GP

CE IVD

fT4

Fast Test Kit

(Immunofluorescence Assay)

IF1068 for Getein 1100
IF5068 for Getein 1160
IF3068 for Getein 1180
REF IF2068 for Getein 1600
IF4068 for Getein 1200

Instructions for Use

INTENDED USE

fT4 Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of free T4 in human serum, plasma and whole blood samples. This test can be used as an aid in the assessment of thyroid status.

SUMMARY

Thyroxine (T4) is the main thyroid hormone secreted into the bloodstream by the thyroid gland. Together with triiodothyronine (T3), it plays a vital role in regulating the body's metabolic rate, influences the cardiovascular system, growth and bone metabolism, and is important for normal development of gonadal functions and nervous system.

T4 circulates in the bloodstream as an equilibrium mixture of free and serum bound hormone. Free T4 (fT4) is the unbound and biologically active form, which represents only 0.03 % of the total T4. The remaining T4 is inactive and bound to serum proteins such as thyroxine binding globulin (TBG, 75%), pre-albumin (15%), and albumin (10%). The determination of free T4 has the advantage of being independent of changes in the concentrations and binding properties of these binding proteins; additional determination of a binding parameter (T uptake, TBG) is therefore unnecessary. Therefore, free T4 is a useful tool in clinical routine diagnostics for the assessment of the thyroid status. It should be measured together with TSH if thyroid disorders are suspected and is also suitable for monitoring thyrosuppressive therapy.

PRINCIPLE

The test kit is based on immunofluorescence competitive method to quantitatively detect the content of T4 in human serum, plasma or whole blood.

The test uses an T4 monoclonal antibody conjugated with fluorescence and T4-BSA coated on the test line. After the sample has been applied to the test strip, the analyte competes with T4-BSA coated on the test line to bind to fluorescent labeled T4 monoclonal antibody and forms different antigen-antibody complexes respectively. The fluorescence intensity of test line has relationship with the amount of free T4 in sample.

CONTENTS

1. A kit for Getein 1100/Getein 1160/Getein 1180 contains:
Package specifications: 25 tests/kit, 10 tests/kit
1) Getein fT4 test card in a sealed pouch with desiccant
2) Disposable pipette
3) Reaction tube
4) Sample diluent
5) Instruction for use: 1 piece/kit
6) SD card: 1 piece/kit

2. A kit for Getein 1200/Getein 1600 contains:
Package specifications: 2×24 tests/kit, 2×48 tests/kit
Sealed cartridge with 24/48 Getein fT4 test cards
Instruction for use: 1 piece/kit

Materials required for Getein 1200/Getein 1600:
1) Sample diluent: 1 bottle/kit
2) Box with pipette tips: 96 tips/kit
3) Mixing plate: 1 piece/kit

3. A test card consists of:
A plastic shell and a reagent strip which is composed of a sample pad, nitrocellulose membrane, fluorescent labeled T4 monoclonal antibody, T4-BSA, polyclonal IgG antibody, absorbent paper and liner.

Note: Do not mix or interchange different batches of kits.

APPLICABLE DEVICE

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

STORAGE AND STABILITY

Store the test kit at 4~30°C with a valid period of 24 months.
Use the test card for Getein 1100/Getein 1160/Getein 1180 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. 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. For professional use only.
3. Do not use the kit beyond the expiration date.
4. Do not use the test card if the foil pouch or the cartridge is damaged.
5. Do not open pouches or the cartridge until ready to perform the test.
6. Do not reuse the test card.
7. Do not reuse the disposable pipette.
8. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
9. Carefully read and follow instruction for use to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum, plasma and whole blood samples***. Heparin, EDTA and sodium citrate can be used as the anticoagulant for plasma and whole blood. Samples should be free of hemolysis.
2. Suggest using serum and plasma samples for better results.
3. The test should be performed within 4 hours after whole blood collection.
4. If testing is delayed, serum and plasma samples may be stored up to 7 days at 2~8°C or stored at -20°C for 6 months before testing (whole blood sample may be stored up to 3 days at 2~8°C).
5. Refrigerated or frozen sample should be reached room temperature and be homogeneous before testing. Avoid multiple freeze-thawcycles.
6. Do not use heat-inactivated or hemolysis samples.
7. SAMPLE VOLUME ***(for Getein1100/Getein1160/ Getein1180): 100 µL***.

TEST PROCEDURE

1. Collect specimens according to instruction for use.
2. Test card, sample and reagent should be reached to room temperature before test.

For Getein 1100:
1. Confirm SD card lot No. in accordance with test kit lot No. Perform “SD card” calibration when necessary.
2. Remove the test card from the sealed pouch immediately before use. Put the test card on a clean table, horizontally placed.
3. Using a pipette or disposable pipette, add ***100 uL*** sample to a reaction tube then ***100 uL*** sample diluent to the same reaction tube, mix gently and thoroughly and wait for ***2-5 minutes***. Using a pipette or the same disposable pipette, deliver ***100 uL*** of the mixture into the sample well on the test card.

Note:
① It is necessary to squeeze the head of the disposable pipette when aspirating the liquid, ***make sure the liquid level is flush with the black scale line***, otherwise the sample volume will be inaccurate.
② It is recommended to wait ***2-5 minutes*** after mixing the samples, otherwise the test result will be inaccurate.

4. 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. Enter testing interface of Getein 1160/Getein 1180.
3. Remove the test card from the sealed pouch immediately before use. Put the test card on a clean table, horizontally placed.
4. Using a pipette or disposable pipette, add ***100 uL*** sample to a reaction tube then ***100 uL*** sample diluent to the same reaction tube, mix gently and thoroughly and wait for ***2-5 minutes***. Using a pipette or the same disposable pipette, deliver ***100 uL*** of the mixture into the sample well on the test card.

Note:
① It is necessary to squeeze the head of the disposable pipette when aspirating the liquid, ***make sure the liquid level is flush with the black scale line***, otherwise the sample volume will be inaccurate.
② It is recommended to wait ***2-5 minutes*** after mixing the samples, otherwise the test result 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 printed 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 the sample diluent at the correct position of Getein 1200/Getein 1600.
3. 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 test card and the sample insertion is correct and complete.

TEST 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 instruction for use of Getein 1100/Getein 1160/Getein 1180/Getein 1200/Getein 1600.

Others: Measuring range of the fT4 test kit is 0.30-100.00 pmol/L.

EXPECTED VALUE

The expected normal value for fT4 was determined by testing samples from 261 apparently healthy individuals. The reference range of fT4 is 12.00-22.00 pmol/L calculated by using normal distribution methods (99% confidence interval).

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

PERFORMANCE CHARACTERISTICS

Measuring Range	0.30-100.00 pmol/L
Lower Detection Limit	≤0.30 pmol/L
Within-Run Precision	≤15%
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. Interferents in samples may influence the results. The table below listed the maximum allowance of these potential interferent.

Interferent	Triglyceride	Bilirubin
Concentration(Max)	20g/L	0.1g/L

REFERENCES

1. Kronenberg HM, Melmed S, Polonsky KS, et al. Williams Textbook of Endocrinology. Saunders Elsevier, Philadelphia, 12th edition, 2011, chapter 10, p. 301-311.
2. DeGroot LJ, Larsen PR, Hennemann G. Transport of Thyroid Hormone and Cell Uptake. The Thyroid and Its Diseases. Wiley and Sons, New York, 1984:62-65.
3. Wu AHB. Tietz Clinical Guide to Laboratory Tests. Saunders Elsevier, Philadelphia, 4th edition, 2006.
4. Brent GA. Thyroid Function Testing. Springer, Berlin, 1st edition, 2010.
5. US Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories. 5th ed. Washington, DC: US Government Printing Office; January 2007.
6. World Health Organization. Laboratory Biosafety Manual. 3rd ed. Geneva: World Health Organization; 2004.
7. Clinical and Laboratory Standards Institute. Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline-Third Edition. CLSI Document M29-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2005.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on the test kit 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		

Thank you for purchasing fT4 Fast Test Kit (Immunofluorescence Assay).

Please read this instruction for use carefully before operating to ensure proper use.

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