GB QUIK – TROPONIN I (Serum/Plasma)

KIT NAME	KIT SIZE	CAT. NO
GB QUIK – **Troponin I** RAPID TEST KIT	25T	GBQTPI0025T
GB QUIK – **Troponin I** RAPID TEST KIT	50T	GBQTPI0050T

INTENDED TO USE

The Troponin I Rapid Test Device (Serum/Plasma) is a rapid visual immuneassay for the qualitative presumptive detection of cardiac Troponin I in human serum or plasma specimens. This kit is intended to be used 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.[1] 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.[2] 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.[3] 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.4 Because of its high specificity and sensitivity in the myocardial tissue, Troponin I has recently become the most preferred biomarker for myocardial infarction.

PRICIPLE

The Troponin I Rapid Test Device (Serum/Plasma) has been designed to detect cardiac Troponin I through visual interpretation of color development in the strip. The membrane was immobilized with anti-cTnI antibodies on the test region. During the test, the specimen is allowed to react with colored anti-cTnI antibodies colloidal gold conjugates, which were precoated on the sample pad of the test. The mixture then moves on the membrane by a capillary action, and interact with reagents on the membrane. If there were enough cTnI in specimens, a colored band will form at the test region of the membrane. Presence of this colored band indicates a positive result, while its absence indicates a negative result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

KIT CONTENTS:

S. No	Component	QTY
1	Test Casette	25 nos
2	Prefilled Buffer Solution tube	25 nos
3	Sample Dropper	25 nos

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened, preferably at 2°C-30°C. Do not expose the kit over 30°C. Do not freeze the kit. Ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch if it is stored at 2°C-30°C.

SPECIMEN

The Troponin I Rapid Test Device (Serum/Plasma) is intended only for use with human serum or plasma specimens. Only clear, non-hemolyzed specimens are recommended for use with this test. Serum or plasma should be separated with soonest possible opportunity to avoid hemolysis. Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens. Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped. Icteric, lipemic, hemolysed, heat treated and contaminated sera may cause erroneous results.

WARNING AND PRECAUTION

1. For professional In Vitro diagnostic use only.
2. Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re- use under any circumstances.
5. Handle **all** specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assay.
7. Humidity and temperature can adversely affect results.

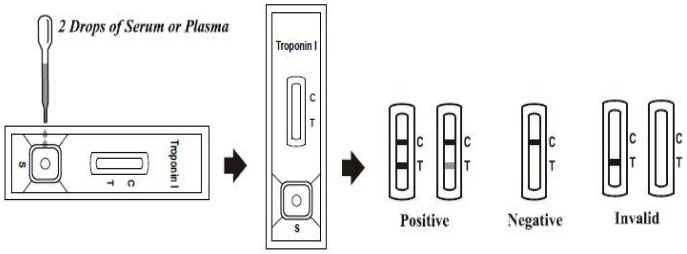
STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test is not stable out off the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

TEST METHODS

Allow test device, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. To obtain a best result, the assay should be performed within one hour.
2. Transfer 2 drops of serum or plasma to the specimen well of the device with a disposable pipette provided in the kit, and then start the timer.
As the test begins to work, you will see color move across the membrane.
3. Wait for the colored **band(s)** to appear. The result should be read at 10 minutes.
4. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: Two 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 colored band appears in the control region (C). No apparent 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 reading time must be discarded.

Please review the procedure and repeat with a new test. If the problem persists, Dis-continue using the kit immediately and contact your local distributor.

NOTE:

1. Insufficient specimen volume, incorrect operation procedure, or performing 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. It confirms 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 TEST METHODS

1. The Troponin I Rapid Test Device (Serum/Plasma) is for professional in vitro diagnostic use, and should be used for the qualitative detection of cardiac Troponin I only. There is no meaning attributed to linen color intensity or width.

2. The Troponin I Rapid Test Device (Serum/Plasma) will only indicate the presence of Troponin I in the specimen and should not be used as the sole criteria for the diagnosis of tuberculosis.

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 antibodies 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 CHARACTERSTICS

Table: Troponin I Rapid Test vs. EIA

Method		Troponin I Rapid Test Device		Total Results
EIA	Results	Positive	Negative	
	Positive	138	2	140
	Negative	1	315	316
Total Results		139	317	456

Relative Sensitivity: 100%
Relative Specificity: 98.7%
Overall Agreement: 98.9%

REFERENCE

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.

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