



ichroma™ PRL

INTENDED USE

ichroma™ PRL is a fluorescence Immunoassay (FIA) for the quantitative determination of Prolactin (PRL) in human serum/plasma. It is useful as an aid in management and monitoring of hypothalamic-pituitary disorders.

For *in vitro* diagnostic use only.

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.

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 ichroma™ tests to show PRL concentration in sample.

COMPONENTS

ichroma™ PRL consists of 'Cartridges', 'Detection Buffer tubes', and an 'ID chip'.

- The cartridge contains a test strip, the membrane which has anti human PRL 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 detection buffer contains anti human PRL-fluorescence conjugate, anti rabbit IgG-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide in phosphate buffered saline (PBS) as a preservative.
- 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-pack for the shipment.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Follow instructions and procedures described in this 'Instruction for use'.
- Use only fresh samples and avoid direct sunlight.
- Lot numbers of all the test components (cartridge, ID chip and detection 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 incorrect test result(s).
- Do not reuse cartridges or detection buffer tubes. A detection 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 until just before use. Do not use cartridge, if pouch is damaged or has already been opened.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with local regulations. Sample with severe hemolysis and/or hyperlipidemia must not be used.
- Allow cartridge, detection buffer and sample to be at room temperature for approximately 30 minutes before use.
- The instrument for ichroma™ tests may generate slight vibration during use.
- 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.
- **ichroma™ PRL** will provide accurate and reliable results subject to the below conditions.
 - **ichroma™ PRL** should be used only in conjunction with the instrument for ichroma™ tests.
 - **Have to use recommended anticoagulant sample.**

Sample type	Recommended anticoagulant
Plasma	K ₂ EDTA
Serum	Not applicable.

LIMITATION 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.

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.
- After the cartridge pouch is opened, the test should be performed immediately.

MATERIALS SUPPLIED

REF CFPC-27

Components of **ichroma™ PRL**

- Cartridge Box:
 - Cartridges 25
 - ID Chip 1
 - Instruction for Use 1
- Detection Buffer Box:
 - Detection Buffer tubes 25

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **ichroma™ PRL**.

Please contact our sales division for more information.

- Instrument for **ichroma™** tests
 - **ichroma™ Reader** **REF** FR203
 - **ichroma™ II** **REF** FPFR021
- **ichroma™ Printer** **REF** FPFR007
- **Boditech Hormone Control** **REF** CFPO-95

SAMPLE COLLECTION AND PROCESSING

The sample type for **ichroma™ PRL** is human 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.
- Once the sample was frozen, it should be thawed one time and only for test, because repeated freezing and thawing can result in the changed test values.

TEST SETUP

- Check the contents of **ichroma™ PRL**: Sealed Cartridge, Detection Buffer Tubes and ID Chip.
- Ensure that the lot number of the cartridge matches that of the ID chip as well as the detection buffer.
- 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.
- Turn on the Instrument for **ichroma™** tests. (Please refer to the 'Instrument for **ichroma™** tests Operation Manual' for complete information and operating instructions.)

TEST PROCEDURE

<Multi mode>

- 1) Transfer 75 µL of sample (serum/plasma/control) 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 dispense it into the sample well on the cartridge.
- 4) 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.
- 5) To scan the sample-loaded cartridge, insert it into the cartridge holder of the instrument for **ichroma™** tests. 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) Tap the 'Start' button or press the 'Select' button on the instrument for **ichroma™** tests to start the scanning process.
- 7) The instrument for **ichroma™** tests will start scanning the sample-loaded cartridge immediately.
- 8) Read the test result on the display screen of the instrument for **ichroma™** tests.

<Single Mode>

- 1) Transfer 75 µL of sample (serum/plasma/control) 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 dispense it into the sample well on the cartridge.
- 4) Inserting the cartridge into the holder of the instrument for ichroma™ test. 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) Tap the 'Start' button or press the 'Select' button on the instrument for ichroma™ tests.
- 6) The Instrument for ichroma™ tests will automatically start scanning the sample-loaded cartridge after 10 minutes.
- 7) Read the test result on the display screen of the instrument for ichroma™ tests.

INTERPRETATION OF TEST RESULT

- Instrument for ichroma™ tests calculates the test result automatically and displays PRL concentration of the test sample in terms of ng/mL.
- The cut-off (reference range)
 - Women

Menstrual cycle:	5-35 ng/mL
Menopausal phase:	5-35 ng/mL
 - Men: 3-25 ng/mL
- Working range: 1-100 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 materials are not provided with **ichroma™ PRL**. For more information regarding obtaining the control materials, contact Boditech Med Inc.'s Sales Division for assistance. (Please refer to the instruction for use of control material.)

PERFORMANCE CHARACTERISTICS

■ **Specificity**

There, in test samples, are biomolecules such as the below table in higher concentration than their normal physiological levels. But this doesn't interfere with the **ichroma™ PRL** test measurements, nor occurs any significant cross-reactivity.

Compound	Spiked concentration	Cross-reactivity (%)
hLH	250 mIU/mL	< 0.001
	1,000 mIU/mL	< 0.001
hFSH	250 ng/mL	< 0.001
	1,000 ng/mL	< 0.001
hCG	500 mIU/mL	< 0.001
	500,000 mIU/mL	< 0.001
hTSH	500 µIU/mL	< 0.001
hGH	1,000 ng/mL	0.4

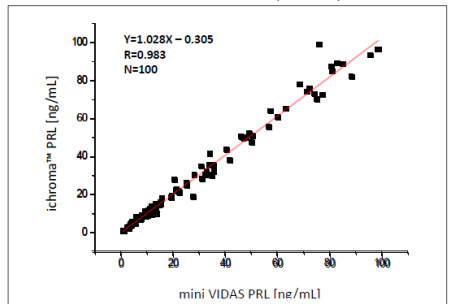
■ **Precision**

The intra-assay precision was calculated by one evaluator, who tested different concentration of control standard thirty times each with three different lots of **ichroma™ PRL**. The inter-assay precision was confirmed by 4 different evaluators with 3 different lots, testing ten times each different concentration.

PRL (ng/mL)	Intra assay		Inter assay	
	Mean (ng/mL)	CV (%)	Mean (ng/mL)	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

■ **Comparability**













PRL concentrations of 100 serum samples were quantified independently with **ichroma™ PRL** and mini VIDAS (BioMerieux Inc. France) 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 $Y = 1.028X - 0.305$ and $R = 0.983$ respectively.



REFERENCES

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3. Freeman ME, Kanyicska B, Lerant A, Nagy G. Prolactin: structure, function, and regulation of secretion. Physiol Rev. 2000. 80(4):1523-631.
4. Bartke A. Prolactin in the male: 25 years later. J Androl. 2004. 25(5):661-6.
5. Bachelot A, Binart N. Reproductive role of prolactin. Reproduction. 2007. 133(2):361-9.

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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