Hormone

IVD

ichroma™ TSH

INTENDED USE

ichroma™ TSH is a fluorescence Immunoassay (FIA) for the quantitative determination of TSH in human serum/plasma. It is useful as an aid in management and monitoring of measurement in the assessment of thyroid function.

For *in vitro* diagnostic use only.

INTRODUCTION

The determination of serum or plasma levels of thyroid stimulating hormone (TSH or thyrotropin) is recognized as an important measurement in the assessment of thyroid function. Thyroid stimulating hormone is secreted by the anterior lobe of the pituitary gland, and induces the production and release of thyroxine (T4) and triiodothyronine (T3) from the thyroid gland. It is a glycoprotein with a molecular weight of approximately 28,000 daltons, consisting of two chemically different subunits, alpha and beta. Although the concentration of TSH in the blood is extremely low, it is essential in the maintenance of normal thyroid function. The release of TSH is regulated by a TSH-releasing hormone (TRH) produced by the hypothalamus. The levels of TSH and TRH are inversely related to the level of thyroid hormone. When there is a high level of thyroid hormone in the blood, less TRH is released by the hypothalamus, so less TSH is secreted by the pituitary. The opposite action will occur when there are decreased levels of thyroid hormones in the blood. This process, known as a negative feedback mechanism, is responsible for maintaining the proper blood levels of these hormones.

PRINCIPLE

The test uses a sandwich immunodetection method; the detector antibodies in buffer bind to antigens in sample, forming antigen-antibody complexes, and migrate onto nitrocellulose matrix to be captured by the other immobilized-antibody on test strip.

More antigens in the sample will form more antigen-antibody complexes which lead to stronger fluorescence signal by detector antibodies, which is processed by instrument for ichroma™ tests to show TSH concentration proportional to the amount of antibody in the sample.

COMPONENTS

ichroma™ TSH consists of 'Cartridges', 'Detector Vials, 'Detector Diluent', 'Mixing Tubes' and an 'ID chip'.

- The cartridge contains a test strip, the membrane which has anti human TSH at the test line, with chicken IgY at the control line.
- Each cartridge is individually sealed in an aluminum foil pouch containing a desiccant. 25 sealed cartridges are packed in a box which also contains an ID chip.
- The Detector vial contains anti human TSH-fluorescence conjugate, Anti-chicken IgY-fluorescence conjugate, bovine serum albumin (BSA) as a stabilizer and sodium azide as a preservative in phosphate buffered saline (PBS).
- The detection buffer in lyophilized form is in 2 vials.
- The Detector diluent contains sodium azide as a preservative in distilled water.
- The Detector diluent is dispensed in a vial.
- The Detector vial and Detector diluent are packed in cartridge box with mixing tubes.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Follow 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, ID chip, detector vial and detector diluent) 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. A cartridge should be used for testing one sample only.
- The cartridge should remain sealed in its original pouch until just before use. Do not use the cartridge, if pouch is damaged or has already been opened.
- Frozen sample should be thawed only once. For shipping, samples must be packed in accordance with local regulations. Sample with severe hemolysis and/or hyperlipidemia must not be used.
- Allow Cartridge, detector vial, detector diluent and sample to be at room temperature for approximately 30 minutes before use.
- The instrument for ichroma™ tests may generate slight vibration during use.
- Used mixing tubes, pipette tips and 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™ TSH** will provide accurate and reliable results subject to the below conditions.
  - **ichroma™ TSH** should be used only in conjunction with instrument for ichroma™ tests.
  - Have to use recommended anticoagulant sample.

Recommended anticoagulant
Sodium Heparin

STORAGE AND STABILITY

Component	Storage condition: Storage Temperature	Shelf life	Note
Cartridge	4 - 30 °C.	20 months	Disposable
Detector Vial	4 - 30 °C.	20 months	Unopened
	4 - 30 °C.	1 month	Opened
Detector diluent	4- 30 °C.	20 months	Unopened
	4- 30 °C.	3 months	Opened

- After the detector diluent is added to the detector vial for reconstitution, it is stable for a month if stored at 4-30 °C with the lid closed.
- After the 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(s) due to the non-responsiveness of the antigen to the antibodies which is 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 CFPC-22

Components of **ichroma™ TSH**

- Cartridge Box:
  - Cartridges 25
  - ID Chip 1
  - Instruction for Use 1
  - Mixing Tubes 25
  - Detector vial (Lyophilized) 2
  - Detector diluent (2.5mL) 1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from **ichroma™ TSH**.

Please contact our sales division for more information.

- Instrument for ichroma™ tests
  - **ichroma™ Reader** REF FR203
  - **ichroma™ II** REF FPRR021
- **Printer** REF FPRR007
- **Boditech Hormone Control** REF CFPO-95

SAMPLE COLLECTION AND PROCESSING

The sample type for **ichroma™ TSH** 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 2 weeks at 2-8 °C prior to being tested.
- If testing will be delayed more than 2 weeks, samples should be frozen at -20 °C. Samples stored frozen at -20 °C for 3 months doesn't 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™ TSH**: Sealed Cartridge, Detector vials, Detector diluent, Mixing Tubes, ID Chip.
- Ensure that the lot number of the cartridge matches that of the ID chip as well as the detector vial and detector diluent.
- Keep the sealed cartridge (if stored in refrigerator), detector vial and detector diluent 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 ichroma™ tests. (Please refer to the 'Instrument for ichroma™ tests Operation Manual' for complete information and operating instructions.)

TEST PROCEDURE

<Multi Mode>

1) Transfer 1,000 µL of detector diluent using a pipette to a detector vial (Lyophilized form).
2) Close the lid of the detector vial and allow it to stand for 30 minutes before use. Contents are completely dissolved by swirling gently.
   ※ Avoid formation of foam. Do not shake.
3) When the lyophilized form is completely dissolved in the vial, it becomes detection buffer.
4) Transfer 150 µL of sample (Human serum/plasma/control) using a transfer pipette to a mixing tube.
5) Add 75 µL detection buffer to the mixing tube containing sample.
6) Close the lid of the mixing tube and mix the sample

thoroughly by shaking it about 10 times. (The sample mixture must be used immediately.)

7) Pipette out 75 µL of a sample mixture and load it into the sample well on the cartridge.
8) Leave the sample-loaded cartridge at room temperature for 12 minutes.
   ⚠ *Scan the sample-loaded cartridge immediately when the incubation time is over. If not, it will cause inexact test result.*
9) 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.
10) Press 'Select' or Tab 'START' button on the instrument for ichroma™ tests to start the scanning process.
11) Instrument for ichroma™ tests will start scanning the sample-loaded cartridge immediately.
12) Read the test result on the display screen of the instrument for ichroma™ tests.

<Single Mode>

1) Transfer 1,000 µL of detector diluent using a pipette to a detector vial.
2) Close the rid of the detector vial and allow it to stand for 30 minutes before use. Contents are completely dissolved by swirling gently.
   ※ Avoid formation of foam. Do not shake.
3) When the lyophilized form is completely dissolved in the vial, it becomes detection buffer.
4) Transfer 150 µL of sample (Human serum/plasma/control) using a transfer pipette to a mixing tube.
5) Add 75 µL detection buffer to the mixing tube containing sample.
6) Close the lid of the mixing tube and mix the sample thoroughly by shaking it about 10 times. (The sample mixture must be used immediately.)
7) Pipette out 75 µL of a sample mixture and load it into the sample well on the cartridge.
8) Inserting the sample-loaded cartridge into the 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.
9) Press 'Select' or Tab 'START' button on the instrument for ichroma™ tests to start the scanning process.
10) The cartridge goes inside the Instrument for ichroma™ tests and the instrument for ichroma™ tests will automatically start scanning the sample-loaded cartridge after 12 minutes.
11) 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 TSH concentration of the test sample in terms of µIU/mL.
- The reference range

Type	TSH(µIU/mL)
Adults	0.34-5.6

- Working range : 0.1-100 µIU/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 not provided with **ichroma™ TSH**. 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)	0.03 µIU/mL
Limit of Detection (LoD)	0.07 µIU/mL
Limit of Quantitation (LoQ)	0.1 µIU/mL

- **Analytical specificity**

- Cross reactivity

There was no significant cross-reactivity from these materials with the **ichroma™ TSH** test measurement.

Cross reactivity materials	Concentration
hCG	1,500,000 mIU/ml
LH	1,500 mIU/ml
FSH	1,500 mIU/ml
PRL	1,500 µIU/ml

- Interference

Except sodium citrate, there was no significant interference from these materials with the **ichroma™ TSH** test measurement. Sodium citrate had effect on **ichroma™ TSH** test in the procedure. Therefore, the use of samples containing sodium citrate is not recommended.

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
Sodium Citrate	16 mg/ml
Sodium Heparin	54 mg/ml

- **Precision**

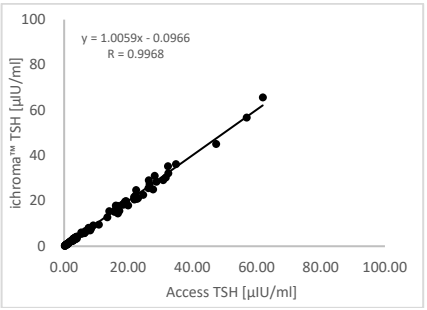
- Between Lot
  One person tested three different lots of **ichroma™ TSH,** ten times at each concentration of the control standard.
- Between person
  Three different persons tested **ichroma™ TSH,** ten times at each concentration of the control standard.
- Between day
  One person tested **ichroma™ TSH** for five days, ten times at each concentration of the control standard.
- Between site
  One person tested **ichroma™ TSH** at three different sites, five times at each concentration of the control standard.

TSH Conc. [μIU/mL]	Between-lot		Between-person	
	AVG	CV(%)	AVG	CV(%)
0.35	0.38	3.7	0.38	4.1
3.50	3.99	6.5	3.96	7.4
35.00	36.03	1.7	36.19	1.9
TSH Conc. [μIU/mL]	Between-day		Between-site	
	AVG	CV(%)	AVG	CV(%)
0.35	0.37	4.8	0.37	3.7
3.50	4.00	4.5	4.03	5.2
35.00	36.02	1.8	36.28	1.6

- **Accuracy**
  The accuracy was confirmed by testing with 3 different lots of **ichroma™ TSH.** The tests are repeated 6 times in each different concentration

TSH Conc. [μIU/mL]	Lot 1	Lot 2	Lot 3	AV	Recovery (%)
0.18	0.19	0.18	0.19	0.19	106.8
0.53	0.53	0.54	0.53	0.53	101.9
3.68	3.76	3.97	3.84	3.86	104.9
19.25	18.74	19.42	18.74	18.97	98.5
52.50	50.84	52.58	50.82	51.41	97.9

- **Comparability**
  TSH concentrations of 100 serum samples were quantified independently with **ichroma™ TSH** and Access2 (Beckman Coulter Inc. USA) 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= 1.0059X - 0.0966 and R = 0.9968 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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