GP

CE IVD

PTH
Fast Test Kit
(Immunofluorescence Assay)

IF1111 for Getein 1100
IF5111 for Getein 1160
IF3111 for Getein 1180
IF2111 for Getein 1600
REF IF4111 for Getein 1200

Instructions for use

INTENDED USE

PTH Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of parathyroid hormone (PTH) in human serum and plasma samples. It is mainly used for auxiliary evaluation of parathyroid gland function and as an adjunctive diagnosis for hypercalcemia or hypocalcemia. For professional and laboratory use only.

SUMMARY

Parathyroid hormone (PTH) is a peptide hormone composed of 84 amino acids, and its secretion is regulated by plasma calcium concentration. PTH secretion is inhibited by an increase in plasma calcium concentration, and stimulated by a decrease of plasma calcium concentration. Elevated PTH suggests that hyperparathyroidism or parathyroid adenoma causes an increase in PTH release, which leads to a higher than normal concentration of PTH in the blood, leading to an increase in osteoclast activity, calcium from the bone into the blood, and promotes tubular reabsorption of calcium ions and phosphate excretion, resulting in an increase in the concentration of calcium in the blood and a decrease in the concentration of phosphorus in the blood. If the level of PTH decreases, it may be due to hypoparathyroidism, which is commonly caused by radiotherapy, which destroys the function of the parathyroid glands, or surgery, which damages the parathyroid glands and causes hypoparathyroidism.

Testing the level of PTH in blood can help determine parathyroid function. Clinically, it plays an auxiliary role in the differential diagnosis of hyperparathyroidism, hypoparathyroidism, hypercalcemia, hypocalcemia, metabolic bone disease and other diseases.

PRINCIPLE

PTH Fast Test Kit (Immunofluorescence Assay) is a lateral flow immunoassay in a double-antibody sandwich design. After the sample has been applied to the test card, the fluorescence-labelled PTH monoclonal antibody bind with PTH in sample and forms a marked antigen-antibody complex. The complex moves to the detection area by capillary action, then it is captured by another PTH monoclonal antibody coated on the detection area of nitrocellulose membrane, forming a double-antibody complex. The complex generates a fluorescent signal and the intensity increases in proportion to the amount of PTH in sample. Fluorescent signals intensity can be analyzed by applicable device thus the PTH in sample be detected quantitatively.

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
PTH 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
Reaction tube	10 pcs	25 pcs	/	/
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

Main key components in the kit
-Fluorescence labelled PTH monoclonal antibody, PTH 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**.
2. Heparin or EDTA can be used as the anticoagulant for plasma samples.
3. It is recommended to test the sample within 4 hours after collection. If testing is delayed, serum and plasma samples are stable for 3 days when stored at 2~8°C and 6 months when stored at -20°C.
4. Refrigerated or frozen sample should reach room temperature before testing. Avoid multiple freeze-thaw cycles.

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 a disposable pipet or pipette to add ***100 μL*** of sample into the reaction tube. Then, aspirate and dispense the sample 8-10 times to ensure thorough mixing. After mixing, **immediately** deliver the entire mixture (approximately 100 μL) into the sample well on the test card using the pipette or the same disposable pipet.

Note:
When sampling with disposable pipet, ensure the liquid level is flush with the scale line of the disposable pipet, otherwise the sample volume will be inaccurate.

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 a disposable pipet or pipette to add ***100 μL*** of sample into the reaction tube. Then, aspirate and dispense the sample 8-10 times to ensure thorough mixing. After mixing, **immediately** deliver the entire mixture (approximately 100 μL) into the sample well on the test card using the pipette or the same disposable pipet.

Note:

When sampling with disposable pipet, ensure the liquid level is flush with the scale line of the disposable pipet, otherwise the sample volume will be inaccurate.

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. Place samples in the designed area of the sample holder, insert the holder and select the right test item, 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.

LIMITATIONS

1. The test results of this reagent are for clinical reference only, and cannot be used as the basis for diagnosis or exclusion of cases alone additional tests should be performed accordingly.
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	18 g/L
Bilirubin	0.1 g/L

EXPECTED VALUE

The expected normal value for PTH was determined by testing samples from apparently healthy individuals.

Group	n	95% Reference range (pg/mL)
Healthy human	265	15.0-65.0

The reference ranges for plasma samples are the same as those for serum samples. 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.

RESULTS

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.

PTH Fast Test Kit (Immunofluorescence Assay) results are provided in pg/mL.

Results in pg/mL may be converted to pmol/L as shown with an example below.

PTH Fast Test Kit (Immunofluorescence Assay) result as reported by the system (example) 10 pg/mL

The reported example results equal: 1.06 pmol/L

PERFORMANCE CHARACTERISTICS

1. Measuring Range 6.0-1900.0 pg/mL
2. Limit of Detection ≤ 6.0 pg/mL
3. Within-Run Precision ≤ 10%
4. Between-lot Precision ≤ 15%

REFERENCES

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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on PTH 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
	Contains sufficient for <n> tests	EU REP	Authorized representative
CE	CE mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		Keep dry
	Keep away from sunlight		Caution
UDI	Unique device identifier		

Thank you for using PTH Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use 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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