
^99ROC
SAC|||2022100^BARCODE|||||50005|3
ORC|NW||||||20221216145012
TQ1||||||R^HL70485
OBR|1|2022100||29070^^99ROC
TCD|29070^^99ROC
ORC|NW||||||20221216145012
TQ1||||||R^HL70485
OBR|2|2022100||29080^^99ROC
TCD|29080^^99ROC
ORC|NW||||||20221216145012
TQ1||||||R^HL70485
OBR|3|2022100||29090^^99ROC
TCD|29090^^99ROC
```

3.3.9. OUL_R22 Upload Message - Result Quantitative (ISE-Na)

Note : Structure for all ISE parameters are the same

Application Code: 29070

Sample ID 2022100

```
MSH|^~\&|cobas pure||Host||20221216145225+0900||OUL^R22^OUL_R22|937|P|2.5.1|||NE|AL||UN
ICODE UTF-8|||LAB-29^IHE
PID|||000008||^U||20000101|F
SPM|1|2022100&BARCODE||SERPLAS^^99ROC|||||P^HL70369|||~|20221216145012|||||PS
CO^^99ROC||SC^^99ROC
SAC|||2022100^BARCODE|||||50005|3|||||||1^:1
OBR|1|2022100||29070^^99ROC|||||G
ORC|SC|||CM
TQ1||||||R^HL70485
OBX|1|NM|29070^29070^99ROC^^IHELAW|1|6.4|mmol/L^^99ROC||27^^99ROC|||F|||yapk2~REALTI
ME||ISE^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216145224|||||||RSLT
OBX|2|CE|29070^29070^99ROC^^IHELAW|1|^99ROC||27^^99ROC|||F|||yapk2~REALTIME||ISE^R
OCHE~MC02-03^ROCHE~1^ROCHE|20221216145224|||||||RSLT
TCD|29070^^99ROC|^1^:1
INV|2999002|OK^HL70383~CURRENT^^99ROC|IS|10291|1|1|||||20240331|||644055
INV|2999001|OK^HL70383~CURRENT^^99ROC|DIL|9534|1|1|||||20240630|||669174
INV|2999004|OK^HL70383~CURRENT^^99ROC|REF|4740|1|1|||||20240930|||644535
OBX|3|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20221216145137|||
27^^99ROC|||F|||yapk2~REALTIME||ISE^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216145224|||||||
||RSLT
OBX|4|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|598|||27
^^99ROC|||F|||yapk2~REALTIME||ISE^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216145224|||||||
|RSLT
OBX|5|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2422~2419|||27^^99R
OC|||F|||yapk2~REALTIME||ISE^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216145224|||||||RSLT
```

```

OBX|6|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|1^99ROC|||27^99R
OC|||F|||||yapk2~REALTIME||ISE^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216145224|)|||||RSLT
OBX|7|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
80.0 - 180.0|||27^99ROC|||F|||||yapk2~REALTIME||ISE^ROCHE~MC02-03^ROCHE~1^ROCHE|202212
16145224|)|||||RSLT
OBX|8|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|-99999
99 - 9999999|||27^99ROC|||F|||||yapk2~REALTIME||ISE^ROCHE~MC02-03^ROCHE~1^ROCHE|202212
16145224|)|||||RSLT
OBX|9|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
-9999999 - 9999999|||27^99ROC|||F|||||yapk2~REALTIME||ISE^ROCHE~MC02-03^ROCHE~1^ROCHE|
20221216145224|)|||||RSLT

```

3.3.10. OML_O33 Message from host with test order (Calculated Test)

Application Code: 31002

Sample ID 2022108

```

MSH|^~\&|Host||cobasPure||20221216145014+0200||OML^O33^OML_O33|72ecc98c-1878-4fa4-a|P|2
.5.1|||NE|AL||UNICODE UTF-8|||LAB-28R^ROCHE
PID|||000008||^U|||20000101|F
SPM|1|2022108&BARCODE||SERPLAS^99ROC|||||P^HL70369|||||20221216145014|)|||||SC^
^99ROC
SAC|||2022108^BARCODE|)|||||50005|4
ORC|NW|)|||||20221216145014
TQ1|)|||||R^HL70485
OBR|1|2022108||31002^99ROC
TCD|31002^99ROC

```

3.3.11. OUL_R22 Upload Message - Calculated Test Original Data upload ON (Calculated Test)

Application Code: 31002

Sample ID 2022105

Original Data upload ON

```

MSH|^~\&|cobas pure||Host||20230310163321+0900||OUL^R22^OUL_R22|327|P|2.5.1|||NE|AL||UN
ICODE UTF-8|||LAB-29^IHE
PID|||^^^U|||U
SPM|1|test1&BARCODE||SERPLAS^99ROC|||||P^HL70369|||~|20230310083940|)|||||PSCO
^99ROC|||SC^99ROC
SAC|||test1^BARCODE|)|||||50005|1|)|||||1^:1
OBR|1|""||31002^99ROC|)|||||
ORC|SC|)|||CM
TQ1|)|||||R^HL70485
OBX|1|NM|31002^31002^99ROC^^IHELAW|1|15.8|mmo1/L^99ROC||101^99ROC|||F|||||chew11~BAT
CH||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230310085047|)|||||RSLT
OBX|2|CE|31002^31002^99ROC^^IHELAW|1|^99ROC|||101^99ROC|||F|||||chew11~BATCH||c303^R
OCHE~MC02-03^ROCHE~1^ROCHE|20230310085047|)|||||RSLT
TCD|31002^99ROC|^1^:1
OBX|3|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|)|||101^99ROC|||F
|||||chew11~BATCH||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230310085047|)|||||RSLT
OBX|4|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|)|||101^
99ROC|||F|||||chew11~BATCH||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230310085047|)|||||RS
LT
OBX|5|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|)|||101^99ROC|||F||
|||chew11~BATCH||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230310085047|)|||||RSLT

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OBX|6|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|0^99ROC|||101^99
ROC|||F||||chew1~BATCH||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230310085047|||RSLT
OBX|7|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
||101^99ROC|||F||||chew1~BATCH||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230310085047|||
||||RSLT
OBX|8|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|-99999
99 - 9999999|||101^99ROC|||F||||chew1~BATCH||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|202303
10085047|||RSLT
OBX|9|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
-9999999 - 9999999|||101^99ROC|||F||||chew1~BATCH||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|
20230310085047|||RSLT
OBR|2|""|20630^99ROC|||
ORC|SC|||CM
TQ1|||||R^HL70485
OBX|1|NM|20630^20630^99ROC^^^IHELAW|1|7.17|mmol/L^99ROC||N^HL70078|||F||||chew1~BAT
CH||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230310085046|||RSLT
OBX|2|CE|20630^20630^99ROC^^^IHELAW|1|^99ROC||N^HL70078|||F||||chew1~BATCH||c303^R
OCHE~MC02-03^ROCHE~1^ROCHE|20230310085046|||RSLT
TCD|20630^99ROC|^1^:1
INV|2063001|OK^HL70383~CURRENT^99ROC|R1|1408|1|21|||||20230531|||614042
INV|2063001|OK^HL70383~CURRENT^99ROC|R3|1408|1|21|||||20230531|||614042
OBX|3|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20230310084017|||
N^HL70078|||F||||chew1~BATCH||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230310085046|||
||RSLT
OBX|4|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|732||N^
^HL70078|||F||||chew1~BATCH||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230310085046|||
|RSLT
OBX|5|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2748~2743||N^HL70
078|||F||||chew1~BATCH||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230310085046|||RSLT
OBX|6|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2^99ROC||N^HL70
078|||F||||chew1~BATCH||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230310085046|||RSLT
OBX|7|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
0.110 - 41.6||N^HL70078|||F||||chew1~BATCH||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|202303
10085046|||RSLT
OBX|8|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|-99999
99 - 9999999||N^HL70078|||F||||chew1~BATCH||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|202303
10085046|||RSLT
OBX|9|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
-9999999 - 9999999||N^HL70078|||F||||chew1~BATCH||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|
20230310085046|||RSLT
OBR|3|""|20410^99ROC|||
ORC|SC|||CM
TQ1|||||R^HL70485
OBX|1|NM|20410^20410^99ROC^^^IHELAW|1|3.37|mmol/L^99ROC||101^99ROC|||F||||chew1~BAT
CH||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230310085038|||RSLT
OBX|2|CE|20410^20410^99ROC^^^IHELAW|1|^99ROC||101^99ROC|||F||||chew1~BATCH||c303^R
OCHE~MC02-03^ROCHE~1^ROCHE|20230310085038|||RSLT
TCD|20410^99ROC|^1^:1
INV|2041001|OK^HL70383~CURRENT^99ROC|R1|2118|1|4|||||20230228|||640736
OBX|3|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20230310084009|||
101^99ROC|||F||||chew1~BATCH||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230310085038|||
||RSLT
OBX|4|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|817||10
1^99ROC|||F||||chew1~BATCH||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230310085038|||
|RSLT
OBX|5|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|||101^99ROC|||F||

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|||chew1~BATCH||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230310085038|||||||RSLT
OBX|6|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|0^^99ROC|||101^^99
ROC|||F|||||chew1~BATCH||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230310085038|||||||RSLT
OBX|7|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
0.100 - 20.7|||101^^99ROC|||F|||||chew1~BATCH||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|202303
10085038|||||||RSLT
OBX|8|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|-99999
99 - 9999999|||101^^99ROC|||F|||||chew1~BATCH||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|202303
10085038|||||||RSLT
OBX|9|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
-9999999 - 9999999|||101^^99ROC|||F|||||chew1~BATCH||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|
20230310085038|||||||RSLT

```

3.3.12. OUL_R22 Upload Message - Calculated Test Original Data upload OFF (Calculated Test)

Application Code: 31002

Sample ID 2022105

Original Data upload OFF

```

MSH|^~\&|cobas pure||Host||20221216150230+0900||OUL^R22^OUL_R22|947|P|2.5.1|||NE|AL||UN
ICODE UTF-8|||LAB-29^IHE
PID|||000008||^U||20000101|F
SPM|1|2022108&BARCODE||SERPLAS^99ROC|||||P^HL70369|||~|20221216145014|||||PS
CO^99ROC|||SC^99ROC
SAC|||2022108^BARCODE|||||50005|4|||||||1^:1
OBR|1|2022108||31002^99ROC|||||G
ORC|SC|||CM
TQ1|||||R^HL70485
OBX|1|NM|31002^31002^99ROC^^IHELAW|1|0.0238|mg/dL^99ROC||37^99ROC|||F|||||yapk2~REAL
TIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216150230|||||||RSLT
OBX|2|CE|31002^31002^99ROC^^IHELAW|1|^99ROC||37^99ROC|||F|||||yapk2~REALTIME||c303^
ROCHE~MC02-03^ROCHE~1^ROCHE|20221216150230|||||||RSLT
TCD|31002^99ROC|^1^:1
OBX|3|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|||37^99ROC|||F|
|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216150230|||||||RSLT
OBX|4|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|||37^9
9ROC|||F|||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216150230|||||||R
SLT
OBX|5|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|||37^99ROC|||F||
||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216150230|||||||RSLT
OBX|6|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|0^^99ROC|||37^99R
OC|||F|||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216150230|||||||RSL
T
OBX|7|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
|||37^99ROC|||F|||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216150230|||
|||||RSLT
OBX|8|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|-99999
99 - 9999999|||37^99ROC|||F|||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221
216150230|||||||RSLT
OBX|9|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
-9999999 - 9999999|||37^99ROC|||F|||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE
|20221216150230|||||||RSLT

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3.3.13. OUL_R22 Upload Message - Result HbA1c Original Data Upload ON (HbA1c)

Application Code: 20660

Sample ID: 2022116

Original Data upload ON

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MSH|^~\&|cobas pure||Host||20221220112305+0900||OUL^R22^OUL_R22|6052|P|2.5.1|||NE|AL||U
NICODE UTF-8|||LAB-29^IHE
PID|||000002||^U||20000101|F
SPM|1|2022116&BARCODE||WB^HL70487|||P^HL70369||~|20221220111036|||PSCO^
^99ROC||
SAC|||2022116^BARCODE|||50053|1|||1^:1
OBR|1|""|20660^99ROC|||
ORC|SC|||CM
TQ1|||R^HL70485
OBX|1|NM|20660^20660^99ROC^IHELAW|1|1.04|mmol/L^99ROC|27^99ROC||F|||chew11~REAL
TIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221220112304|||RSLT
OBX|2|CE|20660^20660^99ROC^IHELAW|1|^99ROC||27^99ROC||F|||chew11~REALTIME||c303
^ROCHE~MC02-03^ROCHE~1^ROCHE|20221220112304|||RSLT
TCD|20660^99ROC|^1^:1
INV|2066002|OK^HL70383~CURRENT^99ROC|R1|1102|1|28|||20231031|||645103
INV|2066002|OK^HL70383~CURRENT^99ROC|R3|1102|1|28|||20231031|||645103
OBX|3|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20221220111146||
27^99ROC||F|||chew11~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221220112304|||
||RSLT
OBX|4|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|747||27
^99ROC||F|||chew11~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221220112304|||
||RSLT
OBX|5|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2436~2432||27^99R
OC||F|||chew11~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221220112304|||RS
LT
OBX|6|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|1^99ROC||27^99R
OC||F|||chew11~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221220112304|||RS
LT
OBX|7|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
2.48 - 24.8||27^99ROC||F|||chew11~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221
220112304|||RSLT
OBX|8|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|-99999
99 - 9999999||27^99ROC||F|||chew11~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|2022
1220112304|||RSLT
OBX|9|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
-9999999 - 9999999||27^99ROC||F|||chew11~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCH
E|20221220112304|||RSLT
OBR|2|""|20661^99ROC|||
ORC|SC|||CM
TQ1|||R^HL70485
OBX|1|NM|20661^20661^99ROC^IHELAW|1|0.000000|mmol/L^99ROC|27^99ROC||F|||chew11~
REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221220112304|||RSLT
OBX|2|CE|20661^20661^99ROC^IHELAW|1|^99ROC||27^99ROC||F|||chew11~REALTIME||c303
^ROCHE~MC02-03^ROCHE~1^ROCHE|20221220112304|||RSLT
TCD|20661^99ROC|^1^:1
INV|2066002|OK^HL70383~CURRENT^99ROC|R1|1102|1|28|||20231031|||645103
INV|2066002|OK^HL70383~CURRENT^99ROC|R3|1102|1|28|||20231031|||645103
OBX|3|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20221220111146||
27^99ROC||F|||chew11~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221220112304|||
||RSLT
OBX|4|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|748||27
^99ROC||F|||chew11~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221220112304|||

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||| RSLT
OBX|5|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2435~2431|||27^99R
OC|||F|||chew11~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221220112304||| ||| RSLT
OBX|6|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|1^99ROC|||27^99R
OC|||F|||chew11~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221220112304||| ||| RSLT
OBX|7|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
0.186 - 1.61|||27^99ROC|||F|||chew11~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|2022
1220112304||| ||| RSLT
OBX|8|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|-99999
99 - 9999999|||27^99ROC|||F|||chew11~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|2022
1220112304||| ||| RSLT
OBX|9|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
-9999999 - 9999999|||27^99ROC|||F|||chew11~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCH
E|20221220112304||| ||| RSLT
OBR|3|2022116||20662^99ROC||| ||| G
ORC|SC|||CM
TQ1||| ||| R^HL70485
OBX|1|NM|20662^20662^99ROC^^^IHELAW|1|2.15|%^99ROC||37^99ROC~102^99ROC|||F|||chew1
1~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221220112304||| ||| RSLT
OBX|2|CE|20662^20662^99ROC^^^IHELAW|1|^99ROC||37^99ROC~102^99ROC|||F|||chew11~REA
LTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221220112304||| ||| RSLT
TCD|20662^99ROC|^1^:1
OBX|3|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|||37^99ROC~102^
^99ROC|||F|||chew11~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221220112304||| |||
|| RSLT
OBX|4|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|||37^9
9ROC~102^99ROC|||F|||chew11~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|2022122011230
4||| ||| RSLT
OBX|5|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2437~2433|||37^99R
OC~102^99ROC|||F|||chew11~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221220112304|
||| ||| RSLT
OBX|6|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2^99ROC|||37^99R
OC~102^99ROC|||F|||chew11~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221220112304|
||| ||| RSLT
OBX|7|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
-999999 - 9999999|||37^99ROC~102^99ROC|||F|||chew11~REALTIME||c303^ROCHE~MC02-03^RO
CHE~1^ROCHE|20221220112304||| ||| RSLT
OBX|8|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|-99999
99 - 9999999|||37^99ROC~102^99ROC|||F|||chew11~REALTIME||c303^ROCHE~MC02-03^ROCHE~1
^ROCHE|20221220112304||| ||| RSLT
OBX|9|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
-9999999 - 9999999|||37^99ROC~102^99ROC|||F|||chew11~REALTIME||c303^ROCHE~MC02-03^R
OCHE~1^ROCHE|20221220112304||| ||| RSLT

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3.3.14. OUL_R22 Upload Message - Result HbA1c Original Data Upload OFF (HbA1c)

Application Code: 20662

Sample ID: 2022117

Original Data upload OFF

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MSH|^~\&|cobas pure||Host||20221216172516+0900||OUL^R22^OUL_R22|1099|P|2.5.1||NE|AL||U
NICODE UTF-8||LAB-29^IHE
PID||000008||^U||20000101|F
SPM|1|2022117&BARCODE|WB^HL70487|||P^HL70369||~|20221216171335|||PSCO^

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^99ROC|||
SAC|||2022117^BARCODE|||||50056|1|||||||||||||^1^:^1
OBR|1|2022117||20662^^99ROC|||||G
ORC|SC|||CM
TQ1||||||R^^HL70485
OBX|1|NM|20662^20662^99ROC^^IHELAW|1|16.7|%^99ROC||102^^99ROC|||F|||yapk2~REALTIME|
|c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216172515||||||RSLT
OBX|2|CE|20662^20662^99ROC^^IHELAW|1|^99ROC|||102^^99ROC|||F|||yapk2~REALTIME||c303
^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216172515||||||RSLT
TCD|20662^^99ROC|^1^:^1
OBX|3|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|||102^^99ROC|||F
|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216172515||||||RSLT
OBX|4|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|||102^^
99ROC|||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216172515||||||R
SLT
OBX|5|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2437~2433|||102^^99
ROC|||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216172515||||||R
SLT
OBX|6|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2^^99ROC|||102^^99
ROC|||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20221216172515||||||R
SLT
OBX|7|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
-999999 - 999999|||102^^99ROC|||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE
|20221216172515||||||RSLT
OBX|8|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|-99999
9 - 999999|||102^^99ROC|||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|2022
1216172515||||||RSLT
OBX|9|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
-9999999 - 9999999|||102^^99ROC|||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCH
E|20221216172515||||||RSLT

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3.3.15. OUL_R22 Upload Message - Result Qualitative (photometric) result ON (TH2Q2)

Application Code: 21070

Sample ID 2022120137

Result Value of photometric qualitative result ON

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MSH|^~\&|cobas_pure||Host||20230510142222+0900||OUL^R22^OUL_R22|62|P|2.5.1|||NE|AL||UNI
CODE UTF-8||LAB-29^IHE
PID|||?||^U||U
SPM|1|2022120137&BARCODE||UR^^HL70487||||P^^HL70369||~||20230510151027|||||PS
CO^^99ROC||SC^^99ROC
SAC|||2022120137^BARCODE|||||50053|1|||||||||||||^1^:^1
OBR|1|2022120137||21070^^99ROC|||||G
ORC|SC|||CM
TQ1||||||R^^HL70485
OBX|1|NM|21070^21070^99ROC^^IHELAW|1|31.0|mAbs^^99ROC||26^^99ROC~112^^99ROC|||F|||ya
pk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230510142221||||||RSLT
OBX|2|CE|21070^21070^99ROC^^IHELAW|1|^99ROC|||26^^99ROC~112^^99ROC|||F|||yapk2~REAL
TIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230510142221||||||RSLT
TCD|21070^^99ROC|^1^:^1
INV|2107002|OK^^HL70383~CURRENT^^99ROC|R1|119|1|40|||||20231031|||647249
INV|2107002|OK^^HL70383~CURRENT^^99ROC|R3|119|1|40|||||20231031|||647249
OBX|3|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20230510141153|||

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26^99ROC~112^99ROC||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|202305101
42221|||||||RSLT
OBX|4|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|743|||26
^99ROC~112^99ROC||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230510142
221|||||||RSLT
OBX|5|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|||26^99ROC~112^9
9ROC||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230510142221|||||||R
SLT
OBX|6|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|0^99ROC|||26^99R
OC~112^99ROC||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230510142221||
|||||||RSLT
OBX|7|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
-99999 - -0.00001|||26^99ROC~112^99ROC||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^RO
CHE~1^ROCHE|20230510142221|||||||RSLT
OBX|8|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|-99999
99 - 9999999|||26^99ROC~112^99ROC||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^
ROCHE|20230510142221|||||||RSLT
OBX|9|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
-9999999 - 9999999|||26^99ROC~112^99ROC||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^RO
CHE~1^ROCHE|20230510142221|||||||RSLT

```

3.3.16. OUL_R22 Upload Message - Result Qualitative (photometric) result OFF (TH2Q2)

Application Code: 21070

Sample ID 2022103

Result Value of photometric qualitative result OFF

```

MSH|^~\&|cobas pure||Host||20230512161757+0900||OUL^R22^OUL_R22|232|P|2.5.1|||NE|AL||UN
ICODE UTF-8||LAB-29^IHE
PID||?||^U
SPM|1|2022120140&BARCODE||UR^HL70487||||P^HL70369||~|20230512160711|||||PS
CO^99ROC||SC^99ROC
SAC||2022120140^BARCODE||||50053|1|||||||1^:1
OBR|1|2022120140||21070^99ROC||||G
ORC|SC|||CM
TQ1|||||R^HL70485
OBX|1|NM|21070^21070^99ROC^^IHELAW|1|^99ROC|26^99ROC~112^99ROC||F||||yapk2~REAL
TIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230512161757|||||||RSLT
OBX|2|CE|21070^21070^99ROC^^IHELAW|1|3^99ROC||26^99ROC~112^99ROC||F||||yapk2~REA
LTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230512161757|||||||RSLT
TCD|21070^99ROC|^1^:1
INV|2107002|OK^HL70383~CURRENT^99ROC|R1|119|1|40|||||20231031|||647249
INV|2107002|OK^HL70383~CURRENT^99ROC|R3|119|1|40|||||20231031|||647249
OBX|3|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20230512160736|||
26^99ROC~112^99ROC||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|202305121
61757|||||||RSLT
OBX|4|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|743|||26
^99ROC~112^99ROC||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230512161
757|||||||RSLT
OBX|5|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|||26^99ROC~112^9
9ROC||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230512161757|||||||R
SLT
OBX|6|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|0^99ROC|||26^99R
OC~112^99ROC||F||||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230512161757||
|||||||RSLT
OBX|7|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|

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```
-99999 - -0.00001|||26^99ROC~112^99ROC|||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROC
HE~1^ROCHE|20230512161757|||RSLT
OBX|8|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|-99999
99 - 9999999|||26^99ROC~112^99ROC|||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^
ROCHE|20230512161757|||RSLT
OBX|9|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
-9999999 - 9999999|||26^99ROC~112^99ROC|||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^RO
CHE~1^ROCHE|20230512161757|||RSLT
```

3.3.17. OUL_R22 Upload Message - Subresults for cobas e flow Tests ON (HIV DUO)

Application Code: 12018 HIV DUO

Sample ID 2022113

Subresults for **cobas e** flow Tests ON

```
MSH|^~\&|cobas pure|Host||20221221155542+0900|OUL^R22^OUL_R22|6194|P|2.5.1||NE|AL||U
NICODE UTF-8||LAB-29^IHE
PID|||000002||^U||20000101|F
SPM|1|2022113&BARCODE|SERPLAS^99ROC|||P^HL70369||~|20221220131723|||
|SC^99ROC
SAC||2022113^BARCODE|||50005|1|||1^:1
OBR|1|2022113|10172^99ROC|||G
ORC|SC||CM
TQ1|||R^HL70485
OBX|1|NM|10172^10172^99ROC^IHELAW|1|0.00500|μIU/mL^99ROC|27^99ROC||F|||chew11~B
ATCH|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221216154150|||RSLT
OBX|2|CE|10172^10172^99ROC^IHELAW|1|^99ROC|27^99ROC||F|||chew11~BATCH|e402^RO
CHE~ME01-10^ROCHE~1^ROCHE|20221216154150|||RSLT
TCD|10172^99ROC|1^:1
INV|1310172|OK^HL70383~CURRENT^99ROC|ASY|53417|1|18|||20230930||631966
INV|1018448|OK^HL70383~CURRENT^99ROC|PRC|10720|1|1|||20240630||668921
OBX|3|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20221216152319||
27^99ROC||F|||chew11~BATCH|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221216154150|||
||RSLT
OBX|4|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|329||27
^99ROC||F|||chew11~BATCH|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221216154150|||
RSLT
OBX|5|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2426~2425||27^99R
OC||F|||chew11~BATCH|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221216154150|||RSLT
OBX|6|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|1^99ROC||27^99R
OC||F|||chew11~BATCH|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221216154150|||RSLT
OBX|7|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
0.00500 - 100||27^99ROC||F|||chew11~BATCH|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|202212
16154150|||RSLT
OBX|8|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|-99999
99 - 9999999||27^99ROC||F|||chew11~BATCH|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|2022121
6154150|||RSLT
OBX|9|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
-9999999 - 9999999||27^99ROC||F|||chew11~BATCH|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|2
0221216154150|||RSLT
OBX|10|NM|10172_EFS^10172_EFS^99ROC^S_RAW^Raw Supplemental^IHELAW|1|603.5092|COUNT^99R
OC|27^99ROC||F|||chew11~BATCH|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221216154150||
||RSLT
OBX|11|NM|10172_EFV^10172_EFV^99ROC^S_RAW^Raw Supplemental^IHELAW|1|-118.9720|COUNT^99
ROC|27^99ROC||F|||chew11~BATCH|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221216154150||
||RSLT
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OBX|12|NM|10172_EFC^10172_EFC^99ROC^S_RAW^Raw Supplemental^IHELAW|1|244.5737|COUNT^^99R
OC||27^^99ROC|||F|||chew1~BATCH||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221216154150|||
|||RSLT
OBX|13|NM|10172_PMT^10172_PMT^99ROC^S_RAW^Raw Supplemental^IHELAW|1|22990|COUNT^^99ROC|
|27^^99ROC|||F|||chew1~BATCH||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221216154150|||
||RSLT
OBR|2|2022113||12018^^99ROC|||G
ORC|SC|||CM
TQ1|||R^HL70485
OBX|1|NM|12018^12018^99ROC^^^IHELAW|1|0.172|COI^^99ROC||N^HL70078|||F|||chew1~BATCH
||e402^ROCHE~MS02-10^ROCHE~0^ROCHE|20221220133712|||RSLT
OBX|2|CE|12018^12018^99ROC^^^IHELAW|1|-1^^99ROC|||N^HL70078|||F|||chew1~BATCH||e402
^ROCHE~MS02-10^ROCHE~0^ROCHE|20221220133712|||RSLT
OBX|3|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2449~2445~2441|||N^
^HL70078|||F|||chew1~BATCH||e402^ROCHE~MS02-10^ROCHE~0^ROCHE|20221220133712|||
|RSLT
OBX|4|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|1^^99ROC|||N^HL70
078|||F|||chew1~BATCH||e402^ROCHE~MS02-10^ROCHE~0^ROCHE|20221220133712|||RSLT
OBX|5|NM|AHIV_01^AHIV_01^99ROC^^^IHELAW|1|0.0834|COI^^99ROC|||F|||chew1~BATCH||e40
2^ROCHE~MS02-10^ROCHE~0^ROCHE|20221220133712|||RSLT
OBX|6|CE|AHIV_01^AHIV_01^99ROC^^^IHELAW|1|-1^^99ROC|||F|||chew1~BATCH||e402^ROCHE
~MS02-10^ROCHE~0^ROCHE|20221220133712|||RSLT
OBX|7|NM|HIVAG_01^HIVAG_01^99ROC^^^IHELAW|1|0.151|COI^^99ROC|||F|||chew1~BATCH||e4
02^ROCHE~MS02-10^ROCHE~0^ROCHE|20221220133712|||RSLT
OBX|8|CE|HIVAG_01^HIVAG_01^99ROC^^^IHELAW|1|-1^^99ROC|||F|||chew1~BATCH||e402^ROC
HE~MS02-10^ROCHE~0^ROCHE|20221220133712|||RSLT
OBX|9|NM|11013^11013^99ROC^^^IHELAW|1|*****|COI^^99ROC||SUP^^99ROC|||F|||chew1~BAT
CH||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221220133707|||RSLT
OBX|10|CE|11013^11013^99ROC^^^IHELAW|1|*****^99ROC||SUP^^99ROC|||F|||chew1~BATCH
||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221220133707|||RSLT
TCD|11013^^99ROC|^1^:1
INV|1311013|OK^^HL70383~CURRENT^^99ROC|ASY|59137|1|15|||20230430|||596294
INV|1018448|OK^^HL70383~CURRENT^^99ROC|PRC|10720|1|1|||20240630|||668921
OBX|11|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20221220131837||
|SUP^^99ROC|||F|||chew1~BATCH||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221220133707|||
||RSLT
OBX|12|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|319|||S
UP^^99ROC|||F|||chew1~BATCH||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221220133707|||
||RSLT
OBX|13|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2447~2443~2439|||S
UP^^99ROC|||F|||chew1~BATCH||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221220133707|||
||RSLT
OBX|14|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|1^^99ROC|||SUP^^9
9ROC|||F|||chew1~BATCH||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221220133707|||RSL
T
OBX|15|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1
|0.000000 - 0.000000||SUP^^99ROC|||F|||chew1~BATCH||e402^ROCHE~ME01-10^ROCHE~1^ROCH
E|20221220133707|||RSLT
OBX|16|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1| - ||
|SUP^^99ROC|||F|||chew1~BATCH||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221220133707|||
||RSLT
OBX|17|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1
| - |||SUP^^99ROC|||F|||chew1~BATCH||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221220133707
|||RSLT
OBX|18|NM|11013_EFS^11013_EFS^99ROC^S_RAW^Raw Supplemental^IHELAW|1|803.9008|COUNT^^99R
OC||SUP^^99ROC|||F|||chew1~BATCH||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221220133707||

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|||||RSLT
OBX|19|NM|11013_EFV^11013_EFV^99ROC^S_RAW^Raw Supplemental^IHELAW|1|-118.9901|COUNT^99
ROC||SUP^99ROC|||F||||chew11~BATCH||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221220133707||
|||||RSLT
OBX|20|NM|11013_EFC^11013_EFC^99ROC^S_RAW^Raw Supplemental^IHELAW|1|275.4054|COUNT^99R
OC||SUP^99ROC|||F||||chew11~BATCH||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221220133707||
|||||RSLT
OBX|21|NM|11013_PMT^11013_PMT^99ROC^S_RAW^Raw Supplemental^IHELAW|1|24682|COUNT^99ROC|
|SUP^99ROC|||F||||chew11~BATCH||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221220133707||||
||||RSLT
OBX|22|NM|11014^11014^99ROC^^^IHELAW|1|*****|COI^99ROC||SUP^99ROC|||F||||chew11~BA
TCH||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221220133637||||||RSLT
OBX|23|CE|11014^11014^99ROC^^^IHELAW|1|*****^99ROC||SUP^99ROC|||F||||chew11~BATCH
||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221220133637||||||RSLT
TCD|11014^99ROC|^1^:1
INV|1311014|OK^^HL70383~CURRENT^99ROC|ASY|57796|1|14|||||20230430|||596294
INV|1018448|OK^^HL70383~CURRENT^99ROC|PRC|10720|1|1|||||20240630|||668921
OBX|24|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20221220131807||
|SUP^99ROC|||F||||chew11~BATCH||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221220133637||||
||||RSLT
OBX|25|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|318|||S
UP^99ROC|||F||||chew11~BATCH||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221220133637||||
||||RSLT
OBX|26|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2448~2444~2440|||S
UP^99ROC|||F||||chew11~BATCH||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221220133637||||
||||RSLT
OBX|27|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|1^99ROC|||SUP^9
9ROC|||F||||chew11~BATCH||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221220133637||||||RSL
T
OBX|28|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1
|0.000000 - 0.000000||SUP^99ROC|||F||||chew11~BATCH||e402^ROCHE~ME01-10^ROCHE~1^ROCH
E|20221220133637||||||RSLT
OBX|29|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1| - ||
|SUP^99ROC|||F||||chew11~BATCH||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221220133637||||
||||RSLT
OBX|30|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1
| - |||SUP^99ROC|||F||||chew11~BATCH||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221220133637
||||||RSLT
OBX|31|NM|11014_EFS^11014_EFS^99ROC^S_RAW^Raw Supplemental^IHELAW|1|727.0084|COUNT^99R
OC||SUP^99ROC|||F||||chew11~BATCH||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221220133637||
||||RSLT
OBX|32|NM|11014_EFV^11014_EFV^99ROC^S_RAW^Raw Supplemental^IHELAW|1|-118.8533|COUNT^99
ROC||SUP^99ROC|||F||||chew11~BATCH||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221220133637||
||||RSLT
OBX|33|NM|11014_EFC^11014_EFC^99ROC^S_RAW^Raw Supplemental^IHELAW|1|275.6789|COUNT^99R
OC||SUP^99ROC|||F||||chew11~BATCH||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221220133637||
||||RSLT
OBX|34|NM|11014_PMT^11014_PMT^99ROC^S_RAW^Raw Supplemental^IHELAW|1|23492|COUNT^99ROC|
|SUP^99ROC|||F||||chew11~BATCH||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221220133637||||
||||RSLT
OBX|35|NM|12018^12018^99ROC^^^IHELAW|1|""|N^^HL70078|||B||||chew11~BATCH||e402^ROC
HE~MS02-10^ROCHE~0^ROCHE|20221220133707||||||RSLT
OBX|36|CE|12018^12018^99ROC^^^IHELAW|1|""|N^^HL70078|||B||||chew11~BATCH||e402^ROCHE
~MS02-10^ROCHE~0^ROCHE|20221220133707||||||RSLT
INV|12018|OK^^HL70383~CURRENT^99ROC|KIT|134|1|""|1|||20230430|||596294
OBX|37|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20221220131807||

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|N^HL70078|||B|||chew1~BATCH|e402^ROCHE~MS02-10^ROCHE~0^ROCHE|20221220133707|||
|||RSLT
OBX|38|EI|CombID^Measurement Cell Test Combination ID^99ROC^S_OTHER^Other Supplemental^
IHELAW|1|1||N^HL70078|||B|||chew1~BATCH|e402^ROCHE~MS02-10^ROCHE~0^ROCHE|20221220
133707|||RSLT
OBX|39|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2449~2445~2441||N
^HL70078|||B|||chew1~BATCH|e402^ROCHE~MS02-10^ROCHE~0^ROCHE|20221220133707|||
|||RSLT
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3.3.18. OUL_R22 Upload Message - Subresults for cobas e flow Tests OFF (HIV DUO)

Sample ID: 2022120133

ACN: 12018 HIV DUO

Subresults for **cobas e** flow Tests OFF

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MSH|^~\&|cobas pure||Host||20221222120213+0900||OUL^R22^OUL_R22|6335|P|2.5.1||NE|AL||U
NICODE UTF-8||LAB-29^IHE
PID||?|^U||U
SPM|1|2022120133&BARCODE||SERPLAS^99ROC||||P^HL70369||~||20221222114205||||
||SC^99ROC
SAC||2022120133^BARCODE||||50013|1|||||^1^:1
OBR|1|2022120133|12018^99ROC||||G
ORC|SC||CM
TQ1||||R^HL70485
OBX|1|NM|12018^12018^99ROC^^IHELAW|1|2.81|COI^99ROC|N^HL70078||F|||chew1~REALTI
ME|e402^ROCHE~MS02-10^ROCHE~0^ROCHE|20221222120213|||||RSLT
OBX|2|CE|12018^12018^99ROC^^IHELAW|1|1^99ROC||N^HL70078||F|||chew1~REALTIME|e4
02^ROCHE~MS02-10^ROCHE~0^ROCHE|20221222120213|||||RSLT
OBX|3|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2449~2445~2441||N
^HL70078||F|||chew1~REALTIME|e402^ROCHE~MS02-10^ROCHE~0^ROCHE|20221222120213||||
||RSLT
OBX|4|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|1^99ROC||N^HL70
078||F|||chew1~REALTIME|e402^ROCHE~MS02-10^ROCHE~0^ROCHE|20221222120213|||||R
SLT
OBX|5|NM|12018^12018^99ROC^^IHELAW|1|""|N^HL70078||B|||chew1~REALTIME|e402^R
OCHE~MS02-10^ROCHE~0^ROCHE|20221222120205|||||RSLT
OBX|6|CE|12018^12018^99ROC^^IHELAW|1|""|N^HL70078||B|||chew1~REALTIME|e402^ROC
HE~MS02-10^ROCHE~0^ROCHE|20221222120205|||||RSLT
INV|12018|OK^HL70383~CURRENT^99ROC|KIT|134|1|""|||20230430||596294
OBX|7|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20221222114305||
N^HL70078||B|||chew1~REALTIME|e402^ROCHE~MS02-10^ROCHE~0^ROCHE|20221222120205||
||RSLT
OBX|8|EI|CombID^Measurement Cell Test Combination ID^99ROC^S_OTHER^Other Supplemental^I
HELAW|1|1||N^HL70078||B|||chew1~REALTIME|e402^ROCHE~MS02-10^ROCHE~0^ROCHE|202212
22120205|||||RSLT
OBX|9|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2449~2445~2441||N
^HL70078||B|||chew1~REALTIME|e402^ROCHE~MS02-10^ROCHE~0^ROCHE|20221222120205||||
||RSLT
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ACN 12000 HIV DUO R

Order Message for HIV DUO R

Sample ID: 2022120137

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MSH|^~\&|Host||cobasPure||20221222102206+0200||OML^033^OML_033|bcd7b1df-70dc-4c2a-a|P|2
.5.1||NE|AL||UNICODE UTF-8||LAB-28^ROCHE
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PID|||?||^ ^ ^ ^ ^U|||U
 SPM|1|2022120137&BARCODE||SERPLAS^ ^99ROC|||P^HL70369|||20221222102206|||
 SC^99ROC
 SAC||2022120137^BARCODE|||50017|1
 ORC|NW|||20221222102206
 TQ1|||R^HL70485
 OBR|1|2022120137|12000^99ROC
 TCD|12000^99ROC

3.3.19. OUL_R22 Upload Message - Subresults for cobas e flow Tests ON (HIV DUO R)

Application Code: 12000

Sample ID: 2022120137

Subresults for **cobas e** flow Tests ON

MSH|^~\&|cobas pure||Host||20221222110316+0900|OUL^R22^OUL_R22|6302|P|2.5.1||NE|AL||U
 NICODE UTF-8||LAB-29^IHE
 PID|||?||^ ^ ^ ^ ^U|||U
 SPM|1|2022120137&BARCODE||SERPLAS^ ^99ROC|||P^HL70369||~ ~ ~||20221222102206|||
 |||SC^99ROC
 SAC||2022120137^BARCODE|||50017|1|||1^:1
 OBR|1|2022120137|12000^99ROC|||G
 ORC|SC|||CM
 TQ1|||R^HL70485
 OBX|1|NM|12000^12000^99ROC^IHELAW|1|^99ROC|N^HL70078||F|||chew11~REALTIME||e40
 2^ROCHE~MS02-10^ROCHE~0^ROCHE|20221222110315|||RSLT
 OBX|2|CE|12000^12000^99ROC^IHELAW|1|34^99ROC|N^HL70078||F|||chew11~REALTIME||e
 402^ROCHE~MS02-10^ROCHE~0^ROCHE|20221222110315|||RSLT
 OBX|3|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2450~2446~2442||N^
 ^HL70078||F|||chew11~REALTIME||e402^ROCHE~MS02-10^ROCHE~0^ROCHE|20221222110315|||
 |||RSLT
 OBX|4|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|1^99ROC||N^HL70
 078||F|||chew11~REALTIME||e402^ROCHE~MS02-10^ROCHE~0^ROCHE|20221222110315|||R
 SLT
 OBX|5|NM|11013^11013^99ROC^IHELAW|1|*****|COI^99ROC|SUP^99ROC||F|||chew11~REA
 LTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222104207|||RSLT
 OBX|6|CE|11013^11013^99ROC^IHELAW|1|*****^99ROC||SUP^99ROC||F|||chew11~REALTI
 ME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222104207|||RSLT
 TCD|11013^99ROC|1^:1
 INV|1311013|OK^HL70383~CURRENT^99ROC|ASY|59137|1|15|||20230430||596294
 INV|1018448|OK^HL70383~CURRENT^99ROC|PRC|10722|1|1|||20240630||668921
 OBX|7|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20221222102337||
 SUP^99ROC||F|||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222104207|||
 |||RSLT
 OBX|8|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|319||SU
 P^99ROC||F|||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222104207|||
 |||RSLT
 OBX|9|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2447~2443~2439||SU
 P^99ROC||F|||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222104207|||
 |||RSLT
 OBX|10|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|1^99ROC||SUP^9
 9ROC||F|||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222104207|||
 RSLT
 OBX|11|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1
 |0.000000 - 0.000000||SUP^99ROC||F|||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^R
 OCHE|20221222104207|||RSLT

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OBX|12|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1| - ||
|SUP^^99ROC|||F|||chewl1~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222104207||
|||||RSLT
OBX|13|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1
| - |||SUP^^99ROC|||F|||chewl1~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222104
207|||||||RSLT
OBX|14|NM|11013_EFS^11013_EFS^99ROC^S_RAW^Raw Supplemental^IHELAW|1|742.2681|COUNT^^99R
OC||SUP^^99ROC|||F|||chewl1~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222104207
|||||||RSLT
OBX|15|NM|11013_EFV^11013_EFV^99ROC^S_RAW^Raw Supplemental^IHELAW|1|-118.3405|COUNT^^99
ROC||SUP^^99ROC|||F|||chewl1~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|2022122210420
7|||||||RSLT
OBX|16|NM|11013_EFC^11013_EFC^99ROC^S_RAW^Raw Supplemental^IHELAW|1|273.8869|COUNT^^99R
OC||SUP^^99ROC|||F|||chewl1~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222104207
|||||||RSLT
OBX|17|NM|11013_PMT^11013_PMT^99ROC^S_RAW^Raw Supplemental^IHELAW|1|23426|COUNT^^99ROC|
|SUP^^99ROC|||F|||chewl1~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222104207||
|||||RSLT
OBX|18|NM|11013^11013^99ROC^^^IHELAW|1|*****|COI^^99ROC||SUP^^99ROC|||F|||chewl1~RE
ALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110207|||||||RSLT
OBX|19|CE|11013^11013^99ROC^^^IHELAW|1|*****^99ROC||SUP^^99ROC|||F|||chewl1~REALT
IME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110207|||||||RSLT
TCD|11013^^99ROC|^1^:^1
INV|1311013|OK^^HL70383~CURRENT^^99ROC|ASY|59137|1|15|||||20230430|||596294
INV|1018448|OK^^HL70383~CURRENT^^99ROC|PRC|10722|1|1|||||20240630|||668921
OBX|20|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20221222104337||
|SUP^^99ROC|||F|||chewl1~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110207||
|||||RSLT
OBX|21|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|319|||S
UP^^99ROC|||F|||chewl1~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110207|||
||||RSLT
OBX|22|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2447~2443~2439|||S
UP^^99ROC|||F|||chewl1~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110207|||
||||RSLT
OBX|23|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|1^^99ROC|||SUP^^9
9ROC|||F|||chewl1~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110207|||||||
RSLT
OBX|24|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1
|0.000000 - 0.000000||SUP^^99ROC|||F|||chewl1~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^R
OCHE|20221222110207|||||||RSLT
OBX|25|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1| - ||
|SUP^^99ROC|||F|||chewl1~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110207||
|||||RSLT
OBX|26|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1
| - |||SUP^^99ROC|||F|||chewl1~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110
207|||||||RSLT
OBX|27|NM|11013_EFS^11013_EFS^99ROC^S_RAW^Raw Supplemental^IHELAW|1|753.9590|COUNT^^99R
OC||SUP^^99ROC|||F|||chewl1~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110207
|||||||RSLT
OBX|28|NM|11013_EFV^11013_EFV^99ROC^S_RAW^Raw Supplemental^IHELAW|1|-117.5861|COUNT^^99
ROC||SUP^^99ROC|||F|||chewl1~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|2022122211020
7|||||||RSLT
OBX|29|NM|11013_EFC^11013_EFC^99ROC^S_RAW^Raw Supplemental^IHELAW|1|275.4258|COUNT^^99R
OC||SUP^^99ROC|||F|||chewl1~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110207
|||||||RSLT
OBX|30|NM|11013_PMT^11013_PMT^99ROC^S_RAW^Raw Supplemental^IHELAW|1|24319|COUNT^^99ROC|
|SUP^^99ROC|||F|||chewl1~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110207||

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||||| RSLT
OBX|31|NM|11013^11013^99ROC^^^IHELAW|1|*****|COI^^99ROC||SUP^^99ROC|||F|||||chew11~RE
ALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110307||||||| RSLT
OBX|32|CE|11013^11013^99ROC^^^IHELAW|1|*****^99ROC||SUP^^99ROC|||F|||||chew11~REALT
IME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110307||||||| RSLT
TCD|11013^^99ROC|^1^:^1
INV|1311013|OK^^HL70383~CURRENT^^99ROC|ASY|59137|1|15|||||20230430|||596294
INV|1018448|OK^^HL70383~CURRENT^^99ROC|PRC|10722|1|1|||||20240630|||668921
OBX|33|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20221222104437||
|SUP^^99ROC|||F|||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110307||
||||| RSLT
OBX|34|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|319|||S
UP^^99ROC|||F|||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110307|||
||||| RSLT
OBX|35|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2447~2443~2439|||S
UP^^99ROC|||F|||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110307|||
||||| RSLT
OBX|36|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|1^^99ROC|||SUP^^9
9ROC|||F|||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110307|||||||
RSLT
OBX|37|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1
|0.000000 - 0.000000||SUP^^99ROC|||F|||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^R
OCHE|20221222110307||||||| RSLT
OBX|38|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1| - ||
|SUP^^99ROC|||F|||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110307||
||||| RSLT
OBX|39|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1
| - |||SUP^^99ROC|||F|||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110
307||||||| RSLT
OBX|40|NM|11013_EFS^11013_EFS^99ROC^S_RAW^Raw Supplemental^IHELAW|1|743.5250|COUNT^^99R
OC||SUP^^99ROC|||F|||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110307
||||||| RSLT
OBX|41|NM|11013_EFV^11013_EFV^99ROC^S_RAW^Raw Supplemental^IHELAW|1|-117.3569|COUNT^^99
ROC||SUP^^99ROC|||F|||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|2022122211030
7||||||| RSLT
OBX|42|NM|11013_EFC^11013_EFC^99ROC^S_RAW^Raw Supplemental^IHELAW|1|275.3297|COUNT^^99R
OC||SUP^^99ROC|||F|||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110307
||||||| RSLT
OBX|43|NM|11013_PMT^11013_PMT^99ROC^S_RAW^Raw Supplemental^IHELAW|1|23914|COUNT^^99ROC|
|SUP^^99ROC|||F|||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110307||
||||| RSLT
OBX|44|NM|11014^11014^99ROC^^^IHELAW|1|*****|COI^^99ROC||SUP^^99ROC|||F|||||chew11~RE
ALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222104137||||||| RSLT
OBX|45|CE|11014^11014^99ROC^^^IHELAW|1|*****^99ROC||SUP^^99ROC|||F|||||chew11~REALT
IME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222104137||||||| RSLT
TCD|11014^^99ROC|^1^:~1
INV|1311014|OK^^HL70383~CURRENT^^99ROC|ASY|57796|1|14|||||20230430|||596294
INV|1018448|OK^^HL70383~CURRENT^^99ROC|PRC|10722|1|1|||||20240630|||668921
OBX|46|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20221222102307||
|SUP^^99ROC|||F|||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222104137||
||||| RSLT
OBX|47|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|318|||S
UP^^99ROC|||F|||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222104137|||
||||| RSLT
OBX|48|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2448~2444~2440|||S
UP^^99ROC|||F|||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222104137|||

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||||RSLT
OBX|49|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|1^^99ROC|||SUP^^9
9ROC|||F||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222104137|||||||
RSLT
OBX|50|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1
|0.000000 - 0.000000|||SUP^^99ROC|||F||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^R
OCHE|20221222104137|||||||RSLT
OBX|51|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1| - ||
|SUP^^99ROC|||F||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222104137||
|||||RSLT
OBX|52|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1
| - |||SUP^^99ROC|||F||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222104
137|||||||RSLT
OBX|53|NM|11014_EFS^11014_EFS^99ROC^S_RAW^Raw Supplemental^IHELAW|1|9654.1318|COUNT^^99
ROC||SUP^^99ROC|||F||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|2022122210413
7|||||||RSLT
OBX|54|NM|11014_EFV^11014_EFV^99ROC^S_RAW^Raw Supplemental^IHELAW|1|-118.3523|COUNT^^99
ROC||SUP^^99ROC|||F||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|2022122210413
7|||||||RSLT
OBX|55|NM|11014_EFC^11014_EFC^99ROC^S_RAW^Raw Supplemental^IHELAW|1|273.0786|COUNT^^99R
OC||SUP^^99ROC|||F||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222104137
|||||||RSLT
OBX|56|NM|11014_PMT^11014_PMT^99ROC^S_RAW^Raw Supplemental^IHELAW|1|22647|COUNT^^99ROC|
|SUP^^99ROC|||F||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222104137||
|||||RSLT
OBX|57|NM|11014^11014^99ROC^^^IHELAW|1|*****|COI^^99ROC||SUP^^99ROC|||F||||chew11~RE
ALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110137|||||||RSLT
OBX|58|CE|11014^11014^99ROC^^^IHELAW|1|*****^99ROC|||SUP^^99ROC|||F||||chew11~REALT
IME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110137|||||||RSLT
TCD|11014^^99ROC|^1^:1
INV|1311014|OK^^HL70383~CURRENT^^99ROC|ASY|57796|1|14| |||||20230430|||596294
INV|1018448|OK^^HL70383~CURRENT^^99ROC|PRC|10722|1|1| |||||20240630|||668921
OBX|59|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20221222104307||
|SUP^^99ROC|||F||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110137||
|||||RSLT
OBX|60|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|318|||S
UP^^99ROC|||F||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110137|||
||||RSLT
OBX|61|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2448~2444~2440|||S
UP^^99ROC|||F||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110137|||
||||RSLT
OBX|62|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|1^^99ROC|||SUP^^9
9ROC|||F||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110137|||||||
RSLT
OBX|63|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1
|0.000000 - 0.000000|||SUP^^99ROC|||F||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^R
OCHE|20221222110137|||||||RSLT
OBX|64|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1| - ||
|SUP^^99ROC|||F||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110137||
|||||RSLT
OBX|65|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1
| - |||SUP^^99ROC|||F||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110
137|||||||RSLT
OBX|66|NM|11014_EFS^11014_EFS^99ROC^S_RAW^Raw Supplemental^IHELAW|1|9733.5021|COUNT^^99
ROC||SUP^^99ROC|||F||||chew11~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|2022122211013
7|||||||RSLT
OBX|67|NM|11014_EFV^11014_EFV^99ROC^S_RAW^Raw Supplemental^IHELAW|1|-117.4019|COUNT^^99

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ROC|SUP^^99ROC||F||||chew11~REALTIME|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|2022122211013
7||||||RSLT
OBX|68|NM|11014_EFC^11014_EFC^99ROC^S_RAW^Raw Supplemental^IHELAW|1|274.7795|COUNT^^99R
OC|SUP^^99ROC||F||||chew11~REALTIME|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110137
||||||RSLT
OBX|69|NM|11014_PMT^11014_PMT^99ROC^S_RAW^Raw Supplemental^IHELAW|1|23155|COUNT^^99ROC|
|SUP^^99ROC||F||||chew11~REALTIME|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110137||
||||||RSLT
OBX|70|NM|11014^11014^99ROC^^^IHELAW|1|*****|COI^^99ROC|SUP^^99ROC||F||||chew11~RE
ALTIME|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110237||||||RSLT
OBX|71|CE|11014^11014^99ROC^^^IHELAW|1|*****^99ROC|SUP^^99ROC||F||||chew11~REALT
IME|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110237||||||RSLT
TCD|11014^99ROC|^1^:~1
INV|1311014|OK^^HL70383~CURRENT^^99ROC|ASY|57796|1|14|20230430||596294
INV|1018448|OK^^HL70383~CURRENT^^99ROC|PRC|10722|1|1|20240630||668921
OBX|72|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20221222104407||
|SUP^^99ROC||F||||chew11~REALTIME|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110237||
||||||RSLT
OBX|73|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|318||S
UP^^99ROC||F||||chew11~REALTIME|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110237|||
||||RSLT
OBX|74|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2448~2444~2440||S
UP^^99ROC||F||||chew11~REALTIME|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110237|||
||||RSLT
OBX|75|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|1^99ROC||SUP^^9
9ROC||F||||chew11~REALTIME|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110237||||||
RSLT
OBX|76|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1
|0.000000 - 0.000000||SUP^^99ROC||F||||chew11~REALTIME|e402^ROCHE~ME01-10^ROCHE~1^R
OCHE|20221222110237||||||RSLT
OBX|77|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1| - ||
|SUP^^99ROC||F||||chew11~REALTIME|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110237||
||||RSLT
OBX|78|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1
| - ||SUP^^99ROC||F||||chew11~REALTIME|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110
237||||||RSLT
OBX|79|NM|11014_EFS^11014_EFS^99ROC^S_RAW^Raw Supplemental^IHELAW|1|9926.6125|COUNT^^99
ROC|SUP^^99ROC||F||||chew11~REALTIME|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|2022122211023
7||||||RSLT
OBX|80|NM|11014_EFV^11014_EFV^99ROC^S_RAW^Raw Supplemental^IHELAW|1|-117.3291|COUNT^^99
ROC|SUP^^99ROC||F||||chew11~REALTIME|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|2022122211023
7||||||RSLT
OBX|81|NM|11014_EFC^11014_EFC^99ROC^S_RAW^Raw Supplemental^IHELAW|1|275.0688|COUNT^^99R
OC|SUP^^99ROC||F||||chew11~REALTIME|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110237
||||||RSLT
OBX|82|NM|11014_PMT^11014_PMT^99ROC^S_RAW^Raw Supplemental^IHELAW|1|22885|COUNT^^99ROC|
|SUP^^99ROC||F||||chew11~REALTIME|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222110237||
||||RSLT
OBX|83|NM|AHIV_01^AHIV_01^99ROC^^^IHELAW|1|0.0622|COI^^99ROC||F||||chew11~REALTIME|
|e402^ROCHE~MS02-10^ROCHE~0^ROCHE|20221222110315||||||RSLT
OBX|84|CE|AHIV_01^AHIV_01^99ROC^^^IHELAW|1|-1^99ROC||F||||chew11~REALTIME|e402^R
OCHE~MS02-10^ROCHE~0^ROCHE|20221222110315||||||RSLT
OBX|85|NM|AHIV_02^AHIV_02^99ROC^^^IHELAW|1|0.0662|COI^^99ROC||F||||chew11~REALTIME|
|e402^ROCHE~MS02-10^ROCHE~0^ROCHE|20221222110315||||||RSLT
OBX|86|CE|AHIV_02^AHIV_02^99ROC^^^IHELAW|1|-1^99ROC||F||||chew11~REALTIME|e402^R
OCHE~MS02-10^ROCHE~0^ROCHE|20221222110315||||||RSLT

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Roche Diagnostics

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OBX|111|NM|12000^12000^99ROC^^^IHELAW|1|""|""|N^HL70078||B||||chew1~REALTIME||e402
^ROCHE~MS02-10^ROCHE~0^ROCHE|20221222110307||||||RSLT
OBX|112|CE|12000^12000^99ROC^^^IHELAW|1|""|""|N^HL70078||B||||chew1~REALTIME||e402^R
OCHE~MS02-10^ROCHE~0^ROCHE|20221222110307||||||RSLT
INV|12000|OK^HL70383~CURRENT^^99ROC|KIT|134|1|""|""|20230430|||596294
OBX|113|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20221222104407|
|N^HL70078||B||||chew1~REALTIME||e402^ROCHE~MS02-10^ROCHE~0^ROCHE|20221222110307|
||||||RSLT
OBX|114|EI|CombID^Measurement Cell Test Combination ID^99ROC^S_OTHER^Other Supplemental
^IHELAW|1|1|N^HL70078||B||||chew1~REALTIME||e402^ROCHE~MS02-10^ROCHE~0^ROCHE|2022
1222110307||||||RSLT
OBX|115|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2450~2446~2442||
N^HL70078||B||||chew1~REALTIME||e402^ROCHE~MS02-10^ROCHE~0^ROCHE|20221222110307||
||||RSLT

```

3.3.20. OUL_R22 Upload Message - Subresults for cobas e flow Tests OFF (HIV DUO R)

Application Code: 12000

Sample ID 2022120134

Subresults for **cobas e** flow Tests OFF

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MSH|^~\&|cobas pure||Host||20230512165613+0900||OUL^R22^OUL_R22|239|P|2.5.1||NE|AL||UN
ICODE UTF-8||LAB-29^IHE
PID||?|^^^^^U||U
SPM|1|2022120139&BARCODE||SERPLAS^^99ROC||||P^HL70369||~|20230512161622||||
||SC^^99ROC
SAC||2022120139^BARCODE||||50015|1|||||^1^:1
OBR|1|2022120139||12000^99ROC||||G
ORC|SC||CM
TQ1|||||R^HL70485
OBX|1|NM|12000^12000^99ROC^^^IHELAW|1|^99ROC|N^HL70078||F||||vogtm13~REALTIME||e4
02^ROCHE~MS02-10^ROCHE~0^ROCHE|20230512165613||||||RSLT
OBX|2|CE|12000^12000^99ROC^^^IHELAW|1|34^99ROC|N^HL70078||F||||vogtm13~REALTIME||
e402^ROCHE~MS02-10^ROCHE~0^ROCHE|20230512165613||||||RSLT
OBX|3|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1||N^HL70078||F||
||vogtm13~REALTIME||e402^ROCHE~MS02-10^ROCHE~0^ROCHE|20230512165613||||||RSLT
OBX|4|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|0^99ROC||N^HL70
078||F||||vogtm13~REALTIME||e402^ROCHE~MS02-10^ROCHE~0^ROCHE|20230512165613||||||
RSLT
OBX|5|NM|12000^12000^99ROC^^^IHELAW|1|""|""|N^HL70078||B||||vogtm13~REALTIME||e402^
ROCHE~MS02-10^ROCHE~0^ROCHE|20230512163507||||||RSLT
OBX|6|CE|12000^12000^99ROC^^^IHELAW|1|""|""|N^HL70078||B||||vogtm13~REALTIME||e402^R
OCHE~MS02-10^ROCHE~0^ROCHE|20230512163507||||||RSLT
INV|12000|OK^HL70383~CURRENT^^99ROC|KIT|153|1|""|""|20240930|||690303
OBX|7|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20230512161607||
N^HL70078||B||||vogtm13~REALTIME||e402^ROCHE~MS02-10^ROCHE~0^ROCHE|20230512163507||
||||RSLT
OBX|8|EI|CombID^Measurement Cell Test Combination ID^99ROC^S_OTHER^Other Supplemental^I
HELAW|1|1||N^HL70078||B||||vogtm13~REALTIME||e402^ROCHE~MS02-10^ROCHE~0^ROCHE|20230
512163507||||||RSLT
OBX|9|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1||N^HL70078||B||
||vogtm13~REALTIME||e402^ROCHE~MS02-10^ROCHE~0^ROCHE|20230512163507||||||RSLT
OBX|10|NM|12000^12000^99ROC^^^IHELAW|1|""|""|N^HL70078||B||||vogtm13~REALTIME||e402
^ROCHE~MS02-10^ROCHE~0^ROCHE|20230512165507||||||RSLT
OBX|11|CE|12000^12000^99ROC^^^IHELAW|1|""|""|N^HL70078||B||||vogtm13~REALTIME||e402^R
OCHE~MS02-10^ROCHE~0^ROCHE|20230512165507||||||RSLT

```


SLT

OBX|7|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|0.000000 - 0.000000||N^HL70078||F|||||chew1~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222115535|||||||RSLT

OBX|8|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|-999999 - 999999||N^HL70078||F|||||chew1~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222115535|||||||RSLT

OBX|9|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1|-999999 - 999999||N^HL70078||F|||||chew1~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222115535|||||||RSLT

OBX|10|NM|10049_EFS^10049_EFS^99ROC^S_RAW^Raw Supplemental^IHELAW|1|2018.7165|COUNT^99ROC||N^HL70078||F|||||chew1~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222115535|||||||RSLT

OBX|11|NM|10049_EFV^10049_EFV^99ROC^S_RAW^Raw Supplemental^IHELAW|1|-117.5330|COUNT^99ROC||N^HL70078||F|||||chew1~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222115535|||||||RSLT

OBX|12|NM|10049_EFC^10049_EFC^99ROC^S_RAW^Raw Supplemental^IHELAW|1|274.7137|COUNT^99ROC||N^HL70078||F|||||chew1~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222115535|||||||RSLT

OBX|13|NM|10049_PMT^10049_PMT^99ROC^S_RAW^Raw Supplemental^IHELAW|1|24118|COUNT^99ROC||N^HL70078||F|||||chew1~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221222115535|||||||RSLT

3.3.22. OUL_R22 Upload Message- Result Quantitative Result (TSH)

Application Code: 10172

Sample ID: 2022113

MSH|^~\&|cobas pure||Host||20221216154212+0900||OUL^R22^OUL_R22|994|P|2.5.1||NE|AL||UNICODE UTF-8||LAB-29^IHE

PID|||000008||^U||2000101|F

SPM|1|2022113&BARCODE|SERPLAS^99ROC|||||P^HL70369||~||20221216152236|||||||SC^99ROC

SAC|||2022113^BARCODE|||||50016|2|||||||1^:1

OBR|1|2022113||10172^99ROC|||||G

ORC|SC|||CM

TQ1||||||R^HL70485

OBX|1|NM|10172^10172^99ROC^^^IHELAW|1|0.00500|μIU/mL^99ROC||27^99ROC||F|||||yapk2~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221216154150|||||||RSLT

OBX|2|CE|10172^10172^99ROC^^^IHELAW|1|^99ROC||27^99ROC||F|||||yapk2~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221216154150|||||||RSLT

TCD|10172^99ROC|^1^:1

INV|1310172|OK^HL70383~CURRENT^99ROC|ASY|53417|1|18|||||20230930|||631966

INV|1018448|OK^HL70383~CURRENT^99ROC|PRC|10720|1|1|||||20240630|||668921

OBX|3|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20221216152319||27^99ROC||F|||||yapk2~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221216154150|||||||RSLT

OBX|4|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|329||27^99ROC||F|||||yapk2~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221216154150|||||||RSLT

OBX|5|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|2426~2425||27^99ROC||F|||||yapk2~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221216154150|||||||RSLT

OBX|6|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|1^99ROC||27^99ROC||F|||||yapk2~REALTIME||e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221216154150|||||||RSLT

```

OBX|7|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
0.00500 - 100|||27^^99ROC|||F|||yapk2~REALTIME|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|2022
1216154150|||RSLT
OBX|8|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|-99999
99 - 9999999|||27^^99ROC|||F|||yapk2~REALTIME|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221
216154150|||RSLT
OBX|9|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1|
-9999999 - 9999999|||27^^99ROC|||F|||yapk2~REALTIME|e402^ROCHE~ME01-10^ROCHE~1^ROCHE
|20221216154150|||RSLT
OBX|10|NM|10172_EFS^10172_EFS^99ROC^S_RAW^Raw Supplemental^IHELAW|1|603.5092|COUNT^^99R
OC||27^^99ROC|||F|||yapk2~REALTIME|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221216154150||
||RSLT
OBX|11|NM|10172_EFV^10172_EFV^99ROC^S_RAW^Raw Supplemental^IHELAW|1|-118.9720|COUNT^^99
ROC||27^^99ROC|||F|||yapk2~REALTIME|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221216154150|
||RSLT
OBX|12|NM|10172_EFC^10172_EFC^99ROC^S_RAW^Raw Supplemental^IHELAW|1|244.5737|COUNT^^99R
OC||27^^99ROC|||F|||yapk2~REALTIME|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221216154150||
||RSLT
OBX|13|NM|10172_PMT^10172_PMT^99ROC^S_RAW^Raw Supplemental^IHELAW|1|22990|COUNT^^99ROC|
|27^^99ROC|||F|||yapk2~REALTIME|e402^ROCHE~ME01-10^ROCHE~1^ROCHE|20221216154150|||
||RSLT

```

3.3.23. OUL_R22 Upload Message - Semiquantitative Upload (TH2S2) ON

Application Code: 21073

Sample ID: 2022120141

```

MSH|^~\&|cobas pure||Host||20230512153212+0900||OUL^R22^OUL_R22|207|P|2.5.1||NE|AL||UN
ICODE UTF-8||LAB-29^IHE
PID||?|^U||U
SPM|1|2022120141&BARCODE||UR^^HL70487||||P^^HL70369||~|20230512152133||||PS
CO^^99ROC||SC^^99ROC
SAC||2022120141^BARCODE||||50053|1|||||^1^:^1
OBR|1|2022120141|21070^^99ROC||||G
ORC|SC|||CM
TQ1|||||R^^HL70485
OBX|1|NM|21070^21070^99ROC^^IHELAW|1|235|mAbs^^99ROC|26^^99ROC~112^^99ROC|||F|||yap
k2~REALTIME|c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230512153211||||RSLT
OBX|2|CE|21070^21070^99ROC^^IHELAW|1|3^^99ROC||26^^99ROC~112^^99ROC|||F|||yapk2~REA
LTIME|c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230512153211||||RSLT
TCD|21070^^99ROC|^1^:~1
INV|2107002|OK^^HL70383~CURRENT^^99ROC|R1|119|1|40||||20231031|||647249
INV|2107002|OK^^HL70383~CURRENT^^99ROC|R3|119|1|40||||20231031|||647249
OBX|3|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20230512152150||
26^^99ROC~112^^99ROC|||F|||yapk2~REALTIME|c303^ROCHE~MC02-03^ROCHE~1^ROCHE|202305121
53211||||RSLT
OBX|4|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|743||26
^^99ROC~112^^99ROC|||F|||yapk2~REALTIME|c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230512153
211||||RSLT
OBX|5|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|||26^^99ROC~112^^9
9ROC|||F|||yapk2~REALTIME|c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230512153211||||R
SLT
OBX|6|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|0^^99ROC||26^^99R
OC~112^^99ROC|||F|||yapk2~REALTIME|c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230512153211||
||RSLT
OBX|7|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|

```

```
-99999 - -0.00001|||26^99ROC~112^99ROC|||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230512153211|||RSLT
OBX|8|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|-99999
99 - 9999999|||26^99ROC~112^99ROC|||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230512153211|||RSLT
OBX|9|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1|-9999999 - 9999999|||26^99ROC~112^99ROC|||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230512153211|||RSLT
```

3.3.24. OUL_R22 Upload Message - Semiquantitative Upload (TH2S2) OFF

Application Code: 21073

Sample ID: 2022120140

```
MSH|^~\&|cobas pure||Host||20230512161750+0900||OUL^R22^OUL_R22|231|P|2.5.1||NE|AL|UN
ICODE UTF-8||LAB-29^IHE
PID||?|^U||U
SPM|1|2022120140&BARCODE||UR^HL70487|||P^HL70369||~|20230512160711|||PS
CO^99ROC||SC^99ROC
SAC||2022120140^BARCODE|||50053|1|||^1^:^1
OBR|1|2022120140|21073^99ROC|||G
ORC|SC||CM
TQ1|||R^HL70485
OBX|1|NM|21073^21073^99ROC^^IHELAW|1|^99ROC||112^99ROC|||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230512161749|||RSLT
OBX|2|CE|21073^21073^99ROC^^IHELAW|1|3^99ROC||112^99ROC|||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230512161749|||RSLT
TCD|21073^99ROC|^1^:^1
INV|2107002|OK^HL70383~CURRENT^99ROC|R1|119|1|40|||20231031||647249
INV|2107002|OK^HL70383~CURRENT^99ROC|R3|119|1|40|||20231031||647249
OBX|3|DTM|PT^Pipetting_Time^99ROC^S_OTHER^Other Supplemental^IHELAW|1|20230512160728||112^99ROC|||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230512161749|||RSLT
OBX|4|EI|CalibrationID^CalibrationID^99ROC^S_OTHER^Other Supplemental^IHELAW|1|744||112^99ROC|||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230512161749|||RSLT
OBX|5|EI|QCTID^QC Test ID^99ROC^S_OTHER^Other Supplemental^IHELAW|1||112^99ROC|||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230512161749|||RSLT
OBX|6|CE|QCSTATE^QC Status^99ROC^S_OTHER^Other Supplemental^IHELAW|1|0^99ROC||112^99ROC|||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230512161749|||RSLT
OBX|7|ST|TR_TECHNICALLIMIT^TR_TECHNICALLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|0.000000 - 999999||112^99ROC|||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230512161749|||RSLT
OBX|8|ST|TR_REPEATLIMIT^TR_REPEATLIMIT^99ROC^S_OTHER^Other Supplemental^IHELAW|1|-9999999 - 9999999||112^99ROC|||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230512161749|||RSLT
OBX|9|ST|TR_EXPECTEDVALUES^TR_EXPECTEDVALUES^99ROC^S_OTHER^Other Supplemental^IHELAW|1|-9999999 - 9999999||112^99ROC|||F|||yapk2~REALTIME||c303^ROCHE~MC02-03^ROCHE~1^ROCHE|20230512161749|||RSLT
```

3.3.25. OML_O33 Message from host with test order for different sample type in None

Rack

None Rack number 50084

Application Code: 20631

Sample ID: 2022120140

Application Code: 20630

Sample ID: 2022120121

```

MSH|^~\&|Host||cobasPure||20230822113846+0200||OML^033^OML_033|8b346b35-3412-4d26-8|P|2
.5.1|||NE|AL||UNICODE UTF-8|||LAB-28R^ROCHE
PID|||?||^U||U
SPM|1|2022120140&BARCODE||UR^HL70487|||||P^HL70369|||||20230822113846|||||||SC^
^99ROC
SAC|||2022120140^BARCODE|||||50084|4
ORC|NW|||||20230822113846
TQ1||||||R^HL70485
OBR|1|2022120140||20631^^99ROC
TCD|20631^^99ROC

```

```

MSH|^~\&|Host||cobasPure||20230822113839+0200||OML^033^OML_033|e3baca5d-0166-409f-8|P|2
.5.1|||NE|AL||UNICODE UTF-8|||LAB-28R^ROCHE
PID|||?||^U||U
SPM|1|2022120121&BARCODE||SERPLAS^^99ROC|||||P^HL70369|||||20230822113839|||||||
SC^^99ROC
SAC|||2022120121^BARCODE|||||50084|1
ORC|NW|||||20230822113839
TQ1||||||R^HL70485
OBR|1|2022120121||20630^^99ROC
TCD|20630^^99ROC

```

EU Declaration of Conformity

Manufacturer: Hitachi High-Tech Corporation
Address: 1-17-1 Toranomon, Minato-ku, Tokyo 105-6409, Japan
Single Registration Number: JP-MF-000016991

European Representative: Roche Diagnostics GmbH
Address: Sandhofer Strasse 116, 68305 Mannheim, Germany
Product Name: **cobas pure integrated solutions**

We, Hitachi High-Tech Corporation, declare under our sole responsibility that **cobas pure integrated solutions** (Refer to Appendix I for the components) is/are in conformity with the following European Union harmonisation legislation:

- REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
- DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances
- DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC

Intended use/purpose: cobas pure integrated solutions is an automated analyzer, intended for running qualitative and quantitative clinical chemistry and immunochemistry assays as well as ion selective measurements.

Notified Body's name/number (if applicable) Not applicable

IVDR conformity assessment procedures: Annex II and III of REGULATION (EU) 2017/746 (Class A)

Starting Serial No.: See Appendix II

Applied standards: See Appendix III

on behalf of the company

Date: 21-Jun-2023

DocuSigned by:

Signer Name: Yoshihiro Kawabe
Signing Reason: I approve this document
Signing Time: 21-6-2023 | 5:29:41 午後 JST
BAED48270E964289885A9C77871D4151

Yoshihiro Kawabe
General Manager
Medical Systems Quality Assurance Dept
Corporate Quality Assurance Div.
Hitachi High-Tech Corporation

Contact address:
Hitachi High-Tech Corporation
1-17-1 Toranomon, Minato-ku, Tokyo 105-6409, Japan

on behalf of the company

Date: 22-Jun-2023

DocuSigned by:

Signer Name: noda takayuki
Signing Reason: I approve this document
Signing Time: 22-Jun-2023 | 12:35:06 PM JST
32427F2C1AB9418A9A250B54ACAD1CFD

Takayuki Noda
General Manager
Medical Systems Design 1st Dept
Analytical & Medical Solution Business Group
Hitachi High-Tech Corporation

Appendix I
List of components for cobas pure integrated solutions

Product name or component name	Basic UDI-DI	Order information	Risk classification for REGULATION (EU) 2017/746
sample supply unit	761333601772B8	09031537001	Class A
cobas e 402 analytical unit	761333601773BA	09031553001	Class A
cobas c 303 analytical unit	761333601771B6	09031529001	Class A
cobas pure liquid waste container	761333601774BC	09033394001	Class A

Appendix II
List of applicable product name and serial number

REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU:

Product name or component name	Starting serial number
sample supply unit	From 2201-01 onward
cobas e 402 analytical unit	From 2201-01 onward
cobas c 303 analytical unit	From 2201-01 onward (NAKA site shipment) From U301-01 onward (OMUTA site shipment)
cobas pure liquid waste container	Shipment from March 2022 onward

DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances:

Product name or component name	Starting serial number
sample supply unit	From 2201-01 onward
cobas e 402 analytical unit	From 2201-01 onward
cobas c 303 analytical unit	From 2201-01 onward (NAKA site shipment) From U301-01 onward (OMUTA site shipment)
cobas pure liquid waste container	Shipment from March 2022 onward

DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC:

Product name or component name	Starting serial number
sample supply unit	From 2201-01 onward
cobas e 402 analytical unit	From 2201-01 onward
cobas c 303 analytical unit	From 2201-01 onward (NAKA site shipment) From U301-01 onward (OMUTA site shipment)
cobas pure liquid waste container	Shipment from March 2022 onward

Appendix III
List of applied standards:

REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

Standard number, year	Name of applied standard
EN ISO 13485: 2016	Medical devices – Quality management systems - Requirements for regulatory purposes
EN ISO 14971: 2019	Medical devices - Application of risk management to medical devices
IEC 62366-1:2015 +AMD 1:2020	Medical devices - Part 1: Application of usability engineering to medical devices - Amendment 1
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 18113-1: 2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 1: Terms, definitions and general requirements
EN ISO 18113-3: 2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 3: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
IEC 61010-2-101: 2015	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 61326-2-6: 2012/ EN 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment

DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances:

Standard number, year	Name of applied standard
EN IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC:

Standard number, year	Name of applied standard
EN 300 330 V2.1.1	Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz
IEC61010-2-101:2002	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 62479:2010:	Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)
EN 301 489-1 V1.9.2:	Electro Magnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
EN 301 489-3 V1.6.1:	Electromagnetic compatibility and Radio spectrum Matters (ERM); Electro-Magnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz

End of the document

cobas[®] pure integrated solutions*
Simplicity meets Excellence

*In development and not commercially available



01 cobas e 402 analytical unit¹

Up to **120 Immunochemistry** tests per hour
28 reagent positions

02 Sample Supply unit¹

Up to **50** samples direct loading
Up to **50** samples direct unloading
STAT port

03 cobas c 303 analytical unit¹

Up to **450 photometric** tests per hour
Up to **450 ISE** tests per hour
Up to **750 tests** per hour
(mixed mode photometric and ISE)
42 reagent positions

cobas[®] pure integrated solutions

Simplicity meets Excellence

Today more than ever, the importance of accurate and timely diagnostics is clearly understood. The journey from blood collection to the final test result, however, requires the highest level of dedication, expertise and diligence of the laboratory staff.

To support you in this, Roche has developed innovative integrated solutions renowned for quality and excellence.

cobas[®] pure integrated solutions is the newest member of the **cobas[®]** family of systems which is designed to deliver excellence, while at the same time simplifying your daily work. **cobas[®] pure** combines clinical chemistry, immunochemistry and ISE testing on a footprint of just 2 square meters, giving access to our broad menu of more than 230 parameters – including many unique high medical value assays to labs who have to deal with limited space.

To simplify daily operation, **cobas[®] pure** comes with new features that minimize the hands on work for the operators, thus saving precious time.

To ensure simple and effective work for network organizations, **cobas[®] pure** provides fully standardized results and operation to **cobas[®] pro** integrated solutions – Roche's latest analyzer designed for larger labs.

Because simplifying any step of the journey can help deliver fast and accurate diagnosis.

A female scientist with short blonde hair, wearing a white lab coat over a mustard-colored top and blue nitrile gloves, is looking down at a black tablet she is holding. She is standing in a modern laboratory with large glass windows in the background. The background shows laboratory equipment, including a fume hood and various containers, which are slightly out of focus. The lighting is bright and even.

*Your time is precious
We help you use it wisely*

In the lab, every minute counts – for you and your team, for the physician and the healthcare institution, for the patient and their family.

Empower your physicians to take action faster

Standards are being raised across health systems, as patient and physician satisfaction and fast clinical decision making are becoming more prominent quality metrics. Choosing an analyzer that supports short and predictable turnaround times at peak times is a key to meet these standards.

Get answers fast with short and predictable turnaround times

cobas® pure integrated solutions is designed to support fast and predictable turnaround times across all assays.

93% of Roche immunoassays have reaction time of 18 minutes or less, with STAT assays having just 9 min reaction time.²

To offer full transparency, **cobas® pure integrated solutions** allows the operator to see the time to result per sample and per test as well as the time to last result on all ordered tests.

Roche reaction times²



9 minutes



18 minutes



27 minutes



Benefit from reduced system preparation and hands-on time

Free up staff time with reduced hands-on maintenance efforts

With **cobas® pure** integrated solutions, every effort has been made to reduce hands-on maintenance tasks to a minimum. The new and smart concept of self-operating maintenance executes maintenance tasks automatically in the background and reduces the manual burden of daily maintenance to 8 min.¹

Save time and costs with cobas® AutoCal

The clinical chemistry module of **cobas® pure** integrated solutions comes with a significantly simplified calibration concept – automated calibration. With **cobas® AutoCal**, new reagent lots for the majority of clinical chemistry tests are calibrated automatically, without the need for manual calibration. This can lead to 56 % less calibration events, saving up to 105 hours of hands-on time yearly.*³

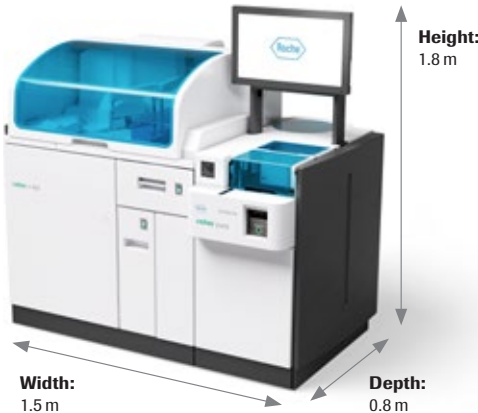
*For a common, daily routine workload, as compared to **cobas** 6000 <501|601> Mid Volume Commercial Lab



*Your space is limited
We help you make the best of it*

cobas® pure integrated solutions is designed to deliver true productivity for your lab and access to our complete Serum Work Area assay menu on a compact footprint of just 2 square meters.

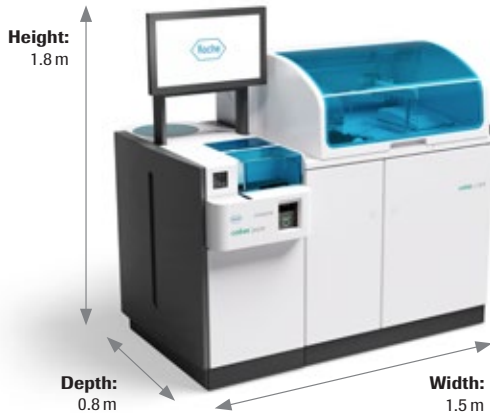
Three compact configurations*



Immunochemistry Configuration
Footprint $\approx 1.2 \text{ m}^2$



Serum Work Area Configuration
Footprint $\approx 2.0 \text{ m}^2$



Clinical Chemistry Configuration
Footprint $\approx 1.2 \text{ m}^2$

Consolidate clinical chemistry & immunochemistry on a single platform

- 
One
sample tube for all CC & IM tests to handle
- 
One
set of results to track
- 
One
platform to manage and to be trained on
- 
One
user interface to interact with
- 
One
manufacturer to partner with

*The width and depth dimensions shown here are the floor(footprint) dimensions⁴

Increase productivity with our improved reagent carriers in clinical chemistry and immunochemistry

Ready to use reagents

cobas® pure uses the latest reagent generation from Roche – **cobas e** pack green and **cobas c** pack green. These reagents do not require any preparation, mixing, waiting or pre-opening. The operator can simply take them out of the fridge and load them directly onto the analyzer.



No preparing



No mixing



No waiting



No pre-opening

Take out of the fridge

Load onto the analyzer

Industry's leading onboard stability

Using space intelligently is about achieving the highest output within the existing space. The average onboard stability for the immunochemistry reagents is 110 days, with 98 % of the assays having an onboard stability of 4 months. The average on board stability for clinical chemistry is 137 days, with 57 % of the reagents having an onboard stability of 6 months.^{5,6}

Immunochemistry⁵



cobas e
pack green

- Up to 4 months onboard stability
- ≈ 3 times longer average onboard stability compared to previous generation systems

Clinical chemistry⁶



cobas c
pack green

- Up to 6 months onboard stability
- ≈ 2 times longer average onboard stability compared to previous generation systems



*Your team is pushed to their limits
We help them focus on the tasks that matter*

Whilst the pressure to deliver continuously increases, keeping your team engaged and focused on value-adding tasks can be difficult but is of paramount importance for your lab's success. The **cobas® pure** integrated solutions is designed to eliminate hurdles that may cause unnecessary stress.

Safety of results¹

Disposable AssayTips/AssayCups
cobas pure immunochemistry analytical unit utilizes single-use disposable AssayTips and AssayCups to completely eliminate the risk of sample carry over.

Carryover evasion program
The sample probes on the **cobas pure** clinical chemistry analytical unit are rinsed inside and outside with deionized water each time after dispensing a sample. Additionally, for applications that are sensitive to sample carryover, special wash can be programmed for an extra wash of reagent probes, sample probes and reaction cells with basic and acidic wash solutions.

Ultrasonic Mixing
The **cobas pure** clinical chemistry analytical unit features ultrasonic mixing for non-contact mixing of sample and reagent to eliminate the risk of carryover during this event.

Sample

Liquid Level Detection

Foam detection

Clot detection

Reagent

Liquid Level Detection

Foam detection

Clinical Chemistry

Carryover evasion program

Ultrasonic Mixing of sample and reagent

Immunochemistry

Single-use AssayTip

Single-use AssayCup

Reliability

cobas® pure integrated solutions is designed to deliver the reliability that Roche is known for. With more than 75,000 analytical units globally, the **cobas** family of solutions demonstrates a distinctive uptime* of more than 99 %.⁷ Having a reliable analyzer means less interruption of services and less time spent on troubleshooting, thus higher productivity with more predictable turnaround times.

99 % uptime⁷

* Uptime: Percentage of the time when system is up and running vs. the time the system is not running due to unplanned incidents. Calculation:
(365 days/Mean time between repair visit) × (Mean time for repair visit + Travel Time)⁷

Bring more confidence to your team
with reliable and safe solutions

Unplanned downtime and lack of confidence in results are some of the most stressful things that can happen in the lab. They shift attention to time-consuming, hands-on workarounds or sample reruns which can affect staff morale and motivation.

Additionally, they pose risks to the quality of results and the lab's reputation. With **cobas® pure integrated solutions** we deliver distinctive reliability through sound system architecture and confidence in the results through various safety features.





Enable your team to work more efficiently through standardized solutions

Lab standardization enables you to do more work on fewer instruments, through consolidation of workflow, systems and reagents. Standardization also provides efficient and compatible solutions for network cooperation.

Essential benefits of standardization

Improved speed and accuracy of care

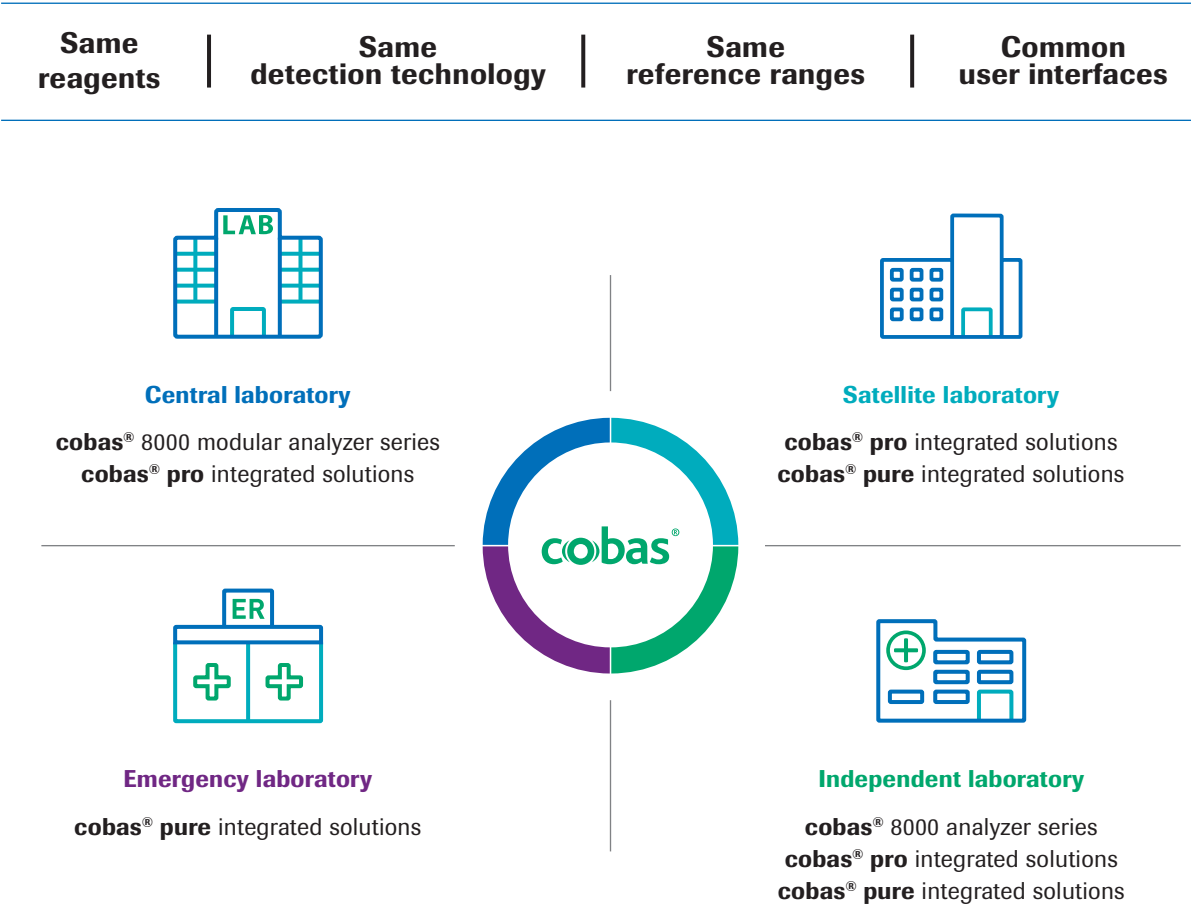
Same reagents and detection technology mean standardized reference ranges which improve the speed and accuracy of care.

Simplified training and staff allocation

Common user interfaces between our **cobas**® systems simplify training and allow for flexible staff allocation as healthcare centers are consolidating into larger integrated health networks.

Optimized patient management

Consistent results over time and across different locations enable optimized patient management.





*Your future is unpredictable
We help you succeed through continuous
access to innovations*

Choosing the right solution and vendor to partner with is not a small undertaking – it is a choice that impacts your lab's ability to fulfill performance and quality standards but also your ability to remain competitive. At Roche we believe in the power of innovation to advance and improve diagnostics – for a better future of the patients and your lab.

*Support better outcomes by
delivering greater medical value*



*Focused innovation of
our assay portfolio*

Extending evidence base

Extending the evidence-base for existing assays through clinical studies to generate higher awareness and broader access to innovation.

New claims for existing assays

Generating new claims for existing assays for a wider range of application.

Discovery of new assays

Menu expansion in the areas of unmet medical needs to help clinicians improve outcomes for their patients.

Bring Personalized Healthcare to clinical practice

Supporting better patient care, contributing to health economics and empowering labs to play a greater role in medical decision making.

*Commitment to exceptional
assay quality*

Advanced assay design

- Outstanding precision across measuring range
- High sensitivity in areas where it matters
- Wider measuring ranges, fewer dilutions and repeats

Consistent, standardized results

- Consistent patient results across all platforms
- Excellent lot-to-lot consistency
- Assays standardized against reference method or reference material

Designed for convenience

- Short and predictable assay Turn Around Times
- Low sample volume
- No reagent preparation required

*Introducing the new generation
of solutions from Roche –
cobas® integrated solutions*

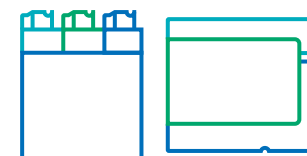


cobas® pure integrated solutions



cobas® pro integrated solutions

Delivering seamless design today and into the future



**Shared reagents
packs**



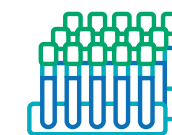
**Consistent
results**



**Consistent
operation**



**Same
technologies**



**Same assay
menu**



cobas® pure integrated solutions

General technical specifications

Dimensions and Weights	Width	Depth	Height	Weight
Sample Supply Unit (SSU), (excl. STAT port and incl. touch screen monitor)	450	800	1,750 mm	200 kg
	17.7	31.5	70.0 inch	441 lb
cobas c 303 (incl. ISE) analytical unit	1,000	800	1,375 mm	400 kg
	39.4	31.5	54.1 inch	882 lb
cobas e 402 analytical unit	1,000	800	1,375 mm	400 kg
	39.4	31.5	54.1 inch	882 lb
SWA System Configuration <c 303 SSU e 402>	2,450	800	1,750 mm	1,000 kg
	96.5	31.5	70.0 inch	1,764 lb

cobas® pure integrated solutions	
Specifications of the electrical power supply	
Distance to system	≤ 5 m (16 feet)
Electrical supply	Single Phase AC
	200 / 208 / 220 / 230 / 240 V
	50 / 60 Hz
Max. power fluctuation	≤ 10 %
Power consumption	≤ 4.0 kVA
	Whole System: < 4.0 kVA
	SSU: < 0.5 kVA
	cobas c 303 AU: < 1.5 kVA
	cobas e 402 AU: < 2.0 kVA

cobas[®] pure integrated solutions

General technical specifications continued

	cobas c 303 (incl. ISE)	cobas e 402
Deionized water supply and consumption		
Distance to instrument	≤ 5 m	≤ 5 m
	≤ 16 feet	≤ 16 feet
Conductivity	≤ 1.0 µS/cm	≤ 1.0 µS/cm
Water pressure	50 to 340 kPa	50 to 340 kPa
	0.5 to 3.4 bar	0.5 to 3.4 bar
Water temperature	> 12 °C	≥ 12 °C
	> 53.6 °F	≥ 53.6 °F
Approx. deionized water consumption	max. 16 L/h	max. 12 L/h
Maximum liquid waste volumes		
Highly concentrated liquid waste flow rate	< 1.2 L/h	≤ 3 L/h
Diluted liquid waste flow rate	< 14.8 L/h	≤ 10 L/h
Environmental conditions during operation		
Maximum altitude above sea level	3,000 m	3,000 m
Floor conditions	≤ 1/200 or ≤ 0.5% inclination	≤ 1/200 or ≤ 0.5% inclination
	Bearing load ≥ 5 kN/m²	Bearing load ≥ 5 kN/m²
Ambient temperature	0 – 2,000 m above sea level 18 – 32 °C (64.4 – 89.6 °F)	0 – 2,000 m above sea level 18 – 32 °C (64.4 – 89.6 °F)
	> 2,000 m above sea level 18 – 30 °C (64.4 – 86 °F)	> 2,000 m above sea level 18 – 30 °C (64.4 – 86 °F)
Ambient temperature fluctuation	≤ 2 °C/hour (≤ 3.6 °F/h)	≤ 2 °C/hour (≤ 3.6 °F/h)
Ambient humidity	30 – 85 %	30 – 85 %



cobas e 402 analytical unit	Specifications
Specifications of the reagent system	
Reagent pack types	cobas e pack green
Reagent loading / unloading	Manual
Reagent Identification	RFID
Capacity of reagent disk	28 reagent packs
Reagent storage temperature	5 – 10 °C (41 – 50 °F)
Specifications of the sampling system	
Sampling cycle time	30 seconds
Sample pipetting volume	4 – 60 µL (1 µL steps)
Sample Liquid level detection	Available
Sample clot detection	Available
Sample air aspiration detection	Available
Specifications of the reaction system	
Number of incubator disk positions	38
Reaction volume	120 µL
Incubator temperature	37 °C ± 0.3 °C (98.6 °F ± 0.5 °F)
Reaction times for tests	9/18/27 min
Mixer	Vortex
Specifications of the ECL measuring system	
Measuring Cell	ECL measuring cell
Number of measuring cells	1
Maximum throughput*	120 tests/hour

*Throughput may differ based on the mix of test orders per sample

*Excellent performance, simple to use and beautifully designed. The new Immunochemistry analyzer – **cobas e** 402 analytical unit.*



*The new **cobas c** 303 analytical unit – combining photometric and ISE testing on a footprint of just 1.2 square meters.*

cobas c 303 analytical unit	Specifications
Specifications of the reagent system	
Reagent pack types	cobas c pack green
Reagent loading/unloading	Manual
Reagent Identification	RFID
Capacity of reagent disk	42 reagent packs
Reagent storage temperature	5 – 15 °C (41 – 59 °F)
Specifications of the sampling system	
Sampling cycle time	8 seconds
Sample pipetting volume	1.0 – 25.0 µL (0.1 µL steps)
Sample Liquid level detection	Available
Sample clot detection	Available
Sample air aspiration detection	Available
Specifications of the reaction system	
Number of reaction cells	128
Reaction volume	75 – 185 µL (detectable reaction volume)
Incubation bath temperature	37.0 +/- 0.1 °C
Reaction time	3 – 10 min (1 min steps)
Mixer	Ultrasonic
Specifications of the photometric system	
Measurements per reaction cell/10 min	46
Photometer lamp	12 V, 50 W
Photometer	Multiple wavelengths spectrophotometer
Maximum throughput*	Photometric only: 450 tests/hour
	ISE only: 450 tests/hour (150 samples/hour)
	Mixed mode Photometric & ISE: 750 tests/hour (300 photometric + 450 ISE tests/hour)**
	HbA1c only: 225 tests/hour

* Throughput may differ based on the mix of test orders per sample
** The ISE unit and the c 303 photometric measuring unit share the same sample pipetter

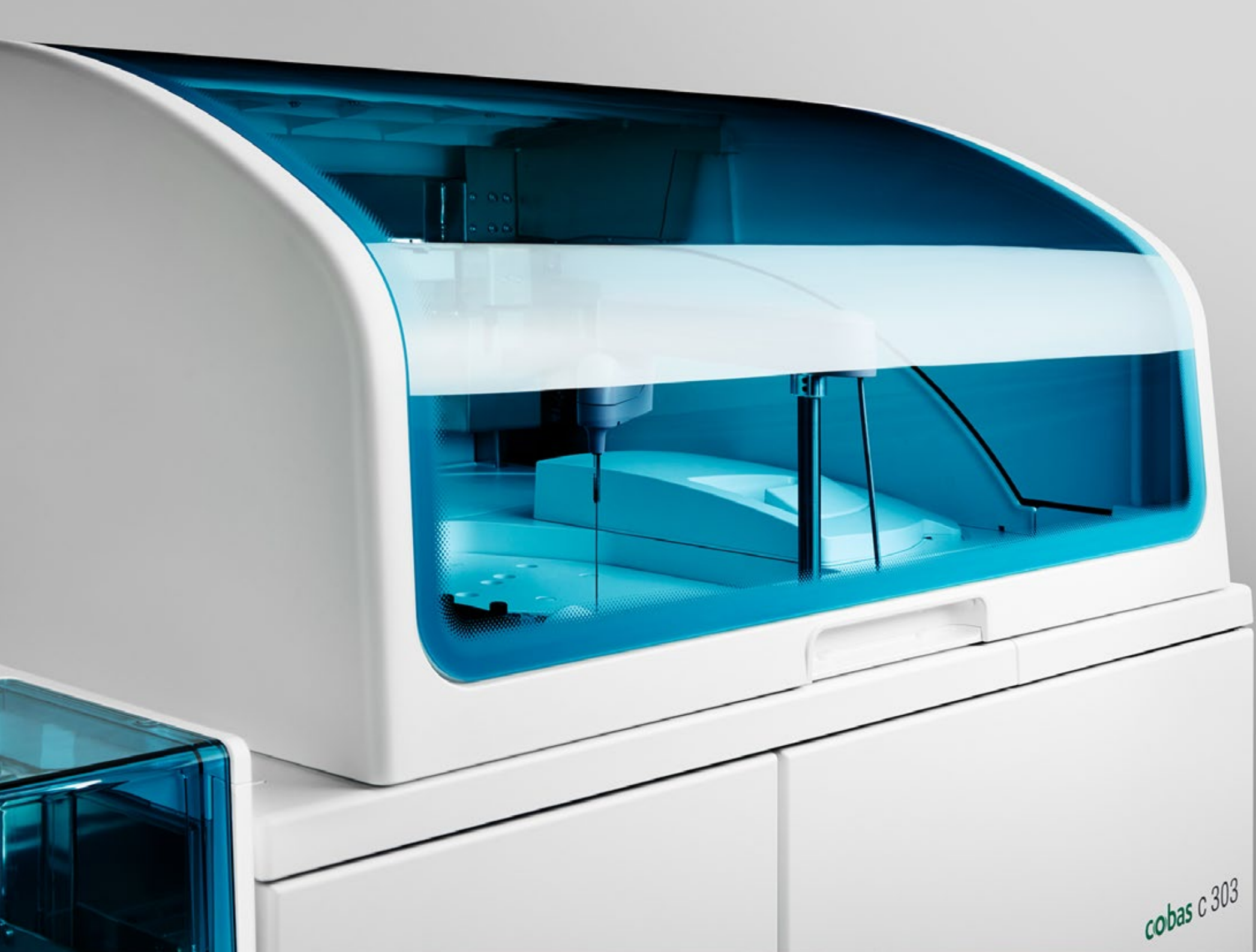
ISE unit (integrated in the c 303 analytical unit*)

Applications
Sample types
Number of electrodes
Maximum throughput**
Sampling cycle time
Electrode handling
Sample Liquid level detection
Sample clot detection
Sample air aspiration detection
Sample pipetting volumes (serum/plasma/urine)
Reagent pipetting volumes per sample

* The ISE unit and the c 303 photometric measuring unit share the same sample pipetter
** Throughput may differ based on the mix of test orders per sample

Specifications

Na ⁺ : Sodium
K ⁺ : Potassium
Cl ⁻ : Chloride
Serum/Plasma, Urine
Ion-selective electrodes: 3 (Na ⁺ , K ⁺ and Cl ⁻)
Reference electrode 1
ISE only: 450 tests/hour (150 samples)
24 seconds per sample for ISE
2D barcode placed on the electrode package
Available
Available
Available
15 µL For reruns of urine samples with a decreased sample volume after Test data alarm: 10 µL
DIL 780 µL
IS 720 µL
REF 130 µL



References

- 1 *cobas® pure integrated solutions User Guide – Publication Ver 1.0 · Draft Ver 3.*
- 2 *Elecsys assay menu cobas pure – Analysis (source method sheets cobas e pack green).*
- 3 *cobas pure – AutoCal Estimated Time Savings – Internal Calculation.*
- 4 *cobas pure – footprint dimensions – Internal Document.*
- 5 *Elecsys assay menu cobas pure – Analysis (source method sheets cobas e pack green, CMP Database).*
- 6 *Clinical Chemistry assay menu cobas pure – Analysis (source method sheets cobas c pack green).*
- 7 *Roche Diagnostics Internal Reporting Data On File – GCS reporting / Product reports Q1/2020, CPS Finance Report from Tableau, ICB Q1 2020.*

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