CK-MB CALIBRATOR

2°C 8°C

REF 1578-0291 **Packaging:** 3 x 1 mL

INTENDED USE

Material for the preparation of reference curves for the quantitative determination of CK-MB using Medicon reagent with Diatron Pictus® P700 and P500 analyzers. For in vitro Diagnostic use only by trained laboratory professionals.

COMPOSITION

Lyophilized preparation based on human serum, containing human CK-MB in buffer. Preservatives.

⚠ **WARNINGS – PRECAUTIONS**

- For in vitro use only
- The material contains sodium azide (NaN3) <0.1%. Avoid swallowing and contact with skin and mucous membranes.
- Biological materials of human origin contained in this product were tested for Anti-HCV, HbsAg and Anti-HIV 1 and 2 using FDA approved methods and were found to be non-reactive. As there is no known test method that can offer complete assurance that products of human origin will not transmit infectious agents this product should be handled as a potentially infectious material.
- Any serious incident that may occur in relation to this device must be reported by the user to the manufacturer and the competent authority of the country in which the user and/or the patient is established!

⚠ **PREPARATION**

Remove the rubber stopper very carefully. As the material is packed under vacuum, sudden air influx may force material out of the vial. Reconstitute by adding exactly 1 ml of cold (2°-8°C) deionized or distilled water. Place the rubber stopper back on the vial, swirl gently 2-3 times and let it stand for 10 minutes. Mix gently to obtain a homogeneous mixture. Ideally use a hematology tubes mixer for 20 minutes. Avoid foaming. Use 30 minutes after water addition. Replace cap immediately after use and store at 2-8°C. Unsuitable storage, handling, or errors during the analytical procedure may give erroneous results.

MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

- CK-MB reagent
- Automated biochemical analyzer
- Common laboratory equipment.

⚠ **STORAGE - STABILITY**

The material is stable, unopened up to the expiry date stated on the label when stored at 2-8ºC. After reconstitution the material is stable for 3 days when stored tightly capped after use at 2-8ºC.

⚠ **DETERIORATION**

The material should not be used:

- After prolonged exposure to direct sunlight or high temperature
- After the expiry date
- When microbial growth is evident

PROCEDURE

Refer to the appropriate User's Guide and the accompanying Instrument Setting Sheet for analyzer-specific assay instructions for calibration.
If any trends or sudden shifts in values are detected, review all operating parameters. Control recovery should lie within acceptable intervals. Results outside the specified values even after recalibration could be due to reagent/calibrator/control deterioration, unsuitable storage conditions, instrument malfunction, or error during test procedure.
Every laboratory should establish its own corrective measures in case control recovery lies outside acceptable intervals.
Make sure the LOT on the vial is the same as on the value sheet accompanying the material.

⚠ **WASTE DISPOSAL**

This product contains sodium azide (NaN_3), which forms sensitive explosive compounds with copper or lead. Flush waste pipes with water after the disposal of undiluted reagent in order to avoid azide build up in the drain pipes. Dispose of all waste material in accordance with local guidelines. Safety data sheet is available for professional use on request.

ASSIGNED VALUES – Lot specific

Please refer to the value sheet for the specific lot available at https://medicondoc.com.

SYMBOLS


Manufacturer


In vitro diagnostic medical device


Temperature Limit


Catalogue Number


Caution


Biological Risks

* PICTUS®: Registered Trademark of Diatron Medical Instruments Limited, Táblás utca 39, H-1097 Budapest, Hungary, used here after contractual agreement.

MEDICON HELLAS S.A. - Melitona 5-7, 153 44 Gerakas, Greece. Tel: +302106606000 - Fax: +302106612666 – www.mediconsa.com

Version 2 - Last updated 2020.06.30

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