QDx Instacheck™ Tn-I

INTENDED USE

QDx Instacheck™ Tn-I along with **QDx Instacheck™ Reader** is a fluorescence immunoassay that measures cardiac Troponin-I (Tn-I) concentration in human serum/plasma.

INTRODUCTION

Cardiac troponins are currently the most sensitive and specific biochemical markers of myocardial necrosis. There are three types of troponin in heart muscle fibers. These are Troponin-C, -I, and -T. Together they contribute to make cardiac muscle fibers contract. The clinical measurement of serum cardiac troponin-I (Tn-I) has become an important tool in the diagnosis of acute myocardial infarction. Blood concentration of Troponin-I in healthy adults is below 0.4 ng/ml but it shows great increase in several malignant diseases; mostly primary coronary syndrome, myocardial injury and infarction. Serum Tn-I is a more reliable than creatin kinase (CK-MB) as a prognostic marker in people with ischemic chest pain. National and international scientific organizations have suggested the use of these markers when implementing new diagnostic strategies in patients with acute coronary syndrome. Since Tn-I is well known to be an important prognostic indicator of heart diseases, its most definitive role is in monitoring post-treatment clinical status and post-therapeutic evaluation of patients.

PRINCIPLE

QDx Instacheck™ Tn-I is based on an immunoassay system using antigen-antibody reaction and fluorescence technology.
When a test sample and the detection buffer are mixed thoroughly and then loaded in to the sample well on the test cartridge, the complex of antibody (anti-Tn-I)-antigen (Tn-I)-antibody (anti-Tn-I) produces fluorescence on the membrane of the test cartridge.
Thus, more the Tn-I in the test sample, more the complexes that get accumulated on the cartridge membrane.
QDx Instacheck™ Reader scans the intensity of the fluorescence produced on the membrane and then displays the Tn-I concentration on the LCD screen of the reader.

COMPONENTS AND REAGENTS

QDx Instacheck™ Tn-I consists of a Test Cartridge, an ID Chip and a Detection Buffer Vial.

- The cartridge contains a test strip, the membrane which has anti human Tn-I at the test line, while streptavidin at the control line.
- Each cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed cartridges are packed in a box which also contains an ID chip.
- The detection buffer contains anti human Tn-I-fluorescence conjugate, biotin-BSA-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide as a preservative in phosphate buffered saline.
- The detection buffer is dispensed in a vial. Detection buffer vial is packaged in a Styrofoam box with ice-pack for the shipment

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Carefully follow the instructions and procedures described in this 'Instruction for use'.
- Use only fresh samples and avoid direct sunlight.
- Lot numbers of all the test components (cartridge, ID chip and detection buffer) must match each other.
- Do not interchange the test components between different lots or use the test components after the expiration date, either of which might yield misleading of test result(s).
- Do not reuse. A sample mixing tube should be used for processing one sample only. So should a cartridge.
- The cartridge should remain sealed in its original pouch before use. Do not use the cartridge, if is damaged or already opened.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with the regulations. Sample with severe hemolytic and hyperlipidemia cannot be used and should be recollected.
- Just before use, allow the cartridge, detection buffer and sample to be at room temperature for approximately 30 minutes.
- **QDx Instacheck™ Tn-I** as well as the **QDx Instacheck™ Reader** should be used away from vibration and/or magnetic field. During normal usage, it can be noted that **QDx Instacheck™ Reader** may produce minor vibration.
- Used sample mixing tubes, pipette tips and cartridges should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- An exposure to larger quantities of sodium azide may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure.
- **QDx Instacheck™ Tn-I** will provide accurate and reliable results subject to the following conditions.
  - Use **QDx Instacheck™ Tn-I** should be used only in conjunction with **QDx Instacheck™ Reader**.
  - Any anticoagulants other than **heparin, sodium citrate** should be avoided.

STORAGE AND STABILITY

- The cartridge is stable for 20 months (while sealed in an aluminum foil pouch) if stored at 4-30 °C.
- The detection buffer dispensed in a vial is stable for 20 months if stored at 2-8 °C.
- After the test cartridge pouch and the detection buffer vial are opened, **QDx Instacheck™ Tn-I** should be performed within 30 minutes.

LIMITATIONS OF THE TEST SYSTEM

- The test may yield false positive result(s) due to the cross-reactions and/or non-specific adhesion of certain sample components to the capture/detector antibodies.
- The test may yield false negative result. The non-responsiveness of the antigen to the antibodies is most common where the epitope is masked by some unknown components, so as not to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may cause the false negative as it makes antigen unrecognizable by the antibodies.
- Other factors may interfere with the test and cause erroneous results, such as technical/procedural errors, degradation of the test components/reagents or presence of interfering substances in the test samples.

- Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results.

MATERIALS SUPPLIED

REF IFPC-3

Components of QDx Instacheck™ Tn-I

- **Test Cartridge Box:**
  - Test Cartridges 25
  - ID Chip 1
  - Package Insert 1
  - Sample Mixing Tubes 25
- **Detection Buffer Zipper bag:**
  - Detection Buffer Vial 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **QDx Instacheck™ Tn-I**. Please contact our sales division for more information.

- **QDx Instacheck™ Reader REF** FPRR010
- Thermal Printer

SAMPLE COLLECTION AND PROCESSING

The sample type for **QDx Instacheck™ Tn-I** is human serum/plasma.

- It is recommended to test the sample within 24 hours after collection.
- The serum or plasma should be separated from the clot by centrifugation within 3 hours after the collection of whole blood. If longer storage is required, e.g. if the test could not be performed within 24 hours, serum or plasma should be immediately frozen below -20 °C. The freezing storage of sample up to 3 months does not affect the quality of results.
- Once the sample was frozen, it should be used one time only for test, because repeated freezing and thawing can result in the change of test values.

TEST SETUP

- Check the contents of **QDx Instacheck™ Tn-I**: Sealed Cartridge, Detection Buffer Vial, Sample Mixing Tubes and ID Chip.
- Ensure that the lot number of the cartridge matches that of the ID chip as well as the detection buffer.
- Keep the sealed cartridge (if stored in refrigerator) and the detection buffer tube at room temperature for at least 30 minutes just prior to the test. Place the cartridge on a clean, dust-free and flat surface.
- Turn on the **QDx Instacheck™ Reader**.
- Insert the ID Chip into the ID chip port of the **QDx Instacheck™ Reader.**
- Press the 'Select' button on the **QDx Instacheck™ Reader**.
- (Please refer to the '**QDx Instacheck™ Reader** Operation Manual' for complete information and operating instructions.)

TEST PROCEDURE

[Single mode]

1. Transfer 75 µL of sample (Human serum/plasma) to an empty sample mixing tube using a transfer pipette and add 75 µL detection buffer to it.
2. Close the lid of the sample mixing tube and mix the sample thoroughly by shaking it about 10 times. (The sample mixture must be used immediately.)
3. Pipette out 75 µL of a sample mixture and load it into the sample well on the cartridge.
4. Leave the sample-loaded cartridge at room temperature for 12 minutes.
   ⚠ *Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inexact test result.*
5. To scan the sample-loaded cartridge, insert it into the cartridge holder of the **QDx Instacheck™ Reader**. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow has been marked on the cartridge especially for this purpose.
6. Press 'Select' button on the **QDx Instacheck™ Reader** to start the scanning process.
7. **QDx Instacheck™ Reader** will start scanning the sample-loaded cartridge immediately.
8. Read the test result on the display screen of the **QDx Instacheck™ Reader**.

[Multi mode]

1. Transfer 75 µL of sample (human serum/plasma) to an empty sample mixing tube using a transfer pipette and add 75 µL detection buffer to it.
2. Close the lid of the sample mixing tube and mix the sample thoroughly by shaking it about 10 times. (The sample mixture must be used immediately.)
3. Pipette out 75 µL of a sample mixture and load it into the sample well on the cartridge.
4. Leave the sample-loaded cartridge at room temperature for 12 minutes.
5. For scanning the sample-loaded test cartridge, insert it into the test cartridge holder of the **QDx Instacheck™ Reader**. Ensure proper orientation of the test cartridge before pushing it all the way inside the test cartridge holder of the **QDx Instacheck™ Reader**. An arrow has been marked on the test cartridge especially for this purpose.
6. Press 'Select' button on the **QDx Instacheck™ Reader** to start the scanning process.
7. **QDx Instacheck™ Reader** will start scanning the sample-loaded test cartridge cartridge immediately.
8. Read the test result on the display screen of the **QDx Instacheck™ Reader**.

INTERPRETATION OF TEST RESULT

- **Result**
  - Alternate Result Unit**:** The default result unit for **QDx Instacheck™ Tn-I** is ng/mL. When selecting the alternate result unit, µg/L, the conversion factor used by the QDx Instacheck system is 1.0. The conversion formula to change to the alternate result unit is:
    ng/mL x 1.0 = µg/L
- **Limits and Ranges**
  - Working range: 0.10–50 ng/mL
  - Lower limits of measurement:

Limit of Blank (LoB):	0.07 ng/mL
Limit of Detection (LoD):	0.11 ng/mL
Limit of Quantitation (LoQ):	0.30 ng/mL

- The LoB and LoD were determined in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP17-A2 requirements.
- The LOB is the 95th percentile value from n ≥ 60 measurements of analyte-free samples over several independent series.
- The LoD is determined based on the LoB and the standard deviation of low concentration samples.
- The LoQ (functional sensitivity) is the lowest analyte concentration that can be reproducibly measured with an intermediate precision CV of ≤ 20 %.

- **Expected Values**

- In studies performed with the **QDx Instacheck™ Tn-I** assay involving 100 healthy volunteers in Korea, the upper reference limit (99th percentile) for Tn-I was 0.11 ng/mL. The lowest concentration with a CV less than or equal to 10 % with the **QDx Instacheck™ Tn-I** assay was 0.50 ng/mL.
- Due to the release kinetics of Tn-I, a result below the decision limit within the first hours of the onset of symptoms does not rule out myocardial infarction with certainty. If myocardial infarction is still suspected, repeat the test at appropriate intervals.
- A cut-off of 0.3 ng/mL Tn-I is recommended for diagnosis of AMI, as this yields optimal performance of 91 % of sensitivity and 92.1 % of specificity. However, laboratories should establish their own diagnostic cut-off concentration based on the clinical practice at their perspective institutions.

QUALITY CONTROL

- Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay and should be performed at regular intervals.
- The control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are not provided with **QDx Instacheck™ Tn-I**. For more information regarding obtaining the control materials, contact the technical section at **Diasys Diagnostics India Private Limited.**
- **Internal Control**: **QDx Instacheck™ Tn-I** has an in-built quality control indicator that satisfies the routine quality control requirements. This internal control test is performed each time a clinical sample is tested. A valid control indicates that the cartridge was inserted and read properly by the **QDx Instacheck™ Reader**. An invalid result from the internal control leads to display an error message on the **QDx Instacheck™ Reader** indicating that the test should be repeated.

PERFORMANCE CHARACTERISTICS

1. **Specificity**

There in test samples, are biomolecules such as as heparin, protein kinase A (PKA), creatine kinase, autoantibodies, and free and binary or ternary troponin complex were added to the test sample(s) at concentrations much higher than their normal physiological levels in blood. **QDx Instacheck™ Tn-I** test results did not show any significant cross-reactivity with these biomolecules.

2. **Precision**

The intra-assay precision was calculated by one evaluator, who tested different concentration of control standard ten times each with three different lots of **QDx Instacheck™ Tn-I.** The inter-assay precision was confirmed by 3 different evaluators with 3 different lots, testing three times each different concentration.

Tn-I (ng/mL)	Intra-assay		
	Mean	SD	CV (%)
0.20	0.18	0.03	22.77
0.40	0.39	0.02	8.31
2.70	2.65	0.07	4.96
9.00	9.02	0.19	2.79
26.00	25.99	0.76	2.14
Tn-I (ng/mL)	**Inter-assay**		
	Mean	SD	CV (%)
0.20	0.20	0.04	38.40
0.40	0.38	0.03	18.27
2.70	2.58	0.13	5.53
9.00	9.02	0.27	3.00
26.00	26.00	0.68	2.6

3. **Diagnostic sensitivity and specificity**

A total of 122 serum/plasma samples, 46 positive and 76 negative, were tested a commercially available troponin I assay. The sample were tested by QDx Instacheck™ Reader. The sample concentrations were between approx. 0.10 and 18.44 ng/mL.

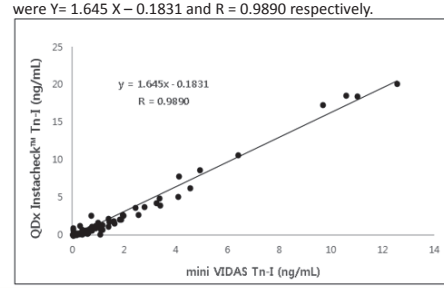
A Receiver Operating Characteristic (ROC) curve was calculated from the peak troponin values.

Calculation of the peak values of the commercially available cardiac troponin I test measured in parallel yielded the following results for the officially stated ROC optimized cut-off of 0.30 - 0.50 ng/mL.

Cut-off µg/L (ng/mL)	Sensitivity (%)	N	95% CI (%)	Specificity (%)	N	95% CI (%)
0.30	91.3	42/46	79.2~97.6	92.11	70/76	83.6~97.0
0.50	78.26	36/46	63.6~89.1	94.74	72/76	85.3~97.8

4. **Comparability**

Tn-I concentrations of 150 clinical samples were quantified independently with **QDx Instacheck™ Tn-I** and mini VIDAS (BioMerieux Inc. France) as per prescribed test procedures. Test results were compared, and their comparability was investigated with linear regression and coefficient of correlation (R). Linear regression and coefficient of correlation between the two tests were Y= 1.645 X – 0.1831 and R = 0.9890 respectively.



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Note: Please refer to the table below to identify various symbols.

Σ	Sufficient for <n> tests
	Read instruction for use
	Use by Date
LOT	Batch code
REF	Catalog number
	Caution
	Manufacturer
EC REP	Authorized representative of the European Community
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
CE	This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices

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Revision No. 06
Date of last revision: February 18, 2019

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