TruLab CRP

Assayed quality control material for monitoring assay performance of quantitative in vitro determination of C-reactive protein (CRP)

Order Information

5 9610 99 10 045 Level 2 3 x 2 mL

Description

TruLab CRP is a liquid stable control based on human blood material (serum). The CRP concentration in TruLab CRP Level 2 is in the pathological range.

Storage

The vials of TruLab CRP hs both opened and unopened must be stored at $2-8^{\circ}C$.

Stability

Unopened: Until the end of the indicated month of expiry

Opened: At least three months

Proper storage and handling of this product must be observed.

Warnings and Precautions

- Each individual blood donation used for production of TruLab CRP was found to be non-reactive when tested with approved methods for HBsAg, anti-HIV 1+2 and anti-HCV. As there is no possibility to exclude definitely that products derived from human blood transmit infectious agents, it is recommended to handle the calibrator with the same precautions used for patient specimens.
- Contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
- Please refer to the safety data sheets and take the necessary precautions for the use of calibrators and controls.
- For professional use only!

Preparation

TruLab CRP is liquid and ready to use.

Procedure

Please refer to the reagent package insert for instructions for use.

Assay Values

TruLab CRP assay values have been determined by calibration with ERM®/IFCC reference material in accordance with established protocols.

Assay values may vary slightly with different reagents and methodologies used. The assay values listed below are specific for this lot number of control only.

Literature

- Röhle G, Siekmann L. Quality assurance of quantitative determination. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 1393-1401
- Biosafety in Microbiological and Biomedical Laboratories.
 U.S. Department of Health and Human Services, Washington 1993 (HHS Publication No. [CDC] 93-8395)
- Dati F. Reference materials and guidelines for standardization of methods in laboratory medicine. In: Thomas L, editor. Clinical laboratory diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 1393-1401

Waste Management

Please refer to local legal requirements.

Manufacturer

DiaSys Diagnostic Systems GmbH Alte Strasse 9

IVD (65558 Holzheim Germany

		Lot No.	Expiry Date	Target Value	Range
TruLab CRP Level 2	CRP FS	35030	2025-01-11	6.10 mg/dL	4.45 – 7.75 mg/dL
				61.0 mg/L	44.5 – 77.5 mg/L
TruLab CRP Level 2	CRP U-hs	35030	2025-01-11	5.68 mg/dL	4.15 – 7.21 mg/dL
				56.8 mg/L	41.5 – 72.1 mg/L
TruLab CRP Level 2	InnovaStar: CRP IS	35030	2025-01-11	5.39 mg/dL	3.93 – 6.85 mg/dL
				53.9 mg/L	39.3 – 68.5 mg/L