



11810669001V31.0

BlankCell

cobas[®]

REF 11729306 122

2 x 50 mL

For USA: Elecsys BlankCell

Lot: 185171

Expiration date: 2016-12

English**Intended use**

BlankCell is only used for instrument calibration by Roche Technical Service.

Summary

Reagent for service personnel to perform

- Initial BlankCell calibration
- PMT HV adjustment
- Artificial media test

Reagents - working solutions

2 x 50 mL, for 225 measurements (corresponding to 75 initial BlankCell calibrations)

BCR1 Phosphate buffer 300 mmol/L, tripropylamine 180 mmol/L, detergent ≤ 0.1 %, preservative, pH 6.8.

BCR2 Phosphate buffer 300 mmol/L, tripropylamine 180 mmol/L, tris (2,2'-bipyridyl)ruthenium(II)-complex 10 nmol/L, detergent ≤ 0.1 %, preservative, pH 6.8.

Precautions and warnings

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**

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.

Either bring the cooled reagents to approximately 20 °C before loading or place in reagent disk of the analyzer 45 minutes before use.

Avoid foam formation.**Storage and stability**

Store at 2-8 °C.

Close tightly after use.

Stability:

- Stable up to the stated expiration date.
- The reagent should not be kept for more than 3 weeks at 15-25 °C.

Materials provided

- BlankCell

Materials required (but not provided)

- Elecsys 2010, MODULAR ANALYTICS E170 or **cobas e** immunoassay analyzers. See operator's manual for additionally required materials.

Initial BlankCell calibration:

The initial BlankCell calibration has to be performed:

- after PMT HV adjustment (see below)
- after service activities:
 - PMT replacement
 - measuring cell replacement / cell cleaning and similar steps
 - Sipper probe replacement
 - Sipper tubing replacement
 - ANG-EP replacement
 - L-AMP(1) replacement
 - Magnet drive replacement
 - a lengthy period of non-use
- as a preventive measure at service intervals of about 6 months

For detailed information consult the service manual.

Target values for BCR1 and BCR2: see table.

Artificial media test:

Consult the service manual for detailed information about the procedure, calculation and interpretation of results.

Target values for BCR1 and BCR2: see table.

Target values

BCR1	300	counts
BCR2	93000	counts

PMT HV adjustment:

BCR2 signal has to be adjusted to meet the target range.

For detailed information consult the service manual.

Target range

BCR2	88000 - 98000	counts
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Symbols

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

	Contents of kit
	Analyzers/Instruments on which reagents can be used
	Reagent
	Calibrator
	Volume after reconstitution or mixing
	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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