

# TruLab Protein

## Order Information

Cat. No.		Kit size
5 9500 99 10 046	Level 1	3 x 1 mL
5 9510 99 10 046	Level 2	3 x 1 mL

## Intended Use

Assayed quality control to monitor the analytical performance of reagents used for quantitative in vitro determination of various serum proteins on automated photometric systems.

## Description

TruLab Protein is a liquid-stable control based on human plasma. It consists of two levels containing different analyte concentrations. Contains chemical additives.

## Storage

The control, both opened and unopened, must be stored at 2 – 8°C. Avoid contamination and protect from light.

## Stability

Unopened: Up to the date of expiry indicated on the kit  
Note: Myoglobin concentration is provided but may change within shelf life. In case of observed instabilities, target values for Myoglobin will be adapted.

Opened: 12 weeks except Myoglobin. The open-vial stability of Myoglobin cannot be guaranteed.

Proper storage and handling of this product must be observed.

## Warnings and Precautions

1. Contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Contains material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. 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 control with the same precautions used for patient specimens.
4. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
5. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
6. Please refer to the safety data sheets (SDS) and take the necessary precautions for the use of calibrators and controls.
7. For professional use only.

## Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

## Preparation

The control is ready to use.

## Materials Required

General laboratory equipment

## Procedure

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

## Target Values

DiaSys target values have been determined under standardized conditions using DiaSys reagents specified by product code and corresponding DiaSys calibrator mentioning the traceability in its value sheet. All target values of TruLab Protein are traceable to DiaSys reagent/calibrator system. The target values of single proteins have been determined by independent accredited laboratories in accordance with established protocols.

The analyte concentrations in TruLab Protein are lot specific and stated on the corresponding value sheet.

Target values may vary with reagents and methods used.

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

## Control Ranges

Ranges of acceptance were calculated as assigned value  $\pm$  the maximum tolerable deviation of a single value according to the Guidelines of the German Federal Medical Council (Rilibäk) from 2003 [3].

For the analytes not listed in the Rilibäk the ranges are given as  $\pm$  20% of the target value.


Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines.

## Literature

1. 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.
2. Biosafety in Microbiological and Biomedical Laboratories, U.S. Department of Health and Human Services, Washington June 2020 (HHS Publication 6th Edition 604 pages).
3. Bundesärztekammer. Richtlinie der Bundesärztekammer zur Qualitätssicherung quantitativer laboratoriumsmedizinischer Untersuchungen. Deutsches Ärzteblatt 2003;100:A 3335-38.

Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.



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