CK-MB Rapid Test

Cat. No.:DTS583
Pkg.Size:

Intended use

This test is intended for professional uses as an aid in the diagnosis of the present of CK-MB protein in blood.

General Description

A CK-MB immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the CK-MB in serum, plasma whole blood. Measurement of CK-MB aids in the rapid diagnosis of heart or renal disease.

Storage

The CK-MB Test kit should bestored at room temperature 4-30°C (40-86°F).

Specimen Collection And Preparation

Whole Blood specimen collection: Collect an anticoagulated blood sample by using sodium citrate or heparin as the anti-coagulant.Note: CK-MB is unstable in serum or whole blood specimens. Whole blood or serum specimen must be tested as soon as possible.

Assay Procedure

1. Remove the test disk from the foil pouch, and place it on a flat, dry surface.
2. Holding the sample dropper above the test disk and add 1 hanging drop into the Sample Well. After the drop is absorbed into the Sample Well, add another hanging drop, repeat the procedure until a total of 3 hanging drops (total about 120 µl of blood) have been added to the Sample Well. If specimen drops are added too quickly, specially for blood specimen, it may cause clogging of the Sample Well.
3. As the test begins to work, you will see purple color move across the Result Window in the center of the test disk. Note:If purple color dye does not begin to flow through the “Result Window” within 30 seconds, add one more drop of sample.
4. Interpret test results at 10 to 15 minutes. Do not interpret test results after 20 minutes.

Caution: The above interpretation time is based on reading the test results at room temperature of 15 to 30°C. If your room temperature is significantly lower than 15°C, then the interpretation time should be properly increased.

45-16 Ramsey Road Shirley, NY 11967, USA
Tel: 631-624-4882 ·Fax:631-614-7828
E-mail: info@creative-diagnostics.com
www.creative-diagnostics.com

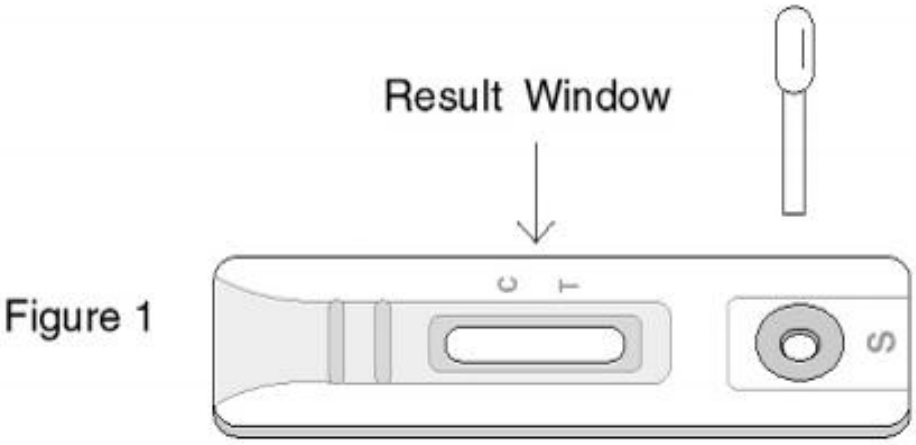

Figure 1

Interpretation of Results

1. A purple band will appear at the left section of the Result Window. This shows that the test is working properly. This band is the Control Band.
2. The right section of the Result Window indicates the test results. If another color band appears at the right section of the Result Window, this band is the Test Band.

PositiveResult: The presence of two color bands (“T” band and “C” band) within the result window regardless of which band appears first indicates a positive result (Figure 2). Note: Generally, the higher the analyte level in the specimen, the stronger the “T” band color will be. When the specimen analyte level is close to but still within the sensitivity limit of the test, the color of the “T” band will be very faint.

Negative: Result The presence of only one purple color band within the Result Window indicates a negative result (Figure 3).

Invalid Result: If after performing the test no purple color band is visible within the Result Window, this result is considered invalid. (Figure 4). Not following the procedures correctly or using a test kit that has deteriorated can cause invalid results. It is recommended that the specimen be retested.

Note: A positive result will not change once you have established your answer at 20 minutes. Interpreting test results after 20 minutes, the sensitivity of the test will be higher than 5 ng/ml. Some specimens with a high rheumatoid factor concentration may yield a nonspecific positive result. Specimens containing very low levels of CK-MB may develop “T” band color over 15 minutes.

45-16 Ramsey Road Shirley, NY 11967, USA
Tel: 631-624-4882 ·Fax:631-614-7828
E-mail: info@creative-diagnostics.com
www.creative-diagnostics.com

Figure 2

Positive

Figure 3

Negative

Figure 4

Invalid

Sensitivity

The analytical sensitivity of the test is 5ng/ml CK-MB.

Precautions

The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration.

1. Do not use the test kit if the pouch is damaged or the seal is broken.
2. Do not eat or smoke while handling specimens.
3. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Clean up spills thoroughly using an appropriate disinfectant.
6. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.

Limitations

Although the CK-MB Test is accurate in detecting CK-MB, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not bebased on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have

45-16 Ramsey Road Shirley, NY 11967, USA
Tel: 631-624-4882 ·Fax:631-614-7828
E-mail: info@creative-diagnostics.com
www.creative-diagnostics.com

been evaluated.

REFERENCES

1. Andersen PT, Miller-Petersen J. Henneberg EW, et al, “Hypermyoglobinemia After Successful Arterial Embolectomy,”Surgery, 1987, 102:25-31.
2. Cummins B, Russell GJ, Chandler ST, et al, “Uptake of Radioiodinated Cardiac Specific Troponin I Antibodies in Myocardial Infarction,”Cardiovasc Res, 1990, 24(4):317-327.
3. Delanghe J, Chapelle JP, el Allaf M, et al, “Quantitative Turbidimetric Assay for Determining Myoglobin Evaluated,”Ann Clin Biochem, 1991, 28(Pt 5):474-9.
4. Donnelly R and Hillis WS, “Cardiac Troponin T,” Lancet, 1993, 341(8842): 410-1.
5. Gibler WB, Gibler CD, Weinshenker E, et al, “Myoglobin as an Early Indicator of Acute Myocardial Infarction,”Ann Emerg Med, 1987, 16:851-6.
6. Mair J, Smidt J, Artner-Dworzak E, et al, “Rapid Diagnosis of Myocardial Infarction by Immunoturbidimetric Myoglobin Measurement,” Lancet, 1991, 337(8753):1343-4.
7. Parmacek MS and Leiden JM, “Structure, Function, and Regulation of Troponin C,”Circulation, 1991, 84(3):991-1003.
8. “Troponin T and Myocardial Damage,” Lancet, 1991,338(8758):23-4, (editorial).
9. Serrano S, Chueca P, Carrasco E, et al, “Predictive Value of Myoglobin in Early Diagnosis of Acute Mtocardial Infarction,”Ann Emerg Med, 1990, 19(8):953.
10. Silva DP Jr, Landt Y, Porter SE, et al, “Development and Application of Monoclonal Antibodies to Human Cardiac Myoglobin in A Rapid Fluorescence Immunoassay,”Clin Chem, 1991, 37(8):1356-64.
11. Vrenna L, Castaldo AM, Castaldo P, et al, “Comparison Between Nephelometric and RIA Methods for Serum Myoglobin, and Efficiency of Myoglobin Assay for Early Diagnosis of Myocardial Infarction,” Clin Chem, 1992, 38(5):789-90.

45-16 Ramsey Road Shirley, NY 11967, USA
Tel: 631-624-4882 ·Fax:631-614-7828
E-mail: info@creative-diagnostics.com
www.creative-diagnostics.com