QDx Instacheck™ β-HCG

INTENDED USE

QDx Instacheck™ β-HCG in conjunction with the **QDx Instacheck™ Reader** is a fluorescence immunoassay for quantitative measurement of total beta human chorionic gonadotropin (total β-hCG) concentration in human whole blood/serum/plasma. It is useful as an aid in management and monitoring of total beta human chorionic gonadotropin (total β-hCG) level in human..

INTRODUCTION

Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after implantation. hCG can be detected in the urine and serum of pregnant women as early as 6 to 15 days after conception. The concentration of hCG increases to 50 mIU/ml one week post implantation and reaches to about 100 mIU/ml at the time of the first missed menstrual period and the peak at 100,000-200,000 mIU/ml at the first trimester.

PRINCIPLE

such that the detector antibody in buffer binds to hCG in sample and antigen-antibody complexes are captured to another hCG antibody that has been immobilized on test strip as sample mixture migrates nitrocellulose matrix. Thus the more hCG antigen in sample, the more antigen-antibody complexes accumulated on the test strip. Signal intensity of fluorescence on detector antibody reflects the amount of antigen captured and is processed by **QDx Instacheck™ Reader** to show total β-hCG concentration in specimen. The working range of **QDx Instacheck™ β-HCG** test is 5-50,000 mIU/mL.

COMPONENTS AND REAGENTS

QDx Instacheck™ β-HCG consists of a 'Cartridge', an 'ID chip', a 'Sample diluent tube' and a 'Detection buffer tube'

- The cartridge contains a test strip; on the membrane of which, murine antibodies against hCG and streptavidin have been immobilized at the test line and the control line respectively.
- 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 pre-dispensed in a tube contains fluorochrome-labeled anti-hCG antibodies, fluorescent-labeled biotin-BSA, bovine serum albumin (BSA) as a stabilizer and sodium azide in phosphate buffered saline (PBS) as a preservative.
- The detection buffer is dispensed in each detection buffer tube. 25 detection buffer tubes are packed in a separate box which is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.
- The sample diluent pre-dispensed in a tube contains sodium azide in phosphate buffered saline (PBS). 25 sample diluent tubes are packed in a separate box.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Carefully follow the instructions and procedures described in this insert as well as the **QDx Instacheck™ Reader** operation manual.
- Lot numbers of all the test components (cartridge, ID chip and detection buffer tube) must match with each other.
- Neither interchange the test components form different lots nor use the test components beyond the expiration date.
- Test performed by using any test component having mismatching lot number or that beyond the expiration date may yield misleading test result(s).
- **QDx Instacheck™ β-HCG** is compatible only with **QDx Instacheck™ Reader**.
- The cartridge should remain sealed in its original pouch until just prior to use. Do not use the cartridge should it be damaged or the pouch found already opened.
- Allow a minimum of 30 minutes for the cartridge (if stored in a refrigerator) and the detection buffer tube to attain room temperature prior to performing the test.
- **QDx Instacheck™ β-HCG** as well as the **QDx Instacheck™ Reader** should be used away from vibration and/or magnetic field. During normal usage, **QDx Instacheck™ Reader** may produce minor vibrations which should be regarded as normal.
- A detection buffer tube should be used for processing one serum/plasma sample only. Similarly a cartridge should be used for testing one processed serum/plasma sample only. Both the detection buffer tube as well as the cartridge should be discarded after single use.
- Being potentially infectious used detection buffer tube(s), transfer pipette(s) and cartridge(s) should be handled carefully and disposed of by appropriate method in accordance with relevant local regulations.
- Sodium azide is not likely to be a human health hazard in the quantity present in the detection buffer. Generally, 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.

STORAGE AND STABILITY

- The cartridge is stable for 20 months (while sealed in the aluminum foil pouch) if stored at 4-30 °C.
- The detection buffer dispensed in the detection buffer tube is stable for 20 months if stored at 2-8°C.
- The sample diluent buffer dispensed in a tube is stable for 24 months if stored at 4 - 30°C.
- After the cartridge pouch is opened, the test should be performed immediately.

LIMITATIONS OF THE TEST SYSTEM

QDx Instacheck™ β-HCG provides accurate and reliable test results subject to the following constraints:

- **QDx Instacheck™ β-HCG** should be used only in conjunction with **QDx Instacheck™ Reader**.
- The test should always be performed on freshly collected blood sample(s).
- Anticoagulants other than sodium heparin and EDTA have not been evaluated for the purpose of this test.
- The test sample must be at room temperature prior to testing. If the test samples are to be shipped for the purpose of this test, appropriate precautions must be exercised.
- The test should not be performed on hemolysed samples. If a test sample appears to be hemolysed, fresh serum sample should be obtained, processed and tested.
- Effectiveness of the test is highly dependent on storage of test components and test samples at prescribed optimal conditions.

- The test may yield false positive result(s) due to cross-reactions of some components of blood with the capture/detector antibodies and/or non-specific adhesion of certain components having similar epitopes to bind with these antibodies.
- The test may also yield false negative results; the most common factor being non-responsiveness of the antigen to the antibodies due to its epitopes being masked by some unknown components such that the antigen cannot be detected or captured by the antibodies. False negative results may also be obtained due to instability or degradation of the hCG antigen with time and/or temperature making it unrecognizable by the antibodies.
- Other factors interfering with the test and causing erroneous results include technical/procedural errors, degradation of the test components/reagents as well as 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.

SAMPLE COLLECTION AND PROCESSING

The test can be performed on whole blood/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
- However, the whole blood sample should not be kept in a freezer in any case.
- 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.

MATERIALS SUPPLIED

REF IFPC-20

Components of QDx Instacheck™ β-HCG

- **Cartridge Box:**
  - Cartridges 25
  - ID Chip 1
  - Package Insert 1
- **Box containing Detection Buffer Tube:**
  - Detection Buffer Tubes 25
- **Box containing Sample Diluent Tube:**
  - Sample Diluent Tubes 25

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

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

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

TEST SETUP

1. Check the components of **QDx Instacheck™ β-HCG**: Sealed Cartridge, Detection Buffer Tubes, Sample Diluents and ID Chip.
2. Ensure that the lot number of the cartridge matches that of the ID chip, sample diluent as well as the detection buffer.
3. 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.
4. Turn on 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.*)

TEST PROCEDURE

[Single mode]

1. Transfer of sample (30 µL Human serum, plasma, control/50 µL whole blood) using a transfer pipette to a tube containing the detection buffer.
2. Close the lid of the detection buffer 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. For scanning 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.
5. Press 'Select' button on the **QDx Instacheck™ Reader** to start the scanning process.
6. **QDx Instacheck™ Reader** will start scanning the sample-loaded cartridge after 15 minutes.
7. Read the test result on the display screen of the **QDx Instacheck™ Reader**.

[Multi mode]

1. Transfer of sample (30 µL Human serum, plasma, control/50 µL whole blood) using a transfer pipette to a tube containing the detection buffer.
2. Close the lid of the detection buffer 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 15 minutes.
5. For scanning 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**.

*When the concentration of a sample is higher than 50,000 mIU/mL, it can be diluted with a diluent provided.

TEST PROCEDURE-USING SAMPLE DILUENT

1. Transfer 30 µL of sample (Human whole blood/serum/plasma /control) to a sample diluent tube provided with pipette.
2. Close the lid and mix the sample thoroughly by shaking it about 10 times.
3. Proceed to the step **1** of the **TEST PROCEDURE.** (Following to the single mode or multi mode)

INTERPRETATION OF TEST RESULT

- **QDx Instacheck™ Reader** calculates the test result automatically and displays hCG concentration of the test sample in terms of mIU/mL.
- Working range of **QDx Instacheck™ β-HCG** is 5-50,000 mIU/mL.
- Cut-off of **QDx Instacheck™ β-HCG** is 20 mIU/mL.
- Total βhCG level during pregnant stage

pregnant women (weeks since LMP*)	Total βhCG level [mIU/mL] range
3	5 - 50
4	5 - 426
5	18 - 7,340
6	1,080 – 56,500
7 - 8	7,650 – 229,000
9 - 12	25,700 – 288,000
13 - 16	13,300 – 254,000
17 - 24	4,060 – 165,400
25 - 40	3,640 – 117,000

* LMP is the last menstrual periods date from the first day of your last period

- In case of the test is performed with sample dilution procedure, please follow the below equation to obtain correct result. [Final Sample Concentration = Reported Concentration x 10]

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 standards are not provided with **QDx Instacheck™ β-HCG**. For more information regarding obtaining the control standards, contact the technical section at **Diasys Diagnostics India Private Limited**.
- **Internal Control**: **QDx Instacheck™ β-HCG** 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. **Specificity:** There, in test samples, are biomolecules such as L-Ascorbic acid, hemoglobin, triglycerides, cholesterol, glucose, bilirubin, heparin were shown as below for interference study. But this doesn't interfere with the **QDx Instacheck™ β-HCG** test measurements, nor occurs any significant interference.

Interfering Substance	Concentration added
L-Ascorbic acid	3 mg/dL
hemoglobin	500 mg/dL
triglycerides	1000 mg/dL
cholesterol	70 mg/dL
glucose	120 mg/dL
bilirubin	20 mg/dL
heparin	143 U/mL
EDTA	15 mg/L

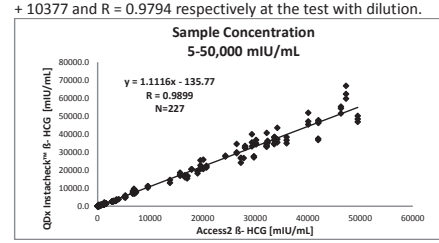
2. **Imprecision**: The intra-assay precision was calculated by one evaluator, who tested different concentration of control standard ten times each with three different lots of **QDx Instacheck™ β-HCG.** The inter-assay precision was confirmed by 4 different evaluators with 3 different lots, testing ten times each different concentration.

Whole blood sample hCG Concentration (mIU/mL)	Intra assay		Inter assay	
	Mean value (mIU/mL)	CV (%)	Mean value (mIU/mL)	CV (%)
7.5	6.9	22.1	6.9	21.0
15.1	15.9	16.8	15.7	14.9
178.4	189.4	3.6	191.8	4.4
2,039	2038.4	5.7	1972.4	4.8
22,322	22680.4	7.1	22775.6	5.3
35,416	34019.5	4.4	33519.2	4.0
98,563*	100845.8	3.8	102486.5	4.6
225,491*	226324.4	4.6	230127.8	6.0

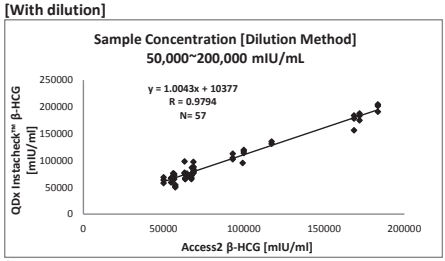
Serum sample hCG Concentration (mIU/mL)	Intra-assay		Inter-assay	
	Mean (mIU/mL)	CV (%)	Mean (mIU/mL)	CV (%)
* 195,560	192,890.8	6.8	193,959.2	6.6
* 155,400	151,555.1	5.7	159,474.5	4.9
* 77,700	77,064.8	6.0	76,175.9	6.8
38,850	39,470.4	5.9	41,666.8	7.2
12,007	10,431.0	3.8	10,490.6	6.3
1,214	1,238.2	2.4	1,222.3	4.2
152	157.2	3.4	157.6	6.3
19	17.8	8.2	17.4	9.0
5	4.8	10.7	4.7	13.5

* For samples with the concentration of higher than 50,000 mIU/mL, they were diluted with diluent as described above.

3. **Comparability** (Correlation**):** hCG concentrations of 284 serum samples were quantified independently with **QDx Instacheck™ β-HCG** and Beckman Coulter Access2 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 = 1.1116X – 135.779 and R=0.9899 respectively at the test without dilution. Linear regression and coefficient of correlation between the two tests were y = 1.0043x + 10377 and R = 0.9794 respectively at the test with dilution.



[With dilution]



* The values were obtained with dilution as described above.

REFERENCES

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3. Lenton EA, LM Neal, R Sulaiman "Plasma concentration of human chorionic gonadotropin from the time of implantation until the second week of pregnancy", Fertil. Steril. 1982; 37(6): 773-778.
4. Batzer FR. "Hormonal evaluation of early pregnancy", Fertil. Steril. 1980; 34(1): 1-13

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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CE