



# ichroma™

## T4

### INTENDED USE

**ichroma™ T4** is a fluorescence Immunoassay (FIA) for the quantitative determination of thyroxine (T4) in human serum/plasma. It is useful as an aid in management and monitoring of thyroid disorder. For *in vitro* diagnostic use only.

### INTRODUCTION

Thyroxine (T4) is one of two major hormones produced by the thyroid gland (the other is called triiodothyronine, or T3). T4 and T3 are regulated by a sensitive feedback system involving the hypothalamus and the pituitary gland. The hypothalamus releases the thyrotropin-releasing hormone (TRH), which stimulates the pituitary to release the thyroid stimulating hormone (TSH). This causes the thyroid to release T3 and T4 and these in turn regulate the release of TRH and TSH via a feedback control mechanism. Normally, elevated blood levels of T4 and T3 act to decrease the amount of TSH secreted, thereby reducing the production and release of T4 and T3. Over 99% of T4 is reversibly bound to three plasma proteins in blood: thyroxine binding globulin (TBG) binds close to 70%, thyroxine binding pre-albumin (TBPA) binds 20%, and albumin binds 10%. Approximately 0.03% of T4 is in the free, unbound state in blood at any one time.

T4 is a useful marker for the diagnosis of hypothyroidism and hyperthyroidism. The level of T4 decreases in hypothyroidism, myxedema and chronic thyroiditis (Hashimoto's disease). Increased levels of T4 have been found in hyperthyroidism due to Grave's disease and Plummer's disease.

### 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 T4 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

**ichroma™ T4** consists of 'Test cartridges', 'Detection Buffer Tubes' and an 'ID chip'.

- The test cartridge contains a test strip, the membrane which has bovine serum albumin (BSA) conjugated T4 at the test line, while streptavidin at the control line.
- Each test cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed test cartridges are packed in a box which also contains an ID chip.
- The detection buffer contains anti human T4-fluorescence conjugate, biotin-BSA-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide as a preservative in phosphate buffered saline.
- The detection buffer is pre-dispensed in a tube. 25 detection buffer tubes are packaged in a Box and further packed in a Styrofoam box with ice-pack for the shipment.

### 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 (test cartridge, ID chip and detection buffer) 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).
- Do not reuse. A detection buffer tube should be used for processing one sample only. So should a test cartridge.
- The test cartridge should remain sealed in its original pouch before use. Do not use the test cartridge, if is damaged or already opened.
- Frozen sample should be thawed only once. 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 test cartridge, detection buffer and sample to be at room temperature for approximately 30 minutes.
- **ichroma™ T4** as well as the instrument for **ichroma™** tests should be used away from vibration and/or magnetic field. During normal usage, it can be noted that instrument for **ichroma™** tests may produce minor vibration.
- Used detection buffer tubes, pipette tips and test cartridges 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.
- **ichroma™ T4** will provide accurate and reliable results subject to the following conditions.
  - Use **ichroma™ T4** should be used only in conjunction with instrument for **ichroma™** tests.
  - Any anticoagulants other than EDTA should be avoided.

### STORAGE AND STABILITY

- The test cartridge is stable for 20 months (while sealed in an aluminum foil pouch) if stored at 4 - 30°C.
- The detection buffer pre-dispensed in a tube is stable for 20 months if stored at 2 - 8°C.
- After the test cartridge pouch is opened, the test should be performed immediately.

### LIMITATION 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.

## MATERIALS SUPPLIED

### REF CFPC-26

#### Components of **ichroma™ T4**

- Test Cartridge Box:
  - Test Cartridges 25
  - ID Chip 1
  - Instruction For Use 1
- Box containing Detection Buffer Tubes
  - Detection Buffer tubes 25

## MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **ichroma™ T4**. Please contact our sales division for more information.

- Instrument for **ichroma™** tests
  - **ichroma™** Reader **REF** FR203
  - **ichroma™** D **REF** 13303
- **ichroma™** Printer **REF** FPRR007
- **ichroma™** Universal Control **I** **REF** CFPO-25

## SAMPLE COLLECTION AND PROCESSING

The sample type for **ichroma™ T4** 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. If longer storage is required, e.g. if the test could not be performed within 24 hours, serum or plasma should be immediately frozen below -20°C. The freezing storage of sample up to 3 months does not affect the quality of results.
- 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

- Check the contents of **ichroma™ T4**: Sealed Test Cartridge, Detection Buffer Tubes and ID Chip.
- Ensure that the lot number of the test cartridge matches that of the ID chip as well as the detection buffer.
- Keep the sealed test cartridge (if stored in refrigerator) and the detection buffer tube at room temperature for at least 30 minutes just prior to the test. Place the test cartridge on a clean, dust-free and flat surface.
- Turn on the instrument for **ichroma™** tests.
- Insert the ID Chip into the ID chip port of the instrument for **ichroma™** tests.
- Press the 'Select' button on the instrument for **ichroma™** tests. (Please refer to the 'Instrument for **ichroma™** tests Operation Manual' for complete information and operating instructions.)

## TEST PROCEDURE

- 1) Transfer 10 µL (Human serum / plasma / control) of sample using a transfer pipette to a tube containing the detection buffer.
- 2) Close the lid of the detection buffer tube and mix the sample thoroughly by shaking it about 10 times. (The sample mixture must be used immediately.)
- 3) Pipette out 75 µL of a sample mixture and load it into the sample well on the test cartridge.
- 4) Leave the sample-loaded test cartridge at room temperature for 10 minutes.
- 5) To scan the sample-loaded cartridge, insert it into the cartridge holder of the instrument for **ichroma™** tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow has been marked on the cartridge especially for this purpose.
- 6) Press 'Select' button on the instrument for **ichroma™** tests to start the scanning process.
- 7) Instrument for **ichroma™** tests will start scanning the sample-loaded cartridge immediately.
- 8) Read the test result on the display screen of the instrument for **ichroma™** tests.

## INTERPRETATION OF TEST RESULT

- Instrument for **ichroma™** tests calculates the test result automatically and displays T4 concentration of the test sample in terms of nmol/L and µg/dL.
- T4 Conversion factor is 12.87(1 µg/dL = 12.87 nmol/L)
- The cut-off (reference range)

State	Range
Normal value	60-120 nmol/L
Hyperthyroidism	> 140 nmol/L
Hypothyroidism	< 50 nmol/L
- Working range : 20~300.0 nmol/L

## 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 **ichroma™ T4**. 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

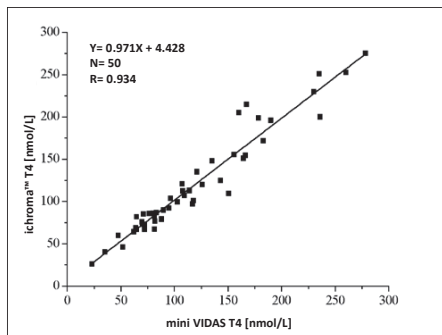
- **Specificity:** There, in test samples, are biomolecules such as below the table were added to the test sample(s) at concentrations much higher than their normal physiological levels in blood. **ichroma™ T4** test results did not show any significant cross-reactivity with these biomolecules.

Compound	Spiked concentration (nmol/L)	%Cross-reactivity
Tetraiodothyroacetic Acid	300	5.16
Moniodotyrosine	1,000	0.01
Diiodotyrosine	1,000	<0.01
Phenytoln	1,000	<0.01
Phenylbutazone	1,000	<0.01
l-Triiodothyronine	500	1.24
d-Triiodothyronine	500	0.81
l-Tyrosine	5,000	<0.01
d-Tyrosine	5,000	<0.01

- **Precision:** The intra-assay precision was calculated by one evaluator, who tested different concentration of control standard twenty times each with three different lots of **ichroma™ T4**. The inter-assay precision was confirmed by 3 different evaluators with 3 different lots, testing ten times each different concentrations.

Sample (nmol/L)	Intra-assay		Inter-assay	
	Mean (nmol/L)	CV (%)	Mean (nmol/L)	CV (%)
31.2	31.5	4.6	31.2	4.9
79.4	79.9	5.0	80.5	4.3
118.5	121.1	4.1	121.5	4.4
285.2	289.3	1.5	289.6	2.2












- Comparability:** T4 concentrations of 50 clinical samples were quantified independently with **ichroma™ T4** and mini VIDAS (BioMerieux Inc. France) 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  $Y = 0.971X + 4.428$  and  $R = 0.934$  respectively.



## REFERENCES

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- Larsen P.R., Dockalova J., Sipula D., Wu F. M. Immunoassay of Thyroxine in unextracted Human Serum. *J. Clin. Endocrinol. Metab.*, 1973, 37(2):177-182
- Wagner M. S., Wajner S. M., Maia A. L. The Role of Thyroid Hormone in testicular Development and Function. *J. Endocrinol.*, 2008, 199(3) : 351-365
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**Note:** Please refer to the table below to identify various symbols

	Read instructions for use
	Use by
	Batch code
	Catalog number
	Caution
	Manufacturer
	Authorized representative of the European Community
	In vitro diagnostic medical device
	Temperature limit
	Do not reuse
	This product fulfills the requirements of the Directive 98/79/EC on in vitro diagnostic medical devices

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