CK-MB CONTROL

2°C – 8°C

REF 1578-0295 **Packaging:** 2 x 3 x 2 mL

INTENDED USE
Material for internal quality control of CK-MB assays 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 2 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**

Unopened the control is stable up to the expiry date stated on the label, when stored at 2-8°C. After reconstitution the control is stable for:
·8 hours at 15 - 25°C
·5 days at 2-8°C
·1 month at (-25) to (-15)°C
It is recommended to dispense the remaining reconstituted control in aliquots and store at –20°C for future use.

⚠ **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
For the quality control process refer to the user's manual of the analyzer.
Each laboratory should establish its own control frequency, however good laboratory practice suggests that controls be tested each date patient samples are tested and each time calibration is performed.
The results obtained by any individual laboratory may vary from the given mean value but should fall within the corresponding acceptable ranges given in the enclosed table. If any trends or sudden shifts in values are detected, review all operating parameters.
Each laboratory should establish guidelines for corrective actions to be taken if controls do not recover within the specified limits. 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
IVD *In vitro* diagnostic medical device
Temperature Limit
REF 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.

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