



ft3

Fast Test Kit

(Immunofluorescence Assay)

IF1067 for Getein 1100

IF5067 for Getein 1160

IF1067 for Getein 1180

IF2067 for Getein 1600

IF4067 for Getein 1200



Instruction for Use

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 T3 monoclonal antibody conjugated with fluorescence and T3-BSA coated on the test line. After the sample has been applied to the test strip, the analyte

competes with T3-BSA coated on the test line to bind to fluorescent labeled 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.

CONTENTS

1. A kit for Getein 1100/Getein 1160/Getein 1180 contains:

Package specifications: 25 tests/kit, 10 tests/kit

- 1) Getein ft3 test card in a sealed pouch with desiccant
- 2) Disposable pipette
- 3) Reaction tube
- 4) Sample diluent 5
- 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 ft3 test cards

Instruction for use: 1 piece/kit

Materials required for Getein 1200/Getein 1600:

- 1) Sample diluent 5: 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 T3 monoclonal antibody, T3-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 exposed to

air. If the test cards can't be used 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.

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.
6. Do not reuse the disposable pipette.
7. Handle all specimens as potentially infectious. Proper handling and disposal methods should be followed in accordance with local regulations.
8. 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 reach room temperature and be homogeneous before testing. Avoid multiple freezethaw cycles.
6. Do not use heat-inactivated samples or hemolysis samples.
7. **SAMPLE VOLUME (Getein 1100/Getein 1160/Getein 1180): 100 μ L.**

TEST PROCEDURE

1. Collect specimens according to instruction for use.
2. Test card, sample and reagent 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. Enter testing interface of Getein 1100.
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 μ L** sample to a reaction tube then **100 μ L** sample diluent 5 to the same reaction tube, mix gently and thoroughly and wait for **5-10 minutes**. Using a pipette or the same disposable pipette, deliver **100 μ L** 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 **5-10 minutes** after mixing the samples, otherwise the test result 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. 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.
- 5.Using a pipette or disposable pipette, add **100 μ L** sample to a reaction tube then **100 μ L** sample diluent 5 to the same reaction tube, mix gently and thoroughly and wait for **5-10 minutes**. Using a pipette or the same disposable pipette, deliver **100 μ L** 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 **5-10 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 automati-

cally 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. Put the sample diluent 5 at the correct position in 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 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 test kit is 0.60 pmol/L~50.00 pmol/L.

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	0.60 pmol/L~50.00 pmol/L
Low of Detection	≤ 0.60 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. Bowerbank, S.L., Carlin, M.G., & Dean, J. (2019). A direct comparison of liquid chromatography-mass spectrometry with clinical routine testing immunoassay methods for the detection and quantification of thyroid hormones in blood serum. Analytical and Bioanalytical Chemistry, 411, 2839 - 2853.
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 15223-1:2021.

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		Batch code
	Temperature limit		In vitro diagnostic medical device
	Contains sufficient for <n> tests		Authorized representative in the European Community/ European Union
	CE mark		Do not use if package is damaged and consult instructions for use
	Catalogue number		

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

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

Version: WIF71-S-10



Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.getein.com



CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo N° 18, CP 29006, Málaga, Spain
Tel: +34951214054