QDx Instacheck™ HbA1c

INTENDED USE

QDx Instacheck™ HbA1c along with **QDx Instacheck™ Reader** is a fluorescence Immunoassay (FIA) for the quantitative determination of HbA1c (Hemoglobin A1c) in human whole blood. It is useful as an aid in management and monitoring of the long-term glycemic status in patients with diabetes mellitus.

INTRODUCTION

Glycated protein is formed post-translationally through the slow, nonenzymatic reaction between glucose and amino groups on proteins. HbA1c is a clinically useful index of mean glycemia during the preceding 120 days, the average life span of erythrocytes. Carefully controlled studies have documented a close relationship between the concentrations of HbA1c and mean glycemia. HbA1c is considered as a more reliable parameter in monitoring glycemia over the glycemic reading with the conventional glucometer.

PRINCIPLE

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

The more antigens in the sample, the more antigen-antibody complexes are formed. This then leads to stronger intensity of the fluorescence signal, which is processed by **QDx Instacheck™ Reader** to produce the content of glycated hemoglobin in terms of percent of the total hemoglobin in blood.

COMPONENTS AND REAGENTS

QDx Instacheck™ HbA1c consists of 'Cartridges', 'Detection Buffer Tubes', 'Hemolysis Buffer Vial' and an 'ID chip'.

- The cartridge contains a test strip, the membrane which has anti human HbA1c at the test line, with rabbit IgG at the control line.
- Each cartridge is individually sealed in an aluminum foil pouch containing of a desiccant. 25 sealed cartridges are packed in a box which also contains an ID chip.
- The detection buffer contains anti human HbA1c-fluorescence conjugate, anti-rabbit IgG-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide as a preservative in phosphate buffered saline.
- The detection buffer is pre-dispensed in a tube. 25 detection buffer tubes are packaged in a box and further packed in a Styrofoam box with ice-packs for shipping.
- The hemolysis buffer contains nonionic detergent and sodium azide as preservative in PBS

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Carefully follow the instructions and procedures described in this 'Instruction for use'.
- It is recommended to use fresh samples.
- It is possible to use frozen samples. Please refer to "SAMPLE COLLECTION AND PROCESSING".
- Do not expose QDx Instacheck™ HbA1c test kit to direct sunlight.
- Lot numbers of all the test components (Cartridge, ID chip and detection buffer and hemolysis 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 misleading test result(s).
- Do not reuse. A detection buffer 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. HbA1c 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™ HbA1c** as well as the QDx Instacheck™ Reader should be used away from vibration and/or magnetic field. During normal usage, it can be noted the QDx Instacheck™ Reader may produce minor vibration.
- Used detection buffer 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™ HbA1c** will provide accurate and reliable results subject to the following conditions.
  - **QDx Instacheck™ HbA1c** should be used only in conjunction **QDx Instacheck™ Reader**.
  - Any anticoagulants other than **EDTA, sodium 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 pre-dispensed in a tube is stable for 20 months if stored at 2-8 °C.
- The hemolysis buffer dispensed in a vial is stable for 20 months if stored at 4-30 °C.
- 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. 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.
- The test environment conditions for **QDx Instacheck™ HbA1c** are as follow.
  - Temperature: 20-30 °C
  - Humidity: 10-70 %
  - i-Chamber target temperature: 30 °C

MATERIALS SUPPLIED

REF **IFPC-13**

Components of QDx Instacheck™ HbA1c

- **Cartridge Box:**
  - Cartridges 25
  - ID Chip 1
  - Instruction for Use 1
- **Detection Buffer Box:**
  - Detection Buffer tubes 25
  - Hemolysis Buffer Vial (3 mL) 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **QDx Instacheck™ HbA1c**. 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™ HbA1c** is whole blood.

- It is recommended to test the sample within 12 hours after collection.
- Samples may be stored for up to a week at 2-8 °C prior to being tested.
- If testing will be delayed more than a week, samples should be frozen at -70 °C or below. Samples stored frozen at -70 °C or below for 3 months showed no performance difference.
- Once the sample was frozen, it should be used one time only for test, because repeated freezing and thawing can result in erroneous results

TEST SETUP

1. Check the components of **QDx Instacheck™ HbA1c**: Sealed Cartridge, ID chip, instruction for use, detection buffer tube and hemolysis buffer vial.
2. Ensure that the lot number of the test cartridge matches with that of the ID chip, detection buffer as well as hemolysis buffer.
3. Keep the sealed cartridge (if stored in refrigerator) and detection buffer tube and hemolysis buffer at room temperature for at least 30 minutes just prior to performing the test. Place the cartridge on a clean, dust-free and flat surface.
4. Turn on power supply of the **QDx Instacheck™ Reader**.
5. Insert the ID chip into the 'ID Chip Port' of the **QDx Instacheck™ Reader**.
6. Press 'Select' button on the **QDx Instacheck™ Reader**. (*Please refer to the '**QDx Instacheck™ Reader** Operation Manual' for complete information and operating instructions.*)
7. Insert a cartridge into i-Chamber slot. Temperature of i-chamber should be 30 °C.

TEST PROCEDURE

[Multi mode]

1. Draw 100 µL of hemolysis buffer and transfer it into detection buffer tube.
2. Draw 5 µL of fingertip blood or tube blood using 5 µL capillary tube and put the capillary tube into the detection buffer tube.
3. Close the lid of the detection buffer tube and mix the sample thoroughly by shaking it about 15 times.
4. Take out the cartridge half from i-Chamber slot.
5. Pipette out 75 µL of the sample mixture and load it into a sample well in the test cartridge.
6. Wait till the sample mixture flow appears in the windows. (about 10 seconds)
7. Insert the cartridge into i-Chamber slot (30 °C).
8. Leave the cartridge in i-Chamber for 12 minutes before removing.
9. For scanning the sample-loaded 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. An arrow has been marked on the test cartridge especially for this purpose.
10. Press 'Select' button on the **QDx Instacheck™ Reader** to start the scanning process.
11. **QDx Instacheck™ Reader** will start scanning the sample-loaded test cartridge immediately.
12. Read the test result on the display screen of the **QDx Instacheck™ Reader**.

INTERPRETATION OF TEST RESULT

- **QDx Instacheck™ Reader** calculates the test result automatically and displays HbA1c concentration of the test sample in terms of % (NGSP), mmol/mol (IFCC), mg/dL (eAG).
- The cut-off (reference range)
  - NGSP (%): 4.5-6.5 %
  - IFCC (mmol/mol): 26-48 mmol/mol
- Working range
  - NGSP (%): 4-15 %
  - IFCC (mmol/mol): 20.2-140.4 mmol/mol
  - eAG (mg/dL): 68.1-383.8 mg/dL

QUALITY CONTROL

- Quality control tests should be performed as a part of the good testing practice to confirm the expected quality control results and validity of the assay as well as to ensure accuracy of the test results with clinical samples.
- A quality control test should be performed at regular intervals. Before testing a clinical sample using a new test lot, control reagents should be tested to confirm the test procedure, and to verify whether the test produces the expected quality control results. Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control reagents are not provided with **QDx Instacheck™ HbA1c**. For more information regarding obtaining the control reagents, contact the technical section at **Diasys Diagnostics India Private Limited.**
- **Internal Control**: **QDx Instacheck™ HbA1c** test has an in-built quality control indicator that satisfies the routine quality control requirements. This internal control test is performed automatically each time a clinical sample is tested. 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. **Cross-reactivity**
   There was no significant cross-reactivity from these materials with the **QDx Instacheck™ HbA1c** test measurements.

Cross-reactivity material	Standard material conc.		
	5.2 %	6.5 %	10.5 %
	Recovery (%)		
HbA0 (20 mg/mL)	99.9	96.1	99.0
HbA1a,A1b (20 mg/mL)	100.9	96.8	101.0
Acetylated hemoglobin (100 mg/mL)	101.0	98.4	99.7
Carbamylated hemoglobin (100 mg/mL)	100.5	97.8	100.0

Glycated h-Albumin (100 mg/mL)	100.3	97.4	100.6
HbA1d (100 mg/mL)	100.9	97.0	100.3
Acetylaldehyde hemoglobin (100 mg/mL)	100.8	95.6	99.1

2. **Interference**

There was no significant interference from these materials with the **QDx Instacheck™ HbA1c** test measurements.

Interference material	Standard material conc.		
	5.2 %	6.5 %	10.5 %
	Recovery (%)		
Non-interference	101.0	96.2	98.7
Acetaminophen (20 mg/dL)	100.4	97.8	100.9
L-ascorbic acid (500 mg/dL)	101.0	97.8	99.8
Bilirubin (2 g/dL)	100.8	97.8	100.4
D-glucose (1,000 mg/dL)	100.9	97.6	99.8
Intralipid (800 U/L)	100.8	96.2	100.6
Triglyceride (327 M)	100.9	96.1	99.6
Urea (10 g/dL)	100.1	98.1	99.7

3. **Precision**

The intra-assay precision was calculated by one evaluator, who tested different concentration of control standard five times each with three different lots of **QDx Instacheck™ HbA1c.**

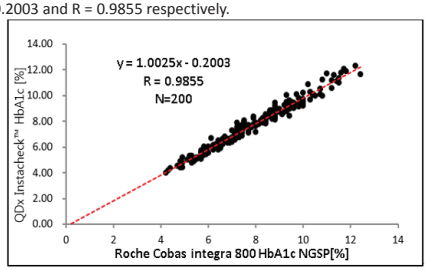
HbA1c (%)	Lot 1	Lot 2	Lot 3	AVG	SD	CV (%)	Accuracy (%)
5.2	5.28	5.18	5.24	5.23	0.12	2.36	100.6
6.5	6.46	6.48	6.34	6.43	0.13	1.99	98.9
10.5	10.4	10.56	10.58	10.51	0.19	1.83	100.1

The inter-assay precision was confirmed by 3 different evaluators with 3 different lots, testing five times each different concentration.

HbA1c (%)	Between-person			Between-lot		
	AVG	SD	CV (%)	AVG	SD	CV (%)
5.2	5.19	0.03	0.61	5.23	0.05	0.96
6.5	6.51	0.02	0.36	6.43	0.07	1.12
10.5	10.50	0.01	0.10	10.51	0.10	0.92

4. **Comparability:**

HbA1c concentrations of 200 clinical samples were quantified independently with **QDx Instacheck™ HbA1c** and Roche Cobas integra800 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=1.0025X - 0.2003 and R = 0.9855 respectively.



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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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