

**OneStep  
 CK-MB Serum/  
 Whole Blood/Plasma  
 RapiCard™ InstaTest**

**Cat #166777-1**

IVD  See external Label  2-30°C  Σ= 1 Test

<b>Sensitivity</b>	<b>100%</b>
<b>Specificity</b>	<b>100%</b>

**INTENDED USE**

The Cortez Diagnostics CK-MB test is an immunochromatography based one step in vitro test.

**SUMMARY AND EXPLANATION**

Creatine kinase is a dimer occurring in various in three isoenzymic forms, depending on the particular combination of its non-identical subunits: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 CK-MB test is a sandwich immunoassay. When serum sample is added to sample pad, it moves through the conjugate pad and mobilizes gold anti-CK-MB conjugate that is coated on the conjugate pad. The mixture moves along the membrane by capillary action and reacts with anti-CK-MB antibody 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.

**TEST PRINCIPLE**

It is designed for qualitative determination of CK-MB in human serum, whole blood or plasma specimens as an aid in the diagnosis of myocardial infarction.

**SPECIMEN COLLECTION AND PREPARATION**

- The serum, whole blood or plasma specimen should be collected under standard laboratory conditions.
- Heat inactivation of specimens, which may cause hemolysis and protein denaturation, should be avoided.
- Patient samples performed best when tested immediately after collection. If specimens are to be stored, the red blood cells should be removed to avoid hemolysis. If the sample cannot be tested within 24 hours, serum or plasma should be frozen until the test can be performed. Whole blood samples should be refrigerated at 2-8°C in stead of being frozen. Allow sample to reach room temperature before proceeding.
- Sodium azide can be added as a preservative up to 0.1% without effecting the test results.
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**MATERIALS AND COMPONENTS**

**Materials provided with the test kit**

- Cortez CK-MB Test device

**Materials required but not provided**

- Serum collection containers.
- Timer or clock.

**ASSAY PROCEDURE**

- Bring all materials and specimens to room temperature.
- Remove the test card from the sealed foil pouch.
- Use micropipetter to transfer 150 µl of sample, or place the transfer pipette supplied with the device in the specimen and depress the bulb to withdraw a sample.
- Hold the pipette in a vertical position over the sample well of the test card and deliver 3-4 drops (120-160 µl) of sample into the sample well.
- Read the result at 10 minutes.

**RESULTS**

- Positive:** If two colored bands are visible within 10 minutes, the test result is positive and valid.  
 Note: Specimens containing very low levels of CK-MB may develop two colored bands over 10 minutes.
- 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.

**PERFORMANCE CHARACTERISTICS**

**Sensitivity:**

Cortez CK-MB test can detect CK-MB in serum with concentration of 7.0 ng/ml or greater.

**Accuracy:**

	<b>Negative (0 ng/ml)</b>	<b>CK-MB (0.8 – 6.9 ng/ml)</b>	<b>CK-MB (≥ 7.0 ng/ml)</b>	<b>Percent Agreement with GC/MS</b>
Number of specimen	43	26	50	
Negative	43	21	0	100%
Positive	0	5	50	90.9%

**Specificity and Cross-Reactivity:**

<b>Compound</b>	<b>Concentration</b>	<b>Cross-reactivity</b>
CK-MB	7.0 ng/mL	100%

**Interference testing:**

The following substances were added to CK-MB negative and 7.0 ng/ml CK-MB spiked serum 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	500 mg/dl

## 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.
2. Good Laboratory Practice recommends the daily use of control materials to validate the reliability of the device. Control materials which are not provided with this test kit are commercially available.

## LIMITATIONS OF 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 CK-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.

<b>ISO 13485</b> <b>ISO 9001</b>   <b>Diagnostic Automation/  Cortez Diagnostics, Inc.</b> 23961 Craftsman Road, Suite E/F, Calabasas, California 91302 USA			
<b>Date Adopted</b>	<b>Reference No. Cat # 166777-1</b>		
<b>2007-12-01</b>	<b>CORTEZ- OneStep  CK-MB (Serum/ Whole  Blood/Plasma)  RapiCard™ InstaTest -2012</b>		
<table border="1" style="display: inline-table;"> <tr> <td>EC</td> <td>REP</td> </tr> </table>	EC	REP	<b>CEpartner4U, Esdoornlaan 13,  3951DB Maarn. The Netherlands.</b> <a href="http://www.cepartner4u.eu">www.cepartner4u.eu</a>
EC	REP		
<b>Revision Date: 08-21-2012</b>			

## EXPECTED VALUES

Cortez CK-MB designed to yield a positive result for CK-MB concentrations at 7.0 ng/ml or greater. The time required for blood CK-MBI level to reach the upper limit of normal has been found to be 4-6 hours after the onset of symptoms. CK-MBI 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.

## PRECAUTION

1. For in vitro diagnostic use only.
2. Do not use test kit beyond expiration date.
3. Handle all specimens as potentially infectious
4. Store the test device at 2 to 30°C. Do Not Freeze.