SHD
SCIENCE HEALTH DIAGNOSTICS

8 683981 703256 100 T
8 683981 703270 200 T
8 683981 703294 400 T

CREATINE KINASE-MB (CK-MB)
(Magnetic Particle Based Chemiluminescence Immunoassay)

INTENDED USE

Creatine Kinase-MB Test Kit (Chemiluminescence Immunoassay) is a quantitative test for use on Innoviqure Spectrum Chemiluminescence Immunoassay Analyzer and Innoviqure Nexus Chemiluminescence Immunoassay Analyzer for the determination of CKMB in human serum and plasma. CKMB plays a critical role in the timely diagnosis of myocardial infarction. The test is designed to assist clinicians with the diagnosis and treatment of chest pain patients.

PACKAGING SPECIFICATIONS

100T/200T/400T

SUMMARY AND EXPLANATION

MI is characterized pathologically by the death of myocardial cells resulting from extended ischemia. The initial ultrastructural alterations include reduced cellular glycogen, relaxed myofibrils, and disruption of the sarcolemma, which can be observed as early as 10-15 minutes following the onset of ischemia. (Thygesen et al., 2019). Creatine kinase-MB (CK-MB) is a specific isoenzyme of creatine kinase (CK) that is primarily found in cardiac muscle cells. It plays a critical role in the diagnosis and evaluation of heart diseases, particularly myocardial infarction (heart attack). In patients with myocardial infarction, the average time from arrival at the emergency room to the elevation of plasma CK-MB subform activity was 1.22 ± 1.17 hours (Puleo et al., 1994). CK-MB is released into the bloodstream when cardiac muscle cells are damaged, making it a valuable biomarker for detecting heart injuries. Its levels in the blood start to rise within 3–6 hours after the onset of cardiac damage, peak at around 12–24 hours, and return to baseline within 48–72 hours. Detection of myocardial cell damage, which may suggest acute myocardial infarction (AMI), relies on the increase or decrease of this biomarker in the blood (Gulati et al., 2021). This relatively short time frame makes CK-MB especially useful for identifying recent cardiac events and distinguishing them from older incidents.

Elevated CK-MB levels indicate myocardial cell damage, which can guide clinicians in making timely decisions about treatment strategies, such as thrombolytic therapy or cardiac catheterization. Moreover, CK-MB is often measured alongside other cardiac biomarkers, such as troponins, to improve diagnostic accuracy. While troponins are more sensitive and specific for myocardial injury, CK-MB remains helpful in detecting reinfarction due to its faster normalization in the bloodstream.

In addition to diagnosing myocardial infarction, CK-MB testing is also used to monitor the effectiveness of treatments and assess the extent of cardiac damage after surgery or other interventions. Its clinical utility lies in its ability to provide rapid and reliable information about cardiac health, enabling early intervention and improving patient outcomes. Given its importance, CK-MB continues to be a widely used biomarker in cardiology, complementing modern diagnostic tools to ensure comprehensive evaluation and management of heart diseases.

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PRINCIPLE OF TESTING

The CKMB test utilizing Magnetic Particle-Based Chemiluminescence Immunoassay (CLIA) combines the sensitivity of chemiluminescence with the specificity of magnetic particles to capture and detect CKMB in samples.

1.Sample Introduction and Pre-Coated Magnetic Particles

A solid phase consisting of magnetic particles is pre-coated with monoclonal antibodies specific to human CKMB (Antibody I). When the sample is added, if CKMB is present, it binds to these antibodies on the magnetic particles, forming an immune complex.

2.Addition of Chemiluminescent-Labeled Antibody

A second reagent containing chemiluminescent-labeled monoclonal antibodies specific to CKMB (Antibody II) is introduced into the reaction mixture. These labeled antibodies bind to the CKMB already captured on the magnetic particles, forming a sandwich immunocomplex.

3.Magnetic Separation and Washing

The magnetic particles are then separated from the solution using a magnet, allowing for the removal of any unbound substances or reagents. The particles are then washed to ensure that only the immune complexes bound to the CKMB are retained.

4.Chemiluminescent Reaction

A chemiluminescent substrate is added to the reaction mixture. The chemiluminescent-labeled antibody conjugates catalyze a reaction that emits light in proportion to the amount of CKMB present in the sample.

5.Detection and Quantification

The emitted light is measured by a chemiluminescence analyzer. The intensity of the light produced is directly correlated with the concentration of CKMB in the sample. A standard curve, created using known concentrations of CKMB, allows for the quantitative determination of CKMB levels.

6.Result Interpretation

The CKMB concentration in the sample is calculated based on the measured light intensity, providing diagnostic information for detecting myocardial injury or acute myocardial infarction (AMI).

MAIN COMPONENTS

This reagent kit consists of Reagent Ra, Reagent Rd, calibrators (optional) and controls (optional).

Characteristics of Reagents

Reagent	For 100 T	Component
Ra	5,50 mL	Magnetic particles coated with recombinant CK-MB
Rd	5,50 mL	Acridinium ester conjugated to recombinant CK-MB antibody

Characteristics of Calibrators

Calibrator	mL/vial	Component
6 point	1,0 mL	Recombinant CK-MB antigen

Characteristics of Controls

Control	mL/vial	Component
2 point	3,0 mL	Recombinant CK-MB antigen (Lyophilized)

STORAGE CONDITIONS AND PERIOD OF VALID

The period of validity of the test kit is 18 months while the package is sealed and stored at 2-8 °C.

APPLICABLE INSTRUMENTS

Innoviqure Spectrum Chemiluminescence Immunoassay Analyzer and Innoviqure Nexus Chemiluminescence Immunoassay Analyzer manufactured by Deniz Biyokimya Urunleri Dis. Tic. A.S.

THE REQUIREMENTS OF SAMPLE

This kit is suitable for Serum / Plasma samples.
Serum / Plasma Collection: The serum or plasma should be separated for analysis immediately after blood collection to avoid hemolysis. Use within 8 hours if the sample is stored at room temperature; use within 48 hours if the sample is stored at 2-8 °C; use within 3 months if the sample is stored at -20°C with one cycle of freeze and thaw.

The sample must reach the equilibrium status at room temperature (20~30°C) before use.

TEST METHOD

- When loading Reagent Ra into the instrument for the first time, mix the reagent thoroughly in its bottle to resuspend any magnetic particles that may have settled during transportation.
- Check the sample volume in the sample tube before each test to ensure that the sample volume in the sample tube is always greater than 110 μL.
- If necessary, perform the calibration procedure. Refer to the manual of the device used for information on how to carry out the calibration procedure.
- Gently swirl the calibrator or control bottle 5-10 times to mix thoroughly before use.
- Sample Loading: Refer to the manual of the instrument used for information on sample loading.
- Press the “Run” button to perform the test.

CONFIDENCE INTERVAL

The serum and plasma samples of healthy donors (n=224) were tested using CKMB Test Kit. The results showed that the 95% percentile of CKMB was 3 ng/mL, the 99% percentile of CKMB was 1 ng/mL.
The above reference values are for reference only. Due to the differences in geography, race, gender and age, it is recommended that each laboratory establish its own reference values (reference range) according to the actual situation.

INTERPRETATION OF TEST RESULTS

The test results of this test kits are only for reference in clinical and cannot be used as the sole indicator for the diagnosis or exclusion of disease. The clinical diagnosis and treatment of patients should be considered in combination with their symptoms, medical history, and other laboratory tests result and treatment reactions.

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LIMITATIONS OF TEST RESULTS

1. The kit can be used for the determination of serum or plasma, and the reliability for the concentration determination of CKMB needs further confirmation.
2. Plasma samples in this kit are recommended to use EDTA, sodium heparin or sodium citrate as anticoagulants. If other anticoagulants are selected, the effect needs to be further confirmed.
3. The concentrations of CKMB obtained from other methods are not directly comparable with the results obtained from this kit.
4. If the test results of this kit are inconsistent with the clinical evaluations, further examination is required.
5. Operation must be carried out strictly in accordance with operating manual, please operate carefully for getting more accurate results, any modification of the operating manual may affect the results.
6. In the case of false positive results, some non-specific components in the sample with similar antigen-determining clusters might participate in the reaction. In case of false negative results, some unknown components might the antigen-determining cluster and disturb the immune recognition reaction. The detection of CKMB might be unsuccessful if the sample has been taken for too long time or the environmental temperature is causing the degradation of analytes.
7. Other factors may also cause inaccuracy in CKMB test results, including technical problems, inappropriate operation or sample factors, such as wrong sample collection process, preservation and handling.
8. The test results are for reference only and should not be taken as the only indicator for clinical diagnosis.

PRODUCT PERFORMANCE REQUIREMENTS

1. Linear Range: within the range of 0,3 ng/mL to 300 ng/mL, the correlation coefficient R value should be greater than or equal to 0,990.
2. Precision:
2.1 Intra-batch precision: the coefficient of variation CV should not be greater than 8.0 %.
2.2 Inter-batch precision: the coefficient of variation CV should not be greater than 15.0 %.
3. Accuracy: The relative deviation should not be greater than 15.0 %.
4. The Limit of Detection: The limit of detection of this kit is no higher than 0,3 ng/mL.

PRECAUTIONS

1. This kit is only used for in vitro diagnosis and should not be used for other purposes.
2. The kit is only for use by laboratory medicine professionals.
3. This product is disposable and cannot be reused.
4. Do not use the contaminated or spoiled samples or expired products for testing.
5. Fresh samples are recommended. Hyperlipidemia, jaundice and hemolysis are not recommended.
6. Do not use for detection if the package is not intact.
7. When using the test kit for detection, the environment temperature should not be too high or too low.
8. During the test, the analyzer should avoid strong electromagnetic environment.
9. All wastes shall be disposed in accordance with infectious materials.
10. The test result of this kit is not the only indicator for disease. Judgement should be made by doctors while considering all relevant indications and clinical symptoms.
11. It is recommended to wear gloves without talcum powder, because the powder may lead to wrong results.
12. If you have any questions or suggestions about this reagent, please contact the manufacturer. 13. The longest transportation period for the test kit must not exceed 12 days under 2-8 °C.

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CALIBRATIONS

Use the relevant reagents and calibrators to perform the calibration. Recalibration is required in the following cases:
(1) Reagents with a different lot number;
(2) Reagents with the same lot number have been used in the analyzer for more than 28 days;
(3) The quality control value is outside the allowable range.

QUALITY CONTROL

The controls are used for quality control. If the results are outside the range, the reagents may have deteriorated or there may be technical problems. In this case the results may be invalid and the materials need to be retested. If necessary, perform the calibration again. For information on troubleshooting, refer to the manual of the instrument used.

ASSAY SPECIFICATIONS (Table 1)

Sample Type	Serum, Plasma
Sample Volume	110 µL
Assay Range	0,3 - 300 ng/mL
Time to First Result	15 minutes
LoB	0,1 ng/mL
LoD (10% CV)	0,3 ng/mL
99th Percentile	1 ng/mL

REFERANCES

K. Thygesen, J. S. Alpert, A. S. Jaffe et al., "Fourth universal definition of myocardial infarction European Heart Journal 2019; 40: 3, 237–269.

M. Gulati, P. D. Levy, D. Mukherjee et al., "AHA/ACC/ASE/CHEST/SAEM/SCCT/ SCMR Guideline for the Evaluation and Diagnosis of Chest Pain: A Report of the American College of Cardiology/ American Heart Association Joint Committee on Clinical Practice Guidelines" Circulation 2021; 144, 368–454.

Puleo, P. R., Meyer, D., Wathen, C., Tawa, C. B., Wheeler, S., Hamburg, R. J., Ali, N., Obermueller, S. D., Triana, F. J., Zimmerman, J. L., Perryman, M. B., & Roberts, R. (1994). Use of a rapid assay of subforms of creatine kinase MB to diagnose or rule out acute myocardial infarction. New England Journal of Medicine, 331(9), 561–566. https://doi.org/10.1056/nejm199409013310901

Deniz Biyokimya

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Index or Symbols

⚠	Attention, see instructions for use	Σ 1	Tests per Kit		Manufacturer
IVD	For *in vitro*		Use by		Do NOT Use Damaged Box
	Store between 2 - 30°C	LOT	Lot Number	REF	Catalogue Number

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