CK-MB Control Set

En

REF: 01R92-01
REF: 01R93-01

FOR USE WITH
ARCHITECT

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 Control Level I & CK-MB Control Level II are for use in the control of the CK-MB Liquid assay on the Architect cSystems.

CK-MB Control Level I
REF: 01R92-01
Package: 5 x 2 mL **Lyophilized**

CK-MB Control Level II
REF: 01R93-01
Package: 5 x 2 mL **Lyophilized**

For use with;

CK-MB Liquid reagent
REF: 01R88-21
01R88-31

CONTENTS / MATERIALS PROVIDED

CK-MB Control Level I (**REF:** 01R92-01) & CK-MB Control Level II (**REF:** 01R93-01) 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. Archem CK-MB Liquid reagent
   REF: 01R88-21
   01R88-31

STANDARDIZATION

The traceability of the method is verified using C.f.a.s. CK-MB Controls (Ref: 11447394 216) and native serum correlation studies with commercial available CKMB 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.
Control 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 Control Level I & CK-MB Control Level II are stable until the expiration date when stored +2 to +8 °C.
2. Opened controls stable **5 days** when stored at dark place +2 to +8°C.
3. CK-MB Control Level I & CK-MB Control Level II are 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 CONTROLS

Lyophilized control 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 control. 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.

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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.

TRADEMARKS

Customer Service:
Contact Archem Diagnostics Industry A.Ş.

Archem Sağlık Sanayi ve Tic. A.Ş.
Mahmutbey Mah. Halkalı Cad. No:124 Kat:4
Bağcılar/İstanbul/Turkey
Tel: + 90 212 444 08 92
Fax: +90 212 629 98 89
info@archem.com.tr **www.archem.com.tr**

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SYMBOLS

IVD	In Vitro Diagnostic Medical Device
LOT	Lot number
CON	Control
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