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Hormone

AFIAS PRL

INTENDED USE

AFIAS PRL is a fluorescence immunoassay (FIA) for the quantitative determination of PRL (Prolactin) in human whole blood/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

This 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 the more antigen-antibody complexes which lead to stronger fluorescence signal by detector antibodies, which is processed by the instrument for AFIAS tests to show PRL concentration in the sample.

COMPONENTS

AFIAS PRL consists of 'cartridges'.

- Each sealed aluminum pouch contains two cartridges.
- Each cartridge packaged in an aluminum pouch has three components including a cartridge part, a detector tube part, and a diluent part.
- The cartridge part contains the membrane called a test strip which has anti-prolactin at the test line and anti-rabbit IgG at the control line.
- The detector tube part has a granule containing the anti-prolactin-fluorescence conjugate, anti-rabbit-IgG-fluorescence conjugate and sodium azide as a preservative in phosphate buffered saline (PBS).
- The diluent part contains tween-20 as a detergent, and sodium azide as a preservative in phosphate buffered saline (PBS).

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Follow 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 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. 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 a cartridge, if the 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 and sample to be at room temperature for approximately 30 minutes before use.
- The instrument for AFIAS tests may generate slight vibration during use.
- Used cartridges and pipette tips should be handled carefully and discarded by an appropriate method in accordance with relevant local regulations.
- The cartridge contains sodium azide (NaN_3), 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.
- **AFIAS PRL** will provide accurate and reliable results subject to the below conditions.
  - **AFIAS PRL** should be used only in conjunction with the instrument for AFIAS tests.
  - Have to use recommended anticoagulant.

Recommended anticoagulant
K_2EDTA, K_3EDTA, Lithium heparin

LIMITATIONS 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

Storage condition			
Component	Storage Temperature	Shelf life	Note
Cartridge	2 - 30°C	20 months	Unopened
		1 month	Resealed

- Return an unused cartridge to the spare cartridge zipper bag containing the desiccant pack. Reseal along entire edge of zip-seal.

MATERIALS SUPPLIED

REF SMFP-8

Components of **AFIAS PRL**

- Cartridge box:
  - Cartridge 24
  - Pipette tip (zipper bag) 24
  - Spare cartridge zipper bag 1
  - ID chip 1
  - Instructions for use 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately with **AFIAS PRL**. Please contact our sales division for more information.

- **Instrument for AFIAS tests**
  - **AFIAS-1** REF FPRR019
  - **AFIAS-3** REF FPRR040
  - **AFIAS-6** REF FPRR020
  - **AFIAS-10** REF FPRR038
- **Boditech Hormone Control** REF CFPO-95
- **Boditech Hormone Calibrator** REF CFPO-107
- **Boditech PRL Control** REF CFPO-226
- **Boditech PRL Calibrator** REF CFPO-252

SAMPLE COLLECTION AND PROCESSING

The sample type for **AFIAS PRL** is human whole blood/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 (whole blood, 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 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 components of the **AFIAS PRL** as described below. : Cartridges, pipette tips, an ID chip, a spare cartridge zipper bag and an instructions for use.
- Ensure that the lot number of the cartridge matches that of the ID chip.
- If the sealed cartridge has 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 AFIAS tests.
- Empty the tip box.
- Insert the ID chip into the 'ID chip port'.

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

TEST PROCEDURE

▶ **AFIAS-1, AFIAS-3, AFIAS-6**

General mode

1) Insert a cartridge into the cartridge holder.
2) Insert a tip into the tip hole of the cartridge.
3) Select the 'General mode' in the instrument for AFIAS tests.
4) Take 150 µL of sample (whole blood/serum/plasma/control) using a pipette and dispense it into the sample well of the cartridge.
5) Tap the 'Start' button on the screen.
6) The test result will be displayed on the screen after 10 minutes.

▶ **AFIAS-10**

Normal mode

1) Insert a cartridge into the cartridge holder.
2) Insert a tip into the tip hole of the cartridge.
3) Tap the 'Load' button of the bay that holds the cartridge with the tip to read the barcode of the cartridge and please confirm the item name written on the cartridge.
4) Insert the sample tube into the tube rack.
5) Insert the tube rack into the loading part of the sampling station.
6) Tap the 'Start' button on the screen.
7) The test result will be displayed on the screen after 10 minutes.

Emergency mode – General tip

1) The test procedure is same with the 'Normal mode 1) – 3)'.
2) Convert the 'Emergency mode' in AFIAS-10.
3) Select the tip type (general tip) on the screen.
4) Select the sample type (whole blood/serum/plasma) on the screen.
5) Take 150 µL of the sample using a pipette and dispense it into the sample well of the cartridge.
6) Tap the 'Start' button on the screen.
7) The test result will be displayed on the screen after 10 minutes.

INTERPRETATION OF TEST RESULT

- The instrument for AFIAS tests calculates the test result automatically and displays PRL concentration of the test sample in terms of ng/mL.
- Working range: 1- 100 ng/mL
- Reference value
  - Women
    Menstrual cycle: 5-35 ng/mL
    Menopausal phase: 5-35 ng/mL
  - Men: 3-25 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 **AFIAS 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) 0.319 ng/mL
  - Limit of Detection (LoD) 0.736 ng/mL
  - Limit of Quantitation (LoQ) 1 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. **AFIAS 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. **AFIAS 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

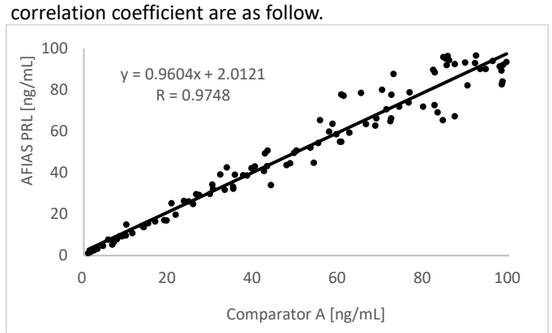
- **Precision**
  - **Single-site study**
    Repeatability (within-run precision)
    Within-laboratory precision (Total precision)
    Lot to lot precision
    3 Lots of **AFIAS PRL** were tested for 21 days. Each standard material was tested 2 times per day. For each test, each material was duplicated.
  - **Between person**
    Three different persons tested three lots of **AFIAS PRL**, ten times at each concentration of the control standard.
  - **Between site**
    One lot of **AFIAS PRL** was tested at three different sites; ten times at each concentration of the control standard.
  - **Between reader**
    One lot of **AFIAS PRL** was tested with three different instruments; five times at each concentration of the control standard.

PRL (ng/mL)	Repeatability		Within-laboratory precision		Lot to lot precision	
	AVG [ng/mL]	CV (%)	AVG [ng/mL]	CV (%)	AVG [ng/mL]	CV (%)
4	3.81	9.28	3.87	9.30	3.95	9.10
10	9.88	5.87	9.85	6.43	9.94	6.69
50	49.58	7.56	49.81	6.78	49.87	6.95
PRL (ng/mL)	Between-person		Between-site		Between-Reader	
	AVG [ng/mL]	CV (%)	AVG [ng/mL]	CV (%)	AVG [ng/mL]	CV (%)
4	4.06	9.17	3.92	8.40	4.01	8.66
10	10.11	6.84	9.91	7.44	10.01	7.19
50	49.2	6.66	51.0	6.76	49.41	6.74

- **Accuracy**
  The accuracy was confirmed by testing with 3 different lots of **AFIAS 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	1.00	1.01	1.01	1.01	101
5	4.88	4.84	5.03	4.92	98
10	10.11	9.75	9.80	9.89	99
20	20.07	20.07	20.42	20.19	101
50	51.96	50.16	52.01	51.38	103
75	75.85	75.38	75.13	75.45	101
100	97.50	98.48	97.81	97.93	98

- **Comparability**
  PRL concentration of 100 clinical samples were quantified independently with **AFIAS PRL (AFIAS-6)** 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 follow.



REFERENCES

1. McNeilly AS. Prolactin and the control of gonadotrophin secretion in the female. J Reprod Fertil. 1980. 58(2):537-49.
2. Linzer DI, Fisher SJ. The placenta and the prolactin family of hormones: regulation of the physiology of pregnancy. Mol Endocrinol. 1999. 13(6):837-40.
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.

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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