gabControl® Troponin I

For the rapid qualitative detection of cardiac troponin I in human whole blood, serum and plasma
Product ID: M11K17

For the rapid qualitative detection of cardiac troponin I in human blood, serum and plasma

For professional in-vitro diagnostic use only.

INTENDED USE

The Troponin I test is a rapid immunochromatographic assay for the qualitative detection of cardiac troponin I (cTnI) in human serum, plasma and whole blood. The assay is intended to aid in the diagnosis of myocardial infarction in emergency room, critical care, point-of-care and hospital settings. The Troponin I test provides a qualitative analytical test result which cannot monitor the rise and fall of cTnI in single testing. Single testing is not recommended for AMI monitoring. Test results should be interpreted by the physician in conjunction with other test results and patient clinical findings.

SUMMARY

The troponin complex is comprised of three subunits: troponin T (TnT), troponin C (TnC) and troponin I (TnI). The three troponin subunits have distinct functions with TnC as the Ca (2+) binding subunit, TnT as the tropomysin binding subunit and TnI as the inhibitory subunits. The troponin complex, together with tropomysin, forms the main component that regulates the Ca (2+)-sensitive ATPase activity of actomyosin in striated muscle (skeletal and cardiac). The TnC of cardiac tissues is identical to that in skeletal tissue, but TnI and TnT cardiac isoforms are different from those of skeletal isoforms, which enables the development of cardiac-specific antibodies. Recent reports have investigated the utility of determining the serum levels of the different isoforms of TnI. Detection of cardiac troponin I (cTnI) in the serum was investigated as an aid in the determination of myocardial damage in patients with acute myocardial infarction (AMI), and several clinical reports have demonstrated the diagnostic value of cTnI in identifying patients with AMI. The temporal release of cTnI into the serum has been investigated and compared to the other established cardiac markers such as CK-MB, myoglobin and TnT. Cumulative data from several reports documented that in patients with AMI, cTnI is released into the bloodstream in levels exceeding the upper reference limit 4-6 hours after the onset of symptoms, with peak levels reached after 12-24 hours. This early release profile is similar to CK-MB. However, CK-MB levels return to normal values after 72 hours, while cTnI levels remains elevated for up to 5-7 days. Due to the distinct structure of cTnI and the availability of highlyspecific detection methods, the utility of this marker for the diagnosis of AMI in complex clinical conditions that involve skeletal muscle damage have been investigated. The high specificity of TnI measurements for the identification of myocardial damage has been demonstrated in conditions such as perioperative period, after marathon runs and following blunt chest trauma. The release of cTnI into the bloodsteam has been documented in clinical conditions other than AMI that involve myocardial damage, such as unstable angina, congestive heart failure, and ischaemic damage due to coronary artery bypass surgery. cTnI levels have also been investigated and deemed valuable in identifying patients with AMI presenting to the ED with chest pain.

PRINCIPLE

The Troponin I test membrane strip contains one test line and one control line. The test and control line are coated with goat polyclonal anti-cardiac troponin I (cTnI) and recombinant LDH antigen, respectively. Mouse monoclonal anti-cardiac troponin I - gold colloid will react specially with troponin I present in human serum, plasma or whole blood. The polyclonal anti-cardiac troponin I (cTnI) on the membrane will react specifically with troponin I present in complex of gold colloid. If the concentration of this marker in the sample is above the cutoff level, colored bands appear at the corresponding test and the control lines. If the concentration of the marker in the sample is lower than the cutoff level, only the colored control line can be seen in the test window..

WARNINGS

- For in vitro diagnostic use only. Do not re-use test device.
- Do not eat or smoke while handling specimens.
- Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
- Avoid splashing or aerosol formation.
- Clean up spills thoroughly using an appropriate disinfectant.
- Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
- Do not use the test kit if the pouch is damaged or the seal is broken.
- The instruction must be followed exactly to get accurate results.

STORAGE AND STABILITY

1. The test device should be stored at 1~30°C. Do not store at refrigerator.
   Warning: If stored in refrigerator, all kit components have to be warmed up 30 minutes before use to reach roomtemperature (15-30 °C).
2. The test device is sensitive to humidity as well as to heat.
3. Perform the test immediately after removing the test device from foil pouch.
4. Do not use it beyond the expiration date.
5. The shelf-life of the kit is as indicated on outer package. Do not use the test kit if the pouch is damaged or the seal is broken
6. Do not re-use the test device.
7. Check the humidity indicator on the desiccant for color change and throw the pouch away if the color indicates saturation (yellow » green).

Specimen Collection, Storage and Precaution

1. **Whole blood**
   Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture. Optimal results were obtained when patient samples were tested immediately after collection. If the whole blood specimens are not tested immediately, they should be refrigerated at 2-8°C. When stored at 2-8°C, they should be used within 24 hours after collection.

2. **Plasma or Serum**
   Plasma: Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture and then centrifuge blood to get plasma specimen.
   Serum: Collect the whole blood into the collection tube (NOT containing anticoagulants such as heparin, EDTA and sodium citrate) by venipuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.

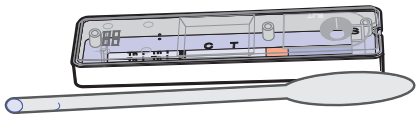
If plasma or serum are not tested immediately, they should be refrigerated at a temperature between 2-8 °C. For storage periods longer than 24 hours, freezing (below -20 °C) is recommended. Specimens should be brought to room temperature (15-30 °C) prior to use. Plasma or serum specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying. Avoid repeated freeze-thaw cycles of the specimens.

PRECAUTIONS

- Anticoagulants such as heparin, EDTA, and sodium citrate do not affect the test result.
- Hemolytic samples, samples containing rheumatoid factors and lipemic, iceteric samples can interfere with the test and impair results.
- Use separately dispoale droppers or pipette tips for each sample in order to avoid cross-contamination of either samples, which could produce erroneous results.
- Repeoducibility of the Troponin I Test has been demonstrated by within-run, between-run and batch-to-batch studies using in-house reference panels. All values were identical to reference panel acceptance criteria.

MATERIALS PROVIDED

- Troponin I Test devices individually foil pouched
- Disposable droppers
- package insert

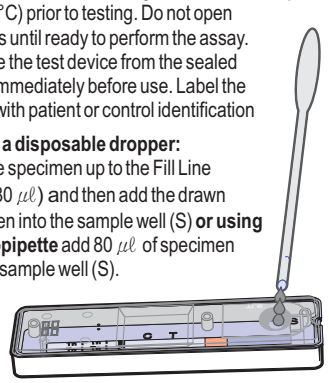


MATERIALS MAYBE REQUIRED BUT NOT PROVIDED

- Timer
- Collection tube
- Micropipette

PROCEDURE

1. Collect specimen according to instructions in Specimen Collection and storage. Test device and sample should be brought 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 sealed pouch immediately before use. Label the device with patient or control identification
2. **Usinge a disposable dropper:**
   Take the specimen up to the Fill Line (about 80 $\mu\ell$) and then add the drawn specimen into the sample well (S) **or using a micropipette** add 80 $\mu\ell$ of specimen into the sample well (S).



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3. Read the result at 15 minutes. For interpretation of results, please see section below, Interpretation of Results. Do not interpret results after 20 minutes.

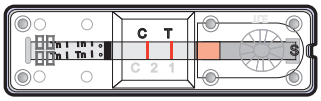
Note: The above interpreting time is based on reading the test results at room temperature of 15~30 °C. If your room temperature is significantly lower than 15 °C, then the interpreting time should be proper increased.

INTERPRETATION OF RESULTS

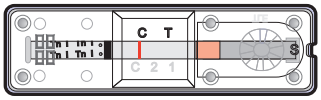
1. A color band will appear at left section of the result window to show that the test is working properly. This band is the "Control Band" (C).

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).

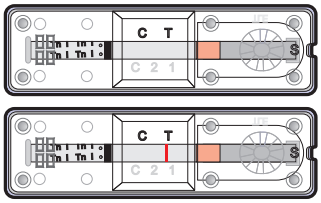
POSITIVE:
The presence of two color bands ("T" band and "C" band) within the result window, no matter which band appears first, indicates a positive result.



NEGATIVE:
The presence of only one purple color band within the result window indicates a negative result.



INVALID:
If the purple color band is not visible within the result window after performing the test, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested.



Note: The intensity of the color in the "test band" region (T) will vary depending on the concentration of Troponin I present in the specimen. Therefore, any shade of red-color in the "test band" region (T) should be considered positive, since the test line starts to form only at the specified cut-off of 1 ng/mL.

LIMITATIONS

1. The test is for professional and in-vitro diagnostic use only.
2. A positive test result may only be used as an indicator of myocardial damage and requires further confirmation. Serial sampling of patients suspected of AMI at multiple time points is also recommended due to the delay between onset of symptoms and the release of cardiac marker proteins into the blood stream.
3. The test is a qualitative screening assay and is not suggested for use in determining the quantitative levels. As with all diagnostic tests, a definitive clinical diagnosis should not made based on the results of a single test. The test results should be used in conjunction with other clinical information such as clinical signs and symptoms and other test results to diagnose AMI. Confirmation of test results should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. Samples containing unusually high titers of certain antibodies such as human anti-mouse or human anti-rabbit antibodies have been known to affect the performance of these devices. However these studies using the **Troponin I** rapid test have not been tested.

QUALITY CONTROL

The **Troponin I test** has a test line (T) and a control line (C) on the surface of the device. Neither the test line nor the control line are visible in the result window before applying a sample. The control line is used for procedural control and shows that the diluent has been applied successfully and that the active ingredients of main components on the strip are functional, but is not a guarantee that the sample has been properly applied and does not represent a positive sample control.

EXPECTED VALUES

The cut-off level is 1 ng/ml for cTnI. The specimens containing cTnI, at the concentration of equal or above established cutoff levels will give positive results using the **Troponin I** rapid test.

PERFORMANCE CHARACTERISTICS

A total of 461 samples collected were tested on the **Troponin I Test.** 127 positive serum samples from patients who had a chest pain, dyspnea or acute myocardial infarction confirmed by commercial quantitative Troponin I assay (≥ 1 ng/ml). And 334 negative serum samples from people who came to Hospital to have regular checkups and did not have any cardiac symptoms, confirmed by quantitative Troponin I assay (<1 ng/ml). Results demonstrated relative sensitivity of 96.9% (123/127) and relative specificity of 97.3% (325/334) when compared with the quantitative assay. The results are summarized in the following tables:

Quantitative Assay	Troponin I Test	
	Positive	Negative
Positive (≥ 1 ng/ml): 127	123	4
Negative (< 1 ng/ml): 334	9	325
Sensitivity	96.9 % (92.2 - 98.8 %)	
Specificity	97.3 % (95 - 98.6 %)	

BIBLIOGRAPHY

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4. Use of troponin for the diagnosis of myocardial contusion after blunt chest trauma. Jackson L, Stewart A. Emerg Med J. März 2005; 22(3):193-195.

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Product Disclaimer:
While every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside the control of the manufacturer and distributor and test results may accordingly be affected by environmental factors and/or user errors. The subject of the diagnosis should consult a doctor for further confirmation of the test result. Warning: The manufacturers and distributors of this product shall not be liable for any direct, indirect, or consequential losses, liability, claims, costs or damages arising from or related to an incorrect or negative diagnosis using this product.

Carefully read package insert

Manufacturer

+1°C +30°C store at 1-30 °C

IVD For in-vitro diagnostic use only

For single use only

LOT Lot number

Expiry date

Content

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