

# cobas e 411 analyzer

Addendum 2.0 to Operator's Manual, Publication version 3.3 Software version 03-02

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### **Publication information**

Publication version	Software version	Revision date	Change description
1.0	03-02	2021-08	<ul> <li>Information on language packs and current software version added.</li> </ul>
2.0	03-02	2023-02	<ul> <li>Updated information on Dead volume, Maintenance schedule, Operator ID, Competitive assays, Sandwich assays, and Pipetting Date/Time.</li> </ul>
⊞ Revision history	ory		

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### **Contact addresses**

### **Inside the European Union and EFTA** member states



Manufacturer of the

instrument

Hitachi High-Tech Corporation 1-17-1 Toranomon, Minato-ku,

Tokyo, 105-6409

Japan





Authorized representative and Importer

Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim

Germany

### **Outside the European Union and EFTA** member states

Manufactured by:

Hitachi High-Tech Corporation

Manufactured for:

Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim

Germany

Distributed in USA by:

Roche Diagnostics

9115 Hague Road Indianapolis,

Indiana, USA

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# **Specifications**

The section *Specifications* is revised to include corrected residual volume for Sample cup on top of primary tube (16 mm diameter).

## **Residual volume**

### Residual volume (rack system)

Sample container	Tube height	"Normal" residual volume	"Reduced" residual volume
Sample cup on top of a primary sample tube (16 mm diameter)	100 mm	150 μL	100 μL

■ Sample container residual volume (rack system)

## Reagent concept

The section Reagent concept > Result calculation for qualitative assays is revised to include corrected Qualitative assay result evaluation table, Sandwich assays, Competitive assays section.

## Result calculation for qualitative assays

#### Residual volume (rack system)

Result	Sandwich test (positive slope)	Competitive test (negative slope)
Nonreactive	Cutoff <sub>Index</sub> < LL	Cutoff <sub>Index</sub> > UL

■ Qualitative assay result evaluation

#### Sandwich assays

Samples with a cutoff index  $\geq 1.0$  are considered *reactive*; those with a cutoff index < 1.0 are considered *non-reactive*. For some tests, a gray zone is introduced.

 ¬Q
 ¬ The result message is displayed on Workplace
 > Data Review > Test Review. The decision about the result message (R.M. column) is taken after rounding is applied.

For qualitative sandwich tests, if the actual cutoff index is 1.001 to 1.004 before rounding, the cutoff index displayed after rounding is 1.00 and the result message *Reac* (reactive) is displayed.

If the actual cutoff index is 0.9995 to 0.9999 before rounding, the cutoff index displayed is still 1.00 after rounding, the result message *Reac* (reactive) is displayed.

#### **Competitive assays**

Samples with a cutoff index > 1.0 are considered non-reactive; those with a cutoff index  $\leq$  1.0 are considered reactive. For some tests, a gray zone is introduced.

The result message is displayed on **Workplace**> **Data Review** > **Test Review**. The decision about the result message (**R.M.** column) is taken after rounding is applied.

For qualitative competitive tests, if the actual cutoff index is 1.001 to 1.004 before rounding, the cutoff index displayed after rounding is 1.00 and the result message *Reac* (reactive) is displayed.

If the actual cutoff index is 0.9995 to 0.9999 before rounding, the cutoff index displayed is still 1.00 after rounding, the result message *Reac* (reactive) is displayed.

# Overview of the analyzer

The section *Overview of the control unit > Data storage* is revised to correct the Data files table.

## Overview of the control unit

**Data storage** 

Data type	Information stored
Parameter data	60 parameters for assays 5 parameters for calculated tests Up to 40 operator IDs Analyzer serial number

■ Data files

# Periodic maintenance schedule

The section *Maintenance schedule* is revised to include the corrected operator and system time in *Every two weeks* maintenance actions.

## **Maintenance schedule**

Frequency	Operator time (min)	System time (min)	Maintenance action
Every two weeks	4	17	Liquid flow cleaning
	7	0	Cleaning the rinse stations

■ Maintenance schedule

# **Overview of workplace functions**

The section *Data review tab* is revised to include the corrected definition of Pipetting Date/Time.

## Data review tab

**Pipetting Date/Time** 

This column displays the date and time the samples were pipetted. The format is designed on the **Utility > System** screen.

## Reagents

A tip about the reagent pack is added at the end of the task procedure *To replace a reagent pack*.

## Replacing reagent packs

-Q- If the application is not visible in the **Utility**> **Application Test Table** before registration of the reagent pack, the application settings must be checked after reagent scan. This is due to the database concept. See: Changing test settings (Page 281 in Operator's Manual)