

CK-MB Calibrator

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package.

INTENDED USE

CK-MB Calibrator is for use in the calibration of the CK-MB Liquid assay on the Architect cSystems.

CK-MB Calibrator

REF: 01R94-01

Package: 5 x 2 mL Lyophilized

For use with;

CK-MB Liquid reagent

REF: 01R88-21

*01R88-31

CONTENTS / MATERIALS PROVIDED

CK-MB Calibrator (REF: 01R94-01) contains human serum.

Sodium Azide (0.09%) is added as a preservative.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Class A volumetric pipette for delivery of 2.0 mL
2. Distilled or deionized water meeting specifications equivalent to USP purified water
3. CK-MB Liquid reagent

REF: 01R88-21

*01R88-31

STANDARDIZATION

The traceability of the method is verified using C.f.a.s. CK-MB (Ref. 11447394 216) and native serum correlation studies with commercial available CK-MB Assay test results.

PRECAUTIONS (General and Users)

IVD

For *in Vitro* Diagnostic Use.

Do not use components beyond the expiration date.

Contains sodium azide.

EUH032 Contact with acids liberates very toxic gas.

Do not mix materials from different kit lot numbers. Human source material.

Calibrator can contain preservatives (as Sodium Azide or others) which total concentration is lower than the limits mentioned in Directive 67/548/CEE and 88/379 CEE.



Treat as potentially infectious. Each plasma donor unit used in the preparation of this

product has been tested by an FDA-approved method and found nonreactive for the presence of HBsAg, HCV, HIV-Ag and antibody to HIV 1/2. Because no known test method can offer complete assurance that hepatitis B virus, Human Immunodeficiency Virus (HIV) or other infectious agents are absent, all human-based products should be handled in accordance with good laboratory practices using appropriate precautions.^{1,2}

Safety data sheets are available www.archem.com.tr or contact your local representative. Emergency Phone Number: In emergency situation please contact the National Poison Solidarity Center (Turkey) for information in Turkish: (114) (24 hours/7 days). Please contact with Archem for information in English: + (90) 212 444 0 892 (Turkey) (8:30-18:30/ except Sundays)

STORAGE AND STABILITY

1. Unopened CK-MB Calibrator is stable until the expiration date when stored +2 to +8 °C.
2. Opened calibrators stable **5 days** when stored at dark place +2 to +8°C.
3. CK-MB Calibrator is stable 30 days when stored -20°C. Reconstitute and store tightly capped in a dark place, kept free of contamination and FROZEN. (Freeze and thaw once only)

PREPARATION OF CALIBRATORS

Lyophilized serum calibrator should be reconstituted by adding 2.0 mL of distilled or deionized water. Close the vial and let stand for 30 minutes. Mix at least 10 minutes on mixer. For best performance store at room temperature 1 hour and then mix again 2-3 minutes before running calibration. Dissolve the contents of the vial by swirling gently to avoid the formation of foam. Don't shake.

INDICATIONS OF INSTABILITY OR DETERIORATION

Presence of extreme turbidity or microbial growth may indicate deterioration.

REFERENCES

1. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register. July 1, 2001; 17:260-273.
2. Directive 2000/54/EC. Official Journal of the European Communities No. L262 from October 17, 2000.

CK-MB Calibrator

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REF: 01R94-01

FOR USE WITH
ARCHITECT

TRADEMARKS

CK-MB Calibrator is a trademark of ARCHEM Diagnostic A.Ş. In various jurisdictions.

The ARCHITECT c System family of instruments consists of c4000, c8000 and c16000 instruments.

ARCHITECT, c4000, c8000, c16000, c System are trademark of Abbott Laboratories in various jurisdictions

All trademarks are property of their respective owner(s)

Customer Service:

Contact Archem Diagnostics Industry A.Ş.



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SYMBOLS

IVD

In Vitro Diagnostic Medical Device

LOT

Lot number

CAL

Calibrator

GTIN

Global Trade Item Number

REF

Reference Number

FOR USE WITH

Identifies products to be used together

PRODUCT OF TURKEY

Product of Turkey



Manufacturer



Expiration date



Temperature limitation



Consult instructions for use



Caution



Sufficient for