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# *"See Now"* 3 tests panel
# (Troponin I, Creatine Kinanse-MB, Myoglobin )

Whole blood/Serum / Plasma

**For in vitro Diagnosis Use** CE

**Product Code: SN 6.X.3**

## INTRODUCTION

The *"See Now"* 3 tests panel Troponin I, CK-MB, Myoglobin, is intended for the qualitative detection of cardiac Troponin I, CK-MB, Myoglobin in whole blood, serum or plasma at or above the cutoff level of: 1.5 ng/mL Troponin I and 7ng/mL CK-MB and100 ng/mL Myoglobin The device is designed for professional use.

This assay provides only a preliminary result. Clinical expertise and professional judgment should be sought to further evaluate the result of the test. It is intended for healthcare professional use

## SPECIMEN COLLECTION AND STORAGE

For serum samples, collect blood in a tube without anticoagulant and allow it to clot.

For plasma samples, collect the blood in a tube containing anticoagulant.

Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.

Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods.

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The human serum, plasma or whole blood specimen should be collected under standard laboratory conditions.

## TEST PROCEDURE

Remove the test device from pouch when ready to perform the test .Label the test device with patient or control identification.

Hold the pipette in a vertical position over the sample well of the test card and deliver 3 drops (120-150 µl) of sample to each sample well.

Read the results at 15 minutes. Ensure that the background of the test area is white before interpreting the result.

## INTERPRETATION OF RESULTS

**Positive: Two** colored lines should be observed. The line in the test region **(T)** is the probe line; the line in the control region **(C)** is the control line, which is used to indicate proper performance of the device. **The color intensity of the test line may be weaker or stronger than that of the control line.**

**Negative:** The control line appears in the test, but the test line is not visible.

**Invalid:** No line appears in the control region. Under no circumstances should a positive sample be identified until the control line forms in the viewing area. If the control line does not form, the test result is inconclusive and the assay should be repeated.

**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 ≥ 1.0ng/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 < 1.0ng/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 ≥ 1.0ng/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 < 1.0ng/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 ≥ 1.0ng/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 < 1.0ng/mL)

Early muscle or cardiac injury. SerialTroponin I testing is suggested in 4 & 8 hrs to rule in acute coronary syndrome.

g) MYG-positive/CKMB-negative/TnI-positive

(MYO ≥ l00 ng/mL, CK-MB < 7.5 ng/mL, Tn I ≥ 1.0ng/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 < 1.0 ng/mL)

Acute myocardial infarction may not happen. If the cardiac injury is suspected, retest in 2 - 4 hours.

## PERFORMANCE CHARACTERISTICS

The See Now rapid cardiac panel can detect next concentrations of cardiac markers:

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**cTnI – 1.5 ng/mL** or greater

**CK-MB – 7 ng/mL** or greater

**Myo – 100 ng/m**L or greater