

TruCal TBA

Order Information

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

Intended Use

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

Description

TruCal TBA is a lyophilized calibrator based on human serum/plasma.

Contains biological additives from bovine/ovine origin.

The calibrator is used to calibrate the DiaSys test Total bile acids 21 FS.

Storage

The unopened calibrator 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

After reconstitution:

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

* Only freeze once

Proper storage and handling of this product must be observed.

Warnings and Precautions

1. Contains material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
2. 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.
3. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
4. 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.
5. Please refer to the safety data sheets (SDS) and take the necessary precautions for the use of calibrators and controls.
1. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations along with the SDS for this product to determine the safe disposal.

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

Preparation

The calibrator is lyophilized; therefore, the vial should be opened very carefully to avoid loss of 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

Procedure

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

Calibrator Value

The value has been made traceable to a commercially available assay.

Value listed below is valid for the indicated lot only.

Literature

1. 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.
2. Chosewood LC, Wilson DE, Centers for Disease Control and Prevention (U.S.), & National Institutes of Health (U.S.). Biosafety in microbiological and biomedical laboratories. Washington D.C.: U.S. Dept. of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institutes of Health; 2009. Page 21-1112.

Additions and/or changes in the document are highlighted in grey. For deletions, please refer to the customer information for the corresponding edition number of the package inserts.



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	Lot No.	Expiry Date	Calibrator Value
TruCal TBA	39033	2029-01-31	45.5 µmol/L