

## TruCal Protein

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

### Order Information

5 9200 99 10 039 5 x 1 mL

### Description

TruCal Protein is a set of five liquid stable calibrators with different levels. The calibrators are based on human blood material (plasma).

### Storage

The unopened and opened bottles of TruCal Protein must be stored at 2 – 8°C.

### Stability

Unopened: Until the end of the indicated month of expiry  
Opened: At least 3 months

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.
- For professional use only!

### Preparation

TruCal Protein is liquid and ready to use.

### 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<sup>®</sup>-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. 1<sup>st</sup> 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)

### Waste management

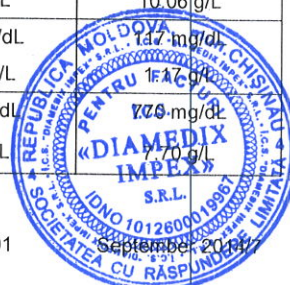
Please refer to local legal requirements.

### Manufacturer

DiaSys Diagnostic Systems GmbH  
Alte Strasse 9  
65558 Holzheim Germany



	Level 1	Level 2	Level 3	Level 4	Level 5
Lot:	23728	23729	23730	23731	23732
Expiry date:	2019-04	2019-04	2019-04	2019-04	2019-04
Albumin	5.87 g/L	11.7 g/L	23.5 g/L	47.0 g/L	93.9 g/L
C3c	20.3 mg/dL	40.5 mg/dL	81.0 mg/dL	162 mg/dL	324 mg/dL
	0.203 g/L	0.405 g/L	0.810 g/L	1.62 g/L	3.24 g/L
C4	5.90 mg/dL	11.8 mg/dL	23.6 mg/dL	47.2 mg/dL	94.4 mg/dL
	0.059 g/L	0.118 g/L	0.236 g/L	0.472 g/L	0.944 g/L
IgG	191 mg/dL	382 mg/dL	765 mg/dL	1530 mg/dL	3059 mg/dL
	1.91 g/L	3.82 g/L	7.65 g/L	15.30 g/L	30.59 g/L
IgM	56.6 mg/dL	113 mg/dL	227 mg/dL	453 mg/dL	906 mg/dL
	0.566 g/L	1.13 g/L	2.27 g/L	4.53 g/L	9.06 g/L
IgA	62.9 mg/dL	126 mg/dL	252 mg/dL	503 mg/dL	1006 mg/dL
	0.629 g/L	1.26 g/L	2.52 g/L	5.03 g/L	10.06 g/L
Prealbumin	7.33 mg/dL	14.7 mg/dL	29.3 mg/dL	58.7 mg/dL	117 mg/dL
	0.073 g/L	0.147 g/L	0.293 g/L	0.587 g/L	1.17 g/L
Transferrin	48.1 mg/dL	96.2 mg/dL	192 mg/dL	385 mg/dL	770 mg/dL
	0.481 g/L	0.962 g/L	1.92 g/L	3.85 g/L	7.70 g/L



## TruLab Protein

Assayed quality control material for monitoring assay performance of quantitative in vitro determination of various serum proteins

### Order Information

5 9500 99 10 046 3 x 1 mL Level 1  
5 9510 99 10 046 3 x 1 mL Level 2

### Description

TruLab Protein is a liquid-stable control based on human blood material (plasma).

### Storage

The unopened and opened bottles of TruLab Protein controls must be stored at 2 – 8°C.

### Stability

Unopened: until the end of the indicated month of expiry  
Opened: at least 12 weeks for albumin, C3c, C4, IgG, IgM, IgA, prealbumin and transferrin and at least 60 days for all other analytes

Proper storage and handling of this product must be observed.

### Warnings and Precautions

- Each individual blood donation used for production of TruLab 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.
- For professional use only!

### Preparation

TruLab Protein is liquid and ready to use.

### Procedure

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

### Assay Values

TruLab Protein assay values for the single proteins have been determined by independent reference laboratories in accordance with established protocols.

Assay values may slightly vary according to different reagents and methodologies used. The assay values listed are valid only for the corresponding lot.

Each laboratory should establish corrective action in case of deviations in control recovery.

### Traceability

System related assay values could change due to changes in the traceability of calibrator and/or changes in the reagent. The performance of the control is not influenced. The difference in recovery is caused only by the reagent and/or calibrator of the relevant system.

If your reagent supplier informs you about a change in the reagent or the traceability, please contact us. We will supply new system related assay values as soon as possible.

### Literature

- Röhle G, Siekmann L. Quality assurance of quantitative determination. In: Thomas L, editor. Clinical laboratory diagnostics. 1<sup>st</sup> 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).

### Waste management

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