

T4

Thyroxine (FIA)

REF: IN017703



25

Intended use

The infinosiTM T4 is a fluorescence immunoassay (FIA) for the in vitro quantitative determination of thyroxine (total T4) in Human serum or plasma. For professional use only.

Summary

References¹⁻⁸

The hormone thyroxine (T4) is the main product secreted by the thyroid gland and is an integral component of the hypothalamus-anterior pituitary-thyroid regulating system. It has the function of anabolically influencing metabolism. Thyroxine is formed in a coupling reaction from two DIT molecules (3,5-diiodotyrosine) in the thyroid gland. It is stored bound to thyroglobulin in the lumina of the thyroid follicles and is secreted as required under the influence of TSH.

The major part (> 99 %) of total thyroxine (T4) in serum is present in protein-bound form. As the concentrations of the transport proteins in serum are subject to exogenous and endogenous effects, the status of the binding proteins must also be taken into account in the assessment of the thyroid hormone concentration in serum. If this is ignored, changes in the binding proteins (e.g. due to estrogen-containing preparations, during pregnancy or in the presence of a nephrotic syndrome etc.) can lead to erroneous assessments of the thyroid metabolic state.

The determination of T4 can be utilized for the following indications: the detection of hyperthyroidism, the detection of primary and secondary hypothyroidism, and the monitoring of TSH-suppression therapy.

Test principle

Competitive principle. Total duration of assay: **25 minutes**

Sample is added to the sample well of the test, the fluorescence-labeled detector T4 antibodies bind to T4 antigens in blood specimen and form immune complexes. As the complexes migrate on the nitrocellulose matrix by capillary action, it can't be captured by T4 antigens that have been immobilized on test strip, otherwise the excess unbound fluorescence-labeled detector T4 antibodies are captured. Thus the more T4 in blood, the less unbound fluorescence-labeled antibodies accumulated on test strip. Signal intensity of detector T4 antibodies reflect the amount of antigens and are processed in the instrument for infinosiTM tests to determine the T4 concentration in blood.

Reagents

Materials provided

- **Test cartridge**, 25 pcs, individually packaged
- **ID chip**, 1 pcs
- **Sample Buffer**, 25 tubes
- **IFU**, 1 copy

Materials required (but not provided)

- infinosiTM 2020 FIA analyzer
- T4 control (DiaSino control is recommended)
- Transfer pipette set (100 µL size)
- Centrifuge (for plasma and serum only)
- Timer

Precautions and warnings

- For in vitro diagnostic use only.
- Carefully follow the instructions and procedures described in this instructions before testing.
- The test cartridge should remain in its original sealed pouch until ready to use. Do not use it if the pouch is damaged or the seal is broken.
- Do not use reagents beyond the labeled expiry date.
- Do not mix or use components from kits with different Lots.
- Don't use Test Cartridge if its Lot does not match with ID Chip that is inserted onto the instrument.
- The infinosiTM T4 should be used only in conjunction with the instrument for infinosiTM tests.
- The tests should be applied by professionally trained staff working in certified laboratories at some remove from the patient and clinic at which the sample is taken by qualified medical personnel.
- infinosiTM T4 assay is single use only. Do not reuse it.
- The Test Cartridge and instrument for infinosiTM tests should be used away from vibration and magnetic field. During normal usage, the Test Cartridge may generate slight vibration, which should be regarded as normal.

- Use separate clean pipette tips and buffer tubes for different specimens. The pipette tips and detector buffer tubes should be used for one specimen only.
- Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
- Blood specimens, used test cartridges, pipette tips and sample buffer tubes are potentially infectious. Proper laboratory safety techniques, handling and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.
- The results should be interpreted by the physician along with clinical findings and other laboratory test results.

Incident report

Any suspected serious incidents related to this assay shall be immediately reported to DiaSino, DiaSino's Authorized Representative in the EU, and the national competent authorities of the Member States where the users and/or patients are located.

Storage and stability

- Store the test kit at 2-30°C, the stability is up to the expiration date printed on package.
- Test cartridge and sample buffer should be used within 1 hour after opening the pack.

Specimen collection and preparation

- The test can be performed with either serum or plasma.
- Collect serum samples in accordance with correct medical practices.
- Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (EDTA recommended).
- Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
- Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.

Quality control

- Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay and should be performed at regular intervals.
- The control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are provided on demand with infinosiTM tests. For more information regarding obtaining the control materials, contact [DiaSino Laboratories Co., Ltd](#) for assistance.

Test setup

- Ensure that the lot number of the cartridge matches that of the sample buffer, and the ID Chip.
- If the sealed cartridge and sample buffer have been stored in refrigerator, place them at room temperature (18-25 °C) at least 30 minutes before measurement.
- Turn on the instrument for infinosiTM tests. Refer to the *'instrument for infinosiTM tests Operation Manual'* for the complete information and operating instructions.

Test procedure

1. Insert ID Chip into the instrument for infinosiTM tests and read ID chip information.
2. Using a pipette to transfer **20 µL** of sample (Human plasma/serum) to the **sample buffer tube** provided in the kit.
3. Close the lid of the sample mixing tube and mix the sample thoroughly for **5-10 seconds**, then leave it at room temperature for **15 minutes**.
4. Pipette out **100 µL** of **sample mixture** and load it onto the sample well on the cartridge.
5. Leave the sample-loaded cartridge at room temperature for **10 minutes**.
6. Insert the sample-loaded cartridge into the cartridge holder of instrument for infinosiTM tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder.
7. Press **"Test"** button on the instrument for infinosiTM tests.
8. Instrument for infinosiTM tests will start scanning the sample-loaded cartridge immediately.

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- Read the test result on the display screen of the instrument for infinosiTM tests.
- Print out the testing results when press "Print" button on the instrument for infinosiTM tests.

Limitations - interference

- The assay is unaffected by icterus (bilirubin < 600 µmol/L or < 35 mg/dL), hemolysis (Hb < 0.559 mmol/L or < 0.9 g/dL), lipemia (Intralipid < 1200 mg/dL), and biotin < 94 nmol/L or < 23 ng/mL.
- Criterion: Recovery within ± 10 % of initial value.
- Heterophilic antibodies and rheumatoid factors in samples may interfere with test results. Heterophilic antibodies in human serum can react with reagent immunoglobulins, interfering with in vitro immunoassays. Patients routinely exposed to animals or animal serum products can be prone to this interference and anomalous values may be observed. Additional information may be required for diagnosis. This kind of samples is not suitable to be tested by this assay.
- Performance of this test has not been established with neonatal samples.
- Serum T4 concentration is dependent upon a multiplicity of factors: hypothalamus gland function and its regulation, TBG concentration, and the binding of T4 to TBG. Thus, total T3 concentration alone is not sufficient to assess clinical status.
- Patients who have received mouse monoclonal antibodies for either diagnosis or therapy can develop HAMA (human Anti-mouse antibodies). HAMA can produce either falsely high or falsely low values in immunoassays which use mouse monoclonal antibodies. Additional information may be required for diagnosis.

Measuring range

1.0-25 µg/dL (defined by the lower detection limit and the maximum of the master curve). Values below the detection limit are reported as <1.0 µg/dL. Values above the measuring range are reported as > 25 µg/dL.

Lower detection limit

1.0 µg/dL

The detection limit represents the lowest analyte level that can be distinguished from zero. It is calculated as the value lying two standard deviations above that of the lowest standard (master calibrator, standard 1+2 SD, repeatability study, n = 21).

Expected values

4.5-13.8 µg/dL

These values correspond to the 2.5th and 97.5th percentiles of results obtained from a total of 118 healthy test subjects examined.

We have not studied the reference intervals in children, adolescents and pregnant women.

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

Specific performance data

Representative performance data are given below. Results obtained in individual laboratories may differ.

Precision

Intra-assay

Determined by using 10 tests in the same batch to test with T4 control, CV ≤ 15%

Inter-assay

Determined by using 3 tests in 3 random and continuous batches to test with T4 control, CV ≤ 20%

Method comparison

A comparison of the infinosiTM T4 assay (y) with the Roche Elecsys T4 (x) using clinical samples gave the following correlation:

Number of samples measured: 137

Linear regression

$$y = 1.0296x - 1.2318$$

$$r = 0.9689$$

Analytical specificity

For the antibody derivative used, the following cross-reactivities were found: L-T4 and D-T4 100 %; L-T3 1.89 %; D-T3 1.44 %; 3-iodo-L-tyrosine 0.002 %; 3,5-diiodo-L-tyrosine 0.008 %.

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Functional sensitivity

1.15 µg/dL

The functional sensitivity is the lowest analyte concentration that can be reproducibly measured with an intermediate precision CV of ≤ 20 %.

References

- Wheeler MH, Lazarus JH. Diseases of the Thyroid. London, Glasgow, Weinheim, New York, Tokyo, Melbourne, Madras: Chapman and Hall Medical, 1994:108-115.
- Pfannenstiel P, Saller B. Schilddrüsenerkrankungen Diagnose und Therapie. Berliner Medizinische Verlagsanstalt GmbH, 1995;2:43-62,97-106.
- Wenzel KW. Pharmacological interference with in vitro tests of thyroid function. Metabolism 1981;30(7):717-732.
- Burrow GN. Thyroid status in normal pregnancy. J Clin Endocrinol Metab 1990;71:274-275.
- Lazarus JH, Othman S. Thyroid disease in relation to pregnancy. Clin Endocrinol 1991;34:91-98.
- Fisher DA. Physiological variations in thyroid hormones; physiological and pathophysiological considerations. Clinical Chemistry 1996;42:1,135-139.
- Burrow GN, Fisher DA, Larsen PR. Maternal and fetal thyroid function. N Engl J Med 1994;331:1072-1078.
- Nelson JC, Wilcox RB. Analytical performance of free and total thyroxine assays. Clinical Chemistry 1996;42:1,146-154.

Symbols



In vitro diagnostic medical device



Temperature limit



Consult instructions for use



Catalog number



Batch code



Date of manufacture



Use-by date



Contains sufficient for <n> tests



Manufacturer



Do not re-use



Do not use if package is damaged and consult instructions for use



European Conformity



Authorized representative in the European Community



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