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ONE STEP MYOGLOBIN TEST

(Whole Blood/Serum/Plasma)

FOR *IN VITRO* DIAGNOSTIC USE

INTENDED USE

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

SUMMARY AND BIOLOGICAL PRINCIPLE OF THE ASSAY

Myoglobin is a low molecular weight cytoplasm protein which is released into the blood stream when muscle cells are damaged. This protein is released into the blood stream more rapidly than any other myocardial marker and elevated levels can be detected as early as 1 hour after the onset of AMI. The peak level appears 4-8 hours after the onset of AMI, but usually returns to normal after 12 hours. The myoglobin range of normal serum is 30-90 ng/ml, but this level can be elevated to 200 ng/ml, or even higher, 1 hour after the onset of AMI and at peak hour can be as high as 900 ng/ml.

The **One Step Myoglobin 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 myoglobin with a high degree of sensitivity. This makes myoglobin more suited for the early diagnosis of AMI.

Principle of the Procedure

The **One Step Myoglobin Test** uses a sandwich immunoassay system and the immunochromatographic detection assay, to be performed in one assay.

If myoglobin is present in the sample in concentrations above the cut-off level, 100 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 myoglobin in the sample. However, a color band will always appear at the control zone (“C”).

STORAGE AND STABILITY

The test can be performed on either serum or plasma. It is recommended that fresh samples be used if possible. If this is not possible, samples should be stored in a refrigerator (2-8°C) before being analyzed. For long term storage, specimens should be frozen at -20°C.

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

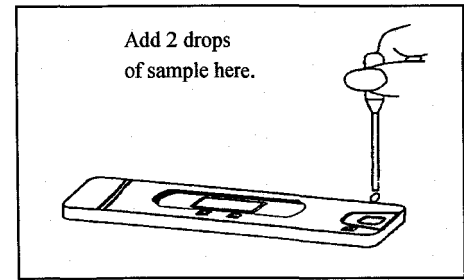
MATERIALS REQUIRED BUT NOT PROVIDED

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.

Note: * Serum or plasma for whole blood, dispense pipette quantity followed by two drops of diluents. Diluent is not included for serum or plasma.



INTERPRETATION OF RESULTS

(Whole Blood)

1. **Positive:**

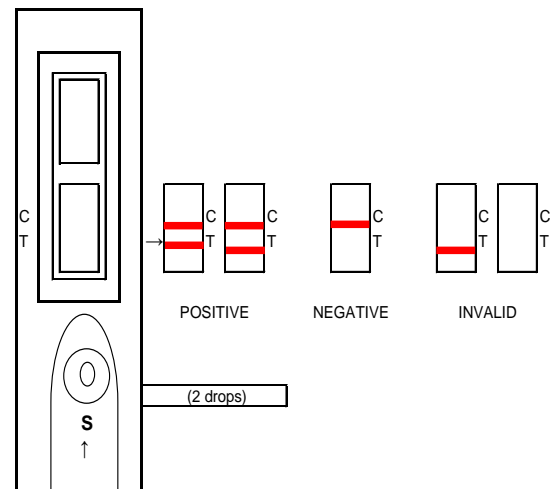
If the Test band (marked with a “T”) becomes visible within 10 minutes.

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. Start 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 myoglobin levels in plasma/serum.
3. A number of conditions, other than myocardial 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.
4. Recent cardioversion or an anginal episode may also increase myoglobin levels.
5. 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 Myoglobin Test** is 100 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.

Accuracy

Cut off	Special
0.5ng/ml	99.9%
0.2ng/ml	97%
0.1ng/ml	93%

Interference testing

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

Substance	Concentration
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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