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Hormone

AFIAS T3

INTENDED USE

AFIAS T3 is a fluorescence Immunoassay (FIA) for the quantitative determination of total Triiodothyronine (total T3) in human serum/plasma. It is useful as an aid in management and monitoring of thyroid disorders.

For *in vitro* diagnostic use only.

INTRODUCTION

3,5,3' Triiodothyronine (T3) is a thyroid hormone with a molecular weight of 651 daltons.[1]

T3 circulates in the blood as an equilibrium mixture of free and protein bound hormone.[2] T3 is bound to thyroxin binding globulin (TBG), prealbumin, and albumin. The actual distribution of T3 among these binding proteins is controversial as estimates range from 38-80 % for TBG, 9-27 % for prealbumin, and 11-35 % for albumin.[3]

T3 plays an important role in the maintenance of the euthyroid state. T3 measurements can be a valuable component in diagnosing certain disorders of thyroid function.[4] Most reports indicate that T3 levels distinguish clearly between euthyroid and hyperthyroid subjects, but provide a less clear-cut separation between hypothyroid and euthyroid subjects.[5] Total T3 measurements may be valuable when hyperthyroidism is suspected and the free T4 is normal.[6] For example, one recognized type of thyroid dysfunction is T3 thyrotoxicosis, associated with a decrease in serum thyroid stimulating hormone (TSH), increased T3 level, normal T4, normal free T4, and normal to increase in vitro Uptake results.[7-11]

T3 levels are affected by conditions which affect TBG concentration.[12-14] Slightly elevated T3 levels may occur in pregnancy or during estrogen therapy, while depressed levels may occur during severe illness, renal failure, myocardial infarction, alcoholism, inadequate nutritional intake, and during therapy with some medications such as dopamine, glucocorticoids, methimazone, propranolol, propylthiouracil, and salicylates.[6,15,16]

Numerous conditions unrelated to thyoid disease may cause abnormal T3 values.[5, 17-20] Consequently, total T3 values should not be used on their own in establishing the thyroid status of an individual. The level of serum T4, TSH and other clinical findings must be considered as well.

PRINCIPLE

The test uses a competitive immunodetection method. In this method, the target material in the sample binds to the fluorescence (FL)-labeled detection antibody in detection buffer, to form the complex as sample mixture. This complex is loaded to migrate onto the nitrocellulose matrix, where the covalent couple of T3 and bovine serum albumin (BSA) is immobilized on a test strip, and interferes with the binding of target material and FL-labeled antibody. If the more target material exists in blood, the less detection antibody is accumulated, resulting in the less fluorescence signal.

COMPONENTS

AFIAS T3 consists of 'Cartridge', 'Pipette tip', 'ID chip' and 'Instruction for use'.

- Each cartridge packaged in an aluminum pouch has three components, solution A part, solution B part and cartridge part.
- Cartridge part contains a test strip, the membrane which has anti human T3-BSA at the test line, while chicken IgY at the control line.
- Solution A part contains ANS and 0.1 % sodium azide as a preservative in NaOH solution.
- Solution B part contains anti human T3-fluorescence conjugate, anti chicken IgY-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and 0.1 % sodium azide in phosphate buffered saline (PBS) as a preservative.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use only.
- Carefully follow the instructions and procedures described in this 'Instruction for use'.
- Use only fresh samples and avoid direct sunlight.
- Lot numbers of all the test components (cartridge and ID chip) must match each other.
- Do not interchange the test components between different lots or use the test components after the expiration date, either of which might yield misleading of test result(s).
- The cartridge should remain sealed in its aluminum pouch until use. Do not use the cartridge if that is damaged or already opened.
- For shipping, samples must be packed in accordance with the regulations. Sample with severe hemolytic and hyperlipidemia cannot be used and should be recollected.
- Just before use, allow the cartridge and sample to be at room temperature for approximately 30 minutes.
- **AFIAS T3** as well as the instrument for AFIAS tests should be used away from vibration and/or magnetic field. During normal usage, it can be noted that the instrument for AFIAS tests may produce minor vibration.
- Used pipette tips, and cartridges should be handled carefully and disposed by an appropriate method in accordance with relevant local regulations.
- An exposure to larger quantities of sodium azide may cause certain health issues like convulsions, low blood pressure and heart rate, loss of consciousness, lung injury and respiratory failure.
- **AFIAS T3** will provide accurate and reliable results subject to the following conditions.
  - Use **AFIAS T3** should be used only in conjunction with the instrument for AFIAS tests.
  - Any anticoagulants other than **sodium heparin** should be avoided.

LIMITATIONS OF THE TEST SYSTEM

- The test may yield false positive result(s) due to the cross-reactions and/or non-specific adhesion of certain sample components to the capture/detector antibodies.
- The test may yield false negative result. The non-responsiveness of the antigen to the antibodies is most common where the epitope is masked by some unknown components, so as not to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may cause the false negative as it makes antigen unrecognizable by the antibodies.
- Other factors may interfere with the test and cause erroneous results, such as technical/procedural errors, degradation of the test components/reagents or presence of interfering substances in the test samples.
- Any clinical diagnosis based on the test result must be supported by a comprehensive judgment of the concerned physician including clinical symptoms and other relevant test results.

STORAGE AND STABILITY

- The cartridge is stable for 20 months (while sealed in an aluminum pouch) if stored at 2-8 °C.

MATERIALS SUPPLIED

REF SMFP-18

Components of **AFIAS T3**

- Cartridge Box Contains
  - Cartridge 24
  - Pipette Tip (Zipperbag) 24
  - ID Chip 1
  - Instruction For Use 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **AFIAS T3**.
Please contact our sales division for more information.

- **AFIAS-1** REF FPRR019
- **AFIAS-6** REF FPRR020
- **Boditech Hormone Control** REF CFPO-95
- **Boditech Hormone Calibrator** REF CFPO-107

SAMPLE COLLECTION AND PROCESSING

The sample type for **AFIAS T3** is human serum/plasma.

- It is recommended to test the sample within 24 hours after collection.
- The serum or plasma should be separated from the clot by centrifugation within 3 hours after the collection of whole blood.
- Samples may be stored for up to a week at 2-8 °C prior to being tested. If testing will be delayed more than a week, samples should be frozen at -20 °C or below.
- Samples stored frozen at -20 °C for 3 months showed no performance difference.
- Once the sample was frozen, it should be thawed one time and only for test, because repeated freezing and thawing can result in the changed test values.
- Sample must be mixed thoroughly after by low speed vortexing or by gently inverting, and centrifuged prior to use to remove particulate matter and to ensure consistency in the results.

TEST SETUP

- Check the components of the **AFIAS T3** as described below. : Cartridge, pipette tip, ID chip and instruction for use
- Keep the sealed cartridge (if stored in refrigerator) at room temperature for at least 30 minutes just prior to the test. Place the cartridge on a clean, dust-free and flat surface.
- Turn on the instrument for AFIAS tests.
- Empty the tip box.
- Insert the ID chip into the "ID chip port".
- Please refer to the instrument for AFIAS tests 'Operation Manual' for complete information and operating instructions.

TEST PROCEDURE

1) Take 150 µL of sample with a pipette and dispense it into the sample well on the cartridge.
2) Insert the cartridge into the cartridge holder.
3) Insert a tip into the tip hole of the cartridge.
4) Tap the 'START' icon on the screen.
5) The test result will be displayed on the screen after 10 minutes.

※ Note: Refer to the instrument for AFIAS tests Operation Manual to select sample type.

INTERPRETATION OF TEST RESULT

- The instrument for AFIAS tests calculate the test result automatically and displays T3 concentration of the test sample in terms of nmol/L.
- The working range of the **AFIAS T3** is 0.77-7.7 nmol/L.
- Conversion factor: nmol/L (SI unit) = 1.54 × ng/mL
  ng/dL = 100 × ng/mL
- The reference range[21]

Subject	ng/mL	nmol/L (SI unit)
Adult	0.8-2.0	1.23-3.08

*It is recommended that each laboratory establish its own reference range.

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 not provided with **AFIAS T3**. For more information regarding obtaining the control materials, contact Boditech Med Inc.'s Sales Division for assistance.
  (Please refer to the instruction for use of control material.)

PERFORMANCE CHARACTERISTICS

- **Analytical Sensitivity**

Limit of Blank	(LoB)	0.26 nmol/L
Limit of Detection	(LoD)	0.29 nmol/L
Limit of Quantification	(LoQ)	0.77 nmol/L

- **Analytical Specificity**
  - **Cross reactivity**
    There was no significant cross-reactivity from these materials with the **AFIAS T3** test measurements.

Cross reactants (Conc.)	Cross reactivity (%)
D-thyroxine (300 ng/ml)	0.08
L-thyroxine (300 ng/ml)	0.08
Reverse T3 (500 ng/ml)	0.09
Salicylic acid (1,000,000 ng/ml)	ND
Monoiodotyrosine (50,000 ng/ml)	ND

  - **Interference**
    Study of interference from table below with **AFIAS T3** showed following results. K_2EDTA and sodium citrate as an anticoagulants, had effect on **AFIAS T3** test in the procedure.

Interference materials (Conc.)	Interference (%)
D-glucose (60 mM/L)	< 0.7
L-Ascorbic acid (0.2 mM/L)	< 0.8
Bilirubin (0.4 mM/L)	< 0.1
Hemoglobin (2 g/L)	< 0.1
Cholesterol (13 mM/L)	< 5.5
Triglyceride (10 mg/ml)	< 2.3
K_2EDTA (10.8 mg/mL)	<16.2
Sodium heparin (54 mg/mL)	<1.1
Sodium citrate (40 mg/mL)	<14.8

- **Precision**
  [Intra-assay] The intra-assay precision was calculated by one evaluator, who tested different concentration of control standard 20 times each with three different lots of **AFIAS T3**.

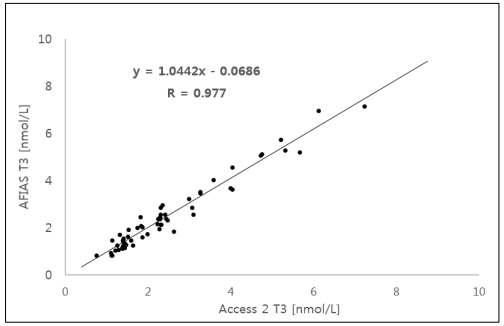
Control	Lot 1	Lot 2	Lot 3	AVG	SD	CV (%)
Level 1	1.08	1.11	1.03	1.06	0.110	10.3
Level 2	2.37	2.40	2.25	2.34	0.148	6.2
Level 3	6.39	6.41	6.11	6.30	0.284	4.5

[Inter-assay] The inter-assay precision was confirmed by 3 different evaluators with 3 different lot **AFIAS T3** during 5 days testing 3 times each different concentration.

Control	Between lot		Between run		Between day		Total	
	Avg.	CV (%)	Avg.	CV (%)	Avg.	CV (%)	Avg.	CV (%)
Level 1	1.07	10.3	1.10	10.0	1.07	8.9	1.09	9.2
Level 2	2.34	6.3	2.35	4.1	2.34	4.7	2.34	6.8
Level 3	6.30	4.5	6.21	3.4	6.34	4.1	6.25	4.1

- **Accuracy**
  The accuracy was confirmed by testing with three different lots of **AFIAS T3**. The recovery (%) in samples (1.08-6.16 nmol/L) were shown 90.3-107.4%.

- **Comparability**
  Using Beckman Coulter Access2 as a comparison machine for **AFIAS T3**, 64 serum samples were independently tested for its T3 concentration following each instrument's procedure. Results of both the test methods were analyzed and their comparability was investigated with linear regression and coefficient of correlation (R). The coefficient of correlation between the two methods was found to be 0.977.



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Note: Please refer to the table below to identify various symbols.

Σ	Sufficient for <n> tests
	Read instruction for use
	Use by Date
LOT	Batch code
REF	Catalog number
	Caution
	Manufacturer
EC REP	Authorized representative of the European Community
IVD	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
CE	This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices

For technical assistance; please contact:
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