FT4

infinosis™

Free Thyroxine (FIA)

REF: IN017705 Σ 25

Intended use
The infinosis™ Free T4 is a fluorescence immunoassay (FIA) for the in vitro quantitative determination of free thyroxine (FT4) in human serum or plasma. It is useful as an aid in management and monitoring of measurement in the assessment of thyroid function. For professional use only.

Summary
References[1,2,3,4]
The thyroid hormone thyroxine (T4) is physiologically part of the regulating circuit of the thyroid gland and has an effect on general metabolism. The major fraction of the total thyroxine is bound to transport proteins (TBG, prealbumin, and albumin). The free thyroxine (fT4) is the physiologically active thyroxine component.
The determination of free thyroxine is an important element in clinical routine diagnostics. Free T4 is measured together with TSH when thyroid function disorders are suspected. The determination of fT4 is also suitable for monitoring thyrosuppressive therapy.
The determination of free T4 has the advantage of being independent of changes in the concentrations and binding properties of the binding proteins; additional determination of a binding parameter (T-uptake, TBG) is therefore unnecessary.

Test principle
Competitive principle. Total duration of assay: **15 minutes**
Sample is added to the sample well of the test, the fluorescence-labeled detector FT4 antibodies bind to FT4 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 FT4 antigens that have been immobilized on test strip, otherwise the excess unbound fluorescence-labeled detector FT4 antibodies are captured. Thus the more FT4 in blood, the less unbound fluorescence-labeled antibodies accumulated on test strip. Signal intensity of detector FT4 antibodies reflect the amount of antigens and are processed in the instrument for infinosis™ tests to determine the FT4 concentration in blood.

Reagents
Materials provided
- **Test Cartridge**, 25 pcs, individually packaged
- **ID Chip** or **QR code of Calibration Curve**, 1 pcs
- **Sample Buffer,** 25 tubes
- **IFU**, 1 copy

Materials required (but not provided)
- infinosis™ FIA analyzer
- FT4 control (DiaSino control is recommended)
- Specimen collection containers
- 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 infinosis™ FT4 should be used only in conjunction with the instrument for infinosis™ 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.
- infinosis™ FT4 assay is single use only. Do not reuse it.
- The Test Cartridge and instrument for infinosis™ 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, handing 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 all the other components 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 infinosis™ 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 infinosis™ tests.
  Refer to the *'instrument for infinosis™ tests Operation Manual'* for the complete information and operating instructions.

Test procedure
1. Insert ID Chip into the instrument for infinosis™ tests or Scan the QR code to read the calibration curve.
2. Using a pipette to transfer **50 µL** of sample (Human plasma/serum) to the sample buffer tube provided in the kit. Close the lid of the sample mixing tube and mix the sample thoroughly for 5-10 seconds by tapping or inverting the tube.
3. Pipette out **100 µL** of **sample mixture** and load it onto the sample well on the cartridge.
4. Leave the sample-loaded cartridge at room temperature for **15 minutes.**
5. Insert the sample-loaded cartridge into the cartridge holder of instrument for infinosis™ tests.
   Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder.
6. Press **"Test"** button on the instrument for infinosis™ tests.
7. Instrument for infinosis™ tests will start scanning the sample-loaded cartridge immediately.
8. Read the test result on the display screen of the instrument for infinosis™ tests.
9. Print out the testing results when press **"Print"** button on the instrument for infinosis™ tests.

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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.
- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.
- 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.
- Serum FT4 values may be elevated under conditions such as pregnancy or administration of oral contraceptives.
- The interpretation of FT4 is complicated by a variety of drugs that can affect the binding of T4 to the thyroid hormone carrier proteins or interfere with its metabolism to T3.
- In rare conditions associated with extreme variations in albumin binding capacity for T4-such as FDH (familial dysalbuminemic hyperthyroxinemia)-direct assessment of FT4 may be misleading.
- Circulating antibodies to T4 and hormone binding inhibitors may interfere with the performance of the assay.
- If a patient, for some reason, reads higher than the highest calibrator report as such (e.g. > 100 pmol/l). Do not try to dilute the samples. TBG variations in different matrices will not allow FT4 hormone to dilute serially.
- A decrease in FT4 values is found with protein-wasting diseases, certain liver diseases and administration of testosterone, diphenylhydantoin or salicylates. A table of interfering drugs and conditions, which affect FT4 values, has been compiled by the Journal of the American Association of Clinical Chemists.
- 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
2.0-100 pmol/L (defined by the lower detection limit and the maximum of the master curve). Values below the detection limit are reported as <2.0 pmol/L. Values above the measuring range are reported as >100 pmol/L

Lower detection limit
2.0 pmol/L
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
11.5-23.8 pmol/L or 0.893-1.849 ng/dL
These values correspond to the 2.5th and 97.5th percentiles of results obtained from a total of 127 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 FT4 control, CV ≤ 15%
Inter-assay
Determined by using 3 tests in 3 random and continuous batches to test with FT4 control, CV ≤ 20%

Method comparison
A comparison of the infinosis™ FT4 assay (y) with the Roche Elecsys FT4 (x) using clinical samples gave the following correlation:

Number of samples measured: 117
Linear regression
y = 1.0595x - 1.5237
r = 0.9695

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 %.

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

References

1. Wheeler MH, Lazarus JH. Diseases of the Thyroid. London, Glasgow, Weinheim, New York, Tokyo, Melbourne, Madras: Chapman and Hall, 1994;107-115.
2. Pfannenstiel P, Saller B. Schilddrüsenkrankheiten Diagnose und Therapie. Berliner Medizinische Verlagsanstalt GmbH 1991;2:43-62,72-89.
3. Ekins RP. Measurement of free hormones in blood. Endocr Rev 1990;11:5.
4. Ekins RP, Ellis SM. The radioimmunoassay of free thyroid hormones in serum. In Robbins J, Braverman LE (eds). Thyroid research, Proceedings of the Seventh International Thyroid Conference, Boston. Amsterdam, Excerpta Medica 1975:597.

Symbols

IVD In vitro diagnostic medical device	2°C 30°C Temperature limit	Consult instructions for use	REF Catalog number
LOT 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	CE European Conformity
EC REP Authorized representative in the European Community			

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