QDx Instacheck™ PRL

INTENDED USE

QDx Instacheck™ PRL in conjunction with **QDx Instacheck™ Reader** is a fluorescence immunoassay for quantitative measurement of prolactin (PRL) concentration in human serum or plasma.

INTRODUCTION

Human Prolactin (PRL: lactogenic hormone) is secreted from the anterior pituitary gland in both men and women. PRL is a single chain polypeptide hormone with a molecular weight of approximately 23 kDa. Normal women have slightly higher basal level of PRL than men; apparently, there is an estrogen-related rise at puberty and a corresponding decrease at menopause. During pregnancy, PRL level increases progressively to 10 and 20 times of normal value, declining to non-pregnant levels by 3-4 weeks post-partum.

The determination of PRL concentration is helpful in diagnosing hypothalamic-pituitary disorders. Microadenomas (small pituitary tumors) may cause hyperprolactinemia, which is sometimes associated with male impotence. High PRL levels are commonly associated with galactorrhea and amenorrhea. PRL concentrations have been shown to be increased by estrogens, thyrotropin-releasing hormone (TRH), and several drugs affecting dopaminergic mechanism. Also, PRL levels are elevated in renal disease and hypothyroidism, and in some situations of stress, exercise, and hypoglycemia. Additionally, the release of PRL is episodic and demonstrates diurnal variation. **QDx Instacheck™ PRL** measures quantitatively the PRL concentration in human serum and plasma.

PRINCIPLE

QDx Instacheck™ PRL uses a sandwich immunodetection method, such that the detector antibody in buffer binds to PRL in blood sample and antigen-antibody complexes are captured to another antibody that has been immobilized on test strip as sample mixture migrates through the nitrocellulose matrix. The more PRL antigen is in blood, the more antigen-antibody complexes are accumulated on the test strip. The signal intensity of fluorescence on the detector antibody reflects the amount of antigen captured and is processed by **QDx Instacheck™ Reader** to find the PRL concentration in the specimen. The working range of **QDx Instacheck™ PRL** is 1-100 ng/mL.

*** Reference range**
Women: 5 ~ 35 ng/mL
Men: 3 ~ 25ng/mL

COMPONENTS AND REAGENTS

QDx Instacheck™ PRL consists of a test cartridge, a detection buffer and an ID chip. The test cartridge is individually sealed with a desiccant in an aluminum pouch, and the detection buffer is dispensed individually in a tube. A box containing the pre-dispensed tubes is delivered separately from the test cartridge in a Styrofoam box filled with ice packs.

- Test Cartridge contains a test strip; on the membrane of which, Anti-PRL antibody and streptavidin have been immobilized at the test line and the control line of respectively.
- Detection Buffer, pre-dispensed in a tube, contains fluorescence-labeled anti-human PRL antibody, fluorescence-labeled BSA-biotin, BSA as a stabilizer, and sodium-azide as a preservative in PBS.

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 (test 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 expiration date.
- Test performed by using any test component of mismatching lot number or that beyond the expiration date may yield misleading test result(s).
- **QDx Instacheck™ PRL** is compatible only with **QDx Instacheck™ Reader**.
- The test cartridge should remain sealed in its original pouch until just prior to use. Do not use the test cartridge should it be damaged or the pouch found already opened.
- Allow a minimum of 30 minutes for the test cartridge (if stored in a refrigerator) and the detection buffer tube to attain room temperature prior to performing the test.
- **QDx Instacheck™ PRL** 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 test sample only. Similarly a test cartridge should be used for testing one processed test sample only. Both the detection buffer tube as well as the test cartridge should be discarded after single use.
- Being potentially infectious, used tip(s), detection buffer tube(s) and test 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 test 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.
- Allow a minimum of 30 minutes for the test cartridge (if stored in a refrigerator) and the detection buffer tube to attain room temperature prior to performing the test.
- Do not remove the test cartridge from the aluminum foil pouch until just prior to use.
- After the test cartridge pouch and the detection buffer tube are opened, the test should be performed within 30 minutes.

LIMITATIONS OF THE TEST SYSTEM

QDx Instacheck™ PRL provides accurate and reliable test results subject to the following constraints:

- The result of **QDx Instacheck™ PRL** should be evaluated with all clinical and laboratory data available. If PRL Test results do not agree with the clinical evaluation, additional tests should be performed.
- The false positive results include cross-reactions with some

components of serum / plasma from individual to antibodies, and non-specific adhesion of some components in serum / plasma that have similar epitopes to capture and detector antibodies. In the case of false negative results, the most common factors are: non-responsiveness of antigen to the antibodies by that certain unknown components are masking its epitope, such that antigen cannot be seen by the antibodies; instability of PRL antigen, resulting in degradation with time and, or temperature, such that they become no longer recognizable by antibodies; and degraded other test components. The effectiveness of the test is highly dependent on storage of kits and sample specimens at optimal conditions.

- Anticoagulants other than EDTA have not been evaluated for the purpose of this test.
- Since the flow characteristic on nitrocellulose membrane and related test result are influenced by temperature and relative humidity, controlled testing environment is required for the best test results. To obtain best test result, check 'Note' in procedure section.
- Other factors may interfere with **QDx Instacheck™ PRL** and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.

MATERIALS SUPPLIED

REF **IFPC-6**

Components of QDx Instacheck™ PRL

- **Test Cartridge Box:**
  - Test Cartridges 25
  - ID Chip 1
  - Package Insert 1
- **Detection Buffer Box*:**
  - Detection Buffer Tubes 25

(***** Box containing the detection buffer tubes is supplied separately from the test cartridge box. It is further packed in a Styrofoam box provided with ice packs for the purpose of shipment.)

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

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

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

TEST SETUP

1. Check the components of **QDx Instacheck™ PRL**: Sealed Test Cartridge, ID Chip and Detection Buffer Tube.
2. Ensure that the lot number of the test cartridge matches with that of the ID chip as well as the detection buffer tube.
3. Keep the test cartridge and detection buffer tube 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.*)

TEST PROCEDURE

[Single mode]

1. Transfer 75 µL of the serum or plasma sample using a transfer pipette to the tube containing the detection buffer**.** For performing a quality control test, pipette out 75 µL control standard reagent instead of serum or plasma sample and transfer it to the detection buffer tube.
2. Close the lid of the detection buffer tube and mix the sample thoroughly with the detection buffer by shaking the tube about 10 times.
3. Pipette out 75 µL of this sample mixture from the detection buffer tube and dispense it into the sample well on the test cartridge.
4. 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. An arrow has been marked on the test 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 test cartridge after 10 minutes.
7. Read the test result on the display screen of the **QDx Instacheck™ Reader**.

[Multi mode]

1. Transfer 75 µL of the serum or plasma sample using a transfer pipette to the tube containing the detection buffer**.** For performing a quality control test, pipette out 75 µL control standard reagent instead of serum or plasma sample and transfer it to the detection buffer tube.
2. Close the lid of the detection buffer tube and mix the sample thoroughly with the detection buffer by shaking the tube about 10 times.
3. Pipette out 75 µL of this sample mixture from the detection buffer tube and dispense it into the sample well on the test cartridge.
4. Leave the sample-loaded test cartridge at room temperature for 10 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. 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 immediately.
8. 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 PRL concentration of the test sample in terms of ng/mL.

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™ PRL**. For more information regarding obtaining the control reagents, contact the technical section at **Diasys Diagnostics India Private Limited**.
- **Internal Control**: **QDx Instacheck™ PRL** 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

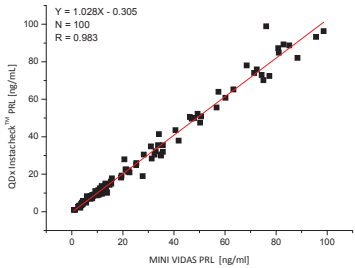
1. **Specificity:** Biomolecules such as hLH, hFSH, hCG, hTSH and hGH were added to the test samples at concentrations much higher than their normal physiological levels. **QDx Instacheck™ PRL** test results showed neither any significant interference from these biomolecules nor any significant cross-reactivity with the same.

2. **Imprecision**: For the intra-assay imprecision, 30 replicates were tested at each control sample. For the inter-assay imprecision, tests were conducted on 9 sequential days, with 9 runs per day and with 9 replicates at each PRL concentration.

Imprecision of QDx Instacheck™ PRL				
PRL (ng/mL)	Intra-assay		Inter-assay	
	Mean	CV (%)	Mean	CV (%)
5.9	5.9	5.6	5.9	4.7
34.5	35.5	4.5	35.3	4.8
65.2	67.1	2.8	65.8	3.0
91.7	93.5	1.6	93.3	2.3

(CV = Coefficient of Variation)

3. **Comparability (Correlation):** PRL concentrations of 100 clinical specimens were quantified independently with **QDx Instacheck™ PRL** and the BioMerieux mini-Vidas system according to the established standard test procedure. The test results were analyzed and their comparability was investigated with linear regression and correlation coefficient (*R*). The value of correlation of coefficient was 0.983 between two methods.



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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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