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

CRP Standard Set

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

REF CRP CALSET51
R1 1x 1 mL, **R2** 1x 1 mL, **R3** 1x 1 mL, **R4** 1x 1 mL, **R5** 1x 1 mL

TECHNICAL SUPPORT AND ORDERS
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CE

IVD

Made in France

I: corresponds to significant modifications

Latest revision: www.biolabo.fr

NTENDED USE

Standard Set for the preparation of reference curve for quantitative immunochemical determination of CRP in human serum.
I Suitable for manual procedure or automated instruments with BIOLABO reagents REF CRP 050E, CRP 620E, REF K150E, K250E

REAGENTS

R1	**CRP1**
R2	**CRP2**
R3	**CRP3**
R4	**CRP4**
R5	**CRP5**

Human origin

5 vials of CRP Standard (5 different levels)
Liquid stabilized plasmas (defibrinated and delipidated) supplemented with purified 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.

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. BIOLABO Reagents (§ INTENDED USE)
2. REF CRP CONTL1 or REF CRP CONTL5: CRP Low Control
3. REF CRP CONTH1 or REF CRP CONTH5: CRP High Control

QUALITY CONTROL

Verify the integrity of each vials and batch-specific values 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, standards are 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.

CALIBRATION VALUES (3)

- Values are traceable to a reference material (RPPHS/CRM470) from the International Federation of Clinical Chemistry (IFCC).
- **Batch-specific** values are indicated on the label of each vial

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