BIOSYNEX® TROPONIN BSS

Réf: SW50002

Rapid test for the detection of Cardiac troponin I (cTnI) in human whole blood, serum or plasma specimens

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1. INTENDED USE

The BIOSYNEX® TROPONIN BSS test is an immunochromatographic rapid test for the qualitative presumptive detection of cardiac Troponin I in human whole blood, serum or plasma specimens. This kit is intended for use as an aid in the diagnosis of a myocardial infarction (MI). The minimum detection level is 0.5 ng/mL. The test is designed for professional in vitro diagnostic use.

A positive result indicates a high risk for myocardial infarction (MI). A negative result, however, does not exclude a MI and further follow-up testing is required including quantitative cardiac troponin testing.

2. SUMMARY

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.

3. TEST PRINCIPLE

The BIOSYNEX® TROPONIN BSS test selectively detects cardiac Troponin I by a visual reading of a colour formation in the reactive area. cTnI is detected with the aid of specific antibodies against the protein. After the addition of the sample, a colour-labelled antibody specifically binds to cTnI if it is present in the sample. When the cTnI-antibody-complexes migrate upward on the membrane by capillary action, they are captured with the aid of another specific antibody at the test result line area (T) of the test. A red test result line is generated. If no cTnI is present the colour labelled antibody cannot bind in the T-line area. No red test result line is formed. Therefore, the presence of a coloured test result line indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a coloured line will always appear in the control line region (C) indicating that proper volume of specimen has been added and membrane wicking has occurred.

4. REAGENTS

The test devices include anti-Troponin I antibody coated pointer particles and anti-Troponin I antibodies coated on the membrane.

5. PRECAUTIONS

- For professional single use *in vitro* diagnostic use only.
- Do not freeze any components of the test kit. Store and transport the test device always at 2-30°C. Humidity and high temperature can adversely affect results.
- Bring all reagents to room temperature (15-30°C) before use.
- Do not use components after stated expiration date (see pouch and box label).
- Do not use test if pouch is damaged.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contained infectious agents.
- Observe established precautions for microbiological risks throughout all procedures and standard guidelines for appropriate disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Do not spill the specimens into the reaction area.
- Do not touch the reaction area of the device to avoid contamination.
- The test device should remain in the sealed pouch until use.
- Interpret results after 10 minutes but not later than 20 minutes.
- Avoid cross-contamination of specimens by using a new specimen pipette for each specimen.
- Do not interchange or mix reagents from different lots. For professional in vitro diagnostic use only.
- Used testing materials should be discarded according to local regulations.

6. STORAGE AND STABILITY

- The kit should be stored at 2-30°C. The test is stable through the expiry date printed on the sealed pouch. Do not freeze!
- The test must remain in the sealed pouch until use.
- 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.

7. MATERIALS

Materials provided

- Test devices, single pouched (Disposable droppers included)
- Disposable pipettes Microsafe – for fingerstick whole blood
- Lancets – for fingerstick whole blood
- Dropper vial with buffer
- Package insert

Materials Required But Not Provided

- Specimen collection containers; citrate containers may be used
- Centrifuge – for preparation of serum / plasma specimens
- Calibrated pipette (50 µL) for serum/plasma specimens
- Timer

8. SPECIMEN COLLECTION AND STORAGE

- The BIOSYNEX® TROPONIN BSS Test Cassette is intended for use with human whole blood, serum, or plasma specimens only.
- Serum or plasma should be separated as soon as possible to avoid haemolysis. Only clear, non-haemolysed specimens are recommended for use with this test.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by fingerstick should be tested immediately.
- **Whole blood collected by fingerstick should be tested immediately: after triggering the lancet, form a large suspended drop of blood. Collect horizontally the blood with the dropper without pressing the bulb. Fill the dropper up to the black line.**
- Citrate, heparin, potassium oxalate and EDTA may be used as anticoagulants for venous whole blood samples collection or for the preparation of plasma samples. Anticoagulant with whole blood may be used as well directly during test procedure.
- 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.
- Icteric, lipemic, haemolysed, heat treated and contaminated specimens may cause erroneous results.
- There is a slight possibility that some whole blood specimens with very high viscosity or which have been stored for more than 2 days may not run properly on the test device. Repeat the test with a serum or plasma specimen from the same patient using a new test device.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

9. DIRECTIONS FOR USE

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

1. Remove the test from its sealed pouch, and use it as soon as possible, within in 1 hour at the latest. For best results, the assay should be performed immediately after opening the sealed pouch. Label the device with patient or control identification and place it on a clean, level surface.

Whole blood (venipuncture or fingerstick)

2. Holding the Microsafe pipette vertically, dispense its content (75 µL) of whole blood (venipuncture or fingerstick) in the round well (S), and then add 1 drop of buffer (40 µL). Start the timer as the test starts to run.
   If using the disposable dropper included in the pouch, dispense 3 drops of whole blood (venipuncture or fingerstick) in the round well (S) and then add 1 drop of buffer

Serum or plasma

2. Dispense 3 drops (75 µL) of serum or plasma in the round well (S) and start the timer as the test starts to run.

NB : Avoid trapping air bubbles in the specimen well (S) and do not add any liquid to the reaction area. As the test begins to work you can see a reddish liquid front moving across the white membrane.

3. Wait for the colour line(s) to appear. Interpret results at 10 minutes. Do not interpret any result after more than 20 minutes.

10. INTERPRETATION OF RESULTS

POSITIVE : 2 lines appear. One line appears in the control line area (C) and one line in the test line area (T). A positive result indicates that Troponin I has been detected.

NOTE : The intensity of colour in the test area (T) may vary depending on the concentration of Troponin I present in the specimen. Therefore, any shade of colour in the test area (T) should be considered positive. Please note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.

NEGATIVE : One line appears in the control line area (C). No line appears in the test line area (T). A negative result indicates that no Troponin I is present in the specimen or that it is below the detection level of the test device.

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INVALID : Control line fails to appear. Results from any test which has not produced a control line at the specified reading time must be discarded.
Insufficient specimen volume, expired test components or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

11. QUALITY CONTROL

Internal Quality Control

An internal procedural control is included in the test. A red line appearing in the control area (C) is an internal positive procedural control. It confirms that sufficient specimen volume was used, and indicates an adequate membrane wicking and a proper procedural technique.

External Quality Control

External controls are not supplied with this kit. It is recommended to perform positive and negative controls for each kit as good laboratory practice and as deemed necessary by internal laboratory procedures to confirm the test procedure and to verify proper test performance.

12. LIMITATIONS

1. The BIOSYNEX® Troponin BSS test is for professional in vitro diagnostic use, and should only be used for the qualitative detection of cardiac Troponin I. This test does not allow for quantitative results, neither can the concentration be determined by this test.
2. The BIOSYNEX® Troponin BSS test 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 minimum detection limit of the assay is 0.5 ng/mL of cTnI in specimens. Thus, a negative result does not at any time rule out the existence of Troponin I in blood, because the protein concentration may be below the minimum detection level of the test. Please keep in mind that the rise of Troponin I takes place several hours after the onset of pain. If the testing takes place too early, cTnI concentrations might still be too low to be detected by the assay. A negative test result does not exclude the possibility of a myocardial infarction at any time.
4. As 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 titres 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.
6. There is a slight possibility that some whole blood specimens with very high viscosity or which have been stored for more than 1 day may not run properly on the test cassette. Repeat the test with a serum or plasma specimen from the same patient using a new test cassette.
7. To run the test properly, the hematocrit of the whole blood should be between 25 and 65%.

13. EXPECTED VALUES

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 minimum detection level of the BIOSYNEX® Troponin BSS test is 0.5 ng/mL.

14. PERFORMANCES CHARACTERITICS

Sensitivity and specificity

The BIOSYNEX® Troponin BSS test has been compared with a leading commercial cTnI chemiluminescence immune assay using clinical specimens. The results show that the sensitivity of the BIOSYNEX® Troponin BSS test is 97.6% and its specificity is 99.4% relative to the leading chemiluminescence immune assay. The overall accuracy is 99.1%

Method		**Chemiluminescence assay**		**Total result**
BIOSYNEX® Troponin BSS test	Results	Positive	Negative	
	Positive	83	2	85
	Negative	2	358	360
Total result		85	360	445

Relative Sensitivity: 83/85 = 97,6% (95%CI*: 91,8%~99,7%) ;
Relative Specificity: 358/360 = 99,4% (95%CI*: 98,0%~99,9%) ;
Overall Accuracy: 99,1% (95%CI*: 97,7%~99,8%) *Confidence Intervals

Precision

Intra-assay

Within-run precision has been determined by using 3 replicates of five specimens: a negative, cTnI 1.0ng/mL positive, cTnI 5.0ng/mL positive, cTnI 10ng/mL positive and cTnI 40ng/mL positive. The negative, cTnI 1.0ng/mL positive, cTnI 5.0ng/mL positive, cTnI 10ng/mL positive and cTnI 40ng/mL positive values were correctly identified >99% of the time.

Inter-assay

Between-run precision has been determined by 3 independent assays on the same five specimens: a negative, cTnI 1.0ng/mL positive, cTnI 5.0ng/mL positive, cTnI 10ng/mL positive and cTnI 40ng/mL positive specimens. Three different lots of BIOSYNEX® TROPONIN BSS have been tested over a 3-day period using negative, cTnI 1.0ng/mL positive, cTnI 5.0ng/mL positive, cTnI 10ng/mL positive and cTnI 40ng/mL positive specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The BIOSYNEX® TROPONIN BSS test has been tested by 10,000ng/mL Skeletal Troponin I, 2,000ng/mL Troponin T, 20,000ng/mL Cardiac Myosin, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, syphilis, rheumatoid factors, HIV, H.pylori, MONO IgM, CMV IgG, Rubella IgG and Toxoplasmosis IgG positive specimens. The results showed no cross-reactivity.

Interfering substances

The following potentially interfering substances were added to cTnI negative and positive specimens. None of the substances at the concentration tested interfered in the assay.

Acetaminophen : 20 mg/dL	*Caffeine : 20 mg/dL*
Acetylsalicylic acid: 20 mg/dL	*Gentisic acid: 20 mg/dL*
Ascorbic acid: 20 mg/dL	*Albumin : 10 500 mg/dL*
Creatin : 200 mg/dL	*Hemoglobin : 1 000 mg/dL*
Bilirubin : 1 000 mg/dL	*Oxalic acid : 600 mg/dL*
Cholesterol : 800 mg/dL	*Triglycerides : 1 600 mg/dL*

15. LITTERATURE

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.

16. SYMBOLS

	Attention, see instructions for use	LOT	Lot number
IVD	For in vitro diagnostic use only		Manufacturer
30°C 2°C	Store between 2-30°C		Do not reuse
Σ	Tests per kit	RÉF	Catalog number
	Do not use if damaged		Expiry

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