

# TruLab L

## Assayed quality control material for monitoring analytical assay performance of quantitative in vitro determination of lipids

### Order Information

5 9020 99 10 065      3 x 3 mL Level 1  
5 9030 99 10 065      3 x 3 mL Level 2

### Description

TruLab L is a lyophilized control based on human blood material (serum) with additives of purified material of human origin.

### Storage

The unopened vials must be stored at 2 – 8°C.

### Stability

Unopened:                      Until the end of the indicated month of expiry

Shelf life of components after reconstitution:

	-20°C *	2 – 8°C	15 – 25°C
NEFA	Storage not possible!	7 days	8 hours
Other analytes	30 days	7 days	8 hours

\* Freeze only once!

Proper storage and handling of this product must be observed. Avoid contamination!

### Warnings and Precautions

1. Only blood donations of European origin were used for the production of TruLab L which were found to be non-reactive when tested with approved methods for HBsAg, anti-HIV 1+2 and anti-HCV. Moreover, HCV and HIV were additionally tested by PCR. As there is not 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.
2. Please refer to the safety data sheets and take the necessary precautions for the use of calibrators and controls.
3. For professional use only!

### Preparation

The lyophilisate is vacuum sealed; therefore, the vial should be opened very carefully to avoid loss of dried material. For reconstitution add exactly 3.0 mL of distilled water. Close the vial carefully and allow the control to stand for 30 minutes swirling occasionally. Avoid foaming! Do not shake! Leave frozen aliquots of the reconstituted TruLab L in the dark at room temperature (18 – 25°C) until they are completely unfrozen. To homogenize after complete defrosting, slightly swivel aliquots and immediately afterwards use them for determination accordingly to the freshly reconstituted TruLab L.

**Note for use with Lp-PLA<sub>2</sub> FS (Cat. No. 1 7181):** For reconstitution of TruLab L Level 2 add exactly 1.0 mL of distilled water. Reconstitution of TruLab L Level 1 should be done with exactly 3.0 mL of distilled water.

### Procedure

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

### Assay Values

The analyte concentrations contained in TruLab L are specific and only valid for the corresponding lot and thus stated in the value sheet of the lot involved. All assay values have been established within standardized conditions with the method stated in the value sheet by using the reagents specified via the product code.

Ranges of acceptance were calculated as assigned value ± the maximum tolerable deviation of a single value according to the Guidelines of the German Federal Medical Council (Rilibaek) from 2003 [3]. For analytes not listed in the Guidelines of the German Federal Medical Council (Rilibaek) ranges are indicated with a deviation of ±20% from the given mean value.

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

### 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 1993 (HHS Publication No. [CDC] 93-8395).
3. Richtlinie der Bundesärztekammer zur Qualitätssicherung quantitativer laboratoriumsmedizinischer Untersuchungen. Deutsches Ärzteblatt Jg. 100, Heft 50; 12. Dezember 2003.

### Waste management

Please refer to local legal requirements.

### Manufacturer



DiaSys Diagnostic Systems GmbH  
Alte Strasse 9  
65558 Holzheim Germany