CE IVD

fT4

Fast Test Kit

(Immunofluorescence Assay)

User Manual

REF **IF1068 for Getein1100**
IF3068 for Getein1180
IF2068 for Getein1600

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 anti-human T4 monoclonal antibody conjugated with fluorescence latex coated on the junction of nitrocellulose membrane and sample pad, and T4-BSA antigen coated on the test line. After the sample has been applied to the test strip, the analyte competes with T4-BSA antigen coated on the test line to bind to fluorescence-latex 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.
Then insert test card into Getein1100/Getein1180 Immunofluorescence Quantitative Analyzer/Automatically inserted by Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100, Getein1180 and Getein1600), the concentration of free T4 in sample will be calculated and displayed on the screen. The value will be stored in Getein1100/Getein1180/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100/Getein1180 contains:
Package specifications: 25 tests/box, 10 tests/box
1) Getein fT4 test card in a sealed pouch with desiccant
2) Disposable pipet
3) Sample diluent 1
4) User manual: 1 piece/box
5) SD card: 1 piece/box
2. A kit for Getein1600 contains:
Package specifications: 2×24 tests/kit, 2×48 tests/kit
Sealed cartridge with 24/48 Getein fT4 test cards
User manual: 1 piece/box
Materials required for Getein1600:
1) Sample diluent 1: 1 bottle/box
2) Box with pipette tips: 96 tips/box
3) 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 (the junction of membrane and sample pad is coated with fluorescence latex-labeled anti-human T4 monoclonal antibody, the test line is coated with T4-BSA antigen, 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
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1600 Immunofluorescence Quantitative Analyzer

STORAGE AND STABILITY

Store the test card at 4~30°C with a valid period of 24 months.
Use the test card for Getein1100/Getein1180 within 1 hour once the foil pouch is opened (Temperature: 4~30°C, Humidity: 30-80%).
For test card of Getein1600: 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 (Temperature: 4~30°C, Humidity: 30-80%).
Store the sample diluent 1 at 0~30°C with a valid period of 24 months.
Store the sample diluent 1 at 2~8°C for better results.

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 pipet.
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 user manual 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-thaw cycles.
6. Do not use heat-inactivated or hemolysis samples.
7. SAMPLE VOLUME (for Getein1100/Getein1180): ***40 μL***.

TEST PROCEDURE

1. Collect specimens according to user manual.

2. Test card, sample and reagent should be reached to room temperature before test.

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 ***40 μL*** of sample into one tube of sample diluent 1, mix gently and thoroughly for 2 min. Then drop ***100 μL*** of sample mixture into the sample port on the test card.
7. Reaction time: ***15 minutes***. Insert the test card into Getein1100 and click on “Start” icon after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1180:

8. Confirm SD card lot No. in accordance with test kit lot No.. Perform “SD card” calibration when necessary.
9. Enter testing interface of Getein1180.
10. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
11. Put the test card on a clean table, horizontally placed.
12. Using sample transfer pipette, deliver ***40 μL*** of sample into one tube of sample diluent 1, mix gently and thoroughly for 2 min. Then drop ***100 μL*** of sample mixture into the sample port on the test card.
13. ***Reaction time: 15 minutes***. Insert the test card into Getein1180 immediately after sample loading. The analyzer will count down the reaction time and automatically test the card after reaction time is elapsed. The result will be shoe on the screen and printed automatically.

For Getein1600:

14. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
15. Place the sample diluent 1 at the correct position of Getein1600.
16. 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/Getein1180.
3. Make sure the test card and the sample insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1180/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/Getein1180/Getein1600.

Others: Measuring range of the fT4 test kit is 0.30-100.00 pmol/L. Dilute the sample which concentration is higher than the upper limit with calf serum, and the dilution ration should be less than 4 times.

EXPECTED VALUE

The expected normal value for free T4 was determined by testing samples from 261 apparently healthy individuals. The reference range of free T4 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	≤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 interferent 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

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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 15223-1:2016.

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 fT4 Fast Test Kit (Immunofluorescence Assay).
Please read this user manual carefully before operating to ensure proper use.

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