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"DIAQUICK" Troponin I Cassette

for whole blood, serum and plasma samples

REF	Content
Z08120CE	- 30 tests individually packed, disposable pipette (30 x Ref. No. Z08120B). - 1 package insert
Z08125CE	- 5 tests individually packed, disposable pipette (5 x Ref. No. Z08120B). - 1 package insert
Z08120B	- 1 test individually packed, disposable pipette - 1 package insert

For in vitro diagnostic use only

GENERAL INFORMATION

METHOD	Sandwich type immunochromatographic assay
SHELF LIFE	18 months from date of production
STORAGE	4 – 25°C
SAMPLE	human whole blood, serum and plasma
RESULTS	after 15 minutes at room temperature
CUT-OFF	1,0 ng/mL

INTENDED USE

The „DIAQUICK" Troponin I Cassette is a rapid one-step chromatographic immunoassay for the qualitative detection of human cardiac Troponin I in whole blood, serum or plasma as an aid in the diagnosis of acute myocardial infarction (AMI).

CLINICAL SIGNIFICANCE

Cardiac troponin I (cTnI) is a cardiac muscle protein with a molecular weight of 22,5 kilodaltons. Together with cardiac troponin T (cTnT) and cardiac troponin C (cTnC), cTnI forms a troponin complex in the heart, which plays a pivotal role in the transmission of intracellular calcium signalling for actin-myosin interaction. In comparison to cTNT, cTnI has a higher specificity and sensitivity for AMI. Human cTnI has additional amino acid residues on its N-terminal end, which do not exist on the skeletal forms, thus making cTnI a specific marker for cardiac infarction. cTnI is released into the bloodstream after the onset of AMI. Its release pattern is similar to CK-MB (4-6 h after the onset of AMI). However, the CK-MB level returns to normal after 36-48 hours, while the level of cTnI remains elevated for up to 6-10 days. The cTnI-level is very low in healthy people and cTnI cannot be detected in patients with skeletal muscle injury. Therefore, it is a specific marker for the diagnosis of AMI. cTnT levels may be falsely increased when the specimen is collected from renal failure patient.
The „DIAQUICK" Troponin I Cassette is a simple test that utilizes a combination of particle conjugated anti-cTnI antibodies and a capture reagent to selectively detect cTnI in whole blood, serum or plasma. The minimum detection level is 1,0 ng/mL.

TEST PRINCIPLE

The „DIAQUICK" Troponin I Cassette is an immunochromatographic assay. When sample is added to the sample pad, it moves through the conjugate pad, where it mobilizes gold anti-cTnI conjugate, which is coated on the conjugate pad. Then, the mixture moves along the membrane by capillary action and reacts with anti-cTnI antibodies, which are coated on the test region. If cTnI is present in the sample at levels of 1,0 ng/mL or higher, a coloured line appears in the test region. If cTnI is present at lower levels, or is not present in the sample at all, the test region will remain colorless. The sample continues to move to the control region and forms a colored line, indicating that the test is working and its result is valid.

WARNINGS AND PRECAUTIONS

- For single professional in vitro diagnostic use only.
- Do not use after the expiration date.
- The test device should remain in the sealed pouch until ready to use.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use test if pouch has been damaged.
- Dispose of the used test device according to the local regulations.
- Humidity and high temperature can adversely affect results.
- All specimens might be potentially infectious. Proper handling and disposal methods should be established. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested

STORAGE

Store as packaged in the sealed pouch at room temperature (4-25°C / 39-77 °F). The „DIAQUICK" Troponin I Cassette is stable until the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use.

- Do not freeze.
- Do not use beyond the expiration date

MATERIALS PROVIDED

- "DIAQUICK" Troponin I Cassette
- disposable pipettes (inside pouch)
- package insert

MATERIALS REQUIRED BUT NOT PROVIDED

- tubes for taking blood samples
- centrifuge (for serum/plasma)
- timer

SAMPLE COLLECTION AND PREPARATION

The „DIAQUICK" Troponin I Cassette can be performed using whole blood, serum or plasma samples, which should be collected under standard laboratory conditions.

Whole blood or plasma specimen collection:
- Collect blood in a tube containing anticoagulant such as heparin or EDTA and centrifuge the blood to get plasma specimen.

Serum specimen collection
- Collect blood in a tube without anticoagulant and allow clotting.

General comments
- Since cTnI is relatively unstable, it is recommended that fresh samples should be used as soon as possible; whole blood sample should be tested within 3 hours of collection. If specimens must be stored, the red blood cells should be removed. Plasma or serum samples may be refrigerated for 24 hours at 2-8°C. If plasma or serum samples must be stored for more than 24 hours, they should be frozen at -20°C or below.
- Heat inactivation of specimens, which may cause hemolysis and protein denaturation, should be avoided.

ASSAY PROCEDURE

1 Allow the „DIAQUICK" Troponin I Cassette, specimen, and/or controls to equilibrate to room temperature prior to testing.

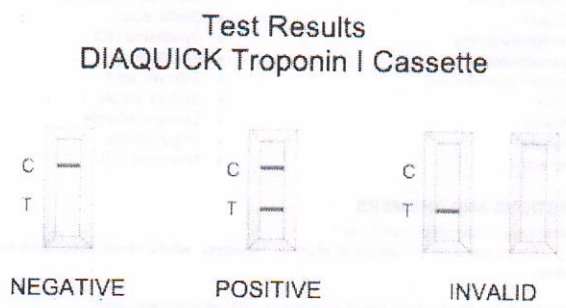
2 Remove the test device from the sealed pouch and use it as soon as possible. Place the „DIAQUICK" Troponin I Cassette on a clean and level surface.

3 Write the specimen ID on the test device.

4 Use the disposable pipette to transfer 100 µL or to deliver 3 drops of sample into the sample well. Always ensure that blood is properly homogenized before you transfer it to the test device.

5 Start the timer. Wait for the red line(s) to appear. The result should be read **at 15 minutes**.

INTERPRETATION OF RESULTS



NEGATIVE: One red line appears in the control line region (C).
No apparent red line appears in the test line region (T).

POSITIVE*: Two distinct red lines appear. One line forms in the control line region (C) and another line forms in the test line region (T).
*Note The intensity of the red color in the test line region (T) will vary depending on the concentration of cTnI present in the specimen. Therefore, also faint reddish test result lines (T) should be considered positive
Note: specimens containing very low levels of cTnI may develop the positive result after more than 15 minutes.

INVALID: The control line (C) is not formed. In this case the result is invalid, even if a test line is visible. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the assay with a new test device. If the problem persists, discontinue using the test kit immediately and contact you local distributor.

QUALITY CONTROL

As an internal procedural control the „DIAQUICK" Troponin I Cassette includes the control line. It is only formed, if sufficient specimen volume has been added and the chromatography has been finished successfully. Control standards are not supplied with this kit; yet, we recommend that positive and negative controls should be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The test result should be used in conjunction with other clinical information such as clinical signs and symptoms and other test results to diagnose AMI. A negative result from a patient sample, which was taken 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.
„DIAQUICK" Troponin I Cassette only provides qualitative results. A quantitative assay method must be used to determine the cTnI concentration.
3. 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.
4. Although [illegible] is accurate in detecting cTnI at a low

incidence of false results can occur. Other clinically available tests are required if questionable results are obtained.

5. Some specimens with a high rheumatoid factor concentration may yield a nonspecific positive result.

EXPECTED VALUES

The „DIAQUICK" Troponin I Cassette is designed to yield a positive result for cTnI concentrations of 1,0 ng/mL or higher. The time required for blood cTnI levels to reach the upper limit of normal has been found to be 4-6 hours after the onset of symptoms. The cTnI level reaches the maximum concentration after 12-24 hours and remains elevated for 6-10 days in some cases. Therefore, a negative result within the first hour after the onset of symptoms does not rule out AMI with certainty. If suspected, repeat the test at appropriate intervals.

PERFORMANCE CHARACTERISTICS

Detection limit

The „DIAQUICK" Troponin I Cassette can detect cTnI at concentrations of 1.0 ng/mL or higher.

Clinical Accuracy

„DIAQUICK" Troponin I Cassette	Quantitative test (Beckman Coulter Access)		Total
	Negative (<1,0 ng/mL)	Positive (>1,0 ng/mL)	
Negative	228	4	232
Positive	7	82	89
Total	235	86	321

Relative Sensitivity: 95% (82/86)
Relative Specificity: 97% (228/235)
Accuracy: 96% (310/321)

INTERFERING SUBSTANCES

The following drugs do not interfere with the „DIAQUICK" Troponin I Cassette test result.

- Ampicillin
- Amoxicillin
- Ascorbic acid
- Acetaminophen
- Bilirubin
- Brompheniramine
- Cyanocobalamine
- Calcium pantothenate
- EDTA
- Ethanol
- Glucose
- Heparin
- Human IgG
- Haemoglobin
- Human albumin
- Nicotinic acid amide
- Oxalic acid
- Pyridoxine HCl
- Riboflavin
- Salicylic acid
- Sodium citrate
- Sodium chloride
- Triglycerides
- Thiamine HCl

QUESTIONS AND ANSWERS

1. What type of specimen can I use?
The preferred specimen is serum or plasma. However, whole blood specimens may also be used.

2. Can I use the fresh whole blood specimens without anticoagulant?
Yes, if fingertip whole blood is used. The whole blood specimen must be added immediately to the test device by dropping it directly from the finger onto the sample well. If end-to-end capillaries are used to collect the whole blood sample, please make sure to use capillaries, which are coated with anticoagulants such as heparin or EDTA. Uncoated end-to-end capillaries must not be used.

3. How much sample do I add to the sample well?
Dispense 100 µL of serum, plasma or whole blood specimen into the sample well.

4. How long do I wait before I can read the test results?
Test results are read 15 minutes after sample addition.

5. Can I read the test results beyond 15 minutes?
No. Results read beyond 15 minutes cannot be considered valid. Due to the nature of the test methodology, the lines may become visible as time progresses.
DO NOT READ TEST RESULTS BEYOND 15 MINUTES

6. How do I interpret a faint line in the test and/or control region?
The intensity of test lines is related to the concentration of cTnI. Faint lines in the test region mean that the sample contains cTnI near the cut-off range. The control line is for a quality control of the test. The appearance of the control line indicates that sufficient sample fluid was added to the test device and all reagents are working properly. Therefore, a pinkish-purple colored line of any intensity is considered a positive test result.

7. What does a positive test result indicate?
A positive test result indicates that the patient has some myocardial cell death and that the patient has marker levels, which are higher than or equal to the diagnostic cut-off value of the test.

REFERENCES

1. Adam JE et al., Cardiac troponin I. A marker with high specificity for cardiac injury. Circulation. 1993, 88:101~106.
2. Apple FS et al., Glycogen phosphorylase BB and other cardiac proteins: challenges to creatine kinase MB as the marker for detecting myocardial injury. Clinical Chemistry. 1995, 41:963~965.
3. Bordor GS et al., Cardiac troponin-I is not expressed in fetal and healthy or diseased adult human skeletal muscle tissue. Clinical Chemistry. 1995, 41:1710~1715.
4. Britta UG et al., Implications of troponin testing in clinical medicine. Curr Control Trials in Cardiovasc Med. 2001, 2:75~84.
5. Brogan GX et al., Improved specificity of myoglobin plus carbonic anhydrase assay versus that of creatinine kinase-MB for early diagnosis of acute myocardial infarction. Ann Emerg Med. 1996, 27:22~28.
6. Brogan GX et al., Evaluation of a new assay for cardiac Troponin I vs Creatine Kinase-MB for the diagnosis of acute myocardial infarction. Academic Emerg Med. 1997, 4:6~12.
7. Heeschen C et al., Evaluation of a rapid whole blood ELISA for quantification of troponin I in patients with acute chest pain. Clinical Chemistry. 1999, 45:1789~1796.
8. Larue C et al., Cardiac-specific immunoenzymometric assay of troponin I in the early phase of acute myocardial infarction. Clinical Chemisty. 1993, 39:972~979.
9. Mair J et al., Equivalent early sensitivities of myoglobin, creatine kinase MB mass, creatine kinase isoform ratios, and cardiac troponins I and T for acute myocardial infarction. Clinical Chemistry. 1995, 41:1266~1272.
10. Mair J et al., Different time courses of cardiac contractile proteins after acute myocardial infarction. Clin Chem Acta. 1994, 231:47~60.
11. Tucker JF et al., Early diagnostic efficiency of cardiac troponin I and Troponin T for acute myocardial infarction. Academic Emerg Med. 1997, 4:13~21.