TruCal Protein high

Calibrator for use in tests for quantitative in vitro determination of various serum proteins on photometric systems

Order Information

5 9200 99 10 037 3 x 1 mL

Description

TruCal Protein high is a liquid stable calibrator based on human blood material (plasma).

Storage

The unopened and opened bottles of TruCal Protein must be stored at $2-8\,^{\circ}\text{C}.$

Stability

Unopened: Until the end of the indicated month of expiry

Opened: At least 12 weeks

Proper storage and handling of this product must be observed.

Warnings and Precautions

- Each individual blood donation used for production of TruCal Protein
 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.
- 4. For professional use only!

Preparation

TruCal Protein is liquid and ready to use.

For calibration 5 calibrator levels are required. Prepare five calibrator levels using TruCal Protein high and NaCl solution 0.9% (9 g/L) according to the instructions in the table below.

 $\underline{\text{Note:}}$ Homogenize diluted levels by thorough mixing and use them immediately.

Procedure

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

Calibrator Values

The assigned values of TruCal Protein have been made traceable to the ERM®-DA470k/IFCC reference material. Calibrator values listed below are specific for this lot number of calibrator only.

Literature

- Stenman UH. Standardization of immunoassays. In: Price CP, Newman DJ, editors. Principles and practice of immunoassay. New York: Stockton Press; 1997.p.243-68.
- 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.
 Biosafety in Microbiological and Biomedical Laboratories. U.S.
- Biosafety in Microbiological and Biomedical Laboratories. U.S. Department of Health and Human Services, Washington 1993 (HHS Publication No. [CDC] 93-8395)

Waste Management

Please refer to local legal requirements.

Manufacturer

IVD (E

DiaSys Diagnostic Systems GmbH Alte Strasse 9 65558 Holzheim Germany

Level	Lot. No.	Expiry date	Dilution			
			Undiluted+NaCl 0.9%			
Level 1			1 + 15			
Level 2			1+7			
Level 3			1+3			
Level 4			1+1			
Level 5	32177	2024-04-14	Undiluted			

Calibrator values	Albumin [g/L]	C3c [mg/dL]	C4 [mg/dL]	lgA [mg/dL]	lgG [mg/dL]	lgM [mg/dL]	Prealbu- min [mg/dL]	Trans- ferrin [mg/dL]
Level 1	4.99	20.4	6.38	63.0	205	53.4	7.00	41.6
Level 2	10.0	40.8	12.8	126	411	107	14.0	83.1
Level 3	20.0	81.5	25.5	252	822	214	28.0	166
Level 4	40.0	163	51.0	504	1644	428	56.0	333
Level 5	79.9	326	102	1008	3287	855	112	665

TruCal Protein high 844 9200 10 02 02 December 2017/9