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T3
Fast Test Kit
(Immunofluorescence Assay)

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 used as an aid in diagnosis of thyroid function.
For professional and laboratory use only.

SUMMARY

The thyroid gland exerts powerful and essential regulatory influences on growth, differentiation, cellular metabolism and general hormonal balance, as well as on the maintenance of metabolic activity and the development of the skeletal and organ system. The hormones thyroxine (T4) and triiodothyronine (T3) circulate in the blood stream, mostly bound to the plasma protein, thyroxine 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

T3 Fast Test Kit (Immunofluorescence Assay) is based on immunofluorescence competitive method to quantitatively detect the content of T3 in human serum or plasma.
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 T3 in the sample. Fluorescent signals intensity can be analyzed by applicable device thus the T3 in sample be detected quantitatively.

APPLICABLE DEVICES

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
T3 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
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:
1. 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".
2. 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

1. For *in vitro* diagnostic use only.
2. For professional and laboratory use only, not for near-patient test and self-testing.
3. Do not use the test card if the foil pouch or the cartridge is damaged.
4. Do not open pouches until performing the test.
5. Handle all specimens as potentially infectious. The foil bag is nondegradable. Proper handling and disposal methods should be followed in accordance with local regulations.
6. 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

1. This test can be used for ***serum and plasma***. 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 (***Getein 1100/Getein 1160/Getein 1180): 100 μL***.

TEST PROCEDURE

1. User must carefully read and operate in strict accordance with the instructions for use before testing, otherwise reliable results cannot be guaranteed.
2. Test kit and sample 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) 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, deliver ***100 μL*** of sample into one tube of sample diluent, mix gently and thoroughly for ***1~5 minutes***. Then drop 100 μL of the sample 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 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, deliver ***100 μL*** of sample into one tube of sample diluent, mix gently and thoroughly for ***1~5 minutes***. Then drop ***100 μL*** of the sample 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 Getein1200/Getein1600:
(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:

It is required to perform “SD card” calibration when using a new batch of kits for Getein 1100/ Getein 1160/Getein 1180.

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 T3 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.

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)
Hemoglobin	5 g/L
Triglyceride	25 g/L
Bilirubin	0.1 g/L

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 nmol/L~10.00 nmol/L
Limit of Detection	≤ 0.30 nmol/L
Within-run Precision	≤ 10%
Between-lot Precision	≤ 15%

REFERENCES

1. Spencer C A, LoPresti J S, Patel A, et al. Applications of a new chemiluminometric thyrotropin assay to subnormal measurement.J Clin Endocrinol Metab. 1990, 70(2):453-460.
2. Spencer C A, Takeuchi M, Kazarosyan M. Current status and performance goals for serum thyrolobulin assays. Clin Chem. 1996,42(1):164-173.
3. Koidl J, Hödl H, Schmid MG et al. 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. Keffer JH. Preanalytical considerations in testing thyroid function. Clin. Chem. 1996, 42(1):125-134. 5.Lindstedt G, Berg G, Jansson S, et al. Clinical use of laboratory thyroid tests and investigations. J Int Fed Clin Chem. 1994, 6(4):136-141.

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 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 *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 mark		Do not use if package is damaged and consult *instructions for use*
REF	Catalogue number		Caution

Thank you for purchasing T3 Fast Test Kit (Immunofluorescence Assay). Please read the instructions for use carefully before operating to ensure proper use.

Version: WIF24-S-10

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EC REP CMC Medical Devices & Drugs S.L.
Add.: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Tel: +34951214054

Catalogue number	Applicable analyzer	Package specification
IF1022-10T	Getein 1100	10 T/kit
IF1022	Getein 1100	25 T/kit
IF5022-10T	Getein 1160	10 T/kit
IF5022	Getein 1160	25 T/kit
IF3022-10T	Getein 1180	10 T/kit
IF3022	Getein 1180	25 T/kit
IF4022	Getein 1200	2*24 T/kit
IF4022-96T	Getein 1200	2*48 T/kit
IF2022	Getein 1600	2*24 T/kit
IF2022-96T	Getein 1600	2*48 T/kit