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Rapid Cardiac Panel Test, Whole Blood

FOR THE QUALITATIVE ASSESSMENT OF CARDIAC ROPONIN I,
CK-MB AND MYOGLOBIN IN HUMAN SERUM AND WHOLE BLOOD

REF

Cat #: R13-421

IVD

For In Vitro Diagnostic Use Only

INTENDED USE

The Immunospec Rapid Cardiac Panel test is an immunochromatography based one step in vitro test. It is designed for qualitative determination of cardiac troponin I (cTnI), CK-MB and Myoglobin in human serum and whole blood specimens as an aid in the diagnosis of myocardial infarction.

SUMMARY AND EXPLANATION

Cardiac troponin I (cTnI) is a cardiac muscle protein with a molecular weight of 22.5 kilodaltons. Together with troponin T (TnT) and troponin C (TnC), TnI forms a troponin complex in heart to play a fundamental role in the transmission of intracellular calcium signal actin-myosin interaction. The human cTnI has an additional amino acid residues on its N-terminal that are not exist on the skeletal forms thus making cTnI a specific marker for indicating cardiac infarction. cTnI is released rapidly into blood after the onset of acute myocardial infarction (AMI). Its release pattern is similar to CK-MB (4-6 hours after the onset of AMI). However, CK-MB level returns to normal after 36-48 hours, while levels of cTnI remains elevated for up to 6-10 days. The level of cTnI is very low in normal healthy people, and not detected in patients with skeletal muscle injury. Therefore, cTnI is a specific marker for diagnosis of acute myocardial infarction.

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 myoglubin, 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 AMI.

Myoglobin is a low molecular weight, cytoplasmic serum protein. Due to its low molecular weight, myoglobin is released more rapidly when muscle cells are damaged than other markers. Serum concentration of myoglobin increases above the normal range as early as 1 hour after myocardial infarction, and peak in approximately 4 to 8 hours after onset. Therefore, myoglobin is better suited for the early diagnosis of AMI.

RapidCardiac Panel test is a sandwich immunoassay. When serum sample is added to sample pad, it moves through the conjugate pad and mobilizes gold antibody conjugate that is coated on the conjugate pad. The mixture moves along the membrane by capillary action and reacts with anti-cardiac marker antibodies that is coated on the test region. If cardiac markers are present at levels of cut-off level or greater, the result is the formation of a colored band in the test region. If there are no cardiac markers 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.

Below are the cut-off concentrations for each cardiac marker using in the test.

Troponin I	1.5 ng/mL (Abbott AxSYM)*
CK-MB	7.0 ng/mL (Abbott AxSYM)
Myoglobin	100 ng/mL (Abbott AxSYM)

*The concentration of Troponin I is not standardized yet. The results from different assay system may vary significantly. Here is the summary of the sensitivity of Rapid Troponin I Test Card on the major assay systems.

Assay System	**Troponin I Concentration (ng/mL)**
Bayer ACS:180	0.11
Abbott AxSYM	1.50
Bayer ADVIA Centaur	0.18
Beckmen Access AccuTnI	0.14
Dade Dimension	0.87
Dade Stratus	0.48

MATERIAL PROVIDED

1. Rapid Cardiac Panel Test device

MATERIALS REQUIRED BUT NOT SUPPLIED

1. Whole blood or plasma: Vacutainer tube, or other appropriate tube, containing heparin or EDTA as an anticoagulant
2. Serum: Vacutainer tube, or other appropriate tube, without anticoagulant
3. Micropipetter (200-1000 µL range) and pipet tips
4. 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. ***EDTA is not recommended as the anti-coagulant*** for whole blood collection because it may interfere the test rerults.
2. The serum, whole blood or plasma specimen should be collected under standard laboratory conditions.
3. Heat inactivation of specimens, which may cause hemolysis and protein denaturation, should be avoided.
4. 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.
5. 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.
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.

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 7-10 drops (300-500 μl) of serum sample or 10 – 15 drops (500 – 800 μL) of whole blood sample into the sample well.
   Note: Please deliver sample drop by drop to ensure the best performance
5. Read the result at 15 minutes.

INTERPRETATION OF RESULTS

Positive:

If two colored bands are visible on any strip of the device within 15 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.

Note: Specimens containing very low levels of cardiac markers may develop two color bands over 15 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:

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

If after 15 minutes, you see one of the following results. It may imply the indicated syndrome.

a) MYG-positive/CKMB-positive/TnI-positive (MYO ≥ 100 ng/mL, CK-MB ≥ 7.0 ng/mL, Tn I ≥ 1.5ng/mL)
Myocardial cell necrosis within the past 12 hours.

b) MYG-positive/CKMB-positive/TnI-negative (MYO ≥ 100 ng/mL, CK-MB ≥ 7.0 ng/mL, Tn I < 1.5ng/mL)
Early muscle or cardiac injury. Serial Troponin I testing is suggested in 4 & 8 hrs to rule in acute coronary syndrome

c) MYG-negative/CKMB-positive/TnI-positive (MYO < l00 ng/mL, CK-MB ≥ 7.0 ng/mL, Tn I ≥ 1.5ng/mL)
Acute myocardial infarction post 12 hours from the onset of early symptoms

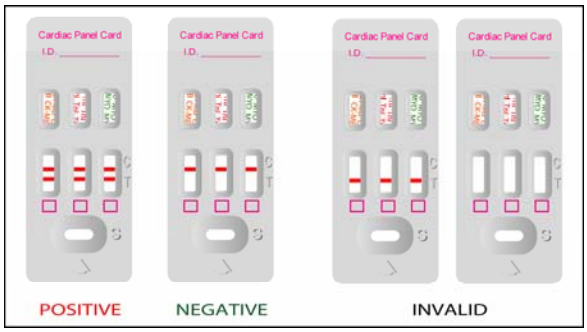
d) MYG-negative/CKMB-positive/TnI-negative (MYO <.100 ng/mL, CK-MB ≥ 7.0 ng/mL, Tn I < 1.5ng/mL)
Early muscle or cardiac injury. Serial Troponin I testing is suggested in 4 & 8 hrs to rule in acute coronary syndrome.

e) MYG-negative/CKMB-negative/TnI-positive (MYO < l00 ng/mL, CK-MB < 7.5 ng/mL, Tn I ≥ 1.5ng/mL)
Acute myocardial infarction post 24-96 hours

f) MYG-positive/CKMB-negative/TnI-negative (MYO ≥ l00 ng/mL, CK-MB < 7.5 ng/mL, Tn I < 1.5ng/mL)
Early muscle or cardiac injury. Serial Troponin I testing is suggested in 4 & 8 hrs to rule in acute coronary syndrome. (MYO ≥ l00 ng/mL, CK-MB < 7.5 ng/mL, Tn I < 1.5ng/mL).

g) MYG-positive/CKMB-negative/TnI-positive (MYO ≥ l00 ng/mL, CK-MB < 7.5 ng/mL, Tn I ≥ 1.5ng/mL).
A very possible myocardial cell necrosis

h) MYG-negative/CKMB-negative/TnI-negative (MYO < l00 ng/mL CK-MB < 7.5 ng/mL, Tn I < 1.5 ng/mL)
Acute myocardial infarction may not happen. If the cardiac injury is suspected, retest in 2 - 4 hours.



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 2-20 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. Serial sampling of patients suspected of AMI is also recommended due to the delay between the onset of symptoms and the release of the cardiac markers in to the bloodstream.
2. A number of conditions, other than myocardiac infarction, including polymyositis, dermatomyositis, systemic lupus erythematosus, shock, severe renal failure, or muscle damage caused by trauma, ischemia and inflammation, can cause elevated levels of myoglobin. These conditions should be considered with appropriate clinical evidence.Recent cardioversion or an anginal episode may increase myoglobin level. Testing 12 hours or later after after onset of myocardial infarction can produce misleading results, because serum levels may already have returned to normal range.
3. RapidCardiac Panel test only provides qualitative result. A quantitative assay method must be used to determine the concentrations of each marker.
4. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

EXPECTED VALUES

Immunospec Rapid Cardiac Panel designed to yield a positive result for the concentrations of cTnI of 0.11 ng/mL at Bayer ACS:180 or 1.5 ng/mL at Abbott AxSYM or greater, CK-MB at 7 ng/mL or greater and myoglobin at 100 ng/mL or greater. The time required for blood cTnI level to reach the upper limit of normal has been found to be 4-6 hours after the onset of symptoms. cTnI level reaches the maximum concentration after 12-24 hours of the onset, and then remains elevated for 6-10 days in some cases. Therefore, a negative result within the first hours of the onset of symptoms does not rule out AMI with certainty. If suspected, repeat the test at appropriate intervals.

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.

Normal serum myoglobin levels range from 30 to 90 ng/mL. After 1 hour of the onset of myocardial infarction, serum myoglobin level can elevate to 200 ng/mL or even higher. During the peak hour, myoglobin level can be as high as 900 ng/mL. The level of myoglobin usually returns to normal 12 hours after the onset of the myocardial infarction. Elevated myoglobin level has also been observed in patients with other diseases as mentioned in LIMITATIONS OF THE PROCEDURE.

PERFORMANCE CHARACTERISTICS

Sensitivity:

Rapid Cardiac Panel test can detect cTnI in serum with concentration of 0.11 ng/mL at Bayer ACS:180 or 1.5 ng/mL at Abbott AxSYM or greater, CK-MB at 7.0 ng/mL or greater and myoglobin at 100 ng/mL or greater.

Accuracy:

The accuracy of the Rapid Cardiac Panel test were evaluated in each component strips.

1. Troponin I

	Troponin I (Abbott AxSYM)		
	Negative (0 ng/mL)	Tn I (0.3 – 0.8 ng/mL)	Tn I (> 1.1 ng/mL)
Number of specimen	89	10	109
Negative	88	5	1
Positive	1	5	108
Specificity/Sensitivity	98.9%	50.0%	99.1%

2. CK-MB

	CK-MB (Abbott AxSYM)		
	Negative (0 ng/mL)	CK-MB (0.8 – 6.9 ng/mL)	CK-MB (≥ 7.0 ng/mL)
Number of specimen	43	26	50
Negative	43	21	0
Positive	0	5	50
Specificity/Sensitivity	100%	19.2%	100%

3. Myoglobin

	Myoglobin (Abbott AxSYM)		
	Negative (0 ng/mL)	Myo (13 – 66 ng/mL)	Myo (> 100 ng/mL)
Number of specimen	66	50	100
Negative	66	34	0
Positive	0	16	100
Specificity/Sensitivity	100%	32.0%	100%

Interference testing:

The following substances were added to cardiac marker negative and cut-off level controls. 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

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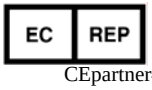

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