C-REACTIVE PROTEIN (CRP)

Diagnostic reagent for determination of CRP concentration.

Liquid. Dual Reagents. Store at 2°C - 8°C. For in Vitro Diagnostic Use. Do not freeze

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
TA101	5 x 100 mL	BY102	5114 Tests	LAB100	2961 Tests	NAB100	667 Tests
TA102	5 x 50 mL	DMT100	840 Tests	LAB101	1579 Tests	NAB101	333 Tests
TA103	5 x 25 mL	KAB100	2927 Tests	MAB100	1909 Tests	TAB100	3474 Tests
BY101	7670 Tests	KAB101	1951 Tests	MAB101	1273 Tests	TAB101	1795 Tests

INTENDED USE

The test is applied for the quantitative determination of CRP in serum.

C-Reactive Protein (CRP), which is synthesized in the liver, is one of the most sensitive acute phase reactants after tissue damage or inflammation. CRP activates the classical complement pathway as a response to the inflammatory reaction.

CRP levels in plasma can rise dramatically after myocardial infarction, stress, trauma, infection, inflammation, surgery or neoplastic proliferation. The increase occurs within 24 to 48 hours and the level may be 2000 times normal. An elevation can be expected in virtually all diseases involving tissue damages so the finding is nonspecific.

Clinical diagnosis should not be made on the findings of a single test result, but should integrate both clinical and laboratory data.

TEST PRINCIPLE

Serum C-reactive protein (CRP) causes agglutination of the latex particles coated with anti-human C-reactive protein. The agglutination of the latex particles is proportional to the CRP concentration and can be measured by turbidimetry.

TEST PARAMETERS

Method : Turbidimetric
Wavelength : 540 nm
Temperature : 37°C
Sample : Serum
Linearity : 1.0 mg/L - 150 mg/L

REAGENT COMPOSITION

Reagent 1:
Glycine buffer ≤ 0.12 mol/L,
Sodium azide ≤ 0.99 g/L,
pH 8.6.

Reagent 2:
Suspension of latex particles coated with anti-human CRP antibodies,

Sodium azide ≤ 0.99 g/L.

CRP Standard: Human serum. C-reactive protein concentration is stated on the vial label.

Concentration value is traceable to the Standard Reference Material BCR 470 (Institute for Reference Materials and Measurements, IRMM).

Human serum used in the preparation of the standard has been tested and found to be negative for the presence of antibodies anti-HIV and anti-HCV, as well as for HBs antigen. However, the standard should be handled cautiously as potentially infectious.

REAGENT PREPARATION

For manual working procedures; if working reagent will be used; shake the Reagent 2 vial gently before pouring its contents into the Reagent 1 bottle. It is advisable to wash the Reagent 2 vial with a small volume of the prepared mixture in order to completely rinse the vial and avoid any losses.

Smaller Working Reagent volumes can be prepared by mixing: 1 mL of Reagent 2 + 4 mL of Reagent 1. Shake the Reagent 2 vial before pipetting.

Working reagents are stable at 2-8ºC in case of closed vials and avoiding contamination after preparation.

REAGENT STABILITY AND STORAGE

Reagents and Standard are stable until the expiry date shown on the label when stored tightly closed and if contaminations are prevented during their use.

Once opened vials are stable minimum 30 days at 2-8°C at optimum conditions. On board stability is strongly related to auto analyzers cooling specification and carry-over values.

Indications of deterioration:

Reagents: Absorbance of the blank over 0.900 at 540 nm.
Standard: Presence of moisture.

SAMPLE

Serum is collected by standard procedures.
CRP in serum is stable for 15 days at 20 - 25°C, 2 months at 2-8ºC and 3 years at -20°C.

For reagents which are related antigen antibody interaction, do not shake the sample, just gently mix.

TEST PROCEDURE

Sample Start
There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

Substrate Start
There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

The C-reactive protein concentration in the sample is calculated using the following general formula:

$$\frac{A2 - A1\ Sample}{A2 - A1\ Standard} \times C\ Standard = C\ Sample$$

Unit Conversion

CRP mg/dL*10=CRP mg/L

REFERENCE INTERVAL (NORMAL VALUES) (Based on CLSI C28-P Document)*

Serum, adults: Up to 5 mg/L. (Up to 0,5 mg/dL)

*It is recommended that each laboratory establish its own reference range.

QUALITY CONTROL AND CALIBRATION

The assay requires the use of an Archem Standard (Calibrator).

ARCHEM Standard

Cat.No. TA101S

CRP Standard (S): Reconstitute with 1.0 mL of distilled water. Stability of standard is 1 month at 2-8ºC.

Commercially available control material with established values determined by this method may be used. We recommend:

Rheumatoid Control Serum Level I
Cat.No. RCN01

Rheumatoid Control Serum Level II
Cat.No. RCN05

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is **30 days.**

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity: 1.0 mg/L

High Linearity: 150 mg/L (15 mg/dL).
For higher values dilute sample 1/5 with distilled water and repeat measurement.

Linearity may considerably vary depending on the instrument used.

Precision Studies (Based on CLSI EP5 Doc.):

Repeatibility (within run) (Intra-assay)

Mean concentration	CV	n
7.4 mg/L	4.5%	20
19.0 mg/L	3.6%	20

Reproducibility (run to run) (Inter-assay)

Mean concentration	CV	n
7.4 mg/L	4.6%	25
19.0 mg/L	3.7%	25

Sensitivity (LOD) (Based on CLSI EP17 document): 19.0 mg/L

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Prozone effect: This method has not zone effect (< 250 mg/L).

Interferences: Hemoglobin (10 g/L), bilirubin (20 mg/dL), lipemia (triglycerides 10 g/L) and rheumatoid factors (200 IU/mL) do not interfere. Other drugs and substances may interfere.

These performance characteristics have been obtained using an analyzer. Results may vary if a different instrument or a manual procedure is used.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1&R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The reagents contain sodium azide (< 0.1%) as a preservative.
8. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.
S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CLSI : Clinical and Laboratory Standards Institute
CV% : Coefficient of Variation Percentage
EP : Evaluation Protocols
GLP : Good Laboratory Practice
IU : International Unit
mA : miliabsorbance
mL : mililiter
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control

REFERENCES

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SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
R2	Reagent 2
CONC	Concentration
INGRED	Reagent Ingredients
REF	Reference Number (Catalog No)
SN	Serial Number
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk

CE

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