CLEARTEST® DIAGNOSTIK

MADE IN GERMANY

TROPONIN I

Rapid Test Device for the qualitative detection of Troponin I in whole blood-, serum- and plasma-specimens, EDTA and Citrat blood.

For professional in vitro diagnostic use only.

IVD CE

INTENDED USE

The Cleartest Troponin I Test Device is a rapid visual immunoassay for the qualitative presumptive detection of cardiac Troponin I in human whole blood, serum, plasma specimens, EDTA or Citrat blood. This kit is intended for use as an aid in the diagnosis of myocardial infarction (MI).

INTRODUCTION

Cardiac Troponin I (cTnI) is a protein found in cardiac muscle with a molecular weight of 22.5 kDa. Troponin I is part of a three subunit complex comprising of Troponin T and Troponin C. Along with tropomyosin, this structural complex forms the main component that regulates the calcium sensitive ATPase activity of actomyosin in striated skeletal and cardiac muscle. After cardiac injury occurs, Troponin I is released into the blood 4–6 hours after the onset of pain. The release pattern of cTnI is similar to CK-MB, but while CK-MB levels return to normal after 72 hours, Troponin I remains elevated for 6–10 days, thus providing for a longer window of detection for cardiac injury. The high specificity of cTnI measurements for the identification of myocardial damage has been demonstrated in conditions such as the perioperative period, after marathon runs, and blunt chest trauma. cTnI release has also been documented in cardiac conditions other than acute myocardial infarction (AMI) such as unstable angina, congestive heart failure, and ischemic damage due to coronary artery bypass surgery. Because of its high specificity and sensitivity in the myocardial tissue, Troponin I has recently become the most preferred biomarker for myocardial infarction.

PRINCIPLE

The Cleartest Troponin I Test Device detects cardiac Troponin I through visual interpretation of color development on the internal strip. Anti-cTnI antibodies are immobilized on the test region of the membrane. During testing, the specimen reacts with anti-cTnI antibodies conjugated to colored particles and precoated on the sample pad of the test. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If there are sufficient cTnI in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

KIT COMPONENTS

Individually packed test devices

Each device contains a strip with colored conjugates and reactive reagents precoated at the corresponding regions.

Disposable pipettes

For adding specimens

Buffer

Phosphate buffered saline with Tween 20 and preservative

Package insert

For operating instructions

MATERIALS REQUIRED BUT NOT PROVIDED

Specimen collection container	For specimen collection
Timer	For timing use
Centrifuge	For preparing serum/plasma specimens

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e. g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection tube for each specimen obtained.
- Read the entire procedure carefully prior to any testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2–30 °C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze**.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

SPECIMEN COLLECTION AND USE

- The Cleartest Troponin I Test Device is intended for use with human whole blood (from venipuncture or fingertip), plasma specimens, serum specimens, EDTA or Citrat blood. If you perform the test with human whole blood, please only use fresh specimen. Please only use citrate tubes for plasma collection.
- Plasma should be separated as quickly as possible, to avoid hemolysis. Please only use clear, non-hemolyzed specimens. Only use citrate as anticoagulant.
- The test should be performed immediately after specimen collection. Do not leave specimens, at room temperature for prolonged periods.
- Bring specimens to room temperature prior to testing.
- If specimens are to be shipped (in this case: citrate plasma), pack them in compliance with all applicable regulations for transportation of pathogenic agents.

PROCEDURE

Bring tests, specimens, buffer, and/or controls to room temperature (15–30 °C) before use.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed within one hour.

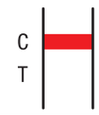
2. Transfer **3 drops of serum or plasma** (approximately 75 µL) to the specimen well of the device with the provided disposable pipette. Then add 1 drop of buffer and start the timer.
   OR
   Transfer **2 drops of whole blood specimen of Citrat or EDTA blood** (approximately 50 µL) to the specimen well of the device with the provided disposable pipette.
   OR
   Allow **2 hanging drops of fingerstick whole blood specimen** to fall into the center of the specimen well (S) on the device, then add 1 drop of buffer and start the timer.
   Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the result area.
   As the test begins to work, color will migrate across the membrane.
3. Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS

POSITIVE

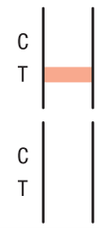
Two pink/rose colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE



Only one pink/rose colored band appears, in the control region (C). No colored band appears in the test region (T).

INVALID



Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE

1. The intensity of the color pink/rose in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. In some instances, a white test line may appear. This indicates a control negative sample. Once the test has been completed, the white line will no longer be visible. This phenomenon occurs in the first few minutes, when a high concentrate of conjugate flows over the membrane. If the test has been conducted and results read according to instructions, the white line will disappear. Please note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

– Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
– External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS OF THE TEST

1. The Cleartest Troponin I Test Device is for professional in vitro diagnostic use, and should only be used for the qualitative detection of cardiac Troponin I. No meaning should be inferred from the color intensity or width of any apparent bands.
2. The Cleartest Troponin I Test Device will only indicate the presence of Troponin I in the specimen and should not be used as the sole criteria for the diagnosis of myocardial infarction.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. The test cannot detect less than 0.5 ng/mL of cTnI in specimens. Thus, a negative result does not at anytime rule out the existence of Troponin I in blood, because the analytes may be absent or below the minimum detection level of the test.
4. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
5. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.

PERFORMANCE CHARACTERISTICS

Table: Cleartest Troponin I Test vs. EIA

Relative Sensitivity: 99.2 % (97.2 % – 99.9 %)*
Relative Specificity: 99.4 % (98.4 % – 99.8 %)*
Overall Agreement: 99.3 % (98.6 % – 99.8 %)*

*95% Confidence Interval

		Cleartest Troponin I Test		Total
		+	–	
EIA Test	+	251	2	253
	–	4	648	652
	Total	255	650	905

LITERATURE REFERENCES

1. Adams, et al. Biochemical markers of myocardial injury, Immunoassay Circulation 88: 750-763, 1993.
2. Mehegan JP, Tobacman LS. Cooperative interaction between troponin molecules bound to the cardiac thin filament. J.Biol.Chem. 266:966, 1991.
3. Adams, et al. Diagnosis of Perioperative myocardial infarction with measurements of cardiac troponin I. N.Eng.J.Med 330:670, 1994.
4. Hossein-Nia M, et al. Cardiac troponin I release in heart transplantation. Ann. Thorac. Surg. 61: 227, 1996.
5. Alpert JS, et al. Myocardial Infarction Redefined, Joint European Society of Cardiology American College of Cardiology: J. Am. Coll. Cardio., 36(3):959, 2000.
6. ESC Pocket Guidelines / Deutsche Gesellschaft für Kardiologie (DGK): Akutes Koronarsyndrom ohne ST-Strecken-Hebung (NSTE-ACS) Version 2020
7. G. D. Menosi: Biomarkers in cardiovascular medicine: towards precision medicine (2019)
8. J. L. Januzzi: Cardiac Troponin and the true false positive (2020)

GLOSSAY OF SYMBOLS

Index of symbols			
REF	Article number		Temperature limitation
	Observe operating instructions	LOT	Batch number
IVD	In-vitro-diagnostic		Expiry date
	Manufacturer		Content sufficient for <n> tests
	Single use		Attention
	Protect from heat and sunlight		Protect from moisture
	Do not use, if package is damaged		
CE	CE marked according to IVD directive 98/79/EG		

ORDER INFO CLEARTEST® TROPONIN I

Package with **1** test cassette	REF C3 26001V	PZN 09631989
Package with **2** test cassettes	REF C3 26002V	PZN 09436153
Package with **5** test cassettes	REF C3 26005V	PZN 02470448
Package with **10** test cassettes	REF C3 26010V	PZN 03361218
Package with **20** test cassettes	REF C3 26020V	PZN 06681567

IVD CE

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