

TruCal Apo A1/B

Calibrator for use with DiaSys tests for quantitative in vitro determination of apolipoprotein A1 and apolipoprotein B on photometric systems

Order information

Cat. No. 1 7170 99 10 045 Kit size 3 x 2 mL

Description

TruCal Apo A1/B is a lyophilized calibrator based on human blood material (plasma) with biological additives from human origin. The calibrator is used for calibration of the DiaSys tests Apolipoprotein A1 FS and Apolipoprotein B FS.

Storage

The calibrators both unopened and reconstituted 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 | +25°C |
|---|----------|----------|----------|
| Reconstituted TruCal Apo A1/B | 6 months | 3 months | 24 hours |
| Calibrator dilutions of reconstituted TruCal Apo A1/B | 6 months | 4 weeks | 24 hours |

* Freeze only once!

Proper storage and handling of this product must be observed. Contamination must be avoided.

NOTE: Homogenize the product by gently swirling before each use.

Warnings and Precautions

Only blood donations of European origin were used for the production of TruCal Apo A1/B, 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 no possibility to exclude definitely that products derived from human blood components transmit infectious agents, it is recommended to handle the calibrator with the same precautions used for patient specimens.

Preparation

The lyophilisate is vacuum-sealed; therefore, the vial should be opened very carefully to avoid loss of dried material. For reconstitution, add exactly 2 mL of distilled water. Close the vial carefully and allow the calibrator to stand for 30 minutes swirling occasionally. Avoid foaming! Do not shake!

For calibration, five calibrator levels are required. Prepare five calibrator levels by manual dilution using reconstituted TruCal Apo A1/B and distilled water or by automated analyzer dilution using reconstituted TruCal Apo A1/B and distilled water or aqueous NaCl solution 0.9% (9 g/L). Follow the instructions given in the table below.

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| Level | Automated dilution | | Manual dilution | | Calibrator values | | Unit |
|---------|--|--|--|-----------------|--------------------------|--------------------------|--------------|
| | Calibrator | Distilled water or aqueous NaCl solution | Calibrator | Distilled water | Apo A1 Cat. No 1 7102... | Apo B Cat. No 1 7112 ... | |
| Level 0 | Distilled water or aqueous NaCl solution only! | | Distilled water or aqueous NaCl solution only! | | 0 0 | 0 0 | mg/dL g/L |
| Level 1 | 1 part | 4 parts | 40 µL | 160 µL | 57.2 0.572 | 59.3 0.593 | mg/dL g/L |
| Level 2 | 2 parts | 3 parts | 80 µL | 120 µL | 114 1.14 | 119 1.19 | mg/dL g/L |
| Level 3 | 3 parts | 2 parts | 120 µL | 80 µL | 172 1.72 | 178 1.78 | mg/dL g/L |
| Level 4 | 4 parts | 1 part | 160 µL | 40 µL | 229 2.29 | 237 2.37 | mg/dL g/L |
| Level 5 | Undiluted | | Undiluted | | 286 2.86 | 297 2.97 | mg/dL g/L |

Notes:

- To avoid contaminations transfer for manual dilution minimum 600 µL of reconstituted calibrator into a clean sample cup and prepare dilutions out of this volume. Homogenize manually diluted levels by thorough mixing before use or storage.
- Please refer to the safety data sheets and take the necessary precautions for the use of calibrators and controls.
- For professional use only!

Unfreeze the reconstituted TruCal Apo A1/B in the dark at room temperature (18 – 25°C). To homogenize after complete defrosting, slightly swivel aliquots and immediately afterwards use them for calibration in the same way as the freshly reconstituted TruCal Apo A1/B.

Procedure

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

Calibrator values

The values were determined using the DiaSys assay methods. The assigned values of TruCal Apo A1/B have been made traceable to a commercially available measurement procedure standardized against the IFCC reference standards (WHO-IRP October 1992). For standardization of Apo A1 the reference standard SP1-01 was used whereas for standardization of Apo B the reference standard SP3-07 was used.

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. 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

