

REF 11662970 122

6 x 380 mL

For USA: Elecsys CleanCell

English**Intended use**

System solution for cleaning the detection unit of Elecsys 2010 and cobas e 411 immunoassay analyzers.

CleanCell is used in conjunction with Elecsys assay reagents.

CleanCell can be used with all reagent lots.

Summary

CleanCell is used to perform the following tasks:

- Cleansing of the tubing system and measuring cell after every measurement
- Conditioning of the electrodes

Reagents - working solutions

6 x 380 mL measuring cell cleaning solution

KOH 176 mmol/L (corresponds to pH 13.2); detergent ≤ 1 %.

Precautions and warnings

For in vitro diagnostic use.

Exercise the normal precautions required for handling all laboratory reagents.

Disposal of all waste material should be in accordance with local guidelines. Safety data sheet available for professional user on request.

For USA: For prescription use only.

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

**Warning**

H290 May be corrosive to metals.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Prevention:

P234 Keep only in original container.

P280 Wear eye protection/ face protection.

P280 Wear protective gloves.

Response:

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

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

P390 Absorb spillage to prevent material damage.

Product safety labeling primarily follows EU GHS guidance.

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

Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).

Reagent handling

The contents are ready for use. **Avoid foam formation.**

Storage and stability

Store at 15-25 °C.

Stability:	
unopened at 15-25 °C	up to the stated expiration date
on the analyzers, open	total of 72 hours (3 days)

Stability:

on the analyzers, alternating between open and closed	4 weeks (do not exceed 72 hours open in total)
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Materials provided

- CleanCell

Materials required (but not provided)

- Elecsys 2010 or cobas e 411 immunoassay analyzers. See appropriate operator's manual for additionally required materials.

Assay

Place the bottles in the appropriate position on the analyzer at least 1 hour before use. Open cap. If the analyzer stands idle for more than 3 hours, the bottles should be closed (to avoid evaporation effect).

For further information, please refer to the appropriate operator's manual for the analyzer concerned, the respective application sheets, the product information and the Method Sheets of all necessary components (if available in your country).

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.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard.

CONTENT	Contents of kit
SYSTEM	Analyzers/Instruments on which reagents can be used
REAGENT	Reagent
CALIBRATOR	Calibrator
→	Volume after reconstitution or mixing
GTIN	Global Trade Item Number

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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