



FT3

Fast Test Kit

(Immunofluorescence Assay)

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 diagnosis of thyroid diseases. For professional and laboratory use only.

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

FT3 Fast Test Kit (Immunofluorescence Assay) 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 the test line decreases proportionally to the amount of free T3 in the sample. Fluorescent signals intensity can be analyzed by applicable device thus the free T3 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
FT3 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	/	/
Sample diluent	10 tubes	25 tubes	1 box	1 box
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

Note:

- 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".
- 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 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.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- For professional and laboratory use only, not for near-patient test and self-testing.
- Do not use the test card if the foil pouch or the cartridge is damaged.
- Do not open pouches until performing the test.
- Handle all specimens as potentially infectious. The foil bag is nondegradable. Proper handling and disposal methods should be followed in accordance with local regulations.
- It is recommended that operators take necessary self-protection measures (work clothes, goggles and disposable gloves, etc) when touching kits or samples.

SPECIMEN COLLECTION AND PREPARATION

- 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.
- Suggest using serum and plasma samples for better results.
- The test should be performed within 4 hours after whole blood collection.
- 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).
- Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
- Do not use heat-inactivated samples or hemolysis

samples.

7. SAMPLE VOLUME (**Getein 1100/Getein 1160/Getein 1180**): **100 µL**.

TEST PROCEDURE

- User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
- Test kit and sample should be brought to room temperature Instructions for Use 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 type on the analyzer (refer to the user manual of analyzer for details).
- (3) Remove the test card from the sealed pouch before use. Horizontally place the test card.
- (4) Using disposable pipet or pipette draw **100 µL** of sample into a reaction tube, then add **100 µL** sample diluent 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 µL** of the mixture into the sample well on the test card.

(5) **Reaction time: 15 minutes**. After reaction time is elapsed, insert the test card into Getein 1100 and press "ENT" button (click on "Start" icon for Android Getein 1100). 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 model on the analyzer (refer to the instructions of analyzer for details)
- (3) Remove the test card from the sealed pouch before use. Horizontally place the test card.
- (4) Using disposable pipet or pipette draw **100 µL** of sample into a reaction tube, then add **100 µL** sample diluent 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 µL** of the mixture into the sample well on the test card.
- (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 (SD card) which can calibrate automatically.
- (2) Place the sample diluent at the correct position in Getein 1200/Getein 1600.
- (3) Place samples in the designed area of the sample holder, insert the holder, set parameters (more operational details refer to the user manual of analyzer) and run the instrument. 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 for Getein 1100/ Getein 1160/Getein 1180.
2. 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.
3. It is recommended to wait **5-10 minutes** after mixing the samples, otherwise the test result will be inaccurate.

RESULTS

Getein 1100/Getein 1160/Getein 1180/Getein 1600/Getein 1200 can scan the test card automatically and display the result on the screen. For additional information, please refer to the instructions for use of Getein 1100/Getein 1160/Getein 1180/Getein 1600/ Getein 1200.

Others: Measuring range of the fT3 is 0.60 pmol/L~50.00 pmol/L.

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	Concentration (Max)
Triglyceride	20 g/L
Bilirubin	0.1 g/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
Limit of Detection	≤ 0.60 pmol/L
Within-run Precision	≤ 15%
Between-lot Precision	≤ 15%

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 fT3 Fast Test Kit (Immunofluorescence Assay) are the most

common ones appearing on medical devices and their packaging. They are explained in more detail 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 <i>instructions for use</i> or consult <i>electronic instructions for use</i>		Batch code
	Temperature limit		<i>In vitro</i> 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 <i>instructions for use</i>
	Catalogue number		Caution

Thank you for purchasing fT3 Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use.

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Catalogue number	Applicable analyzer	Package specification
IF1067-10T	Getein 1100	10 T/kit
IF1067	Getein 1100	25 T/kit
IF5067-10T	Getein 1160	10 T/kit
IF5067	Getein 1160	25 T/kit
IF3067-10T	Getein 1180	10 T/kit
IF3067	Getein 1180	25 T/kit
IF4067	Getein 1200	2*24 T/kit
IF4067-96T	Getein 1200	2*48 T/kit
IF2067	Getein 1600	2*24 T/kit
IF2067-96T	Getein 1600	2*48 T/kit