PreventID® Troponin I

Additional information

• Manual
Troponin I is a cardiac marker used to diagnose myocardial infarctions. The PreventID® Troponin I is a rapid test for the determination of human cardiac troponin I (cTnI) in whole blood. The analytical sensitivity of the test is 1 ng/mL. For professional use only.

Contents

One PreventID® Troponin I contains:

- 1 rapid test device (in aluminium pouch)
- 1 sample dropper

Storage

The test can be stored at 4 – 30°C. Refrigerated tests must be brought to room temperature before use (in foiled pouch). Shelf life: see expiry date on pouch

Precautions

1. For in vitro diagnostic use only.
2. Do not use the test device beyond the expiry date.
3. Do not use the test kit if the pouch is damaged or the seal is broken.
4. Perform the test immediately after removing the test device from the foil pouch.
5. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste in a biohazard container.

Specimen Collection and Test Procedure

Please note: Troponin I is very unstable in blood specimens. Blood must hence be tested as soon as possible.

1. Remove the test disk from the foil pouch
2. Place the test disk with the sample well (smaller window) at the right side on a flat, dry surface (Fig. 1).

3. a) Venous blood (heparinised blood)
   Collect an anticoagulated blood sample by using heparin as the anti-coagulant.
   Hold the sample dropper above the test disk (Fig. 2) and add 1 hanging drop into the sample well. After the drop is absorbed into the sample well, add three more hanging drops so that a total of 4 hanging drops have been added to the sample well. If specimen drops are added too quickly it may cause clogging of the sample well.

   b) Capillary blood:
   Prick fingertip with a sterile lancet. Let flow four hanging drops of blood into the sample well (let each drop absorb before adding the next one).

4. As the test begins to work, you will see purple color move across the result window in the center of the test disk. Note: If purple color dye does not begin to flow through the result window within 1 minute, add one more drop of sample.

5. Interpret test results at 15 minutes. Do not interpret test results after 17 minutes.
Interpretation of the Test

1. A purple band will appear at the left section of the result window. This shows that the test is working properly. This band is the control band (C).

2. The right section of the result window indicates the test results. If another color band appears at the right section of the result window, this band is the test band (T).

Positive Result:
The presence of two color bands ("T" band and "C" band) within the result window regardless of which band appears first indicates a positive result (Fig. 3). Note: Generally, the higher the analyte level in the specimen, the stronger the "T" band color will be. When the specimen analyte level is close to but still within the sensitivity limit of the test, the color of the "T" band will be very faint.

Negative Result:
The presence of only one purple color band in the left section of the result window ("C" band) indicates a negative result (Fig. 4).

Invalid Result:
If no purple color band is visible within the result window, this result is considered invalid (Fig. 5). Not following the procedures correctly or using a test kit that has deteriorated can cause invalid results. It is recommended that the specimen be re-tested.

Limitations of the Test

Although the PreventID® Troponin I test is very accurate in detecting troponin I, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

Please note: Circulation level of Troponin I begins to increase 3 – 5 hours after myocardial injury occurs. Prior to that the test result may be negative.

Literature


Short instruction for the handling of PreventID® Troponin I

- Remove the test disk from the foil pouch, and place it on a flat, dry surface.
- Let four drops of capillary blood or heparinised blood flow into the sample well
- Interpret test results at 15 minutes.


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