PRL

Fast Test Kit

(Immunofluorescence Assay)

IF1048 for Getein 1100
IF5048 for Getein 1160
IF3048 for Getein 1180
IF2048 for Getein 1600
IF4048 for Getein 1200

Instructions for Use REF

CE IVD

INTENDED USE

The PRL Fast Test Kit (Immunofluorescence Assay) is intended for the *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, as well as for monitoring male and female gonadal disorders and managing amenorrhea and galactorrhea. For professional and laboratory use only.

SUMMARY

Prolactin (PRL) is a single-chain polypeptide of 199 amino acids and has 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 both men and women. PRL has been shown to inhibit the secretion of ovarian steroids and to interfere with follicle maturation and the secretion of LH and FSH in human females.

PRINCIPLE

PRL Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay designed in a sandwich format. After the sample is applied to the test strip, the fluorescence-labelled PRL monoclonal antibody binds with the PRL in the sample to form a marked antigen-antibody complex. This complex moves to the detection zone on the test card by capillary action and is captured by another PRL monoclonal antibody. The fluorescence intensity of the test line increases in proportion to the amount of PRL in the sample. The fluorescent signal intensity can then be analyzed by an appropriate device to quantitatively detect the PRL in the sample.

APPLICABLE DEVICE

Getein 1100 Immunofluorescence Quantitative Analyzer
Getein 1160 Immunofluorescence Quantitative Analyzer
Getein 1180 Immunofluorescence Quantitative Analyzer
Getein 1200 Immunofluorescence Quantitative Analyzer
Getein 1600 Immunofluorescence Quantitative Analyzer

CONTENTS

Materials provided	Getein 1100/Getein 1160/ Getein 1180		Getein 1200/ Getein 1600	
	10 T/kit	25 T/kit	2*24 T/kit	2*48 T/kit
PRL test card*	10 pcs	25 pcs	24 test cards in 1 cartridge, and 2 cartridges in 1 box	48 test cards in 1 cartridge, and 2 cartridges in 1 box
Disposable pipet	10 pcs	25 pcs	/	/
Instructions for use	1 pc	1 pc	1 pc	1 pc
SD card	1 pc	1 pc	1 pc in each cartridge	1 pc in each cartridge

* PRL test card

A test card mainly consists of: Fluorescence-labelled PRL monoclonal antibody, PRL monoclonal antibody.

Consumables for Getein 1200/Getein 1600

- Box with pipette tips (96 tips/box)
- Mixing plate (1 piece/box)

Note:

1. The standard curve data can be written to RFID card in the kit. According to the function of RFID card, we define it as "Standard Curve Data Card", short for "SD Card".
2. Do not mix or interchange different batches of kits.

STORAGE AND STABILITY

Realtime stability:

Store the kit at 4~30°C with a valid period of 24 months. The test kits are stable until the expiry date printed on the labels.

In-use stability:

For the test card of Getein 1100/Getein 1160/Getein 1180: Use the test card within 1 hour once the foil pouch is opened.

For test card of Getein 1200/Getein 1600: If the cartridge is opened, it could be stable within 24 hours once exposure to air. The valid period after opening is 7 days, it is recommended to put the cartridge back to the foil bag and reseal along the entire edge of zip-seal if not used up.

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 or the cartridge is damaged.
4. Do not open pouches or the cartridge until ready to perform the test.
5. Do not reuse the test card or pipet.
6. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
7. Carefully read and follow instructions for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for serum and plasma samples. Heparin, EDTA and sodium citrate can be used as the anticoagulant for plasma. Samples should be free of hemolysis.
2. The test should be 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 reach room temperature and be homogeneous before testing. Avoid multiple freeze thaw cycles.
5. Do not use heat-inactivated samples or hemolysis samples.
6. Sample volume (**Getein 1100/Getein 1160/Getein 1180**): 100 μL.

TEST PROCEDURE

1. User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
2. Test kit and sample should be brought to room temperature before testing.

For Getein 1100:

1) Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD card” calibration when necessary.
2) Select the corresponding “Sample” on the analyzer according to the sample type (see the user manual of analyzer for details).
3) Remove the test card from the sealed pouch before use and put the test card on a clean table, horizontally placed.
4) Use disposable pipet or pipette to drop 100 μL of sample into the sample well on the test card.
5) Reaction time: **15 minutes.** Insert the test card into Getein 1100 and click on “Start” icon after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein 1160/Getein 1180:

1) Confirm SD card lot No. in accordance with test kit lot No. Perform “SD card” calibration when necessary.
2) Select the corresponding “Sample” on the analyzer according to the sample type (see the user manual of analyzer for details).
3) Remove the test card from the sealed pouch immediately before use and put the test card on a clean table, horizontally placed.
4) Use disposable pipet or pipette to drop 100 μL of sample into the sample well on the test card.
5) Insert the test card into Getein 1160/Getein 1180 **immediately** after sample loading. The analyzer will count down the reaction time (15 minutes) and automatically test the card after reaction time is elapsed. The result will be shown on the screen and displayed automatically.

For Getein 1200/Getein 1600:

1) Each cartridge for Getein 1200/Getein 1600 contains a specific RFID card which can calibrate automatically.
2) Put the consumables at the correct position in Getein 1200/Getein 1600.
3) Place samples in the designed area of the sample holder,

insert the holder, set parameters (more operational details refer to the user manual of analyzer) and run the instrument, Getein 1200/Getein 1600 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 Getein 1100/Getein 1160/Getein 1180.
3. Make sure the insertion of test card and the sample are correct and complete.

TEST RESULTS

1. Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600 can scan the test card automatically and display the result on the screen. For additional information, please refer to the user manual of Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600.
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.

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. Some substances in blood as listed below may interfere with the test and cause erroneous results. The maximum allowance concentration of each is as follows:

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

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 determine the applicability of the reference ranges through experimentation and establish their own laboratory-specific reference ranges if necessary.

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%

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.
5. Satoshi F, Motoshi K, Kishio T, et al. Orexin A modulates prolactin production by regulating BMP-4 activity in rat pituitary lactotorope cells [J]. Peptides, 2019, 113.
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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 15223-1:2021.

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

Thank you for purchasing PRL Fast Test Kit (Immunofluorescence Assay). Please read this user manual carefully before operating to ensure proper use. Please report any product problems or adverse events to the below manufacture or authorized representative in the European Community in time.

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