Creatinekinase MB Rapid Diagnostic Kit

(Immunochromatography)

Product Name

Creatinekinase MB Rapid Diagnostic Kit (Immunochromatography)

Intended Use

CK-MB is one of the most important myocardial markers, with well-established roles in confirming acute myocardial infarction (AMI) and in monitoring reperfusion during thrombolytic therapy following AMI.

Test Principle

The test utilizes antibodies including a recombinant protein on the nitrocellulose membrane with colloidal gold marked mixed CK-MB antigen as a mark tracer. The reagent is used to detect the CK-MB in serum/plasma according to the principle of double antibody sandwich method and gold immunochromatography assay. The sensitivity can reach to 5ng/ml.

Main components

Sample pad, colloidal gold marked pad, nitrocellulose membrane, absorbent paper and PVC board.

Storage and Expiry

Store as packaged in the sealed pouch at 4-30°C, avoid hot and sunshine, dry place, valid for 24 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw.

Sample requirement

1. Collect venous blood a clean and dry container according to the standard method. Separate the serum or plasma for testing. EDTA, sodium citrate, sodium oxalate, heparin can be used as the anticoagulants

2. After collection, separate the serum and plasma as soon as possible, in order to avoid hemolysis.

3. Use fresh samples. Samples may be stored in a refrigerator or freezer. Do not freeze and thaw the sample repeatedly. Frozen refrigerated samples should be recovered to room temperature before detection.

Test Procedure

Instructions must be read entirely before taking the test. Allow the test device controls to equilibrate to room temperature for 30 minutes (20℃-30℃) prior to testing. Do not open the inner packaging until ready, it must be used in one hour if opened (Humidity: 20%~90%, Temp: 10℃-50℃)

Strip: Remove the test device from the sealed pouch, put the end of the test strip print with arrow into the sample, the interface of serum/plasma should not exceed the max line, take it out and place the test device on a clean and level surface after 10 seconds. Observe the test results immediately within 15 minutes, the result is invalid over 15 minutes.

Cassette: 1. Take off the outer packing, put the cassette onto the desk with the sample window up.

2. Drop 3 drops (100ul) of serum or plasma vertically into the sample hole of cassette.

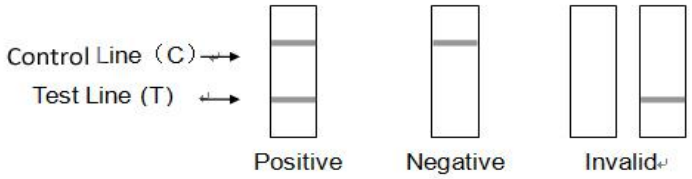
3. Observe the test results within 15 minutes the result is invalid over 15 minutes.

Result Judgment

POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and the other line should be in the test region (T).

NEGATIVE: One red line appears in the control region(C). No apparent red or pink line appears in the test region (T).

INVALID: No red lines appear or control line fails to appear, indicating that the operator error or reagent failure. Verify the test procedure and repeat the test with a new testing device



Limitation

The results of the reagent are only for clinical reference, a confirmed diagnosis should be made only by a physician after all clinical and laboratory findings have been evaluated.

Precaution

1. For IN VITRO diagnostic use only.

2. Do not use after the expiration.

3. All samples and reagents should be considered potentially hazardous and handled in the same manner as an infectious agent after use.

4. Do not use other kinds of quality control sample to test the reagent. Components of different batches cannot be exchanged for use to avoid erroneous results.