



ichroma™ PRL

INTENDED USE

ichroma™ PRL is a fluorescence immunoassay (FIA) for the quantitative determination of PRL (Prolactin) 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 antibodies in buffer bind to antigens in the sample, forming antigen-antibody complexes, and migrate onto nitrocellulose matrix to be captured by the other immobilized antibodies on a test strip.

More antigens in the sample will form more antigen-antibody complexes which lead to stronger fluorescence signal by detector antibodies, which is processed by the instrument for ichroma™ tests to show PRL concentration in the sample.

COMPONENTS

ichroma™ PRL consists of 'cartridges', 'detector tubes' and 'detector diluent'.

- The cartridge contains the membrane called a test strip has anti-prolactin at the test line, and rabbit IgG at the control line. All cartridges are individually sealed in an

aluminum foil pouch containing a desiccant, and they are further packaged in a box.

- The detector tube has a granule containing anti-prolactin-fluorescence conjugate, anti-rabbit IgG-fluorescence conjugate and sodium azide as a preservative in phosphate buffered saline (PBS). All detector tubes are packed in a pouch.
- The detector diluent contains and tween-20 as a detergent and sodium azide as a preservative in phosphate buffer saline (PBS), and it is pre-dispensed in a vial. The detector diluent is packed in a box.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Follow the instructions and procedures described in this 'Instructions for use'.
- Use only fresh samples and avoid direct sunlight.
- Lot numbers of all the test components (cartridge, detector tube, detector diluent and ID chip) 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 detector tubes. A cartridge should be used for testing one sample only. A detector tube should be used for processing of 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.
- If test components and/or sample are stored in refrigerator, then allow cartridge, detector tube, detector diluent 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 cartridges, detector tubes, detector diluent and pipette tips should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- The detector tube and detector diluent contain sodium azide (NaN₃) and it may cause certain health issues like convulsions, low blood pressure, low heart rate, loss of consciousness, lung injury and respiratory failure. Avoid contact with skin, eyes, and clothing. In case of contact, rinse immediately with running water.
- **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.

Recommended anticoagulant

K₂ EDTA, K₃ EDTA, Lithium heparin

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 antigens to the antibodies which is the 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 antigens with time and/or temperature may also cause false negative result as it makes the antigens 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 in conjunction with clinical symptoms and other relevant test results.

STORAGE AND STABILITY

Component	Storage condition		Note
	Storage Temperature	Shelf life	
Cartridge	2 - 30°C	20 months	Disposable
Detector tube	2 - 30°C	20 months	Disposable
Detector diluent	2 - 30°C	20 months	Unopened
		3 months	Opened

- 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
 - Detector tube 25
 - Detector diluent 1
 - ID chip 1
 - Instructions for use 1

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** FPRR021
 - **ichroma™ III** **REF** FPRR037
 - **ichroma™ M3** **REF** FPRR035
- Printer **REF** FPRR007
- Boditech Hormone Control **REF** CFPO-95
- Boditech PRL Control **REF** CFPO-226

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 when collected sample is stored at room temperature.

- The samples (serum, plasma) should be separated from the clot by centrifugation within 3 hours after the collection of whole blood.
- The samples (serum, plasma) may be stored for a week at 2-8 °C prior to being tested. If testing will be delayed more than a week, samples (serum, plasma) should be frozen at -20 °C.
- The samples (serum, plasma) stored frozen at -20 °C for 2 months showed no performance difference.
- However, the whole blood sample should not be kept in a freezer in any case.
- As a repeated freeze-thaw cycle may affect the test result, do not refreeze previously frozen samples.

TEST SETUP

- Check the contents of **ichroma™ PRL**: Sealed cartridges, detector tubes, a detector diluent, an ID chip and an instructions for use.
- Ensure that the lot number of the cartridge matches that of the detector tube, the detector diluent as well as an ID chip.
- If the sealed cartridge, the detector tube, and detector diluent have been stored in a refrigerator, place them on a clean and flat surface at room temperature for at least 30 minutes before testing.
- Turn on the instrument for **ichroma™** tests.
- Insert the ID chip into the 'ID chip port'.

※ Please refer to the instrument for **ichroma™** tests operation manual for complete information and operating instructions.

TEST PROCEDURE

► **ichroma™ Reader, ichroma™ II, ichroma™ M3**

Multi test mode

- 1) Take 150 µL of detector diluent using a pipette and dispense it to the detector tube containing a granule. When the granule form is completely dissolved in the tube, it becomes detection buffer.
(The detection buffer must be used immediately. Do not exceed 30 seconds.)
- 2) Take 75 µL of sample (serum/plasma/control) using a pipette and dispense it to the detector tube.
- 3) Close the lid of the detector tube and mix the sample thoroughly by shaking it about 10 times.
(The sample mixture must be used immediately. Do not exceed 30 seconds.)
- 4) Take 75 µL of the sample mixture and dispense it into the sample well of the cartridge.
- 5) Leave the cartridge at room temperature for 10 minutes.
⚠ Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inaccurate test result.
- 6) 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 is marked on the cartridge especially for this purpose.

- 7) Press the 'Select' or tap the 'Start' button on the instrument for ichroma™ tests to start the scanning process.
(ichroma™ M3 will start the test automatically after inserting.)
- 8) The instrument for ichroma™ tests will start scanning the sample-loaded cartridge immediately.
- 9) Read the test result on the display screen of the instrument for ichroma™ tests.

Single test mode

- 1) The test procedure is same with the 'Multi test mode 1) – 4)'.
- 2) Insert the sample-loaded cartridge into the 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 is marked on the cartridge especially for this purpose.
- 3) Press the 'Select' or tap the 'Start' button on the instrument for ichroma™ tests.
(ichroma™ M3 will start the test automatically after inserting.)
- 4) The cartridge goes inside the instrument for ichroma™ tests and will automatically start scanning the sample-loaded cartridge after 10 minutes.
- 5) Read the test result on the display screen of the instrument for ichroma™ tests.

► ichroma™ III

- 1) The test procedure is same with the 'Single test mode'.

INTERPRETATION OF TEST RESULT

- The instrument for ichroma™ tests calculates the test result automatically and displays PRL concentration of the test sample in terms of ng/mL.
- 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.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are provided on demand with ichroma™ PRL. For more information regarding obtaining the control materials, contact [Boditech Med Inc.'s Sales Division for assistance](#).

(Please refer to the instructions for use of control material.)

PERFORMANCE CHARACTERISTICS

■ Analytical sensitivity

- Limit of Blank (LOB)	0.420 ng/mL
- Limit of Detection (LOD)	0.647 ng/mL
- Limit of Quantitation (LOQ)	1.000 ng/mL

■ Analytical specificity

- Cross-reactivity
Biomolecules listed in the following table were added to the test sample(s) at concentrations much higher than their normal physiological levels in the blood. **ichroma™ PRL** test results did not show any significant cross-reactivity with these biomolecules.

Cross reactants	Concentration
hCG	1,500,000 mIU/mL
LH	1,500 mIU/mL
FSH	1,500 mIU/mL
TSH	1,500 uIU/mL
hGH	1,000 ng/mL

- Interference

Interferents listed in the following table were added to the test sample at the concentration mentioned below. **ichroma™ PRL** test results did not show any significant interference with these materials.

Interferents	Concentration
D-glucose	600 mM/L
L-Ascorbic acid	2 mM/L
Bilirubin[unconjugate]	4 mM/L
Hemoglobin(human)	20 g/L
Cholesterol	130 mM/L
triglyceride	100 mg/mL

■ Precision

- Single-site study

Repeatability (within-run precision)

Within-laboratory precision (total precision)

Lot to lot precision

3 Lots of **ichroma™ PRL** were tested for 20 days. Each standard material was tested 2 times per day. For each test, each material was duplicated.

Single-site study						
PRL [ng/mL]	Repeatability		Within-laboratory precision		Lot to lot precision	
	AVG [ng/mL]	CV (%)	AVG [ng/mL]	CV (%)	AVG [ng/mL]	CV (%)
4	3.99	7.70	4.01	7.73	4.01	6.96
10	10.03	6.87	10.00	6.98	10.01	7.01
50	51.02	5.76	50.77	6.29	50.25	6.31

- Multi-site study

Reproducibility

1 Lot of **ichroma™ PRL** was tested for 5 days in 3 different sites (1 person per 1 site, 1 instrument per 1 site). Each standard material was tested 1 time per and 5 replicates per day.

Multi-site study		
PRL [ng/mL]	Reproducibility	
	AVG [ng/mL]	CV (%)
4	4.04	5.48
10	10.10	5.36
50	50.29	4.87

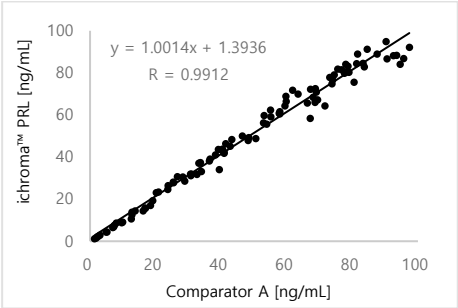
■ **Accuracy**

The accuracy was confirmed by testing with 3 different lots of **ichroma™ PRL**. The tests were repeated 10 times at each concentration of the control standard.

PRL [ng/mL]	Lot 1	Lot 2	Lot 3	AVG [ng/mL]	Recovery
1	0.98	1.01	0.99	0.99	99.1%
5	5.16	4.88	4.80	4.95	98.9%
10	9.86	10.12	9.87	9.95	99.5%
20	19.67	20.53	20.44	20.22	101.1%
50	50.97	51.32	51.74	51.34	102.7%
75	73.42	73.30	72.76	73.16	97.5%
100	96.12	96.02	96.03	96.06	96.1%

■ **Comparability**

PRL concentration of 100 clinical samples were quantified independently with **ichroma™ PRL (ichroma™ II)** and **comparator A** as per prescribed test procedures. Test results were compared, and their comparability was investigated with linear regression and correlation coefficient (R). The regression equation and correlation coefficient are as follows.



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