cobas CRP Test

REF 08024669119 | Σ 10 | SYSTEM cobas b 101

English

Intended use

The Roche **cobas b** 101 is an in vitro diagnostic test system designed to quantitatively determine the C-reactive protein (CRP) in human capillary whole blood and serum, EDTA K2/K3 and lithium heparin anticoagulated whole blood and plasma by photometric measurement. Measurement of CRP is of use for the evaluation of inflammatory disorders and associated diseases, infection and tissue injury. The system is intended for use in point-of-care (PoC) settings such as pharmacies, physician offices, physician office laboratories, clinics and hospitals, and clinical laboratory settings.

Note: Please note that the catalogue number appearing on the package insert retains only the first 8 digits of the licensed 11-digit catalogue number: 08024669190 for the cobas CRP test. The last 3 digits -190 have been replaced by 119 for logistic purposes.

Summary

Most tissue-damaging processes such as infections, inflammatory diseases and malignant neoplasms are associated with a major acute phase response of the C-reactive protein (CRP) and other acute phase reactants (e.g. AAT, AAGP, C3C, C4, HAPT). The CRP response frequently precedes clinical symptoms, including fever. In healthy individuals CRP is a trace protein with a range up to 5 mg/L. After onset of an acute phase response the serum CRP concentration rises rapidly and extensively. Alterations are detectable within 6 to 8 hours and the peak value is reached within 24 to 48 hours. Levels of up to a thousandfold the normal value are associated with severe stimuli such as myocardial infarction, major trauma, surgery, or malignant neoplasms. CRP activates the classical complement pathway. CRP has a half-life of only a few hours, making it an ideal tool for clinical monitoring. Postoperative monitoring of CRP levels of patients indicates either the normal recovery process (decreasing levels to normal) or unexpected complications (persisting high levels). Measuring changes in the concentration of CRP provide useful diagnostic information about how acute and how serious a disease is. It also allows the assessment of complications during the disease and judgements about the disease genesis. Persistence of a high CRP concentration is usually a grave prognostic sign which generally indicates the presence of an uncontrolled infection. CRP determination may replace the classical determination of Erythrocytes Sedimentation Rate (ESR), due to its prompt response to changes in disease activity and its good correlation to ESR.[1,2,3,4]

Test principle

The erythrocytes of the capillary or venous blood sample are separated from the plasma by centrifugation. Then, the plasma sample is diluted with HEPES buffer and transferred into a reaction chamber where it is mixed with CRP antibody-latex reagent. The CRP in the diluted plasma binds with the CRP antibody on the latex particle. The concentration of CRP is calculated as a function of the changed absorbance measured at 525 nm and 625 nm which is in relation to the amount of agglutination.[5,6,7]

Reagents

One test contains:

HEPES buffer: 1.79 mg

Anti-human CRP antibody (goat) Latex-conjugate: 41.84 µg

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.

Reagent handling

Carefully tear open the foil pouch at the tear notch until one side is open.

Discard the disc if the foil pouch is found open or damaged, or if the disc is damaged, or the desiccant is missing, or loose desiccant particles or any other dirt or particles especially at the blood application zone are found.

Use **cobas** CRP Control in the same way as a blood sample.

Storage and stability

Store at 2-30 °C until the expiration date printed on the pouch. Do not freeze. If stored in a refrigerator, allow the disc to warm up in the closed pouch for at least 20 minutes before use. Once the pouch is opened, use the disc within 20 minutes. Protect the disc from direct sunlight. Do not store opened pouches in a refrigerator.

Specimen collection and preparation

For specimen collection and preparation only use suitable tubes or collection containers.

Use fresh human capillary whole blood or serum, EDTA K2/K3 or lithium heparin anticoagulated whole blood or plasma.

Do not use other anticoagulants or other additives.

For EDTA K2/K3 and lithium heparin anticoagulated whole blood and plasma samples, test within 8 hours of sample collection if stored at room temperature. If stored in the refrigerator plasma samples may be used up to 14 days and whole blood samples up to 3 days. Frozen serum and plasma samples stored at -20 °C may be used up to 30 days. Freeze only one time. Mix sample thoroughly before use. Do NOT use frozen whole blood to avoid the risk of hemolysis.

The marking on the disc shows where to apply the sample. If samples are used from a venipuncture or control material, use a standard pipette or dropper to form a drop. The disc is self-filling. Do not push the sample into the disc. Do not use syringes. Assure that the disc is free from blood outside the sample application zone and the hinge cover.

Sample volume: 12 µL

Sample stability on disc

ⓘ After sample application, the disc must be inserted immediately (in ≤ 120 seconds). Please follow the instructions in the **cobas b** 101 Operator's Manual.

Assay

Instructions for use

- Wash hands with soap. Warm water helps to stimulate the blood flow. Rinse the fingers extensively. Dry hands.
- Disinfect the fingertip by wiping three times the area to be lanced with a cotton swab or sterile gauze pad impregnated with 70 %-100 % isopropanol emollient free or 70 %-100 % ethanol emollient free; repeat the procedure with a second cotton swab or sterile gauze pad impregnated with 70 %-100 % isopropanol emollient free or 70 %-100 %ethanol emollient free, then dry with a cotton swab or sterile gauze pad.
- Prick the patient's finger by applying a single-use disposable lancing device (e.g. Accu-Chek Safe-T-Pro Plus). Make sure to follow the lancing device instructions for obtaining a blood sample.
- Wipe off the first drop of blood with a swab.
- With the imprinted side of the disc facing upwards, position the disc's suction point above the drop of blood. The disc is self-filling.
- Apply blood and observe that it has filled the marked area. Check the sample volume: turn the disc on its backside. The area marked in blue has to be filled completely with blood. Do not push the blood into the disc.
- Press hinge cover down firmly to close the disc.
- Assure that the disc is free from blood outside the sample application zone and the hinge cover.
- Insert the disc into the **cobas b** 101 instrument. Close the lid.
- The measurement starts automatically.

For more details, please refer to the **cobas b** 101 Quick Reference Guide or **cobas b** 101 Operator's Manual.

Materials provided

- REF 08024669190, **cobas** CRP Test, 10 tests

Materials required (but not provided)

- Single use disposable lancing device (e.g. Accu-Chek Safe-T-Pro Plus)
- REF 08024723190, **cobas** CRP Control
- REF 06378668190, **cobas b** 101 instrument
- Optical check disc
- General laboratory equipment (e.g., sample transfer pipette for venous blood or alcohol wipes for disinfection of the finger)

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Calibration
This method has been standardized against the ERM DA 472/IFCC reference material. Each disc lot of the **cobas** CRP Test is traceable to ERM DA 472/IFCC reference material.[8,9]

The instrument automatically reads in the lot-specific calibration data from the barcode information printed on the disc, eliminating the need for calibration by the user.

Quality control
For quality control, use **cobas** CRP Control.

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.

QC info disc
Every **cobas** CRP Control kit contains a lot-specific QC info disc for quality control. This QC info disc contains the target values and ranges for the **cobas** CRP Test.

The instrument display prompts the user to insert the QC info disc. The **cobas b** 101 instrument reads the disc providing the lot specific target ranges.

Display of results
At the end of the automatic determination, the **cobas b** 101 instrument shows the result within 3-4 minutes. The concentration of CRP will be displayed in mg/L or in mg/dL.

Limitations - interference
Hematocrit levels between 20 % and 60 % do not affect results.

Criterion: Recovery within ± 10 % of initial values at CRP concentrations of 10.0 mg/L and 40.0 mg/L.

Hemolysis: No significant interference up to a hemoglobin concentration of 500 mg/dL.

Icterus:[10] No significant interference up to a conjugated/unconjugated bilirubin concentration of 50 mg/dL.

Lipemia (Intralipid):[10] No significant interference up to an Intralipid and Triglyceride concentration of 750 mg/dl.

Glycemia:[10] No significant interference up to a glucose level of 1000 mg/dL. A fasting sample is not required.

Rheumatoid factors: No significant interference up to 1200 IU/mL.

Drugs: No interference was found at therapeutic concentrations using common drug panels.[11]

Drug interferences are measured based on recommendations given in CLSI guidelines EP07 and EP37 and other published literature. Effects of concentrations exceeding these recommendations have not been characterized.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Limits and ranges
Measuring range
3.0-400 mg/L or 0.30-40.0 mg/dL

Expected values
Adults: < 5.0 mg/L (< 0.5 mg/dL)[2,12]

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

Specific performance data
Representative performance data on the instruments are given below. Results obtained in individual laboratories may differ.

Precision
Precision was determined using controls in a CLSI EP5-A3 protocol. Precision was measured with 3 lots of **cobas** CRP Test using 5 different serum samples at the medical decision points and 2 **cobas** CRP Control solution levels over 21 days with 2 runs per day and duplicate measurements per run and specimen. The following results were obtained for a representative lot:

	Repeatability			Intermediate precision		
Sample	Mean mg/L	SD mg/L	CV %	Mean mg/L	SD mg/L	CV %
Sample Healthy	5.1	0.13	2.5	5.1	0.17	3.3
Sample Cut off	10.0	0.23	2.3	10.0	0.24	2.4
Sample Decision	39.9	0.93	2.3	39.9	0.98	2.5
Sample Acute	93.4	1.62	1.7	93.4	1.84	2.0
Sample Acute High	351	7.99	2.3	351	8.42	2.4
Control Level 1	9.7	0.29	2.9	9.7	0.30	3.1
Control Level 2	39.2	0.79	2.0	39.2	1.09	2.8

Method comparison
CRPNX
A comparison experiment using 3 different reagent lots with serum samples measured with **cobas** CRP Test on the **cobas b** 101 instrument (y) and CRP-latex X2 "Seiken" NX reagent on the **cobas c** 501 analyzer (x) gave the following correlation for a representative lot (Weighted Deming regression method).[13,14]

Sample size: 140
Slope: 1.00
Intercept: 0.0934
Pearson r: 0.998
Mean bias in the range 3.0-200 mg/L: 0.5 %
Mean bias in the range > 200-400 mg/L: 3.5 %
Bias at 5.0 mg/L: 1.9 %
Bias at 10.0 mg/L: 0.9 %

CRPLX
A second comparison experiment using 3 different reagent lots with serum samples measured with **cobas** CRP Test on the **cobas b** 101 instrument (y) and CRPLX C- Reactive Protein (Latex) reagent on the **cobas c** 501 analyzer (x) gave the following correlation for a representative lot (Weighted Deming regression method).[13,14]

Sample size: 122
Slope: 1.05
Intercept: 0.08
Pearson r: 0.996
Mean bias in the range 3.0-200 mg/L: 6.41 %
Mean bias in the range > 200-400 mg/L: 1.79 %
Bias at 5.0 mg/L: 6.82 %
Bias at 10.0 mg/L: 6.02 %

CRPNX or CRPLX are possibly not commercially available in all regions.

References

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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
	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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