QDx Instacheck™ Myoglobin

INTENDED USE

QDx Instacheck™ Myoglobin along with **QDx Instacheck™ Reader** is a fluorescence Immunoassay (FIA) for the quantitative determination of Myoglobin in human whole blood/ serum/plasma. It is useful as an aid in management and monitoring of acute myocardial infarction (AMI).

INTRODUCTION

Myoglobin is an iron- and oxygen-binding protein found in both skeletal and myocardial muscles. It acts as a transport protein and is involved in diffusion of oxygen in the muscle tissue. Myoglobin is a single-chain globular protein of 154 amino acids. It is composed of a central iron-containing 'Heme' which is enclosed in a compact bundle-like or prism-like arrangement formed by the eight right-handed α-helices[1,2]. Being a cytoplasmic protein having low molecular weight (of 17,699 daltons), myoglobin is released into the serum more rapidly as compared to other cardiac markers upon damage to the myocardial cells. Serum concentration of myoglobin increases above the normal range as early as 1 hour after acute myocardial infarction (AMI), attains peak level in approximately 4 to 8 hours after the onset and normalize rapidly afterwards. Thus myoglobin is better suited as a cardiac marker for early diagnosis of AMI. However, the elevated myoglobin is not specific to AMI owing to its large quantities in skeletal muscles as well. Despite its low clinical specificity and weak predictive value towards AMI, myoglobin is still a promising cardiac marker when other markers such as Creatin Kinase Isoenzyme-MB (CK-MB) and Cardiac Troponin-I (cTn-I) as well as other indicators like clinical signs and ECG are taken into account for diagnosis/confirmation of AMI[3-8].

PRINCIPLE

The test uses a sandwich immunodetection method. The detector antibodies in buffer bind to antigens in the sample, forming antigen-antibody complexes, and migrate onto nitrocellulose matrix to be captured by the other immobilized-streptavidin on a test strip.

More antigens in the sample will form more antigen-antibody complexes which lead to stronger fluorescence signal by detector antibodies, which is processed by the instrument for **QDx Instacheck™** tests to show Myoglobin concentration in the sample.

COMPONENTS AND REAGENTS

QDx Instacheck™ Myoglobin consists of 'Cartridges', 'Detection Buffer Tubes'.

- The cartridge contains he membrane called a test strip which has anti human myoglobin at the test line, with streptavidin at the control line. All cartridges are individually sealed in an aluminum foil pouch containing a desiccant, and they are further packaged in a cartridge box.
- The detection buffer contains anti human myoglobin-fluorescence conjugate, biotin-BSA-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide as a preservative in phosphate buffered saline. It is pre-dispensed in tubes. The detection buffer tubes are packaged in a detection buffer box and further packed in a styrofoam box with ice-pack for the shipment.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Follow the instructions and procedures described in this 'Instructions for use'.
- Use only fresh samples and avoid direct sunlight.
- Lot numbers of all the test components (cartridge, ID chip and detection buffer) must agree 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 incorrect test result(s).
- Do not reuse cartridges or detection buffer tubes. A cartridge should be used for testing one sample only. A detection buffer tube should be used for processing of one sample only.
- The cartridge should remain sealed in its original pouch until just before use. Do not use cartridge, if pouch is damaged or has already been opened.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with local regulations. Sample with severe hemolysis and/or hyperlipidemia must not be used.
- If test components and/or sample are stored in refrigerator, then allow cartridge, detection buffer and sample to be at room temperature for approximately 30 minutes before use.
- The instrument for ichroma™ tests may generate slight vibration during use.
- Used cartridges, detection buffer and pipette tips should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- The detector tube contain sodium azide (NaN_3), and they may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure. Avoid contact with skin, eyes, and clothing. In case of contact, rinse immediately with running water.
- **QDx Instacheck™ Myoglobin** will provide accurate and reliable results subject to the following conditions.
  - **QDx Instacheck™ Myoglobin** s should be used only in conjunction with the instrument for QDx Instacheck™.
  - Have to use recommended anticoagulant.

Recommended anticoagulant
K_3 EDTA, Lithium heparin, Sodium citrate

STORAGE AND STABILITY

Storage condition			
Component	Storage Temperature	Shelf life	Note
Cartridge	2 – 30 °C	20 months	Disposable
Detector tube	2 – 8 °C	20 months	Disposable

- After the cartridge pouch is opened, the test should be performed immediately.

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(s) due to the non-responsiveness of the antigen to the antibodies which is the most common if the epitope is masked by some unknown components, so therefore not being able to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may also cause false negative result as it makes the 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 in conjunction with clinical symptoms and other relevant test results.

MATERIALS SUPPLIED

REF **IFPC-30**

Components of QDx Instacheck™ Myoglobin

- Cartridge box:
  - Cartridges 25
  - ID Chip 1
  - Instruction For Use 1
- Detection Buffer box
  - Detection Buffer tubes 25

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **QDx Instacheck™ Myoglobin**.

Please contact our sales division for more information.

- **QDx Instacheck™ Reade** REF FPRR010
- **Printer** REF FPRR007

SAMPLE COLLECTION AND PROCESSING

The sample type for **QDx Instacheck™ Myoglobin** is human whole blood/serum/plasma.

- It is recommended to test the sample within 24 hours after collection.
- The samples (serum, plasma) should be separated from the clot by centrifugation within 3 hours after the collection of whole blood.
- The samples (whole blood, serum, plasma) may be stored for a week at 2-8 °C prior to being tested. If testing will be delayed more than a week, samples (serum, plasma) should be frozen at -20 °C.
- The samples (serum, plasma) stored frozen at -20 °C for 3 months showed no performance difference.
- However, the whole blood sample should not be kept in a freezer in any case.
- As a repeated freeze-thaw cycle may affect the test result, do not refreeze previously frozen samples.

TEST SETUP

- Check the components of **QDx Instacheck™ Myoglobin**: S Sealed cartridges, detector tubes, (a) detector diluent(s), an ID chip and an instructions for use.
- Ensure that the lot number of the cartridge matches that of the detector tube, the detector diluent as well as an ID chip.
- If the sealed cartridge, the detector tube and the detector diluent have been stored in a refrigerator, place them on a clean and flat surface at room temperature for at least 30 minutes before testing.
- Turn on the instrument for **QDx Instacheck™** tests.
- Insert the ID chip into the 'ID chip port'.

※ **Please refer to the instrument for QDx Instacheck™ tests operation manual for complete information and operating instructions.**

TEST PROCEDURE

Multi test mode

1. Take 10 µL of sample (whole blood/serum/plasma/control) using a pipette and dispense it to the detector tube.
2. Close the lid of the detector tube and mix the sample thoroughly by shaking it about 10 times.
   (The sample mixture must be used immediately. Do not exceed 30 seconds.)
3. Take 75 µL of the sample mixture and dispense it into the sample well of the cartridge.
4. Leave the cartridge at room temperature for 12 minutes.
   Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inaccurate test result.
5. To scan the sample-loaded cartridge, insert it into the cartridge holder of the instrument for **QDx Instacheck™** tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow is marked on the cartridge especially for this purpose.
6. Press the 'Select' or tap the 'Start' button on the instrument for **QDx Instacheck™** tests to start the scanning process.
7. The instrument for **QDx Instacheck™** tests will start scanning the sample-loaded cartridge immediately.
8. Read the test result on the display screen of the instrument for **QDx Instacheck™**.

Single test mode

1. The test procedure is same with the 'Multi test mode 1) – 4)'.
2. Insert the sample-loaded cartridge into the holder of the instrument for **QDx Instacheck™** tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow is marked on the cartridge especially for this purpose.
3. Press the 'Select' or tap the 'Start' button on the instrument for **QDx Instacheck™** tests.
4. The cartridge goes inside the instrument for **QDx Instacheck™** tests and will automatically start scanning the sample-loaded cartridge after 12 minutes.
5. Read the test result on the display screen of the instrument for **QDx Instacheck™** tests.

INTERPRETATION OF TEST RESULT

- The instrument for **QDx Instacheck™** tests calculates the test result automatically and displays Myoglobin concentration of the test sample in terms of ng/mL.
- Reference value: 70 ng/mL
- Working range: 5-500 ng/mL

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.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are provided on demand with **QDx Instacheck™ Myoglobin**. For more information regarding obtaining the control materials, contact Diasys Diagnostics India Private Limited.
  (Please refer to the instructions for use of control material.)

PERFORMANCE CHARACTERISTICS

1. **Analytical Sensitivity**

Limit of Blank (LoB)	1.23 ng/mL
Limit of Detection (LoD)	1.86 ng/mL
Limit of Quantification (LoQ)	5.0 ng/mL

2. **Analytical Specificity**

- Cross-reactivity
  Biomolecules listed in the following table were added to the test sample(s) at concentrations much higher than their normal physiological levels in the blood. **QDx Instacheck™ Myoglobin** test results did not show any significant cross-reactivity with these biomolecules.

Cross reactivity materials	Concentration
Troponin complex	1,000
CK-MB	1,000
D-Dimer	1,000
NT-proBNP	1,000

- Interference
  Interferents listed in the following table were added to the test sample at the concentration mentioned below. **QDx Instacheck™ Myoglobin** test results did not show any significant interference

with these materials.

Interference materials	Concentration
D-glucose	55.5 mmol/L
L-Ascorbic acid	175 µmol/L
Bilirubin (unconjugated)	684 µmol/L
Hemoglobin	10 g/L
Cholesterol	10.3 mmol/L
Triglyceride	16.94 mmol/L
Heparin	330 U/dL
EDTA	3.4 µmol/L
Sodium citrate	2 mg/mL

3. **Precision**

- Single-site study

Repeatability (within-run precision)

within-laboratory precision (Total precision)

Lot to lot precision

3 Lots of **QDx Instacheck™ Myoglobin** were tested for 20 days. Each standard material was tested 2 times per day. For each test, each material was duplicated.

- Multi-site study

Reproducibility

1 Lot of **QDx Instacheck™ Myoglobin** was tested for 5 days in 3 different sites (1 person per 1 site, 1 instrument per 1 site). Each standard material was tested 1 time per and 5 replicates per day.

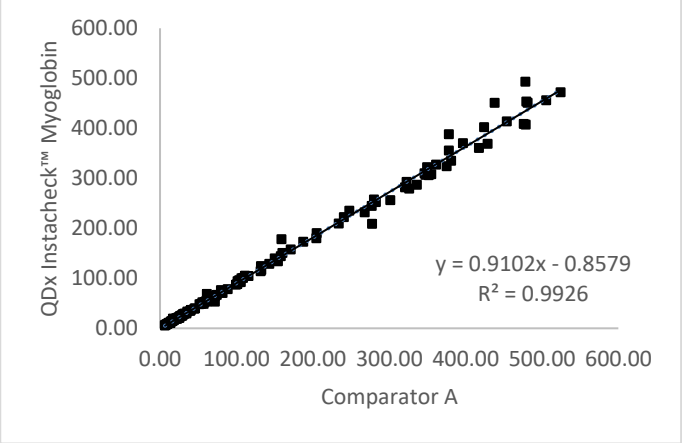
Conc.	Repeatability		Total precision	
[ng/mL]			(within-laboratory precision)	
	AVG	CV (%)	AVG	CV (%)
55	55.36	5.14	54.73	5.33
100	98.68	5.33	99.48	5.54
300	300.79	4.76	301.59	5.11
Conc.	Lot to lot precision		Reproducibility	
[ng/mL]	AVG	CV (%)	AVG	CV (%)
55	54.61	5.64	54.97	5.5
100	100.47	5.69	99.55	5.4
300	300.32	5.69	302.06	6.0

- **Accuracy**

The accuracy was confirmed by testing with 3 different lots of **QDx Instacheck™ Myoglobin**. The tests were repeated 10 times at each concentration of the control standard.

Conc. [ng/mL]	Lot 1	Lot 2	Lot 3	AVG	Recovery (%)
5.00	5.19	5.20	5.18	5.19	104
104.00	106.15	105.81	103.18	105.04	101
203.00	203.90	202.54	202.42	202.95	100
302.00	309.66	287.03	302.24	299.64	99
401.00	401.21	395.88	389.27	395.45	99
500.00	480.41	482.88	475.02	479.43	96

4. **Comparability:** Myoglobin concentration of 120 clinical samples were quantified independently with **QDx Instacheck™ Myoglobin** and **comparator A** as per prescribed test procedures. Test results were compared, and their comparability was investigated with linear regression and correlation coefficient (R). The regression equation and correlation coefficient are as follows.



REFERENCES

1. Kent Lewandrowski, Ahchean Chen and James Januzzi, Cardiac markers for myocardial infarction, Am J Clin Pathol 2002;118 (Suppl 1):S93-S99.
2. Cox, MM, Nelson, DL. Lehninger: Principles of Biochemistry, 3rd edition. W.H. Freeman and Company, New York, 2000, 206.
3. Ordway GA, Garry DJ. Myoglobin: An essential hemoprotein in striated muscle. J Exp Biol.. 2004;207(Pt 20):3441-6.
4. Lewandrowski K, Chen A, Januzzi J. Cardiac markers for myocardial infarction. A brief review. Am J Clin Pathol. 2002:118:S93-9.
5. Vaidya HC. Myoglobin: an early biochemical marker for the diagnosis of acute myocardial infarction. J Clin Immunoassay. 1994;17:35-39.
6. Gibler WB, Gibler CD, Weinshenker C, et al. Myoglobin as an early indicator of acute myocardial infarction. Ann Emerg Med. 1987;16:851-856.
7. Adams JE, Abendschein DR, Jaffe AS. Biochemical markers of myocardial injury: is MB creatine kinase the choice for the 1990s? Circulation. 1993;88:750-763.
8. Mair J, Morandell D, Genser N, et al. Equivalent early sensitivities of myoglobin, creatine kinase–MB mass, creatine kinase isoforms ratios, and cardiac troponins I and T for acute myocardial infarction. Clin Chem. 1995;41:1266-1272.
9. Mercer DW. Role of cardiac markers in evaluation of suspected myocardial infarction. Postgrad Med. 1997;102:113-122.

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

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

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