

PreClean II M

| REF | CONTENT | SYSTEM |
|--------------|---------|-------------|
| 06908853190* | 2 x 2 L | cobas e 402 |
| 06908853214* | | cobas e 801 |

* Some kits shown may not be available in all countries.

English

Intended use

Wash solution for the removal of substances which potentially interfere with the detection of signals.

PreClean II M is used on **cobas e** immunoassay analyzers in conjunction with Elecsys assay reagents.

PreClean II M can be used with all reagent lots.

Summary

PreClean II M is used to remove potentially interfering substances before signal generation - the final step of the analytical procedure.

PreClean II M is required when performing certain Elecsys assays. If required, its use is indicated in the "Materials required (but not provided)" section of the respective assay reagent Method Sheet.

Reagents - working solutions

2 x 2 L detection wash solution

Phosphate buffer 10 mmol/L; sodium chloride 20 mmol/L; detergent ≤ 0.1 %; preservative; pH 7.0.

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.

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

Reagent handling

PreClean II M is ready for use. Avoid foam formation!

Storage and stability

Store at 15-25 °C. Store protected from light.

Exposure to light may cause discoloration of the reagent. Do not use discolored PreClean II M.

| Stability: | |
|----------------------|----------------------------------|
| unopened at 15-25 °C | up to the stated expiration date |
| on the analyzers | 4 weeks |

Materials provided

- PreClean II M

Materials required (but not provided)

- cobas e** analyzer
See operator's manual for additionally required materials.
- Elecsys assay reagents

Assay

Place the PreClean II M bottle in the appropriate position on the analyzer. Insert the system's aspiration tube into the opening until the cap rests on the opening. There is no temperature adjustment required for PreClean II M before use.

For further information, please refer to the appropriate operator's manual for the analyzer concerned, the respective application sheets 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.

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 for definition of symbols used):

| | |
|--|---|
| | Contents of kit |
| | Analyzers/Instruments on which reagents can be used |
| | Reagent |
| | Calibrator |
| | Volume for reconstitution |
| | Global Trade Item Number |

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Additions, deletions or changes are indicated by a change bar in the margin.

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