QDx Instacheck™ iFOB Neo

INTENDED USE

QDx Instacheck™ iFOB Neo is a fluorescence Immunoassay (FIA) for the quantitative determination of hemoglobin in human feces. It is useful as an aid in management and monitoring of colorectal cancer. For *in vitro* diagnostic use only.

INTRODUCTION

Colorectal cancer is the third most common cancer in the world[1], with about 1 million new cases and more than 500, 000 deaths per year. Screening method for colorectal cancer include the immuno chromatography fecal occult blood (iFOB) test, barium enema, sigmoidoscopy and colonoscopy[2]. Large randomized controlled trials have shown that iFOB screening can result in decreased colorectal cancer mortality[3,4]. The traditional FOB test uses the chemical Guaiac, which is sensitive to Hb peroxidase activity. However, the Guaiac-FOB test has low sensitivity to clinically significant colorectal neoplasis and has low specificity due to its non-specificity for human Hb[5,6]. To overcome these potential problems in immunochemical test, QDx Instacheck™ iFOB Neo uses specific monoclonal antibodies against human Hb.

PRINCIPLE

The test uses a sandwich immunodetection method; the detector antibody in buffer binds to antigen in sample, forming antigen-antibody complexes, and migrates onto nitrocellulose matrix to be captured by the other immobilized-antibody on test strip.
The more antigen in sample forms the more antigen-antibody complex and leads to stronger intensity of fluorescence signal on detector antibody, which is processed by instrument for QDx Instacheck™ tests to show iFOB Neo concentration in sample.

COMPONENTS AND REAGENTS

QDx Instacheck™ iFOB Neo consists of 'Cartridges', 'Extraction Buffer Tubes', 'ID chip' and 'Instruction for Use'

- The cartridge contains a test strip, the membrane which has anti human hemoglobin at the test line, while rabbit IgG 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 extraction buffer contains bovine serum albumin (BSA), detergent and sodium azide as a preservative in HEPES buffer.
- The extraction buffer is pre-dispensed in an extraction tube. 25 extraction buffer tubes are packaged in the cartridge box.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Follow the instructions and procedures described in this 'Instruction for use'.
- Use only fresh samples and avoid direct sunlight.
- There should be no contamination with urine or water in samples.
- Samples should not be taken during menstruation, hemorrhoids or when using rectal medications.
- Lot numbers of all the test components (cartridge, ID chip and extraction 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 cartridges or extraction buffer tubes. An extraction buffer tube should be used for processing of one sample only. A cartridge should be used for testing one sample only.
- The cartridge should remain sealed in its original pouch before use. Do not use the cartridge, if is damaged or already opened.
- For shipping, samples must be packed in accordance with the local regulations.
- Allow the cartridge, extraction buffer and sample to be at room temperature for approximately 30 minutes.
- The instrument for QDx Instacheck™ tests may generate slight vibration during use.
- Used extraction 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™ iFOB Neo** will provide accurate and reliable results subject to the bellow conditions.
- **QDx Instacheck™ iFOB Neo** should be used only in conjunction with instrument for QDx Instacheck™ test.

STORAGE AND STABILITY

Storage condition		
Component	Storage Temperature	Shelf life
Cartridge	4 - 30 °C.	20 months
extraction buffer	4 - 30 °C.	20 months

- 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 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 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-37

Components of **QDx Instacheck™ iFOB Neo**

- **Cartridge Box:**
  - Cartridges 25
  - Extraction buffer tube 25
  - ID Chip 1
  - Instruction for Use 1

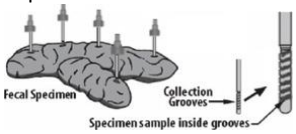
MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

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

- **QDx Instacheck™ II** REF FPRR021
- **QDx Instacheck™ reader** REF FPRR010
- **Printer** REF FPRR007
- **Boditech iFOB Neo Control** REF CFPO-14

SAMPLE COLLECTION AND PROCESSING

- The sample type for QDx Instacheck™ iFOB Neo is human feces.
- Invert an extraction buffer tube and loosen the cap which is attached a sampling stick (yellow color).
- Introduce the sampling stick into the fecal sample six times at different sites. In order to get sampling even in the spirals of the stick and to ensure appropriate specimen to buffer ratio, try to avoid obtaining clumps of fecal matter.



- Return the stick to the extraction buffer tube. Tighten the cap thoroughly and shake the tube vigorously so as to disperse the specimen throughout the extraction buffer in the tube
- The collected specimen should be tested as soon as possible, if not to be used immediately after addition of fecal sample, extraction buffer tube should be refrigerated but must be analyzed using the test cartridge within 7 days.

TEST SETUP

- Check the components of **QDx Instacheck™ iFOB Neo**: Sealed Cartridge, Extraction Buffers and ID Chip
- Ensure that the lot number of the cartridge matches with that of the ID chip as well as that on the Extraction Buffer.
- Keep the sealed cartridge (if stored in refrigerator) and the extraction buffer 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 instrument for QDx Instacheck™ tests.
- Insert the ID Chip into the ID chip port of the instrument for QDx Instacheck™ tests.
  (Please refer to the 'Instrument for QDx Instacheck™ test Operation Manual' for complete information and operating instructions.)

TEST PROCEDURE

1. Collect sample according to the sample collection method using a sampling stick in the 'sample collection and processing'.
2. Break off the black tip on the outside of the black cap.
3. Discard 3 drops of reagent onto the paper towel before applying to the cartridge.
4. Hold the vial upside down and transfer 3 drops of the sample mixture and load it into the sample well on the cartridge.
5. Leave the sample-loaded cartridge at room temperature for 10 minutes.
   ⚠ *Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inexact test result.*
6. 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.
7. Tap 'Start' button on the instrument for QDx Instacheck™ test.
8. The Instrument for QDx Instacheck™ tests will start scanning the sample-loaded cartridge immediately.
9. Read the test result on the display screen of the instrument for QDx Instacheck™ tests.

INTERPRETATION OF TEST RESULT

- Instrument for QDx Instacheck™ tests calculates the test result automatically and displays hemoglobin concentration of the test sample in terms of ng/mL
- The cut-off (reference value): 100 ng/mL (10 μg Hb/g Stool)
- The cut-off (reference value) may depend on the test method and the test object. It is recommended to set a cut-off (reference value) for each laboratory.
- In case of a positive result (above 100 ng/mL), consult a physician to discuss the test result. The physician may decide further course of action.
- Working range: 25-1,000 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.
- 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 standards are not provided with **QDx Instacheck™ iFOB Neo.** For more information regarding obtaining the control standards, contact the technical section at Diasys Diagnostics India Private Limited.
  (Please refer to the instruction for use of control material.)

PERFORMANCE CHARACTERISTICS

- **Analytical sensitivity**

Limit of Blank (LoB)	0.91ng/mL
Limit of Detection (LoD)	1.34ng/mL
Limit of Quantification(LoQ)	25.0 ng/mL

- **Analytical specificity**

- Cross-reactivity
  There was no significant cross-reactivity from these materials with the **QDx Instacheck™ iFOB Neo** test measurements.

Cross-reactivity materials	Concentration (ng/mL)		
	25	100	500
	Cross-reactivity (%)		
Bovine hemoglobin (2,000 μg/mL)	1.22	-0.84	1.12
Chicken hemoglobin (500 μg/mL)	-2.55	0.09	1.11
Fish hemoglobin (100 μg/mL)	0.83	3.35	-1.43
Horse(Equine) hemoglobin (500 μg/mL)	-1.25	-1.17	0.81
Goat hemoglobin (500 μg/mL)	0.15	1.46	1.50
Pig(Swine) hemoglobin (500 μg/mL)	0.62	-0.24	-0.87
Rabbit hemoglobin (500 μg/mL)	-0.53	-0.48	-2.02
Sheep hemoglobin (500 μg/mL)	1.91	0.17	-0.58

- Interference
  There was no significant Interference from these materials

with the **QDx Instacheck™ iFOB Neo** test measurements.

Interference materials	Concentration (ng/mL)		
	25	100	500
	Interference (%)		
Ascorbic acid (350 µmol/L)	0.37	-1.66	0.92
Bilirubin (350 µmol/L)	-4.03	0.01	1.41
Albumin (60 g/L)	-1.99	-3.27	1.47
Glucose (120 mg/dL)	1.47	-1.07	0.78
Triglyceride mixture (500 mg/dL)	0.72	-2.65	-2.40

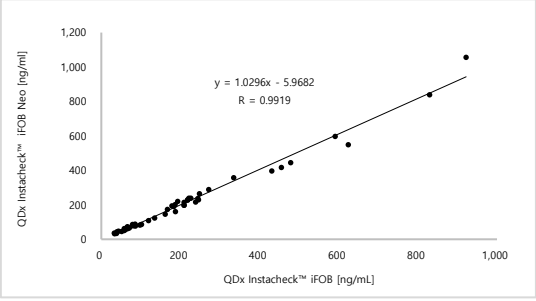
- **Precision**
  - Between lot
    One person tested three different lots of **QDx Instacheck™ iFOB Neo,** five times at each concentration of the control standard.
  - Between person
    Three different persons tested one lot of **QDx Instacheck™ iFOB Neo**, five times at each concentration of the control standard.
  - Between day
    One person tested **QDx Instacheck™ iFOB Neo** for five days, five times at each concentration of the control standard.
  - Between site
    One person tested one lot of **QDx Instacheck™ iFOB Neo** at three different sites, five times at each concentration of the control standard.

Hb (ng/mL)	Between-lot		Between-person		Between-day		Between-site	
	AVG	CV (%)	AVG	CV (%)	AVG	CV (%)	AVG	CV (%)
25	24.90	6.03	24.68	6.06	25.12	6.84	24.11	7.88
100	99.84	3.32	100.78	4.20	98.52	3.60	100.15	3.50
500	501.36	1.99	506.49	1.76	499.48	2.45	496.16	2.22

- **Accuracy**
  The accuracy was confirmed by 3 different lots testing ten times each different concentration.

Hb(ng/mL)	Lot 1	Lot 2	Lot 3	AVG	Recovery (%)
25	24.89	24.26	24.73	24.62	98%
100	100.18	101.32	99.84	100.44	100%
500	503.76	496.10	507.90	502.59	101%

- **Comparability**
  hemoglobin concentrations of 50 feces samples were quantified independently with **QDx Instacheck™ iFOB Neo and QDx Instacheck™ iFOB (QDx Instacheck™ Reader)** 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= 1.0296X – 5.9682 and R = 0.9919 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
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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