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CE IVD

T3

Fast Test Kit

(Immunofluorescence Assay)

IF1022 for Getein1100
IF5022 for Getein1160
IF3022 for Getein1180
REF IF4022 for Getein1200
IF2022 for Getein1600

Instructions for Use

INTENDED USE

T3 Fast Test Kit (Immunofluorescence Assay) is intended for *in vitro* quantitative determination of T3 in human serum and plasma samples. It can be used in the monitoring of hyperthyroidism and hypothyroidism, and also used as an aid in the functional diagnosis of thyroidea.

SUMMARY

The thyroid gland exerts powerful and essential regulatory influences on growth, differentiation, celluar metabolism and general hormonal balance, as well as on the maintenance of metabolic activity and the development of the sketeal and organ system. The hormones thyroxine (T4) and triiodothyronine (T3) circulate in the blood stream, mostly bound to the plasma protein,throxine binding globulin (TBG). The concentration of T3 is much less than that of T4, but its metabolic potency is much greater.

T3 is produced by the thyroid and secreted in response to TSH. T3 determination is an important factor in the diagnosis of thyroid disease. Its measurement has uncovered a variant of hyperthyroidism in thyrotoxic patients with elevated T3 levels and normal T4 levels. An increase in T3 without an increase in T4 is frequently a forerunner of recurrent thyrotoxicosis in previously treated patients. In other patients, euthyroidism attributable to normal T3, although their T4 values are subnormal.

In women, T3 levels are elevated during pregnancy, during estrogen treatment, and contraceptive hormone therapy. When T3 levels parallel TBG increases in a manner analogous to T4 levels, these changes are not reflection of altered thyroid status.

PRINCIPLE

The test uses anti-human T3 monoclonal antibody conjugated with fluorescence latex coated on the junction of nitrocellulose membrane and sample sad, and T3 antigen coated on the test line. After the sample has been applied to the test strip, the fluorescence latex-labelled anti-human T3 monoclonal antibody binds with the T3 in sample and forms marked antigen-antibody complex. The complex moves to the detection zone by capillary action and then it is captured on the test line by T3 antigen. The fluorescence intensity of the test line increases in proportion to the amount of T3 in sample.

Then Insert test card into Getein1100/Getein1160/Getein-1180 Immunofluorescence Quantitative Analyzer/Automatically inserted by Getein1200/Getein1600 Immunofluorescence Quantitative Analyzer (hereafter referred to as Getein1100, Getein1160, Getein1180, Getein1200 and Getein1600), the concentrations of T3 in sample will be measured and displayed on the screen. The value will be stored in Getein1100/Getein1160/Getein1180/Getein1200/Getein1600 and available for downloading. The result can be easily transmitted to the laboratory or hospital information system.

CONTENTS

1. A kit for Getein1100/Getein1160/Getein1180 contains:
Package specifications: 25 tests/kit, 10 tests/kit
1) Getein T3 test card in a sealed pouch with desiccant
2) Disposable pipet
3) Sample diluent 1
4) Instructions for use: 1 piece/kit
5) SD card: 1 piece/kit

2. A kit for Getein1200/Getein1600 contains:
Package specifications: 2×24 tests/kit, 2×48 tests/kit
1) Sealed cartridge with 24/48 Getein T3 test cards
2) Instructions for use: 1 piece/kit

Materials required for Getein1200/Getein1600:
1) Sample diluent 1: 1 bottle/kit
2) Box with pipette tips: 96 tips/kit
3) Mixing plate: 1 piece/kit

3. Sample diluent 1 composition:
Tris(hydroxymethyl)aminomethane,surfactant,preservative,purified water.

4. 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-labelled anti-human T3 monoclonal antibody, the test lines is coated with T3 antigen, and the control line C is coated with goat anti-mouse IgG antibody), absorbent paper and liner.

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

APPLICABLE DEVICES

Getein1100 Immunofluorescence Quantitative Analyzer
Getein1180 Immunofluorescence Quantitative Analyzer
Getein1160 Immunofluorescence Quantitative Analyzer
Getein1200 Immunofluorescence Quantitative Analyzer
Getein1600 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 Getein1100/Getein1160/Getein1180 within 1 hour once the foil pouch is opened.

For test card of Getein1200/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.

PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not use the test card if the foil pouch is damaged.
4. Do not open pouches until ready to perform the test.
5. Do not reuse the test card.
6. Do not reuse the pipet.
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 user manual to ensure proper test performance.

SPECIMEN COLLECTION AND PREPARATION

1. This test can be used for ***serum and plasma samples. Heparin, EDTA and sodium citrate*** can be used as the anticoagulant for plasma. Samples should be free of hemolysis.
2. 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.
3. Refrigerated or frozen sample should reach room temperature and be homogeneous before testing. Avoid multiple freeze-thaw cycles.
4. Do not use heat-inactivated samples or hemolysis samples.
5. SAMPLE VOLUME ***(for Getein1100/Getein1160/Getein1180): 100 μL.***

TEST PROCEDURE

1. Collect specimens according to instructions for use.
2. Test card, sample and reagent should be brought to room temperature before testing.

For Getein1100:
1. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
2. Enter testing interface of Getein1100.
3. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
4. Put the test card on a clean table, horizontally placed.
5. Using disposable pipet, deliver ***100 μL*** of sample into one tube of sample diluent 1, mix gently and thoroughly for 1~5 minutes. Then drop ***100 μL*** of the sample mixture into the sample well on the test card.
6. ***Reaction time: 15 minutes***. Insert the test card into Getein1100 and start test after reaction time is elapsed. The result will be shown on the screen and printed automatically.

For Getein1160/Getein1180:
1. Confirm SD card lot No. in accordance with test kit lot No.. Perform "SD card" calibration when necessary.
2. Enter testing interface of Getein1160/Getein1180.
3. Remove the test card from the sealed pouch immediately before use. Label the test card with patient or control identification.
4. Put the test card on a clean table,horizontally placed.
5. Using disposable pipet, deliver ***100 μL*** of sample into one tube of sample diluent 1, mix gently and thoroughly for 1~5 minutes. Then drop ***100 μL*** of the sample mixture into the sample well on the test card.
6. Insert the test card into Getein1160/Getein1180 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 Getein1200/Getein1600:
1. Each cartridge for Getein1200/Getein1600 contains a specific RFID card which can calibrate automatically.
2. Place the sample diluent 1 at the correct position in Getein1200/Getein1600.
3. Place samples in the designed area of the sample holder, insert the holder and select the right test item, Getein1200/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/Getein1160/Getein1180.
3. Make sure the test card insertion is correct and complete.

TEST RESULTS

Getein1100/Getein1160/Getein1180/Getein1200/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/Getein1160/Getein1180/Getein1200/Getein1600.

Others: Measuring range of the T3 test kit is 0.30 nmol/L~10.00 nmol/L. Dilute the sample which concentration is higher than the upper limit with calf serum or negative samples, and the dilution ratio should be less than 4 times.

EXPECTED VALUE

The expected normal value for T3 and was determined by testing samples from 391 apparently healthy individuals. The reference range of T3 is 1.30 nmol/L~3.10 nmol/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	0.30~10.00 nmol/L
Lower Detection Limit	≤0.30 nmol/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. Interferents in samples may influence the results.The table below listed the maximum allowance of these potential interferent.

Interferent	Hemoglobin	Triglyceride	Bilirubin
Concentration (Max)	5 g/L	25 g/L	0.1 g/L

REFERENCES

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DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on T3 Fast Test Kit (Immunofluorescence Assay) 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
	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 T3 Fast Test Kit (Immunofluorescence Assay).

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

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