



Lot: 1702209760  
Level 1: 209760  
Level 2: 209760  
Level 3: 209760

# CK-MB

## Control - 3 niveles

For precision control in the MB isoenzyme determination  
of Creatine Kinase

### USES

**CK-MB Control 3 niveles** is a lyophilized control based on bovine serum albumin using human CK-MB isoenzyme and is designed to be used in the precision control of **CK-MB NAC UV AA líquida** and **CK-MB DS UV unitest** kits.

### PROVIDED REAGENTS

**CK-MB Control level 1:** lyophilized control based on bovine serum albumin with the addition of human CK-MB isoenzyme in low and/or close to normal activity levels.

**CK-MB Control level 2:** lyophilized control based on bovine serum albumin with the addition of human CK-MB isoenzyme close to normal activity levels.

**CK-MB Control level 3:** lyophilized control based on bovine serum albumin with the addition of human CK-MB isoenzyme in pathological activity levels.

### NON-PROVIDED REAGENTS

Distilled or demineralized water.

### INSTRUCTIONS FOR USE

Carefully open the vial removing the rubber cap to avoid the loss of lyophilized material. Reconstitute adding the quantity of distilled or demineralized water stated on the label. Cap and homogenize gently by inversion until complete dissolution of the material. Avoid foam formation.

Add the necessary volume to a sample container and test as a patient sample. It is advisable to process the control daily, in parallel to patient samples, and to establish control intervals according to the needs of each particular laboratory. The results should be within the defined intervals. Each laboratory should establish the guidelines for corrective measures if the values are established outside the interval. Each laboratory should establish quality control procedures to meet current local regulations or their accreditation requirements.

### WARNINGS

Reagents are for "in vitro" diagnostic use.

The Controls have been prepared from non-reactive material to Hepatitis B surface antigen (HBsAg), antibodies to Hepatitis C virus (HCV) and Human Immunodeficiency Virus (HIV). However, because no known test method can offer complete assurance that infectious agents are absent, the controls and the samples should be handled as potentially infectious material.

Use gloves and adequate eye protection.

Avoid ingestion and/or direct contact with the skin and mu-

cus membranes. In such case, proceed according to the instructions of the competent health authorities.

Use the reagents following the usual work precautions at the clinical laboratory.

All reagents and samples should be discarded according to the current local regulations.

### STABILITY AND STORAGE INSTRUCTIONS

The lyophilized controls are stable at 2-10°C until the expiration date stated on the box. Once reconstituted, they are stable for up to 3 days at 2-10°C or for up to 2 days at 25°C. After use, closed vials firmly and keep them at 2-10°C and protected from light. When the reconstituted controls are stored at -20°C, they are stable for 3 months in such conditions. Aliquot and freeze them immediately after reconstitution. Avoid repeated freezing and thawing.

### WIENER LAB PROVIDES

3 x 3 ml: 1 x 3 ml Level 1  
1 x 3 ml Level 2  
1 x 3 ml Level 3

(Cat. N° 1271553)

### REFERENCES

- Documentación de Wiener Laboratorios.
- Young, D.S. - "Effects of Drugs on Clinical Laboratory Tests", AACC Press, 4<sup>th</sup> ed., 2001.
- Tietz Textbook of Clinical Chemistry, Saunders Co., 3rd ed. (1999).
- CLSI Document "User Demonstration of performance for Precision and Accuracy", EP15-A2 (2005).

CK-MB ASSIGNED VALUES (U/l)* - BT 3000 PLUS / WIENER LAB. CB SERIES									
KIT	LEVEL 1			LEVEL 2			LEVEL 3		
	MEAN	ACCEPTABLE RANGE		MEAN	ACCEPTABLE RANGE		MEAN	ACCEPTABLE RANGE	
CK-MB DS UV unitest	31.3	22.5	40.1	44.8	33.6	56.0	88.0	66.0	110.0
CK-MB NAC UV AA líquida**	34.1	25.6	42.6	46.7	35.0	58.4	90.8	68.1	113.5

CK-MB ASSIGNED VALUES (U/l)* - KONELAB SERIES / WIENER LAB. CT SERIES									
KIT	LEVEL 1			LEVEL 2			LEVEL 3		
	MEAN	ACCEPTABLE RANGE		MEAN	ACCEPTABLE RANGE		MEAN	ACCEPTABLE RANGE	
CK-MB DS UV unitest	38.3	28.7	47.9	51.5	41.2	61.8	102	82	122
CK-MB NAC UV AA líquida**	36.8	27.6	46.0	49.7	39.8	59.6	96.8	77.4	116.2

CK-MB ASSIGNED VALUES (U/l)* - METROLAB 2300 PLUS / WIENER LAB. CM SERIES									
KIT	LEVEL 1			LEVEL 2			LEVEL 3		
	MEAN	ACCEPTABLE RANGE		MEAN	ACCEPTABLE RANGE		MEAN	ACCEPTABLE RANGE	
CK-MB DS UV unitest	33.5	25.1	41.9	44.8	35.8	53.8	89.2	71.4	107.0
CK-MB NAC UV AA líquida**	36.2	27.2	45.3	48.2	38.6	57.8	92.4	73.9	110.9

CK-MB ASSIGNED VALUES (U/l)* - SELECTRA 1 / 2 / E									
KIT	LEVEL 1			LEVEL 2			LEVEL 3		
	MEAN	ACCEPTABLE RANGE		MEAN	ACCEPTABLE RANGE		MEAN	ACCEPTABLE RANGE	
CK-MB DS UV unitest	38.3	26.8	49.8	51.5	38.6	64.4	102	77	128
CK-MB NAC UV AA líquida**	36.8	25.8	47.8	49.7	37.3	62.1	96.8	72.6	121.0

CK-MB ASSIGNED VALUES (U/l)* - TARGA BT 3000									
KIT	LEVEL 1			LEVEL 2			LEVEL 3		
	MEAN	ACCEPTABLE RANGE		MEAN	ACCEPTABLE RANGE		MEAN	ACCEPTABLE RANGE	
CK-MB DS UV unitest	31.3	21.9	40.7	44.8	33.6	56.0	88.0	66.0	110.0
CK-MB NAC UV AA líquida**	34.1	23.9	44.3	46.7	35.0	58.4	90.8	68.1	113.5

CK-MB ASSIGNED VALUES (U/l)* - WIENER LAB. CMD 800 SERIES									
KIT	LEVEL 1			LEVEL 2			LEVEL 3		
	MEAN	ACCEPTABLE RANGE		MEAN	ACCEPTABLE RANGE		MEAN	ACCEPTABLE RANGE	
CK-MB NAC UV AA líquida**	32.7	22.9	42.5	44.7	33.5	55.9	89.1	66.8	111.4

\* at 37°C

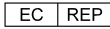
\*\* Values obtained using calibration technique

# Symbols

The following symbols are used in the packaging for Wiener lab. diagnostic reagent kits.



This product fulfills the requirements of the European Directive 98/79 EC for "in vitro" diagnostic medical devices



Authorized representative in the European Community



"In vitro" diagnostic medical device



Contains sufficient for <n> tests



Use by



Temperature limitation (store at)



Do not freeze



Biological risks



Volume after reconstitution



Contents



Batch code



Manufactured by:



Harmful



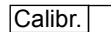
Corrosive / Caustic



Irritant



Consult instructions for use



Calibrator



Control



Positive Control



Negative Control



Catalog number

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**Wiener lab.**

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