

TruCal CK-MB

Calibrator for use in tests for quantitative in vitro determination of CK-MB activity on photometric systems

Order Information

5 9450 99 10 074 6 x 1 mL

Description

TruCal CK-MB is a lyophilized calibrator based on bovine serum albumin with chemical additives and purified materials of specified origin.

CK-MM: human

CK-MB: human, recombinant

TruCal CK-MB is used for calibration of DiaSys CK-MB FS test (Cat. No. 1 1641).

Storage and Stability

Unopened: Until the end of the indicated month of expiry if stored at 2 – 8°C.

Shelf life of components after reconstitution:

(-15) – (-20)°C *	2 – 8°C	15 – 25°C
28 days	2 days	24 hours

* freeze only once!

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

Warnings and Precautions

1. Each individual blood donation used for production of TruCal CK-MB was found to be non-reactive when tested with FDA-approved methods or methods cleared in compliance with the European Directive 98/79/EC, Annex II, List A for HBsAg, anti-HIV 1+2 and anti-HCV. As there is no possibility to exclude definitely that products derived from human blood components and biological material transmit infectious agents, it is recommended to handle the calibrator with the same precautions used for patient specimens.
2. TruCal CK-MB contains animal material. The calibrators should be handled as potentially infectious and with the same precautions used for patient specimens.
3. Please refer to the safety data sheets and take the necessary precautions for the use of calibrators and controls.
4. 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 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!

Allow the calibrator to stand closed for further 60 minutes.

Defrost the reconstituted TruCal CK-MB 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 CK-MB.

Procedure

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

Calibrator values

The calibrator values were determined under standardized conditions using the DiaSys CK-MB FS reagent and the TruCal CK-MB master calibrator. The assigned values of the calibrator have been made traceable to the molar extinction coefficient.

Values listed below are specific for this lot number of calibrator 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. 1404-26.
2. 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 the local requirements.

Manufacturer



DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany

	Lot. No.	Expiry date	Calibrator value	Unit
TruCal CK-MB	31957	2023-05-31	120	U/L
			2.00	µkat/L