Rapid Test Cassette
(Whole Blood/Serum/Plasma)

For professional in vitro diagnostic use. A rapid test for the detection of Cardiac Troponin I (cTnI) and Fatty Acid Binding Protein (FABP) in whole blood, serum or plasma.

[SPECIMEN COLLECTION AND PREPARATION]

- For professional in vitro diagnostic use. Do not use after the expiration date.
- Do not eat, drink or smoke where the specimens or kits are handled.
- Do not use test if it is damaged.
- Handle all specimens as if they contain infectious agents. Establish observances to prevent microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of used equipment.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are exposed.
- The test should be discarded according to local regulations.

[STORAGE AND STABILITY]

Valid: 20°C to 25°C; in a pressurized, dry, light proof, polyethylene-polyamide bag with saturated salt solution and polyethylene bag. Any package opening in whole blood, serum or plasma specimens should be stored at 2°C-8°C for up to 2 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2°C-8°C for up to 2 days. If the test is to be run within 2 days of collection, do not refrigerate. If it cannot be run within 2 days, freeze whole blood at -20°C to 70°C. Frozen whole blood should not be thawed and rethawed and should be used on the same day it is thawed.

If specimens are to be shipped, they should be processed in compliance with local regulations concerning the transport of pathogenic agents.

[INTERPRETATION OF RESULTS]

- **POSITIVE**: A colored line in the test control line region (C) and the presence of one or more colored lines in the test line regions indicates a positive result. This indicates that the concentration of FABP and cardiac Troponin I (cTnI) is greater than 8 ng/mL.
- **NEGATIVE**: A complete absence of the appearance of any colored line(s) in the test line regions indicates a negative result.

In cases where the Control Line appears weak or not visible, retest the cassette using a new specimen.

[PRINCIPLE]

1. The H-FABP/Cardiac Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative, membrane bound immunassay for the detection of FABP and cardiac Troponin I (cTnI) in whole blood, serum or plasma.
2. The membrane is pre-coated with specific capture antibodies in each of the test regions of the test. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with specific antibody conjugated with cardiolipid as a calibrator, and as a control to react with specific capture reagents on the membrane and generate a colored line. The presence of two distinct color lines in the test line regions indicates a positive result. A colored line appears in the control line region (C) indicating that the identification of myocardial damage has been demonstrated in conditions such as the perioperative period, after marathon runs, and blunt chest trauma.
3. To avoid touching the finger directly to the specimen area. Avoid touching the finger directly to the specimen area.
4. Gently rub the hand from wrist to palm to form a rounded drop of blood over the puncture site.
5. The FABP/Cardiac Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) has been used for the detection of FABP and cardiac Troponin I (cTnI) in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of decay to the standard curve can be analyzed in this test cassette.

[LIMITATIONS]

1. The H-FABP/Cardiac Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of FABP and cardiac Troponin I (cTnI) in whole blood, serum or plasma samples only. Neither the quantitative value nor the rate of decay to the standard curve can be analyzed in this test cassette.
2. The H-FABP/Cardiac Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the qualitative level of FABP and Troponin I in the specimen and should not be used as the sole criteria for the diagnosis of myocardial infarction.
3. The H-FABP/Cardiac Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) cannot detect less than 8ng/ml of FABP and 0.5 ng/mL of cardiac Troponin I (cTnI) in specimens. A negative test result does not always mean the absence of myocardial infarction.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect test results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.

**REFERENCES**


Tobacman LS. Cooperative interaction between troponin molecules bound to the cardiac sarcolemma. J Mol Cell Cardiol. 1988;20:1289-1296.

**BIBLIOGRAPHY**