BIOLABO
www.biolabo.fr

MANUFACTURER:
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CRP Control High

For quality control of quantitative determination
of C reactive protein (CRP) by Turbidimetric immunoassay

REF CRP CONTH1	**R1**	1 x 1 mL
REF CRP CONTH5	**R1**	1 x 5 mL

TECHNICAL SUPPORT AND ORDERS
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CE

IVD

Made in France

I: corresponds to significant modifications

INTENDED USE

Titrated control serum for the quality control of quantitative immunochemical determination of CRP in human serum.
Suitable for manual procedure or automated instruments with BIOLABO reagents REF CRP 050E, REF CRP 620E.

REAGENTS

R1 CRP Control High Human origin

Stabilized liquid serum supplemented with CRP

SAFETY CAUTIONS (1) (2)

BIOLABO reagents are designated for professional use in laboratory.
- Material Safety Data Sheet is available upon request.
- Each donor unit used to manufacture this product was tested and found non-reactive for HbsAg, antibody to Hepatitis C and antibody to HIV-1/HIV-2.
- However, no test method can offer complete assurance that infectious agents are absent. All specimens or reagents from biological origin should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions.
- Waste disposal: 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.

REAGENTS PREPARATION

Ready for use

MATERIAL REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. REF CRP CAL SH1: CRP Standard Super High (to be diluted)
3. REF CRP CAL SET51: CRP Standard Set

QUALITY CONTROL

Verify the integrity of the vial and batch-specific value before use
Run in accordance with the IFU of the reagent used

STABILITY AND STORAGE

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

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

Once opened:
- Transfer requested quantity, well recap vials and store at 2-8°C.
- Well recapped in the original vial, at least for 6 weeks when free from contamination.

Do not freeze

PROCEDURE

Run in accordance with the IFU of the reagent used.

CONTROL VALUES (3)

- The value is traceable to a reference material (RPPHS/CRM470) from the International Federation of Clinical Chemistry (IFCC)
- **Batch-specific** value is indicated on the label of the vial

It is recommended that each laboratory validate each new batch-specific values before use. For an optimal use, laboratories should establish their own targets and ranges. These values have to be periodically retested.

LIMITATIONS

Factors which may influence results are bacterial contamination, accuracy of reconstitution volume, respect of automated instrument procedure, temperature...

REFERENCES

(1) *Occupational Safety and Health Standards ; Bloodborne pathogens (29CFR1910.1030) Federal Register July 1, (1998) ; 6, p.267-280*
(2) *Directive du conseil de l'Europe (90/679/CEE) J. O. de la communauté européenne n°L374 du 31.12.1990,p.1-12*
(3) *TIETZ N.W. Textbook of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p.520*

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