

REF 04880340 190

2 x 2 L

For USA: Elecsys ProCell M

English**Intended use**

System solution for generating electrochemical signals in MODULAR ANALYTICS E170, **cobas e 601** and **cobas e 602** immunoassay analyzers.

ProCell M is used in conjunction with Elecsys assay reagents.

ProCell M can be used with all reagent lots.

Summary

ProCell M is used to perform the following tasks:^{1,2,3,4}

- 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 %; preservative, pH 6.8.

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.

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

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**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Prevention:

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.

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 | 5 days |

Materials provided

- ProCell M

Materials required (but not provided)

- MODULAR ANALYTICS E170, **cobas e 601** or **cobas e 602** immunoassay analyzers. See appropriate operator's manual for additionally required materials.

Assay

Place the ProCell M bottle in the appropriate position on the analyzer and insert the system's aspiration tube into the opening until the cap rests on the opening. There is no temperature adjustment required for ProCell 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.

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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ProCell M

cobas[®]



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