

TruCal TBA

Order Information

Cat. No. 1 2240 99 10 037 Kit size 3 x 1 mL

Intended Use

Calibrator for use in tests for quantitative in vitro determination of total bile acids on photometric systems.

Description

TruCal TBA is a lyophilized calibrator based on human blood material (plasma) and contains biological additives from human origin. The calibrator is used for calibration of the DiaSys test Total bile acids 21 FS.

Storage

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

Stability

Unopened: Until the end of the indicated month of expiry

After reconstitution:

(–15) – (–20)°C *	2 – 8°C	15 – 25°C
8 weeks	14 days	48 hours

* freeze only once!

Proper storage and handling of this product must be observed.

Avoid contamination and protect from light.

Warnings and Precautions

- Each individual blood donation used for production of TruCal TBA 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.
- TruCal TBA contains biological material. The calibrator should be handled as potentially infectious and with the same precautions used for patient specimens.
- Please refer to the safety data sheets and take the necessary precautions for the use of calibrators and controls.
- For professional use only.

Waste Management

Refer to local legal requirements.

Preparation

The lyophilisate is vacuum sealed; therefore, the vial should be opened very carefully to avoid loss of dried material. For reconstitution add exactly 1.0 mL of distilled water. Close the vial carefully and allow the calibrator to stand for 30 minutes swirling occasionally. Avoid foaming! Do not shake!

Defrost the reconstituted TruCal TBA protected from light 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 TBA.

Materials Required

General laboratory equipment

Calibrator Values

The assigned values of the calibrator have been made traceable to a commercially available measurement procedure. Values listed below are specific for the indicated lots only.

Literature

- 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. 1402-26.
- Biosafety in Microbiological and Biomedical Laboratories, U,S, Department of Health and Human Services, Washington 2009 (HHS Publication No. [CDC] 21–1112).



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	Lot No.	Expiry Date	Calibrator Value	Unit
TruCal TBA	31609	2023-07-31	44.1	µmol/L