CE IVD

PRL

Fast Test Kit

(Immunofluorescence Assay)

User Manual

REF IF1048 for Getein1100
IF2048 for Getein1600

INTENDED USE

PRL Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of prolactin (PRL) in serum or plasma samples. This test can be used as an aid in the diagnosis of male and female infertility and pituitary dysfunction, monitoring of male and female gonadal disorders and management of amenorrhea and galactorrhea.

SUMMARY

Prolactin is a single chain polypeptide of 199 amino acids and a molecular weight of approximately 23,000 Daltons. It is produced by the anterior pituitary and its secretion is regulated physiologically by inhibitory and releasing factors of the hypothalamus.
The major physiologic action of PRL is the initiation and maintenance of lactation in women. In adults, basal circulating prolactin is present in concentrations up to 30 μg/L. During pregnancy and postpartum lactation, serum prolactin can increase 10 to 20 times. Exercise, stress and sleep also cause transient increases in prolactin levels.
Hyperprolactinemia has been established as a common cause of infertility and gonadal disorders in men and women. Prolactin has been shown to inhibit the secretion of ovarian steroids and to interfere with follicle maturation and the secretion of LH and FSH in the human female.

PRINCIPLE

This test uses an anti-human PRL monoclonal antibody I conjugated with fluorescence latex and another anti-human PRL monoclonal antibody II coated on the test line. After sample has been applied to the test strip, the fluorescence latex-labelled anti-human PRL monoclonal antibody I binds with the PRL antigen in sample and forms marked antibody-antigen complex. The complex moves to the detection zone by capillary action. Then marked antigen-antibody complex is captured on the test line by the anti-human PRL monoclonal antibody II. The fluorescence intensity of the test line increases in proportion to the amount of PRL antigen in the sample.
Insert test card into Getein1100 Immunofluorescence Quantitative Analyzer/Automatically inserted by Getein1600 Immunofluorescence Quantitative Analyzer (hereinafter referred to as Getein1100 and Getein1600), the concentration of PRL antigen in the sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1600 and available for downloading. Results can be easily transmitted to a laboratory or hospital infor-mation system.

CONTENTS

1. A kit for Getein1100 contains:
Package specifications: 25 tests/box, 10 tests/box
1) Getein PRL test card in a sealed pouch with desiccant
2) Disposable pipet
3) User manual: 1 piece/box
4) SD card: 1 piece/box
2. A kit for Getein1600 contains:
Package specifications: 2×24 tests/box, 2×48 tests/box
1) Sealed cartridge with 24/48 Getein PRL test cards
2) User manual: 1 piece/box
Materials required for Getein1600:
1) Box with pipette tips: 96 tips/box
2) Mixing plate: 1 piece/box
3. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane (one end of the membrane is coated with fluorescence latex-labelled PRL antibody I, the test line is coated with another PRL antibody II and the control line is coated with rabbit anti-mouse IgG antibody), absorbent paper and liner.
Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test cardat 4~30℃ with a valid period of 24 months.
Use the test card for Getein1100 within one hour once the foil pouch is opened.
For test card of Getein1600: if the cartridge is opened, it could be stable within 24 hours once exposed to air. If the test cards can't be used up at a time, please put the cartridge back to the foil pouch and reseal along the entire edge of zip-seal. The remaining test cards should be used up within 7 days.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch is damaged.
4. Do not open pouches until ready to perform the test.
5. Do not reuse the test card.
6. Do not reuse the pipet.
7. Handle all specimens as potentially infectious. Proper handling and disposal methods should follow by local regulations.
8. Carefully read and follow the manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum and plasma samples***. ***Heparin, sodium citrate and EDTA*** can be used as the anticoagulant for plasma. Samples should be free of hemolysis.
2. The test should performed within 4 hours after blood collection.
3. If testing is delayed, serum and plasma samples may be stored up to 7 days at 2~8℃ or stored at -20℃ for 6 months before testing.
4. Refrigerated or frozen sample should be reached to room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
5. Do not use heat-inactivated or hemolysis samples.
6. Sample volume: ***(for Getein1100): 100 μL***

TEST PROCEDURE

1. Collect specimens according to user manual.
2. Test card, sample and reagent should be brought to room temperature before testing.
   For Getein1100:
3. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
4. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
5. Put the test card on a clean table, horizontally placed.
6. Using sample transfer pipette, deliver ***100 μL*** of sample into the sample port on the test card.
7. Reaction time: ***15 minutes***. Insert the test card into Getein1100 and press "ENT" button or click on "Start" icon (for

Android Getein1100) after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1600:

9. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
10. Place the sample diluent at the correct position in Getein16-00.
11. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1600 will do the testing and print the result automatically.

Notes:

1. It is required to perform "SD card" calibration when using a new batch of kits.
2. It is suggested to calibrate once for one batch of kits for Getein1100.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

1. Getein1100/Getein1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein1100/Getein1600.
2. Due to different methodologies or antibody specificity, there may be deviations between the test results of different manufacturers, so they can't be compared directly.

EXPECTED VALUE

The expected reference range for PRL was determined by testing serum samples from apparently 355 healthy adult males and females.

PRL expected range:

Reference Group		N	Median	Range(ng/mL)
Male		146	5.53	2.64-13.13
Female	Premenopausal (< 50 years)	121	8.28	3.34-26.72
	Postmenopausal (> 50 years)	88	6.20	2.74-19.64

It is recommended that each laboratory establish its own expected values for the population it serves.

PERFORMANCE CHARACTERISTICS

Measuring Range	0.50 ng/mL~200.00 ng/mL
Lower Detection Limit	≤ 0.50 ng/mL
Within-Run Precision	≤ 10%
Between-Run Precision	≤ 15%

LIMITATIONS

1. As with all diagnostic tests, a definitive clinical diagnosis should not be made based on the result of a single test. The test results should be interpreted considering all other test results and clinical information such as clinical signs and symptoms.
2. Samples containing interferents may influence the results. The table below listed the maximum allowance of these potential interferents.

Interferent	Hemoglobin	Triglyceride	Bilirubin	Cholesterol
Concentration (Max)	500 mg/dL	1800 mg/dL	10 mg/dL	400 mg/dL

REFERENCES

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3. Cacho ND, Butjosa A, Cuadras D, et al. Prolactin levels in Drug-Naïve First Episode nonaffective Psychosis Patients compared with healthy controls. Sex differences [J]. Psychiatry Research, 2019.
4. Mohammad JA, Friedrich P. Prolactin and Prolactin-inducible protein (PIP) in the pathogenesis of primary acquired nasolacrimal duct obstruction (PANDO) [J]. Medical Hypotheses, 2019, 125.
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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on PRL Fast Test Kit (Immunofluorescence Assay) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2016/ISO 15223-1:2016.

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limit	IVD	*In vitro* diagnostic medical device
	Contains sufficient for <n> tests	EC REP	Authorized representative in the European Community
CE	CE mark		Do not use if package is damaged
REF	Catalogue number		

Thank you for purchasing PRL Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use.

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