BIOLABO
www.biolabo.fr
MANUFACTURER:
BIOLABO SAS,
Les Hautes Rives
02160, Maizy, France

CRP Turbidimetric Immunoassay

Reagent for quantitative determination
of C-Reactive Protein (CRP) in human serum.

REF CRP050E	**R1** 1 x 50 mL	**R2** 1 x 5 mL
REF CRP620E	**R1** 6 x 20 mL	**R2** 1 x 10 mL

TECHNICAL SUPPORT AND ORDERS
Tel: (33) 03 23 25 15 50
Fax: (33) 03 23 256 256
support@biolabo.fr
Latest revision : www.biolabo.fr

CE

IVD

Made in France

I: corresponds to significant modifications

INTENDED USE

This quantitative test is to detect and measure C - reactive protein in human serum to assess the inflammatory status of the body. This test may be used with manual procedure on spectrophotometer or with Biochemistry Clinical Analyzer.

GENERALITIES (1) (4)

C - reactive protein is one of the strongest acute phase reactants and help in non-specific host defence against infectious agents.

Its concentration increased after myocardial infarction, stress, trauma, infection, inflammation, surgery or neoplastic proliferation.

PRINCIPLE (2) (3)

Turbidimetric Immunoassay (TIA): Photometric measurement of turbidity, corresponding to antigen-antibody reaction, by the end-point method at 340 nm.

REAGENTS

R1	**CRP TIA**	Buffer	
Phosphate buffered saline		pH	7.43
Polyethylene glycol		40	g/L
Sodium azide		0.95	g/L

R2	**CRP TIA**	Anti-CRP	
Phosphate buffered saline		pH	7.43
Polyclonal goat anti-human CRP		(variable)	
Sodium azide		0.95	g/L

These reagents are not classified as dangerous according to 1272/2008/EC regulation.

REAGENTS PREPARATION

Ready for use.

MATERIAL REQUIRED BUT NOT PROVIDED

1. Medical analysis laboratory equipment.
2. Spectrophotometer or Biochemistry Clinical Analyzer

SAFETY CAUTIONS

- BIOLABO reagents are designated for professional use in laboratory
- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

I Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

STABILITY AND STORAGE

Stored away from light, well cap in the original vial at 2-8°C, reagent is stable when stored and used as described in the insert:

Unopened,

- Until the expiry date stated on the label of the Kit.

Once opened:

- When free from contamination, 2 separated reagents are stable for :
  - 3 months at 2-8° C,
  - 24 h at room temperature
  - 30 days on the board of analysers.

SPECIMEN COLLECTION AND HANDLING (5)

Use fresh serum.

If the test cannot be carried out on the same day, the serum may be stored at 2-8°C for 48 hours.

If stored for a longer period, the sample should be frozen.

LIMITATIONS (6)

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

CALIBRATION

- REF CRP CALSET51: CRP Standard Set

Or

- REF CRP CALSH1: CRP Standard Super High (successive 1:2 dilutions in saline up to 6 different levels including zero point to generate calibration curve).
- Use saline as zero point

Calibration values are traceable to a reference material (RPPHS/CRM470) from the International Federation of Clinical Chemistry (IFCC).

The calibration frequency depends on proper instrument functions and on the preservation of the reagent.

Make a new calibration when changing reagent batch, if quality control results are found out of the confidence interval and after maintenance operations

QUALITY CONTROL

- REF CRP CONTL1, REF CRP CONTL5: CRP Control Low
- REF CRP CONTH1, REF CRP CONTH5: CRP Control High
- External quality control program.

It is recommended to control in the following cases:

- At least once a run.
- At least once within 24 hours.
- When changing vial of reagent.
- After maintenance operations on the instrument.

If control is out of range, apply following actions:

1. Prepare a fresh control serum and repeat the test.
2. If control is still out of range, use a new vial of calibrator or a fresh calibrator and repeat the test.
3. If control is still out of range, repeat the tests with a new vial of reagent.

If control is still out of range, please contact BIOLABO technical support or your local Agent.

REFERENCE INTERVAL (1)

IFCC Value: < 0.5 mg/dL

These values are applicable only to adults between 20 and 60 years of age

Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCES

On a clinical chemistry analyzer (Cobas Mira).

Detection limit: approximately 0.5 mg/dL

Linearity range: between 0.5 to 22 mg/dL.

Above 22 mg/dL, dilute the specimen with saline and re-assay taking into account the dilution factor to calculate the result. Linearity limit depends on specimen/reagent ratio.

Precision:

[%CV]	Low	Medium	High
Intra-Run	4.06	2.57	3.44
Inter-Run		4.29	6.60

Accuracy:

[mg/dL]	Assigned	Measured
BIOLABO	1.92 (1.63-2.21)	2.09
Biorad 2	2.59 (2.07-3.10)	2.78

Sensitivity: 0.0094 Abs/concentration unit

Specificity: Monospecific

Hook effect: > 84 mg/dL

Comparison study with Nephelometry:

y = 0.9981x - 0.0142 r = 0.9917

Interferences:

No interference for: Haemoglobin (250 mg/dL), Na-citrate (1000 mg/dL), Heparin (50 mg/dL), Bilirubin (20 mg/dL), Triglyceride (2500 mg/dL)

Other substances may interfere with the result (see §Limitations)

PROCEDURE

Let stand reagents, standards, control and specimens at room temperature.

Before use, mix reagent R2 by gentle swirling.

Manual Procedure:

Realise standard curve (§ Calibration)

Pipette into well identified test tubes:	Blank	Standards	Assays
Buffer (R1)	1000 µL	1000 µL	1000 µL
Saline	60 µL		
Standards		60 µL	
Specimen			60 µL
Mix well. Record absorbance A1 against blank at 340 nm			
Anti-CRP (R2)	100 µL	100 µL	100 µL
Mix and let stand for 5 minutes at room temperature. Record absorbance A2 against blank at 340 nm.			

1- With Manual Procedure on Spectrophotometer, performances and stability data should be validated by user

2- Applications proposal are available on request of other analysers

CALCULATION

Manual procedure:

Calculate ΔAbs (Abs A2 – Abs A1) for standards, controls and assays.
Plot a Standard Curve "Concentration = f(ΔAbs)".
Read the concentration of controls and samples on the graph.

Automatic Biochemistry analyzer:

The analyzer provides directly final result.
For more details about calibration and calculation of results, refer to User's manual and specific application.

REFERENCES

(1) *TIETZ N.W. Text book of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p.493, p.481.*
(2) *Marrack, J.R. and Richards, CB., J. Immunol. 20, 1019 – 1040 (1971)*
(3) *Ritchie, RF., J. Lab. Clin. Med. 70, 512 - 517(1967)*
(4) *Pepys MB. et al., Ann. NY Acad. Sci, 389, 459 (1982)*
(5) *Clinical Guide to Laboratory Test, 3rd Ed., N.W. TIETZ (1995) p. 919*
(6) *YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p. 3-511 to 3-512*

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute with