QDx Instacheck™ TSH

INTENDED USE

QDx Instacheck™ TSH in conjunction with instrument for **QDx Instacheck™ tests** is a fluorescence immunoassay for quantitative measurement of thyroid stimulating hormone (TSH) concentration in human serum/plasma as an aid in management and monitoring of measurement in the assessment of thyroid function.

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 the 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 blood is extremely low, it is essential in the maintenance of the normal thyroid function. The release of TSH is regulated by a TSH-releasing hormone (TRH) produced by the hypothalamus. Levels of TSH and TRH are inversely related to the level of thyroid hormone. When the level of thyroid hormone in blood increases, lesser amount of TRH is released by the hypothalamus, so less TSH is secreted by the pituitary. The opposite action will occur when the level of thyroid hormone in blood decreases. 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 the sample, forming antigen-antibody complexes, and migrate onto the nitrocellulose matrix to be captured by the other immobilized-antibodies on test strip.
More antigens in the sample will from more antigen-antibody complexes which lead to stronger fluorescence signal by detector antibodies, which is processed by instrument for **QDx Instacheck™ tests** to show TSH concentration in the sample.

COMPONENTS AND REAGENTS

QDx Instacheck™ TSH consists of a 'cartridge', 'detector vials', and 'detector diluent'.

- The cartridge contains the membrane called a test strip which has anti human TSH 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 vials have lyophilized detection buffer containing anti human TSH-fluorescence conjugate, anti-chicken IgY-fluorescence conjugate, sucrose, mouse IgG, bovine serum albumin (BSA) and sodium azide in phosphate buffered saline (PBS). All detector vials are packed in a zipper bag.
- The detector diluent contains tween 20, triton X-100, and sodium azide in potassium phosphate buffer (Kpi), and it is pre-dispensed in vials. The detector diluent is packed in a zipper bag.

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, detector vial and detector diluent, 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 and sample mixing tubes. A cartridge should be used for testing one sample only. A sample mixing tube 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 QDx Instackeck™ tests may generate slight vibration during use.
- Used cartridges, sample mixing tubes 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.
- **QDx Instacheck™ TSH** will provide accurate and reliable results subject to the below conditions.
  - **QDx Instacheck™ TSH** should be used only in conjunction with the instrument for QDx Instackeck™ 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 vial	4 - 30 °C.	20 months	Unopened
	4 - 30 °C.	1 months	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.

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-4-1

Components of QDx Instacheck™ TSH

- **Cartridge Box:**

- Cartridge	25
- Detector vial	2
- Detector diluent	1
- Sample mixing tubes	25
- ID chip	1
- Instruction for use	1

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

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

SAMPLE COLLECTION AND PROCESSING

The sample type for **QDx Instacheck™ 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 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

1. Check the components of **QDx Instacheck™ TSH**: Sealed cartridges, detector vials, detector diluent, sample mixing tubes, ID Chip.
2. Ensure that the lot number of the cartridge matches that of the detector vial, detector diluent as well as the ID chip.
3. If the sealed cartridge, the detector tube and the detector diluent have been stored in refrigerator, place them on a clean and flat surface at room temperature for at least 30 minutes before testing.
4. Turn on the instrument for **QDx Instacheck™** tests.
5. Insert the ID chip into the 'ID Chip Port' of the instrument for **QDx Instacheck™ tests**.
6. Press 'Select' button on the instrument for **QDx Instacheck™ tests**. (*Please refer to the 'Instrument for **QDx Instacheck™ tests** Operation Manual' for complete information and operating instructions.*)

TEST PROCEDURE

[Multi Mode]

1) Transfer 1,200 µL of detector diluent using a pipette to a detector vial.
2) Close the lid of the detector vial and allow it to stand for 30 minutes. Swirl gently before use.

   ※ 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 pipette to a sample mixing tube.
5) Add 75 µL of detection buffer to the sample mixing tube containing sample.
6) Close the lid of the sample 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 inaccurate test result.*
9) To scan the sample-loaded cartridge, insert it into the cartridge holder of the instrument for **QDx Instacheck™** tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow is marked on the 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) 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 for **QDx Instacheck™** tests.

[Single Mode]

1) Transfer 1,200 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. Swirl gently before use.

   ※ 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 pipette to a sample mixing tube.
5) Add 75 µL detection buffer to the sample mixing tube containing sample.
6) Close the lid of the sample 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 **QDx Instacheck™** tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow is marked on the cartridge especially for this purpose.
9) Press the 'Select' or Tab the 'START' button on the instrument for **QDx Instacheck™** tests to start the scanning process.
10) The cartridge goes inside the Instrument for QDx Instacheck™ tests and the instrument for **QDx Instacheck™** 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 **QDx Instacheck™** tests.

INTERPRETATION OF TEST RESULT

- Instrument for **QDx Instacheck™ tests** calculates the test result automatically and displays TSH concentration of the test sample in terms of µIU/mL.
- Reference range

Type	TSH (µIU/mL)
Adults	0.34-5.6

- Working range of **QDx Instacheck™ TSH** is 0.1-100 µIU/mL.

QUALITY CONTROL

- Quality control tests should be performed as a part of the good testing practice to confirm the expected quality control results and validity of the assay as well as to ensure accuracy of the test results with clinical samples.
- A quality control test should be performed at regular intervals. Before testing a clinical sample using a new test lot, control reagents should be tested to confirm the test procedure, and to verify whether the test produces the expected quality control results. Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control standards are provided on demand with **QDx Instacheck™ TSH**. For more information regarding obtaining the control standards, contact the technical section at **Diasys Diagnostics India Private Limited**.
- **Internal Control**: **QDx Instacheck™ TSH** test has an in-built quality control indicator that satisfies the routine quality control requirements. This internal control test is performed automatically each time a clinical sample is tested. An invalid result from the internal control leads to display an error message on the **QDx Instacheck™ Reader** indicating that the test should be repeated.

PERFORMANCE CHARACTERISTICS

1. Analytical sensitivity

- Limit of Blank (LoB) 0.03 µIU/mL
- Limit of Detection (LoD) 0.07 µIU/mL
- Limit of Quantitation (LoQ) 0.10 µIU/mL

2. 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™ TSH** test results did not show any significant cross-reactivity with these biomolecules.

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

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™ TSH** test results did not show any significant in terference with these materials except for 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
Sodium Citrate	0.1 mM/L
Sodium Heparin	15 IU/mL

3. Precision

3 lots of **QDx Instacheck™ TSH** were tested for 21 days (7 days 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™ TSH** was evaluated with result of 1 lot.

- **Total precision (within-laboratory)**

Total precision (within-laboratory) of **QDx Instacheck™ TSH** was evaluated within result of 1 lot.

- **Lot to lot precision**

Lot to lot precision of **QDx Instacheck™ TSH** was evaluated within results of 3 lots.

- **Between person**

Three different persons tested **QDx Instacheck™ TSH**; ten times at each concentration of the control standard.

- **Between site**

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

Conc.	Repeatability		Total precision	
[µIU/mL]	AVG	CV (%)	AVG	CV (%)
0.70	0.71	5.74	0.70	6.49
3.5	3.47	6.86	3.48	6.54
7	6.98	6.19	7.00	6.23

Conc.	Lot to lot precision		Between person	
[µIU/mL]	AVG	CV (%)	AVG	CV (%)
0.70	0.70	6.26	0.71	6.59
3.5	3.50	6.37	3.53	5.95
7	7.02	6.42	7.00	5.40

Conc.	Between-site	
[µIU/mL]	AVG	CV (%)
0.70	0.71	6.35
3.5	3.47	5.39
7	7.01	5.26

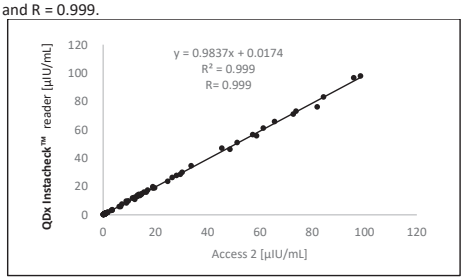
4. Accuracy

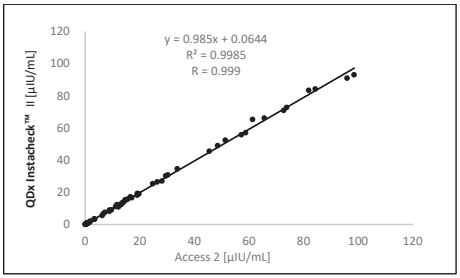
The accuracy was confirmed by testing with 3 different lots of **QDx Instacheck™ TSH.** The tests are repeated 10 times in each different concentration.

TSH Conc. [µIU/mL]	Lot 1	Lot 2	Lot 3	AV	Recovery (%)
0	0.00	0.00	0.00	0.00	-
0.35	0.35	0.34	0.34	0.34	98.2
0.7	0.71	0.66	0.70	0.69	98.3
3.5	3.33	3.42	3.42	3.39	96.8
7	6.77	6.64	6.94	6.78	96.9
35	35.66	33.97	35.64	35.09	100.3
75	75.44	67.95	70.29	71.23	95.0

5. **Comparability**

TSH concentrations of 100 serum samples were quantified independently with **QDx Instacheck™ TSH** and Access2 (Beckman Coulter Inc. USA) as per prescribed test procedures for each instrument. Test results were compared, and their comparability was investigated with linear regression and coefficient of correlation (R). Linear regression and coefficient of correlation between **QDx Instacheck™ reader** and Access 2 were Y= 0.9837X + 0.0174 and R = 0.999 respectively. Linear regression and coefficient of correlation between **QDx Instacheck™ II** and Access 2 were Y= 0.985X + 0.0644 and R = 0.999.





REFERENCES

1. Marshaal, J.C.: Clinic. In Endocrinol. Metab, 1975, 4:545.
2. Burger, H. G., Patel, Y. C. Thyrotropin releasing hormone-TSH. J. Clinic. Endocrinol. Metab. 1977, 6:831-00.
3. Jeffcoate, S.L.: Clinic. In Endocrinol. Metab. 1975, 4:521.
4. Cohen, K.L.: Metabolism, 1977, 26:1165.
5. Pierce, J. G. Endocrinology. 1971, 89:1331-1344.
6. Berger, S. and Quinn, J.L., Fund. Clin. Chem., N. W. Tietz(ed.), W. B. Saunders Co., Phila., PA 14, 824-848(1976).
7. Lundy, L.E., Lee, S.G., Levy, W., et al. Obstet. Gynecol. 1974, 44:14
8. Utiger, R. D., The Thyroid, S.C. Werner and S. H. Ingbar(eds.), Harper and Row, Hagerstown, MD, 1978, 9:196-205.
9. Clinical Guide to Laboratory Tests. Ed. N.W. Tietz, 3rd Ed., W.B. Saunders Company, Philadelphia, PA 19106, 1995

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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