Rapid Diagnostic Kit for Myo/CK-MB/ Troponin I 3-in-1 Combo Test Panel

(Immunochromatography)

Product Name

Rapid Diagnostic Kit for Myo/CK-MB/ Troponin I 3-in-1 Combo Test Panel(Immunochromatography)

Intended Use

In the early diagnosis of myocardial infarction, Myoglobin (Myo) and CK-MB appear earlier, it also can reflect the extent of myocardial injury, but low specificity. Troponin I (cTnI) is a specific marker for diagnosis of AMI patients. For such patients with myocardial infarction, when chest pain last for 4 hours, the cTnI content in sample will beyond the normal range and it will up to the peak after 12 hours. Within 144 hours after the onset of symptoms, increased content can be detected. The clinical diagnosis of myocardial infarction depends on joint detection of Myo, CK-MB and TnI. The 3-in-1 rapid test kit is rapid and sensitive which is used for qualitative testing of Myo, CK-MB and TnI in human serum, is applied to early diagnosis and differential diagnosis of acute myocardial infarction in emergency room, intensive care unit, cardiology, health stations and other institutions of hospitals, provide an objective, comprehensive, efficient new means for clinical diagnosis of myocardial infarction.

Control Line is coated with anti-mouse antibody, Test Line is respectively coated with Myo, CK-MB and cTnI monoclonal antibodies. The testing serum reacts with colloidal gold monoclonal antibodies firstly and then antigen-antibody complexes move along the nitrocellulose membrane, and form the T line with antibody when the sample contains Myo, CK-MB and cTnI, which a positive result. Conversely, it is a negative result.

Detection threshold of the test cassette respectively: Myo:80ng/ml; CK-MB:5ng/ml; TnI:1ng/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 at 4℃ for 3 days, and should be stored at -20 ℃ for 3 months. 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℃).

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.

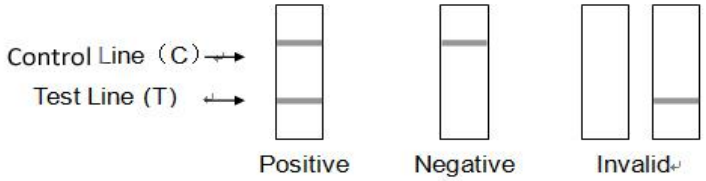
3. Observe the test results within 15 minutes the result is invalid over 15 minutes.

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.



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. To avoid cross-contamination of serum samples, please change a new pipette for each sample.

5.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.