

Cardiac Troponin I (cTnI)

Ref 346 Cardiac Troponin I (25t)
25 test devices

Cardiac Troponin I (cTnI)

Intended use

The Cypress Diagnostics Cardiac Troponin I test is an immunochromatography based one step in vitro test. It is designed for qualitative determination of cardiac troponin I (cTnI) in human serum or plasma samples as an aid in the diagnosis of myocardial infarction.

For *in vitro* diagnostic use only.

For professional use only.

Clinical significance

Cardiac Troponin I (cTnI) is a cardiac muscle protein with a molecular weight of 22.5 kilodaltons. Together with troponin T (TnT) and troponin C (TnC), TnI forms a troponin complex in heart to play a fundamental role in the transmission of intracellular calcium signal actin-myosin interaction. Although troponin I is also found in skeletal muscle, cardiac troponin I (cTnI) has an additional amino acid residues on its N-terminal which distinguishes it from its skeletal muscle form making cTnI a specific marker for indicating cardiac infarction. cTnI is released rapidly into blood stream soon after the onset of acute myocardial infarction (AMI). Its release pattern is similar to CK-MB (4-6 hours after the onset of AMI). However, CK-MB level returns to normal after 36-48 hours, when levels of cTnI remains elevated for up to 6-10 days. The level of cTnI is below 0.06ng/ml in average in healthy people, and also not detected in the patients with skeletal muscle injury. Therefore, cTnI is a specific marker for diagnosis of AMI patients. The level of cTnI may reach 100-1300ng/ml in some AMI patients.

Principle

The Cypress Diagnostics Cardiac Troponin I Test is a chromatographic immunoassay for the qualitative determination of cTnI in human serum, plasma. When serum or plasma sample is added to sample pad, it moves through the conjugate pad and mobilizes gold anti-cTnI conjugate that is coated on the conjugate pad. The mixture moves along the membrane by capillary action and reacts with anti-cTnI antibody that is coated on the test region. If cTnI is present at levels of 1.0ng/ml or greater, the result is the formation of a colored band in the test region. If there is no cTnI in the sample, the area will remain colorless. The sample continues to move to the control area and forms a pink color, indicating the test is working and the result is valid.

Content of the kit

Materials provided:

25 individually wrapped test devices which include one disposable pipette each. Each test cassette contains a membrane coated with anti-cTnI antibody and a colloidal gold conjugate pad coated with gold anti-cTnI conjugate.

Additional material required, not provided: Specimen collection container, timer.

Preparation

All the kit components are ready for use.

Storage and stability

Store as packaged in the sealed pouch at 4-30°C.
DO NOT FREEZE.

Precautions

- The test device should remain in the sealed pouch until use.
- Do not use the test kit beyond the expiration date.
- Each test device is intended to be used once. Do not reuse.
- All serum or plasma samples should be considered potentially hazardous and handled in the same manner as an infectious agent.

Samples

- Separate the serum or plasma from blood by following the laboratory procedure as soon as possible to avoid hemolysis. Only clear, non-hemolyzed samples can be used.
- Testing should be performed immediately after the samples have been collected. Do not leave the samples at room temperature for prolonged periods. Samples may be stored at 2-8°C for up to 2 days. For long-term storage, samples should be kept below -20°C.
- Bring samples to room temperature prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Samples should not be frozen and thawed repeatedly.
- If samples are to be shipped, they should be packed in compliance with national regulations covering the transportation of biological agents.

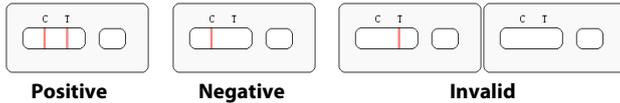
Test procedure

- Read the insert carefully before testing. Allow the test devices, serum or plasma specimen and/or controls to equilibrate to room temperature (15-30°C) prior to testing. Do not open pouches until ready to perform the assay.
- Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
- Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 drops of serum or plasma (approx. 120 µl) to the specimen well (S) in the test device. Waiting for the sample is absorbed completely. For each sample, use a separate pipette and device.
- Wait for the colored line(s) to appear. The result should be read at 15 minutes. Do not read the result after 15 minutes.

Note: Low levels of Troponin I might result in a faint line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 15 minutes.



Interpretation of the results



Positive: Two colored lines should be observed in the viewing window. 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 window, 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.

Quality Control

A procedural control is included in the test. A colored line appearing on the control region of the membrane indicates a proper performance and functional reagents.

Good laboratory practice is required to perform the test properly in order to ensure a repeatable result.

Expected Values

Cypress Diagnostics' Cardiac troponin I Test designed to yield a positive result for cTnI concentrations at 1.0ng/ml or greater. The time required for blood cTnI level to reach the upper limit of normal has been found to be 4-6 hours after the onset of symptoms. CTnI level reaches the maximum concentration after 12-24 hours of the onset, and then remains elevated for 6-10 days in some cases. Therefore, a negative result within the first hours of the onset of symptoms does not rule out AMI with certainty. If suspected, repeat the test at appropriate intervals.

Limitations of the procedure

- The assay is designed for human serum, plasma only.
- The test result should be used in conjunction with other clinical information such as clinical signs/symptoms and other test results to diagnose AMI. A negative result obtained from a patient whose sample was taken at 2-16 hours after the onset of chest pain may help in ruling out AMI. A positive result from a patient suspected of AMI may be used as a rule-in diagnosis and requires further confirmation. Serial sampling of patients suspected of AMI is also recommended due to the delay between the onset of symptoms and the release of the cTnI into the bloodstream.

- Cypress Diagnostics Cardiac Troponin I test only provides qualitative result. A quantitative method must be used to determine the cTnI concentration.
- 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: Cypress Diagnostics' cardiac Troponin I Test can detect cTnI in serum with concentration of 1.0ng/ml or greater.

Interferences: The following substances were added to the negative control and 1.0ng/ml Troponin I spiked serum samples. No interference was found with any of the substances at the following concentrations:

Bilirubin	0.10 mg/ml
Cholesterol	8.0 mg/ml
Hemoglobin	2.50 mg/ml
Triglyceride	2.50 mg/ml

Accuracy: The 1120 randomly serum/plasma samples from patients exhibiting symptoms of AMI samples were analyzed with The Cypress Diagnostics Cardiac Troponin I Test procedure in parallel with a commercially available rapid test. The results indicated that the Sensitivity was 96.9% and the Specificity was 99%. The overall agreement was 98.7%.

		Another CTnI test		Total
		+	-	
Cypress CTnI test	+	190	9	199
	-	6	915	921
	Total	196	924	1120

- Relative sensitivity: 96.9%
- Relative specificity: 99.0%
- Relative accuracy: 98.7%

References

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