Diagnostic Kit for PRL (Prolactin)

A Fluorescence Immunoassay test for quantitative detection of Prolactin (PRL) in human whole blood, serum or plasma with the use of Immunofluorescence Analyzer.

English

- For *in-vitro* diagnostic use

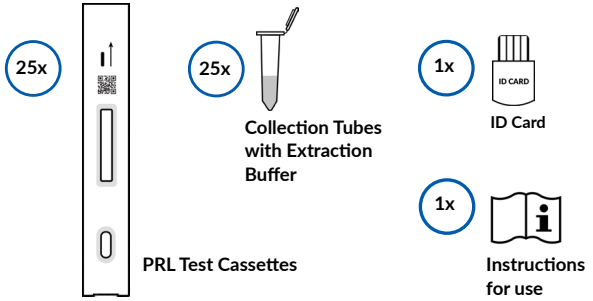
PACKING SPECIFICATION
25 Tests/ Kit (07PLAC5025)

INTENDED USE
The PRL Test Cassette (Whole Blood/Serum/Plasma) is based on Fluorescence Immunoassay for the quantitative detection of Prolactin (PRL) in human whole blood, serum or plasma. The test is intended for healthcare professionals use.

SUMMARY
PRL (Prolactin), also known as lactotropin, is a protein best known for its role in enabling mammals (and birds), usually females, to produce milk. It is influential in over 300 separate processes in various vertebrates, including humans.[1] Prolactin is secreted from the pituitary gland in response to eating, mating, estrogen treatment, ovulation and nursing. It is secreted heavily in pulses in between these events. Prolactin plays an essential role in metabolism, regulation of the immune system and pancreatic development. In usual circumstances, in the absence of galactorrhea, lactation ceases within one or two weeks following the end of breastfeeding. Hypersecretion is more common than hyposecretion, hyperprolactinemia is the most frequent abnormality of the anterior pituitary tumors, termed prolactinomas. Prolactin levels may be checked as part of a sex hormone workup, as elevated prolactin secretion can suppress the secretion of follicle stimulating hormone and gonadotropin-releasing hormone, leading to hypogonadism and sometimes causing erectile dysfunction.

PRINCIPLE
The PRL Test Cassette (Whole Blood/Serum/Plasma) detects PRL (Prolactin) based on fluorescence immunoassay. The sample moves through the strip from sample pad to absorbent pad. If the specimen contains PRL, it attaches to the fluorescent microspheres-conjugated anti-PRL antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of PRL in the sample correlates linearly with the fluorescence signal intensity captured on the T line. According to the fluorescence intensity of the test and standard curve, the concentration of PRL in the sample can be calculated by analyzer to show PRL concentration in specimen.

REAGENTS
The test includes anti-PRL antibody coated fluorophore and anti-PRL antibody coated on the membrane.

MATERIALS PROVIDED


MATERIALS REQUIRED BUT NOT PROVIDED
- Immunofluorescence Analyzer MPQuanti® (07IMA001)
- Pipette
- Centrifuge
- Specimen Collection Containers
- Timer

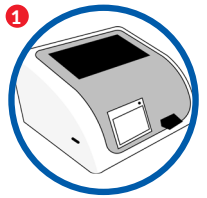
PRECAUTIONS
1. For professional *in-vitro* diagnostic use only.
2. Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse.
3. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
4. Do not eat, drink or smoke in the area where the specimens and tests are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Do not interchange or mix reagents from different lots.
6. Humidity and temperature can adversely affect results.
7. Used testing materials should be discarded in accordance with local regulations.
8. Read the entire procedure carefully prior to any testing.
9. The PRL Test Cassette should only be used with the Analyzer by medical professionals.

STORAGE AND STABILITY
1. The test should be stored at 4 - 30 °C until the expiration date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. Do not freeze.
4. Care should be taken to protect the components of the test from contamination.
5. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

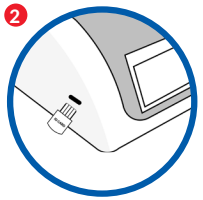
SAMPLE COLLECTION AND PREPARATION
1. Collect the specimens according to standard procedures.
2. Do not leave specimens at room temperature for prolonged periods. Serum and Plasma specimens may be stored at 2 - 8 °C for up to 5 days, for long term storage, specimens should be kept below -20 °C. Whole blood collected by venipuncture should be stored at 2 - 8 °C if the test is to be used within 2 days of collection. Do not freeze whole blood specimens. Whole blood collected by finger stick should be tested immediately.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens. Only clear, non-hemolyzed specimens can be used.
4. EDTA K2, Sodium citrate, can be used as the anticoagulant tube for collecting the blood specimen.

Sample Dilution/Sample Stability
1. The specimen (75 µL of serum/plasma/whole blood) can be added directly with the micro pipette into the buffer.
2. Close the tube and shake the sample by hand vigorously for approximately **10 seconds** to mix the sample and dilution buffer well.
3. Let the diluted sample homogenize for approximately **1 minute**.
4. The diluted sample can be used immediately or stored for up to 8 hours.

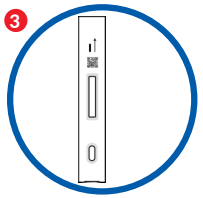
TEST PROCEDURE
Refer to Immunofluorescence Analyzer User Manual for the complete instructions for use of the Test. The test should be in room temperature.
Allow the test cassette, specimen and buffer to reach room temperature (15 - 30 °C) prior to testing.



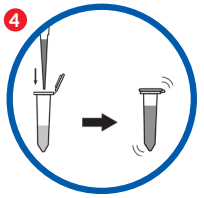
Turn on the Analyzer power.



Take out the ID card and insert it into the ID Card Slot. Choose test mode and/or sample type according to needs.

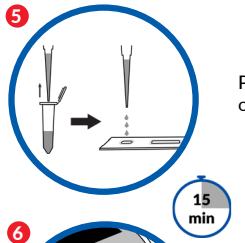


Remove the test cassette from the sealed foil pouch and use it within 1 hour. Best results will be obtained if the assay is performed immediately after opening the foil pouch.

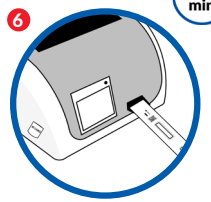


Place the test on a flat and clean surface.

Pipette **75 µL of serum/plasma/whole blood** into the specimen collection tubes with buffer, mix specimen and buffer well.



Pipette **75 µL of diluted specimen** into the sample well of the cassette. Start the timer at the same time.



Test results should be interpreted at **15 minutes** with the use of Immunofluorescence Analyzer.

Caution: There are different test modes of the Immunofluorescence Analyzer. The difference between them is incubation of the test cassette is outside or inside the analyzer. Choose test mode accordingly and confirm sample type. Consult the user manual of the analyzer for detailed operation information.
Operator must consult the Immunofluorescence Analyzer User Manual prior to use and become familiar with the processes and quality control procedures.

INTERPRETATION OF TEST RESULTS

Results read by Immunofluorescence Analyzer.

The result of tests for PRL is calculated by Immunofluorescence Analyzer and display the result on the screen. For additional information, please refer to the user manual of Immunofluorescence Analyzer.

Assay range of PRL is 1.0 - 200 ng/mL.

The default result of this product is (ng/mL), and the conversion relationship with (mIU/L) is 21.2.

The conversion formula is: Current concentration (ng/mL) * 21.2= mIU/L

QUALITY CONTROL

Each PRL Test Cassette contains internal control that satisfies routine quality control requirements. This internal control is performed each time a sample is tested. This control indicates that the test cassette was inserted and read properly by Immunofluorescence Analyzer. An invalid result from the internal control causes an "N/A" message on Immunofluorescence Analyzer. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The PRL Test Cassette (Whole Blood/Serum/Plasma) is for professional *in-vitro* diagnostic use, and should only be used for the quantitative detection of Prolactin (PRL).
2. High concentrations of prolactin may produce a dose hook effect, resulting in incorrect interpretation of prolactin levels. High dose hook effect has not been observed with this test up to 400 ng/mL of Prolactin.
3. The test assay range of this test is 1.0 - 200 ng/mL. If the concentration of the sample is >200 ng/mL, the high-concentration sample should be diluted with calf serum or negative samples, and the maximum dilution factor should not exceed 4 times.
4. The results of PRL Tests are based on measuring the levels of prolactin in a specimen. It should not be used as the sole criterion for treatment decisions.
5. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

EXPECTED VALUES

Gender	Condition	Reference Range	
		ng/mL	mIU/L
Female	Non-pregnant	2 - 25 ng/mL	42.4 - 530
	Pregnant	10 - 209 ng/mL	212 - 4430.8
Male	/	2 - 18 ng/mL	42.4 - 381.6

Note: The establishment of the reference interval for this test is only for specimens from local populations. It is recommended that each laboratory establish an actual reference interval based on the population, age, gender, diet, etc. in each region.

PERFORMANCE CHARACTERISTICS

1. Accuracy

The test deviation is ≤±15%.

2. Assay Range and Detection Limit

- Assay Range: 1 - 200 ng/mL
- Minimum Detection Limit (Analytical Sensitivity): 1 ng/mL

3. Linearity Range

1 - 200 ng/mL, R≥0.990

4. Precision

Intra-lot precision

Within-run precision has been determined by using 10 replicates of 2 specimens containing 5ng/mL and 150 ng/mL of PRL. C.V. is ≤15%.

Inter-lot precision

Between-run precision has been determined by using 10 replicates for each of three lots using 2 specimens containing 5 ng/mL and 150 ng/mL of PRL. C.V. is ≤15%.

5. Interfering substances

The following substances do not interfere with the test results at the indicated concentration: 50ng/mL Testosterone, 100 ng/mL Progesterone, 100,000 mIU/mL hCG, 1,000 pg/mL Estradiol, 20 mg/dL bilirubin, 1 g/dL hemoglobin.

6. Method comparison

The product was evaluated with 78 clinical specimens compared with Commercial PRL device, and the correlation coefficient (r) was 0.951.

BIBLIOGRAPHY

1. Bole-Feysot C, Goffin V, Edery M, Binart N, Kelly PA (June 1998). "Prolactin (PRL) and its receptor: actions, signal transduction pathways and phenotypes observed in PRL receptor knockout mice". Endocrine Reviews. 19 (3): 225–68. doi:10.1210/edrv.19.3.0334. PMID 9626554.

SYMBOLS

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