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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

CE

IVD

Made in France

I: corresponds to significant modifications

INTENDED USE

This reagent is designated for professional use in laboratory (manual or automated method).
This quantitative test is to detect and measure C - reactive protein in human serum to assess the inflammatory status of the body.

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**	Buffer
Tris buffered saline		pH 7.5
Polyethylene glycol		60 g/L
Sodium azide		0.95 g/L

R2	**CRP**	Anti-CRP
Tris buffered saline		pH 7.5
Polyclonal goat anti-human CRP		(variable)
Sodium azide		0.95 g/L

According to 1272/2008 regulation, these reagents are not classified as dangerous.

SAFETY CAUTIONS

- 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.

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.

REAGENTS PREPARATION

Ready for use.

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 years at 2-8° C

SPECIMEN COLLECTION AND HANDLING (5)

Use fresh serum. Specimen without lipemia or haemolysis are preferred.

If the test cannot be carried out on the same day, the serum may be stored:

- at 2-8°C for 72 hours
- at -20°C for 6 months

LIMITS (5) (6)

Excessive turbidity can affect nephelometric methods

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

MATERIAL REQUIRED BUT NOT PROVIDED

1. Medical analysis laboratory equipment.
2. Spectrophotometer or Biochemistry Clinical Analyzer
3. Saline (NaCl 9 g/L)

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

QUALITY CONTROL

- REF CRP CONTL1: CRP Control Low
- REF CRP CONTH1: CRP Control High
- REF TIA CONT21: Control Set
- 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.

I PERFORMANCES

On Kenza 240TX, at 340 nm, 37°C

Linearity Range: between 0.5 mg/dL and 24.8 mg/dL

Precision:

Within-run N = 20	*Low level*	*Normal level*	*High level*	*Between run N = 20*	*Low level*	*Normal level*	*High level*
Mean (mg/dL)	1.44	3.43	10.01	Mean (mg/dL)	1.50	3.65	11.21
S.D. mg/dL	0.09	0.08	0.159	S.D. mg/dL	0.075	0.099	0.267
C.V. %	6,3%	2,3%	1,6%	C.V. %	5.0%	2,7%	2.4%

Prozone effect: from 60 mg/dL

Interferences:

Turbidity	Negative interference from 0.014 OD (eq. 1,2 mmol/L of triglycerides)
Total bilirubin	Negative interference from 76 µmol/L
Direct bilirubin	Negative interference from 95 µmol/L
Ascorbic acid	No interference up to 2500 mg/dL
Glucose	No interference up to 969 mg/dL
Haemoglobin	Negative interference from 24 µmol/L

Other substances may interfere (see § Limits)

On the board stability: 2 months

Calibration Stability: at least 7 days

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

Comparison study on Pentra 400:

50 human specimens between 0,5 and 37,53 mg/dL were analysed with this method and compared to another commercially available reagent (same method):

Y = 0.9905 x – 0.1234 R = 0.9993

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).
- 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.

PROCEDURE

Let stand reagents, standards, control, assays at room temperature.
Before use, mix reagent R2 by gentle swirling.

Manual Procedure:

Generate standard curve (§ Calibration)

Pipette into well identified test tubes:	Blank	Calibration	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

I 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.

Note: Results lower than 0.5mg/dL must be indicated as ≤ 0.5 mg/dL

REFERENCES

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