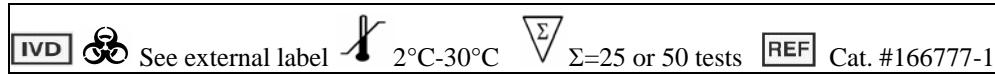




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CK-MB WHOLE BLOOD TEST

*FOR THE QUALITATIVE ASSESSMENT OF CREATINE KINASE(MB ISOENZYME)
IN HUMAN WHOLE BLOOD
Catalog No. 166777-1*

INTENDED USE

The Cortez Diagnostics CK-MB test is an immunochromatography based one step in vitro test. It is designed for qualitative determination of CK-MB in human whole blood specimens as an aid in the diagnosis of myocardial infarction.

SUMMARY AND EXPLANATION

Creatine kinase is a dimer occurring in various in three isoenzymic forms, depending on the particular combination of its non-identical sub-units: BB (brain type); MM (skeletal type); and MB (hybrid type). Creatine kinase-MB isoenzyme is released into circulation later than myoglobin, reaching abnormal levels within 4 to 6 hours after onset of symptoms, it reaches its highest level with a typical range of 39-185 ng/ml after about 18 to 24 hours, and returns to normal in about 2 to 3 days. CK-MB is widely recognized as the traditional marker for the diagnosis of acute myocardial infarction (AMI).

Cortez Diagnostics CK-MB test is a sandwich immunoassay. When whole blood sample is added to sample pad, it moves through the conjugate pad and mobilizes gold mouse anti-CK-MB MAb conjugate that is coated on the conjugate pad. The mixture moves along the membrane by capillary action and reacts with mouse anti-CK-MM MAb that is coated on the test region. If CK-MB is present at levels of 7.0 ng/ml or greater, the result is the formation of a colored band in the test region. If there is no CK-MB in the sample, the area will remain colorless. The sample continues to move to the control area and forms a pink to purple color, indicating the test is working and the result is valid.

MATERIALS PROVIDED

1. Cortez Diagnostics CK-Mb Test device

MATERIALS REQUIRED BUT NOT PROVIDED

1. Whole blood collection containers
2. Timer or clock

STORAGE

Store the test device at 2 to 30°C. Do Not Freeze.

PRECAUTIONS

1. For in vitro diagnostic use only.
2. Do not use product beyond the expiration date.
3. Handle all specimens as potentially infectious.

SPECIMEN COLLECTION AND PREPARATION

1. The whole blood specimen should be collected under standard laboratory conditions
2. Patient samples performed best when tested immediately after collection. If the sample cannot be tested within 24 hours, refrigerate until the test can be performed. Allow sample to reach room temperature before proceeding.
3. Sodium azide can be added as a preservative up to 0.1% without affecting the test results.

QUALITY CONTROL

1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.

PROCEDURE

1. Bring all materials and specimens to room temperature.
2. Remove the test card from the sealed foil pouch.

3. Place the transfer pipette in the specimen and depress the bulb to withdraw a sample.
4. Hold the pipette in a vertical position over the sample well of the test card and deliver 2-3 drops (100-150 µl) of sample into the sample well.
5. Read the result between 10 and 15 minutes.

INTERPRETATION OF RESULTS

Positive:

If two colored bands are visible within 10 minutes, the test result is positive and valid. The test result can be read as soon as a distinct colored band appears in the test area.

Negative:

If test area has no color band and the control area displays a colored band, the result is negative and valid.

Invalid result:

The test result is invalid if a colored band does not form in the control region. The sample must be re-tested, using a new test device.

LIMITATIONS OF THE PROCEDURE

1. The test result should be used in conjunction with other clinical information such as clinical signs and symptoms and other test results to diagnose AMI. A negative result obtained from a patient whose sample was taken at 4-20 hours after the onset of chest pain may help in ruling out AMI. A positive result from a patient suspected of AMI may be used as a rule-in diagnosis and requires further confirmation
2. Cortez DiagnosticsCK-Mb test only provides qualitative result. A quantitative assay method must be used to determine the CK-MB concentration.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

EXPECTED VALUES

Cortez DiagnosticsCK-Mb designed to yield a positive result for CK-MB concentrations at 7.0 ng/ml or greater. The time required for blood CK-MB level to reach the upper limit of normal has been found to be 4-6 hours after the onset of symptoms. CK-MB level reaches the maximum concentration after 18-24 hours of the onset, and then remains elevated for 2-3 days in some cases. Therefore, a negative result within the first 4 hours of the onset of symptoms does not rule out AMI with certainty. If suspected, repeat the test at appropriate intervals.

PERFORMANCE CHARACTERISTICS

Sensitivity:

Cortez DiagnosticsCK-Mb test can detect CK-MB in whole blood with concentration of 7.0 ng/ml or greater.

Interference testing:

The following substances were added to CK-MB negative and 7.0 ng/ml CK-MB spiked whole blood samples. No interference was found with any of the substances at the following concentrations:

Bilirubin	10 mg/dl
Cholesterol	800 mg/dl
Hemoglobin	250 mg/dl
Triglyceride	1250 mg/dl

REFERENCES

1. Adams III J.E, et al. Clin Chem. 1994; 40:1291
2. Apple, F.S.et al., Clin Chem. 1995; 237:95
3. Boor GS, et al. Clin. Chem. Vol. 41, 1710-1715 (1995)
4. Brogan GX, et al. Academic Emerg. Med. Vol. 4, 6-12 (1997)
Tucker JF, et al. Academic Emerg. Med. Vol. 4, 13-21(1997)



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