



08061505001V3.0

# ISE Deproteinizer

cobas®

## Order information

REF	CONTENT	Analyzer(s) on which kit(s) can be used
20763071 122	ISE Deproteinizer (6 × 21 mL)	COBAS INTEGRA 400 plus cobas c systems
04838181 001	ISE Deproteinizer (2 × 11 mL)	cobas c 111

## English

### Intended use

ISE Deproteinizer is a cleaning solution intended for use with the COBAS INTEGRA and cobas c 111 ISE modules for cleaning the ion-selective electrodes and intended for use with cobas c systems for cleaning the ISE flow path.

### Summary

ISE Deproteinizer is a cleaning solution used on the ISE module for the cleaning of the ion-selective electrodes, the mixing tower, and tubing during ISE maintenance. It is also used in the cleaning of the sample probe(s).

### Reagents - working solutions

Sodium hypochlorite (NaOCl): approximately 1.2 %

### Precautions and warnings

For in vitro diagnostic use for health care professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:

Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:

Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:



### Warning

H315 Causes skin irritation.

H319 Causes serious eye irritation.

### Prevention:

P264 Wash skin thoroughly after handling.

P280 Wear protective gloves/ eye protection/ face protection.

### Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.

P332 + P313 If skin irritation occurs: Get medical advice/attention.

P337 + P313 If eye irritation persists: Get medical advice/attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

Product safety labeling follows EU GHS guidance.

Contact phone: all countries: +49-621-7590, USA: 1-800-428-2336

### Reagent handling

Ready for use

### COBAS INTEGRA 400 plus:

Place the ISE Deproteinizer on the ISE rack.

### cobas c 111 analyzer:

Place the aliquoted ISE Deproteinizer in the sample area as indicated on the touch screen of the analyzer.

### cobas c systems:

Use ISE Deproteinizer according to instructions of the cobas c operator's manual.

### Storage and stability

#### COBAS INTEGRA 400 plus:

Shelf life at 2-8 °C: See expiration date on the label

On-board in use and refrigerated on the analyzer: 4 weeks

Replace the bottle when alerted to do so by the system. Discard any remaining solution.

#### cobas c 111 analyzer:

Shelf life at 2-8 °C: See expiration date on the label  
after opening: 8 weeks at 2-8 °C or until the printed expiration date, whichever comes first

### cobas c systems:

Shelf life at 2-8 °C: See expiration date on the label

ISE Deproteinizer for maintenance on cobas c systems is to be prepared freshly.

### Materials provided

See "Reagents – working solutions" section for reagents.

### Materials required (but not provided)

Refer to the appropriate instructions for use and to the operator's manual for additional required materials.

General laboratory equipment

### Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator's manual for analyzer-specific assay instructions.

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

### Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see [dialog.roche.com](http://dialog.roche.com) for definition of symbols used):

CONTENT	Contents of kit
REAGENT	Reagent
→	Volume after reconstitution or mixing
GTIN	Global Trade Item Number



# ISE Deproteinizer

**cobas®****FOR US CUSTOMERS ONLY: LIMITED WARRANTY**

Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.

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US Customer Technical Support 1-800-428-2336

