T3

infinosis™

Triiodothyronine (FIA)

REF: IN017702 Σ 25

Intended use
The infinosis™ T3 is a fluorescence immunoassay (FIA) for the in vitro quantitative determination of triiodothyronine (T3) 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[1-7]
Triiodothyronine (T3) is the hormone principally responsible for the development of the effects of the thyroid hormones on the various target organs. T3 (3,5,3'-triiodothyronine) is mainly formed extrathyroidally, particularly in the liver, by enzymatic 5'-deiodination of T4. Accordingly, the T3 concentration in serum is more a reflection of the functional state of the peripheral tissue than the secretory performance of the thyroid gland.
A reduction in the conversion of T4 to T3 results in a decrease in the T3 concentration. It occurs under the influence of medicaments such as propanolol, glucocorticoids or amiodarone and in severe non-thyroidal illness (NTI), and is referred to as "low T3 syndrome". As with T4, over 99 % of T3 is bound to transport proteins. However, the affinity of T3 to them is around 10-fold lower.
The determination of T3 is utilized in the diagnosis of T3-hyperthyroidism, the detection of early stages of hyperthyroidism and for indicating a diagnosis of thyrotoxicosis factitia.

Test principle
Competitive principle. Total duration of assay: **25 minutes**
Sample is added to the sample well of the test, the fluorescence-labeled detector T3 antibodies bind to T3 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 T3 antigens that have been immobilized on test strip, otherwise the excess unbound fluorescence-labeled detector T3 antibodies are captured. Thus the more T3 in blood, the less unbound fluorescence-labeled antibodies accumulated on test strip. Signal intensity of detector T3 antibodies reflect the amount of antigens and are processed in the instrument for infinosis™ tests to determine the T3 concentration in blood.

Reagents
Materials provided
- **Test Cartridge**, 25 pcs, individually packaged
- **ID chip**, 1 pcs
- **Sample Buffer A,** 1 vial, 2.5 mL
- **Sample Buffer B,** 1 vial, 1 mL
- **Sample Mixing tube**, 25 tubes
- **IFU**, 1 copy

Materials required (but not provided)
- infinosis™ 2020 FIA analyzer
- T3 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™ T3 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™ T3 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 Sample Buffer B at 2-8℃.
- Store all the other components at 2-30℃, 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℃ for up to 3 days. For long-term storage, specimens should be kept below -20℃.

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 ℃) 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 and read ID chip information.
2. Using a pipette to transfer **80 µL** of **Sample Buffer A**, **30 µL** of **Sample Buffer B**, and **20 µL** of **sample** (Human plasma/serum) to the **Sample Mixing Tube** provided in the kit.
3. Close the lid of the sample mixing tube and mix the sample thoroughly for 5-10 seconds by tapping or inverting the tube, then leave the sample-loaded cartridge 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 infinosis™ tests.
   Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder.

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7. Press **"Test"** button on the instrument for infinosis™ tests.
8. Instrument for infinosis™ tests will start scanning the sample-loaded cartridge immediately.
9. Read the test result on the display screen of the instrument for infinosis™ tests.
10. Print out the testing results when press **"Print"** button on the instrument for infinosis™ 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 T3 concentration is dependent upon a multiplicity of factors: hypothalamus gland function and its regulation, TBG concentration, and the binding of T3 to TBG. Thus, total T3 concentration alone is not sufficient to assess clinical status.
- A decrease in total T3 values is found with protein-wasting diseases, certain liver diseases and administration of testosterone, diphenylhy- dantoin or salicylates. A table of interfering drugs and conditions, which affect total T3 values, has been compiled by the Journal of the American Association of Clinical Chemists.

Measuring range
0.40-8.0 ng/mL (defined by the lower detection limit and the maximum of the master curve). Values below the detection limit are reported as < 0.40 ng/mL. Values above the measuring range are reported as > 8.0 ng/mL

Lower detection limit
0.40 ng/mL
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
0.8-2.11 ng/mL
These values correspond to the 2.5th and 97.5th percentiles of results obtained from a total of 152 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 T3 control, CV ≤ 15%
Inter-assay
Determined by using 3 tests in 3 random and continuous batches to test with T3 control, CV ≤ 20%

Method comparison
A comparison of the infinosis™ T3 assay (y) with the Roche Elecsys T3 (x) using clinical samples gave the following correlation:

Number of samples measured: 112
Linear regression
y = 1.0309X - 0.2539
r = 0.9855

Analytical specificity
For the antibody derivative used, the following cross-reactivities were found: D-T3 100 %; L-T4 < 0.18 %; D-T4 < 0.18 %; L-rT3 < 0.05 %; L-T2 < 0.9 %.

Functional sensitivity
0.45 ng/mL
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 Medical, 1994:107-115.
2. Pfannenstiel P, Saller B. Schilddrüsenkrankheiten Diagnose und Therapie. Berliner Medizinische Verlagsanstalt GmbH, 1995;2:30-32,60-62.
3. Fisher DA. Physiological variations in thyroid hormones; physiological and pathophysiological considerations. Clinical Chemistry 1996;42:135-139.
4. Tietz NW. Clinical Guide To Laboratory Tests. 3rd ed. Philadelphia, Pa: WB Saunders Co, 1995:612.
5. Surks MI, Chopra IJ, Mariash CN, Nicoloff JT, Solomon DH. American Thyroid Association guidelines for use of laboratory tests in thyroid disorders. JAMA 1990;63:1529-1532.
6. Becker DV, Bigos ST, Gaitan E, Morris JC, Rallison ML, Spencer CA, et al. Optimal use of blood tests for assessment of thyroid function (letter). JAMA 1993;269:273.
7. Klee GG. Clinical usage recommendations and analytic performance goals for total and free triiodothyronine measurements. Clinical Chemistry 1996;42:155-159.

Symbols

IVD In vitro diagnostic medical device	 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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