QDx Instacheck™ T3

INTENDED USE

QDx Instacheck™ T3 is a fluorescence Immunoassay (FIA) for the quantitative determination of triiodothyronine (total T3) in human serum/plasma. It is useful as an aid in management and monitoring of determination 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 analyte in the sample binds to the fluorescence labeled (FL) 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, and interferes with the binding of analyte and fluorescence labeled (FL) antibody. If more analytes exist in the sample, less detection antibodies are accumulated, resulting in less fluorescence signal.

COMPONENTS AND REAGENTS

QDx Instacheck™ T3 consists of 'cartridges', 'detector tubes', 'detector diluents'.

- The cartridge contains the membrane called a test strip which has T3-BSA at the test line, and chicken IgY at the control line. All cartridges are individually sealed in an aluminum foil pouch containing a desiccant in a box.
- The detector tube has human T3-fluorescence conjugate, anti-chicken IgY-fluorescence conjugate, mouse IgG as a blocker, bovine serum albumin (BSA) and sucrose as a stabilizer and sodium azide as a preservative in sodium phosphate buffer.
- The detector diluents contain ANS, tween 20 and sodium azide in NaOH solution.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- 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, detector tube, detector diluent 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 incorrect test result(s).
- Do not reuse cartridges or detector tubes. A cartridge should be used for testing one sample only. A detector tube should be used for processing of one sample only.
- The cartridge should remain sealed in its original pouch until just before use. Do not use the cartridge, if is damaged or has already been opened.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with the local regulations. Sample with severe hemolysis and/or hyperlipidemia must not be used.
- The instrument for QDx Instacheck™ tests may generate slight vibration during use.
- Used cartridges, detector tubes, detector diluent and pipette tips should be handled carefully and discarded 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.
- No Biotin interference was observed in QDx Instacheck™ when biotin concentration in the sample was below 1200 ng/mL. If a patient has been taking biotin at dosage of more than 0.03 mg a day, it is recommended to test again 24 hours after discontinuation of biotin intake.
- **QDx Instacheck™ T3** will provide accurate and reliable results subject to the below conditions.
  - **QDx Instacheck™ T3** should be used only in conjunction the instrument for QDx Instacheck™ tests.
  - Have to use recommended anticoagulant sample.

Recommended anticoagulant
Sodium Heparin

STORAGE AND STABILITY

Storage condition			
Component	Storage Temperature	Shelf life	Note
Cartridge	4 - 30 °C.	20 months	Disposable
Detector tube	4 - 30 °C.	20 months	Disposable
Detector diluent	4 - 30 °C.	20 months	Unopened
	4 - 30 °C.	3months	opened

- After the cartridge pouch is opened, the test should be performed immediately.

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(s) due to the non-responsiveness of the antigen to the antibodies which is the most common if the epitope is masked by some unknown components, so therefore not being able to be detected or captured by the antibodies. The instability or degradation of the antigen with time and/or temperature may also cause false negative result 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.

MATERIALS SUPPLIED

REF IFPC-22

Components of QDx Instacheck™ T3

- Cartridge Box:
  - Cartridges 25
  - ID Chip 1
  - Instruction for Use 1
  - Detector Tube (Granule) 25
  - Detector Diluent (4.5mL) 2

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **QDx Instacheck™ T3**.

Please contact our sales division for more information.

- Instrument for QDx Instacheck™ tests
  - **QDx Instacheck™ Reader REF** FPRR010
  - **QDx Instacheck™ II REF** FPRR039
- **Printer REF** FPRR007
- **i-Chamber REF** FPRR009
- **Boditech Hormone Control REF** CFPO-95
- **Boditech T3 Control REF** CFPO-240

SAMPLE COLLECTION AND PROCESSING

The sample type for **QDx Instacheck™ 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 month at 2-8 °C prior to being tested. If testing will be delayed more than a month, samples should be frozen at -20 °C.
- Samples stored frozen at -20 °C for 2 months showed no performance difference.
- Once the sample was frozen, it should be used one time only for test, because repeated freezing and thawing can result in the change of test values.

TEST SETUP

1. Check the contents of **QDx Instacheck™ T3**: Sealed Cartridges, Detector tubes, Detector diluents, an ID Chip and Instruction for use.
2. Ensure that the lot number of the cartridges matches that of the detector tubes as well as the detector diluents and the ID chip.
3. If the sealed cartridge and the detection buffer have been stored in a refrigerator, place them on a clean and flat surface at room temperature for at least 30 minutes before testing.
4. Turn on the instrument QDx Instacheck™ test.
   (Please refer to the 'Instrument for QDx Instacheck™ test Operation Manual' for complete information and operating instructions.)

CAUTION

- To minimize erroneous test results, we suggest that the ambient temperature of the cartridge should be 25 °C during the reaction time after loading sample mixture to the cartridge.
- To maintain the ambient temperature to 25 °C, you can use various devices such as an i-Chamber or an incubator and so on.

TEST PROCEDURE

1. Transfer 300 µL of detector diluent using a pipette to a detector tube containing granule. When the granule is completely dissolved in the detector tube, it becomes detection buffer.
   (The detection buffer must be used immediately within 3 minute right after transferring diluent.)
2. Transfer 75µL of sample (Human serum/plasma/ control) using a transfer pipette to a detector tube.
3. Mix well by pipetting 10 times.
4. Close the lid of the detector tube and mix the sample thoroughly by shaking it about 10 times.
5. Incubate the detection buffer + sample mixture at room temperature for 8 minutes.
6. Pipette out 75 µL of a sample mixture and load it into the sample well on the cartridge.
7. Insert the sample-loaded cartridge into the slot of the i-Chamber or an incubator (25 °C).
8. Leave the sample-loaded cartridge in the i-Chamber or an incubator for 8 minutes.
   ⚠*Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inaccurate test result.*
9. To scan the sample-loaded cartridge, insert it into the test cartridge holder of the instrument for QDx Instacheck™ Tests. Ensure proper orientation of the test cartridge before pushing it all the way inside the test cartridge holder. An arrow is marked on the test cartridge especially for this purpose.
10. Press the 'Select' or Tab the 'Start' button on the instrument for QDx Instacheck™ tests to start the scanning process.
11. The instrument for QDx Instacheck™ tests will start scanning the sample-loaded cartridge immediately**.**
12. Read the test result on the display screen of the instrument QDx Instacheck™ tests.

INTERPRETATION OF TEST RESULT

- QDx Instacheck™ tests calculates the test result automatically and displays T3 concentration of the test sample in terms of ng/mL and nmol/L.
- The cut-off (reference range)

Age group of the subject			ng/mL	nmol/L (SI unit)
Adult			0.8–2.0	1.23–3.08
Pediatric Ranges	1-10 years		0.82–2.82	1.26 – 4.34
	11-15 years	Male	0.8–2.33	1.23–3.59
		Female	0.6–2.09	0.92–3.22
	16-17 years	Male	0.71–2.12	1.09–3.27
		Female	0.61–1.51	0.94–2.33

- Working range: 0.5-5.0 ng/mL (0.77-7.7 nmol/L)
- Conversion factor as unit of nmol/L
  - nmol/L (SI unit) = 1.54 × ng/mL
  - ng/dl = 100 × ng/mL

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 **QDx Instacheck™ 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)	0.23 ng/mL
Limit of Detection (LoD)	0.45 ng/mL
Limit of Quantitation (LoQ)	0.77 ng/mL

- **Analytical specificity**

  - Cross reactivity

    Biomolecules such as below the ones in the table were added to the test sample(s) at concentrations much higher than their normal physiological levels in the blood. **QDx Instacheck™ T3** test results did not show any significant cross-reactivity with these biomolecules.

Cross reactants	Concentration
D-thyroxine	300 ng/ml
L-thyroxine	300 ng/ml
Reverse T3	500 ng/ml
Salicylic acid	1,000,000 ng/ml
Monoiodotyrosine	50,000 ng/ml

  - Interference

    Interference materials such as below the ones in the table were added to the test sample(s) the same as the below concentrations. **QDx Instacheck™ T3** test results did not show any significant interference with these materials except for EDTA_K_2, sodium citrate.

Interference materials	Concentration
D-glucose	60 mM/L
L-Ascorbic acid	0.2 mM/L
Bilirubin	0.4 mM/L
Hemoglobin	2 g/L
Cholesterol	13 mM/L
triglyceride	10 mg/ml
EDTA_K_2	10.8 mg/ml
Sodium Heparin	54 mg/ml
Sodium Citrate	40 mg/ml

- **Precision**

  3 Lots of **QDx Instacheck™ T3** were tested for 21days (7days per 1 Lot at 1 site by one operator). Each standard material was tested 2 times per day. For each test, each material was duplicated.

  - **Repeatability (within-run precision)**

    Repeatability of **QDx Instacheck™ T3** was evaluated with results of 1 Lot.
  - **Total precision (within-laboratory)**

    Total precision (within-run, between-run, between-day) of **QDx Instacheck™ T3** was evaluated with results of 1 Lot.
  - **Lot to lot precision**

    Lot to lot precision of **QDx Instacheck™ T3** was evaluated with results of 3 Lots.

T3	Repeatability		Total precision		Lot to lot precision	
[nmol/L]	AVG	CV (%)	AVG	CV (%)	AVG	CV (%)
1.08	1.09	6.63	1.08	6.9	1.08	6.77
2.31	2.32	6.26	2.31	6.6	2.32	6.25
6.16	6.16	6.58	6.17	6.3	6.18	6.22

  - Between person

    Three different persons tested **QDx Instacheck™ T3**; ten times at each concentration of the control standard.
  - Between site

    One person tested **QDx Instacheck™ T3** at three different sites; three times at each concentration of the control standard.

T3	Between site		Between person	
[nmol/L]	AVG	CV (%)	AVG	CV (%)
1.08	1.08	0.07	1.08	0.06
2.31	2.32	0.11	2.27	0.14
6.12	6.14	0.39	6.16	0.35

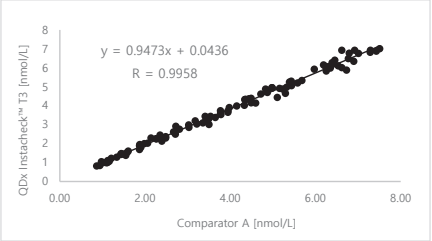
- **Accuracy**

  The accuracy was confirmed by testing with 3 different lots of **QDx Instacheck™ T3.** The tests are repeated ten times in each different concentration.

Expected value [nmol/L]	Lot 1	Lot 2	Lot 3	AVG	Recovery (%)
6.16	6.05	6.14	6.09	6.09	98.91
5.14	5.11	5.27	5.33	5.23	101.8
4.13	4.14	4.09	4.24	4.15	100.7
3.11	3.18	3.16	3.05	3.13	100.7
2.09	2.08	2.05	2.09	2.07	99.0
1.08	1.09	1.12	1.04	1.08	100.5

- **Comparability**

  T3 concentrations of 100 serum samples were quantified independently with **QDx Instacheck™ T3 (QDx Instacheck™ II)** and Comparator A as per prescribed test procedures. Test results were compared, and their comparability was investigated with linear regression and coefficient of correlation (R). Linear regression and coefficient of correlation between the two tests were y = 0.9473x +0.0436 and R = 0.9958 respectively.



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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

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