CE IVD

fT3

Fast Test Kit

(Immunofluorescence Assay)

User Manual

REF IF1067 for Getein1100
IF3067 for Getein1180
IF2067 for Getein1600

INTENDED USE

fT3 Fast Test Kit (Immunofluorescence Assay) is intended for in vitro quantitative determination of free triiodothyronine(fT3) in human serum, plasma and whole blood. It is used as an aid in clinical routine diagnostics for the assessment of the thyroid status.

SUMMARY

Triiodothyronine (T3) is a thyroid hormone. It plays an important role in the body's control of metabolism. T3 circulates in the bloodstream as an equilibrium mixture of free and serum bound hormone. Free T3 (fT3) is the unbound and biologically active form, which represents only 0.2-0.4% of the total T3. The remaining T3 is inactive and bound to serum proteins, while the distribution of T3 between these binding proteins (thyroxine binding globulin, pre-albumin, albumin) is controversially discussed.
The detection of fT3 has the advantage of being independent of changes in the concentrations and binding properties of the binding proteins. Therefore, fT3 is a useful tool in clinical routine diagnostics for the assessment of the thyroid status. Free T3 measurements support the differential diagnosis of thyroid disorders, are needed to distinguish different forms of hyperthyroidism, and to identify patients with T3 thyrotoxicosis.

PRINCIPLE

The test kit is based on immunofluorescence competitive method to quantitatively detect the content of fT3 in human serum, plasma or whole blood.
The test uses an anti-human T3 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 T3-BSA antigen coated on the test line to bind to fluorescence-latex T3 monoclonal antibody and forms different antigen-antibody complexes respectively. The fluorescence intensity of test line has relationship with the amount of free T3 in sample.
Insert test card into Getein1100/Getein1180 Immunofluorescence Quantitative Analyzer/ Automatically inserted by Getein-1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100, Getein1180 and Getein1600), the concentrations of fT3 in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein-1180/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 fT3 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 (one end of the membrane is coated with Triiodothyronine (T3) monoclonal antibody, the test lines are coated with triiodothyronine(T3-BSA) antigen, and the control line is coated with rabbit Anti-mouse immunoglobulin G 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 at 4~40°C , 30%~80% of Humidity for Getein 1100/Getein1180 within 1 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.
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 is damaged.
5. 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 reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
6. Do not use heat-inactivated samples 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 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. Enter testing interface of Getein1100.
5. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
6. Put the test card on a clean table, horizontally placed.
7. 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 the treated sample to the test card.
8. ***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 Getein1180:

9. Confirm SD card lot No. in accordance with test kit lot No..Perform “SD card” calibration when necessary.
10. Enter testing interface of Getein1180.
11. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
12. Put the test card on a clean table,horizontally placed.
13. 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 the treated sample to the test card.
14. ***Reaction time: 15 minutes***. Insert the test card into Getein-1180 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:

15. Each cartridge for Getein1600 contains a specific RFID card which can calibrate automatically.
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 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 test kit is 0.40 pmol/L~50.00 pmol/L. Dilute the sample which concentration is higher than the upper limit, the dilution ratio should be less than 3 times.

EXPECTED VALUE

The expected normal value for fT3 and was determined by testing samples from 254 apparently healthy individuals. The reference range of fT3 is 3.10 pmol/L~6.80 pmol/L calculated by using normal distribution methods (95% confidence interval).

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

PERFORMANCE CHARACTERISTICS

Measuring range	0.40 pmol/L~50.00 pmol/L
Low of Detection	≤ 0.40 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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2. Zhu, Lijie et al. “[Relationship of serum free T3 with the coronary artery calcification and major adverse cardiac events in patients with suspected coronary artery disease].” Zhonghua xin xue guan bing za zhi 42 12 (2014): 1017-21.
3. Julia K, Heike H, Bianca N. Enantiorecognition of triiodothyronine and thyroxine enantiomers using different chiral selectors by HPLC and micro-HPLC. J. Biochem Biophys Methods. 2008, 70(6):1254-1260.
4. Klee GG. Clinical usage recommendations and analytic performance goals for total and free triiodothyronine measurements. Clin Chem. 1996, 42(1):155-159.

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 mark		Do not use if package is damaged
REF	Catalogue number		

Thank you for purchasing fT3 Fast Test Kit (Immunofluorescence Assay).

Please read this user manual carefully before operating to ensure proper use.

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