Total Thyroxine（TT4）Rapid Quantitative Test（Fluorescence immunoassay)
User manual

【Product name】

Total Thyroxine（TT4）Rapid Quantitative Test（Fluorescence immunoassay)

【Package specification】

25 Tests/kit

【Intended use】

This kit is used for quantitative determination of TT4 in human whole blood, plasma and serum.

The hormone thyroxine (T4) is the main product secreted by the thyroid gland and incorporated into the regulatory system in the axis hypothalamus-pituitary-thyroid gland. The metabolism of the anabolic effects. Thyroxine is produced in the coupling reaction two molecules of 3,5-dijodthyrosinu in the thyroid gland. Is stored in bound form on thyroglobulin in thyroid follicle lumens and is secreted under the influence of TSH. A substantial proportion (> 99%) of total thyroxine (T4) in serum is bound to proteins. The concentration of transport proteins in serum is subject to endogenous and exogenous factors, and therefore the status of these binding proteins should be taken into account when assessing levels of thyroid hormones in serum. Apart from the that changes in protein binding (eg, under the influence of estrogen on pregnancy, nephrotic syndrome, etc.) may be such that metabolic status of thyroid gland evaluate incorrectly.

Determination of TT4 may have the following indications: Evaluation of hyperthyroidism, Primary and secondary hypothyroidism and TSH suppression therapy monitoring.

【Test principle】

The TT4 Rapid Test is a one-step chromatographic sandwich immunoassay designed for the quantitative measurement of TT4. The T4 antigen in the sample was first bound with the conjugated compound of fluorescent labeled T4 monoclonal antibody, then moved and combined with another T4 monoclonal antibody fixed on the nitrocellulose membrane, and the double antibody sandwich complex was formed at the detection line of the cellulose nitrate membrane. The quantitative detection results were obtained by NIR-1000 dry fluoroimmunoassay analyser.

【Components】

Name	Quantity	Component
Test cards	25	It is composed of fluorescent pad (coated with fluorescent labeled T4 monoclonal mouse antibody), nitrocellulose membrane (coated with T4 monoclonal mouse antibody and Goat anti mouse IgG antibody), absorbent paper and backing
Sample diluent	25（200μL/tube）	Phosphate buffer
ID card	1	With specific stand curve file

The components in different batches of kits cannot be used interchangeably.

【Storage conditions and validity】

The kit should be stored at 4℃~30℃, out of direct sunlight. It is valid for 18 months. The test card should be used within 15 minutes after unsealing under the environment of 15℃~30℃ and 20% ~ 90% relative humidity.

The production date, batch number and expiration date are shown in the outer package of the product.

【Applicable instruments】

NIR-1000 dry fluoroimmunoassay analyser produced by WWHS Biotech. Inc.

【Sample requirements】

1. Plasma, serum and whole blood can be used as samples. The whole blood should be collected in a tube containing heparin, citrate or EDTA as the anticoagulant. If the serum procedure is used, collect blood in a tube without anticoagulant and allow clotting. Hemolyzed samples should not be used.
2. Venous blood was collected according to routine laboratory methods to avoid hemolysis.
3. It is highly recommended to use fresh samples instead of keeping the samples at room temperature for a long time. After samples were collected, the detection should be completed within 4 hours at room temperature (15℃~30℃). The whole blood sample can be stored at 2℃~8℃ for 24 hours. Plasma and serum samples can be stored at 2℃~ 8℃ for 7 days, -20℃for 30 days.
4. Before testing, the sample should return to room temperature (15℃~30℃). The frozen samples should be completely thawed, rewarming and mixed evenly before use. Repeated freeze-thaw cycles should be avoided.

【Test procedure】

1. Before the test, please read the instructions completely. If the test card and sample are stored in cold storage, they should be balanced at room temperature (15-30)℃ for not less than 30min before use.
2. Start NIR-1000 dry fluoroimmunoassay analyser and correctly select the corresponding sample type on the instrument.
3. Take out the ID card, make sure that the batch number of the ID card is consistent with that of the test card, and insert the ID card into the ID card port of the instrument.
4. Take out the test card from the aluminum foil bag and use it within 15 minutes.
5. Place the test card on a clean horizontal table and mark it horizontally.
6. Mix 100 μL of patient sample with 200μL of sample diluent. Apply 100 μL of diluted samples to the well of the test card.
7. At 15 minutes after addition of samples, insert the test card into NIR-1000 dry fluoroimmunoassay analyser and click the “Instant test” button to read the results.

【Reference interval】

Euthyroid adults are expected to have serum total thyroxine values between 66.0-181.0 nmoL/L. It is strongly recommended that each laboratory should determine its own normal and abnormal values. The results alone should not be the only reason for any therapeutic consequences. The results should be correlated to other clinical observations and diagnostic tests.

【Interpretation of results】

1. This reagent is only used for auxiliary detection. If the test results are abnormal, it should be reviewed in time and judged in combination with clinical symptoms.
2. For samples with TT4 concentration lower than 5.0nmoL/L and higher than 300.0nmoL/L, the detection results are reported as "<5.0nmoL/L" and ">300.0nmoL/L", respectively.
3. Unit conversion relationship: 1 nmoL/L×0.0777=1μg/dL

【Limitations of methods】

1. This kit is only used to detect human plasma/whole blood samples
2. Due to the limitations of immunoassay methods of antigen and antibody reaction, the results cannot be used as the only basis for clinical diagnosis, but should be evaluated with all the existing clinical and experimental data.
3. The content of triglyceride in the sample shall not exceed 15mg/ml, the content of hemoglobin shall not exceed 5mg/ml, and the content of bilirubin shall not exceed 0.5mg/ml, and the relative deviation of the test results shall not exceed ±15%。
4. When the concentration of T4 in the sample is less than 300 nmoL/L, there is no hook effect.
5. HAMA effect was not produced when the concentration of human anti rat in the sample was less than 50ng/ml.
6. When RF concentration in the sample is less than 2000IU/ml, the relative deviation of the test results is within ±15%.

【Performance】

1. Limits of detection

No higher than 5.0nmoL/L.

2. Accuracy

The relative deviation from the target value is within ±15%.

3. Precision

The within and between assay coefficient of variations are within 15%.

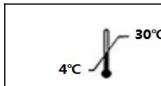
4. Linear range

Within the linear range (5.0 ~300.0 nmoL/L), the linear correlation coefficient R≥0.990.

【Note】

1. This kit is only used for in vitro diagnosis.
2. The test card and sample diluent are disposable and cannot be reused.
3. Please check the integrity and validity of the kit package before use, and then open the package. When it is stored at low temperature, it should be restored to room temperature (15℃ ~ 30℃) before opening the package for use. The reagents with damaged inner package and beyond the validity period cannot be used.
4. The requirements of specimen collection and storage should be strictly observed. If the specimen is turbid, it should be centrifuged and discarded before use.
5. The used kits should be treated as potential infectious substances, and all samples, reagents and potential pollutants should be disinfected and treated according to the relevant local regulations.

【Interpretation of signs】

	Storage temperature		Non reusable
	Avoid light	IVD	In vitro diagnostic reagents
	moisture-proof		See instruction manual

【Reference】

[1] Wheeler MH, Lazarus JH. Diseases of the Thyroid. London Glasgow, Weinheim, New York, Tokyo, Melbourne, Madras: Chapman and Hall Medical, 1994:108-115.

[2] Pfannenstiel P, Saller B. Schilddrüsenkrankheiten Diagnose und Therapie.Berliner Medizinische Verlagsanstalt GmbH, 1995; 02:43:00-62.97-106.

[3] Wenzel KW. Pharmacological interference with in vitro tests of thyroid function. Metabolism 1981 30 (7):717-732.

[4] Burrow GN. Thyroid status in normal pregnancy. J Clin Endocrinol Metabo 1990; 71:274-275.

【Essential information】

Registered/manufacturer name: WWHS Biotech. Inc

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