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ONE STEP CKMB TEST

(Whole Blood/Serum/Plasma)

FOR *IN VITRO* DIAGNOSTIC USE

INTENDED USE

The **One Step CKMB Test** is a rapid Chromatography based *IVD* test. It is designed for qualitative determination of CKMB in human whole blood, serum or plasma as an aid in the diagnosis of Myocardial Infarction (MI).

SUMMARY AND BIOLOGICAL PRINCIPLE OF THE ASSAY

The CKMB is an isoform of the enzyme Creatine Kinase with MW85,745. When heart cells are damaged, it is released into the blood rapidly. The elevated level could be detected as early as 6 hours after the onset of AMI. The CKMB level of normal serum is less than 5 ng/ml; peak levels of CKMB can be 21 ng/ml or higher.

The **One Step CKMB Test** is a fast and simple procedure which is easily read and does not require instrumentation, as is the case with ECGs. The test system uses unique antibodies, one pair selectively identifies CKMB with a high degree of sensitivity. The sensitivity and diagnostic efficacy of CKMB combined with myoglobin is statistically significantly higher when compared to the combination of cTni and myoglobin for the early diagnosis of AMI.

Principle of the Procedure

The **One Step CKMB Test** uses a sandwich immunoassay system and the immunochromatographic detection assay, to be performed in one assay. If CKMB is present in the sample in the sample in concentrations above the cut-off level, 5 ng/ml, a

labeled specific antibody-dye complex will be formed. This complex is then captured by another specific antibody immobilized in the Test Zone (“T”) of the membrane, producing a visible pink-rose color band on the membrane. The color intensity will depend on the concentration of CKMB in the sample. However, a color band will always appear at the control zone (“C”).

SAMPLE COLLECTION & STORAGE

1. Fresh blood samples are preferred. While drawing the blood, an anti-coagulant reagent, such as EDTA, must be added.

The blood samples that were refrigerated over night may be used.

2. Plasma and serum that were refrigerated for a few days may also be used.

QUALITY CONTROL

Although the kit contains an internal quality control function (pink/rose color band in the control region), good laboratory practice recommends the daily use of an outside control to ensure proper kit performance. Quality control samples should be tested according to the quality control requirements established by your laboratory.

PRECAUTIONS

1. For professional *In Vitro* Diagnostic use only.
2. Wear disposable gloves while handling Specimens. Wash hands thoroughly afterwards.
3. De-contaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious, in a biohazard container.
4. Avoid splashing or aerosol formation.
5. Do not use the kit after its expiration date.

MATERIALS PROVIDED

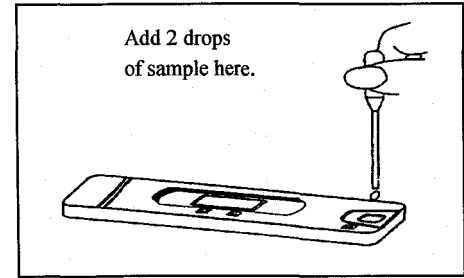
1. Test cards individually foil pouched with a desiccant
2. Plastic dropper
3. Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer/clock
2. Pipette

ASSAY PROCEDURE

1. Read package insert carefully before testing. Allow the test devices, whole blood, serum or plasma to equilibrate to room temperature (15-30°C) prior to testing. Do not open pouches until ready to perform the assay.
2. Remove the test device from the foil pouch and use it as soon as possible.
3. Place the test device on a clean and level surface. Hold the dropper provided vertically and transfer **2** drops of specimen to the specimen well (S) in the test device.
4. Wait 1-5 minutes until the plasma appears in the test window.
5. Read the results within 10 minutes after the serum/plasma appears in the test window.



INTERPRETATION OF RESULTS

(Whole Blood)

1. **Positive:**

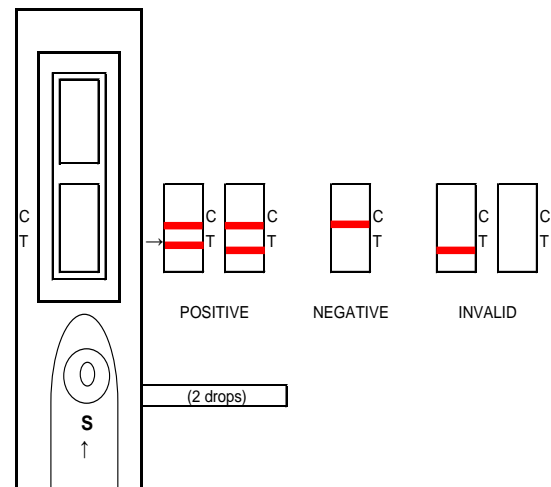
If the Test band (marked with a "T") becomes visible within 10 minutes.

2. **Negative:**

If no color line is visible within 10 minutes after the plasma appears in the test window.

3. **Invalid:**

If the color band does not appear in the Control Zone ("C"), the test results are invalid. The sample may have been added to the wrong window, or the test device may have deteriorated. The specimen should be re-tested using a new test device.



Note: Discard the results after 10 minutes. Starting counting the time once the plasma/serum is visible in the test view.

LIMITATIONS OF PROCEDURE

1. The test is for in vitro use only.
2. The test is limited to the detection of CKMB levels in plasma/serum.
3. 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.

PERFORMANCE CHARACTERISTICS

Sensitivity & Precision

The cut-off for the **One Step CKMB Test** is 5 ng/ml.

The precision of the Test was determined using replicate assays of samples from three different patients' pools, with kits from three different production lots. Each specimen sample was run through ten parallel assays. The data demonstrated

100% precision for the duplicates of each sample and 100% precision using the test kits from different lots.

Interference testing

The following substances were tested for cross reactivity in cTni free serum and in normal serum containing CKMB. None of the substances showed interference or cross reactivity.

Substance	Concentration
CKMM	4,000 ng/ml
Bilirubin	10 mg/ml
Cholesterol	800 mg/ml
Hemoglobin	250 mg/ml
Triglyceride	1,250 mg/ml

Manufactured in the USA by:
HEALTH-CHEM DIAGNOSTICS LLC,
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