08024731001V2.0

cobas CRP Control

REF 08024723190 CONTENT 4 x 2.0 mL SYSTEM **cobas b** 101

English

Intended use

cobas CRP Control solution is used for performing quality control of CRP with **cobas** CRP reagent discs on the **cobas b** 101 instrument.

Summary

cobas CRP Control is a ready-to-use solution based on human serum. The control is used for monitoring accuracy and precision of the **cobas** CRP Test. The adjusted concentrations of the control components are in the low range (Level 1) and in the high range (Level 2).

Reagents - working solutions

Reactive components in the **cobas** CRP Control:

- Colored human serum-based solution containing constituents of human origin
- Preservatives and stabilizers

Level 1, 2 bottles 2 mL each, low range

Level 2, 2 bottles 2 mL each, high range

Target values and ranges

The target values were determined with **cobas b** 101 instruments using at least 3 lots of **cobas** CRP Test. Determinations were performed under strictly standardized conditions on the **cobas** b 101 instrument. The target value is the mean of all values obtained. The target value range is determined to be ± 21 % which includes reagent precision variation within lot and from lot to lot, as well as bias variation of the reagent and the control. Results must be within the specified ranges. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits. The concentrations of the components are lot-specific. The exact values are given in the enclosed value sheet. Target values and ranges for the **cobas b** 101 instrument are also encoded on the QC info disc which is provided in the **cobas** CRP Control kit.

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.

All human material should be considered potentially infectious. All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV and HIV. The testing methods used assays approved by the FDA or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.
However, as no testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen. In the event of exposure, the directives of the responsible health authorities should be followed.[1,2]

Reagent handling

The control is supplied ready for use. Gently mix the contents of each vial before sampling to ensure homogeneity. Avoid foam formation. Treat control material in the same way as samples. Aspirate only a small amount of control solution. Apply the control solution onto the indicated blue application zone on the back side of the **cobas** CRP Test disc. Check that the area marked in blue is completely filled. Dispense the control liquid carefully without touching any other surface to avoid microbial contamination. Proceed as described in the Operator's Manual. When the QC info disc is used, the **cobas b** 101 instrument automatically indicates the control ranges of this specific control lot. The **cobas b** 101 instrument can be set up to show "Pass" or "Fail" on the display. The display shows "Pass" if the QC results are within the control range, and "Fail" if the QC results are out of the control range. For more details, please refer to the Operator's Manual of the **cobas b** 101 instrument.

Storage and stability

Store at 2-8 °C.

Do not use **cobas** CRP Control after the stated expiration date. If there is evidence of microbial contamination or excessive turbidity in the product, discard the vial. **cobas** CRP Control is a stabilized liquid product.

Stability

unopened:	up to the stated expiration date at 2-8 °C
after opening:	7 days at 20-25 °C or 30 days at 2-8 °C provided that the dispensing of the control occurs without microbial contamination and when stored tightly capped

Materials provided

- REF 08024723190, **cobas** CRP Control
- 2 x 2 mL Control Level 1 (low range)
- 2 x 2 mL Control Level 2 (high range)
- 1 x QC information disc

Materials required (but not provided)

- REF 08024669190, **cobas** CRP Test
- REF 06378668190, **cobas b** 101 instrument
- General laboratory equipment

Quality Control

Accurate and reproducible results are dependent upon properly functioning instruments and reagents.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

References

1 Occupational Safety and Health Standards: Bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.

2 Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

For further information, please refer to the appropriate Operator's Manual for the instrument concerned, and the Method Sheets of all necessary components.

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 (for USA: see dialog.roche.com for definition of symbols used):

CONTENT	Contents of kit
SYSTEM	Analyzers/Instruments on which reagents can be used

CE

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