

REF 06908799190

06908799500

2 x 2 L

**English****Intended use**

System solution for generating electrochemical signals in **cobas e** immunoassay analyzers.

ProCell II M is used in conjunction with Elecsys assay reagents.

ProCell II M can be used with all reagent lots.

**Summary**

ProCell II M is used to perform the following tasks:<sup>1,2,3,4</sup>

- Conditioning of the electrodes
- Transport of the assay reactant mixture
- Washing of the streptavidin-coated microparticles
- Signal generation

**Reagents - working solutions**

2 x 2 L system buffer

Phosphate buffer 300 mmol/L, tripropylamine 180 mmol/L; detergent ≤ 0.1 %; pH 6.8.

**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.

Residual ProCell II M should be disposed of after use on the analyzer.

Do not dispose undiluted ProCell II M together with strong alkaline solution, e.g. Elecsys CleanCell M.

Safety data sheet available for professional user on request.

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

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

21 days

**Materials provided**

- ProCell II M

**Materials required (but not provided)**

- **cobas e** 402 and **cobas e** 801 analyzers

See operator's manual for additionally required materials.

- Elecsys assay reagents

**Assay**

Place the ProCell 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 ProCell II M before use.

**References**

- 1 Blackburn GF, Shah HP, Kenten JH, et al. Electrochemiluminescence detection for development of immunoassays and DNA probe assays for clinical diagnostics. Clin Chem 1991;37(9):1534-1539.
- 2 Kenten JH, Casadei J, Link J, et al. Rapid electrochemiluminescence assays of polymerase chain reaction products. Clin Chem 1991;37(9):1626-1632.
- 3 Kenten JH, Gudibande S, Link J, et al. Improved electrochemiluminescent label for DNA probe assays: rapid quantitative assays of HIV-1 polymerase chain reaction products. Clin Chem 1992;38(6):873-879.
- 4 Leland JK, Powell MJ. Electrogenated chemiluminescence: an oxidative-reduction type ECL reaction sequence using tripropyl amine. J Electrochem Soc 1990;137(10):3127-3131.

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.

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

SYSTEM

Analyzers/Instruments on which reagents can be used

REAGENT

Reagent

CALIBRATOR

Calibrator



Volume after reconstitution or mixing

GTIN

Global Trade Item Number

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# ProCell II M

cobas®



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