SCREEN®

SCREEN IFA TEST CK-MB (Whole Blood/Serum/Plasma) Package Insert

REF: SC-1477-20	English

A test for the diagnosis of Creatine Kinase MB (CK-MB) by measuring Creatine Kinase MB in whole blood, Serum or plasma with the use of SCREEN® fluorescence Immunoassay Analyzer.
For professional in vitro diagnostic use only.

INTENDED USE

The CK-MB Test Cassette (Whole Blood/Serum/Plasma) is a chromatographic immunoassay for the quantitative detection of human CK-MB in whole blood, serum or plasma as an aid in the diagnosis of myocardial infarction (MI).

SUMMARY

Creatine Kinase MB (CK-MB) is an enzyme present in the cardiac muscle with a molecular weight of 87.0 kDa.[1] Creatine Kinase is a dimeric molecule formed from two subunits designated as “M” and “B” which combine to form three different isoenzymes, CK-MM, CK-BB, and CK-MB. CK-MB is the isoenzyme of Creatine Kinase most involved in the metabolism of cardiac muscle tissue.[2] The release of CK-MB into the blood following MI can be detected within 3-8 hours after the onset of symptoms. It peaks within 9 to 30 hours, and returns to baseline levels within 48 to 72 hours.[3] CK-MB is one of the most important cardiac markers and is widely recognized as the traditional marker for the diagnosis of MI.
The CK-MB Test Cassette (Whole Blood/Serum/Plasma) is a simple test that utilizes a combination of antibody coated particles and capture reagents to quantitatively detect CK-MB in whole blood, serum or plasma.

PRINCIPLE

The CK-MB Test Cassette (Whole Blood/Serum/Plasma) detects CK-MB based on Fluorescence Immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the test sample contains CK-MB, it attaches to the CK-MB antibody which is conjugated with fluorescent microspheres. Then the complex will be captured by the capture antibody coated on the nitrocellulose membrane (Test line).The concentration of CK-MB in the sample correlates linearly with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and product standard curve, the concentration of CK-MB in the sample can be calculated by SCREEN® Reader to show CK-MB concentration in specimen.

REAGENTS

The test kit include anti-CK-MB antibody conjugated fluorophores and CK-MB antibody coated on the membrane.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. This test contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
4. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
5. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
6. Do not interchange or mix reagents from different lots.
7. Humidity and temperature can adversely affect results.
8. Used testing materials should be discarded in accordance with local regulations.
9. Read the entire procedure carefully prior to any testing.
10. The CK-MB Test Cassette is only operational in the SCREEN® Analyzer. And tests should be applied by professionally trained staff working in certified laboratories at some remove from the patient and clinic at which the sample(s) is taken by qualified medical personnel.

STORAGE AND STABILITY

1. The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND PREPARATION

Preparation
1. Before performing the test, please make sure that all components are brought to room temperature (15-30℃). Cold buffer solution or moisture condensation on the membrane can lead to invalid test results.
2. Take a tube with buffer solution out of the kit. Document patients name or ID on it. Open the screw cap.

Blood Sample Taking
1. Collect the specimen according to standard procedures.
2. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days, for long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be used within 2 day of collection. Do not freeze whole blood specimens. Whole blood collected by finger stick should be tested immediately.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.

Sample Dilution / Sample Stability
1. The specimen **(75ul of serum / plasma / 100ul of whole blood)** can be added directly with the micro pipette into the buffer.
2. Close the tube and shake the sample by hand for approximately 10 seconds so sample and dilution buffer mix well.
3. Let the diluted sample rest for approximately **1 minute**.

MATERIALS

Materials provided

- Test Cassettes
- Specimen Collection Tubes with Extraction Buffer
- ID Card
- Package Insert

Materials required but not provided

- Timer
- Centrifuge
- SCREEN® Fluorescence Immunoassay Analyzer
- Pipette
- Specimen Collection Containers

DIRECTIONS FOR USE

Refer to SCREEN® Fluorescence Immunoassay Analyzer Operation Manual for the complete instructions on use of the Test. The test should be conducted in room temperature. **Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.**
1. Turn on the Analyzer power. Then according to the need, select “standard test” or “Quick test” mode.
2. Remove the ID card and insert it into the Analyzer port.
3. **Serum/plasma:** Pipette **75µl serum/plasma** into the buffer tube; mix the specimen and the buffer well.
   Whole blood: Transfer **100µl whole blood** into the buffer tube with pipette; mix the specimen and the buffer well.
4. **Add diluted specimen with a Pipette:** Pipette **75µl diluted specimen** into the sample well. Start the timer at the same time.
5. There are two test modes for SCREEN® Fluorescence Immunoassay Analyzer, Standard Test mode and Quick Test mode. Please refer to the user manual of SCREEN® Fluorescence Immunoassay Analyzer for details.
   “Quick test” mode: Insert the test cassette into the Analyzer at **15 minutes** after sample application and click "Test", the Analyzer will automatically give the test result after a few seconds.
   “Standard test” mode: Insert the test cassette into the Analyzer immediately after sample application, click "New test" at the same time, the Analyzer will automatically counting down **15 minutes**. After the countdown, the Analyzer will give the result at once.

INTERPRETATION OF RESULTS

Results read by SCREEN® Fluorescence Immunoassay Analyzer.
The result of tests for CK-MB is calculated by SCREEN® Fluorescence Immunoassay Analyzer and display the result on the screen. For additional information, please refer to the user manual of SCREEN® Fluorescence Immunoassay Analyze.
Working range of CK-MB is 0.2-75ng/mL.

QUALITY CONTROL

Each CK-MB Test Cassette contains internal control that satisfies routing quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test device was inserted and read properly by SCREEN® Fluorescence Immunoassay Analyzer. An invalid result from the internal control causes an error message on SCREEN® Fluorescence Immunoassay Analyzer indicating that the test should be repeated.

LIMITATIONS

1. The CK-MB Test Cassette (Whole Blood/Serum/Plasma) is for professional in vitro diagnostic use, and should only be used for the quantitative detection of Creatine Kinase MB.
2. The CK-MB Test cassette (Whole Blood/Serum/Plasma) will only indicate the presence of Creatine Kinase MB antigen in the specimen and should not be used as the sole criteria for evaluating inflammatory conditions.
3. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. High concentrations of Creatine Kinase MB may produce a dose hook effect, resulting in incorrect interpretation of Creatine Kinase MB levels. High dose hook effect has not been observed with this test up to 75ng/mL of Creatine Kinase MB.
5. The hematocrit of the whole blood should be between 25% and 65%.
6. The results of SCREEN® Fluorescence Immunoassay Analyzer are only for the analysis of the results on the tests. It should not be used as a criteria for treatment decisions. If the result is positive, other clinical findings and alternative test methods are recommended to reach proper medical treatments.

EXPECTED VALUES

Concentrations	Clinical Reference
< 5ng/mL	Not indicative of Acute Creatine Kinase MB Infarction
> 5ng/mL	Indicative of Acute Creatine Kinase MB Infarction

PERFORMANCE CHARACTERISTICS

1. Accuracy
The test deviation ≤±15%
3. Sensitivity
The CK-MB Test Cassette (Whole Blood/Serum/Plasma) can detect levels of Creatine Kinase MB as low as 0.2ng/mL whole blood, serum or plasma.
3. Detection range
0. 2~75ng/mL
4. Linear range
0. 2~75ng/mL, R≥0.990
5. Precision
Intra-lot precision
Within-run precision has been determined by using 10 replicates of 5 specimens containing 0ng/mL, 5ng/mL, 10ng/mL, 20ng/mL and 40ng/mL of Creatine Kinase MB. C.V. is ≤ 15%.
Inter-lot precision
Between-run precision has been determined by using 10 replicates for each of three lots using 5 specimens containing 0ng/mL, 5ng/mL, 10ng/mL, 20ng/mL and 40ng/mL of Creatine

Kinase MB. C.V. is ≤ 15%.

6. Cross-reactivity

The CK-MB Test Cassette (Whole Blood/Serum/Plasma) has been tested by 3,200ng/mL CK-MM, 1,700ng/mL CK-BB, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, syphilis,anti-HIV, anti-H.pylori, MONO, anti-CMV, anti-Rubella and anti-Toxoplasmosis positive specimens. The results showed no cross-reactivity.

7. Interfering Substances

The following potentially interfering substances were added to CK-MB negative and positive specimens.

Acetaminophen: 20 mg/dl	Caffeine: 20 mg/dL
Acetylsalicylic Acid: 20 mg/dL	Gentisic Acid: 20 mg/dL
Ascorbic Acid: 20mg/dL	Albumin: 10,500mg/dL
Creatin: 200 mg/dL	Hemoglobin 1,000 mg/dL
Bilirubin: 1,000mg/dL	Oxalic Acid: 600mg/dL
Cholesterol: 800mg/dL	Triglycerides: 1,600mg/dL

None of the substances at the concentration tested interfered in the assay.

LITERATURE REFERENCES

1. Apple FS, Preese LM. Creatine kinase-MB: detection of myocardial infarction and monitoring reperfusion. J Clin Immunoassay, 17:24-9, 1994.
2. Lee, T.H., Goldman, L. Serum enzyme assays in the diagnosis of acute myocardial infarction. Ann Intern Med, 105:221-233, 1986.
3. Kallner A,Sylven C,Brodin.U,etal.Early diagnosis of acute myocardial infarction;a comparison between chemical predictors. Scand J Clin Lab Invest, 49:633-9, 1989

INDEX OF SYMBOLS

	Consult Instructions for Use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
4°C 30°C	Store between 4-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		

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Number: 146418101
Effective Date: 2021-05-20