QDx Instacheck™ TSH WB

INTENDED USE

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

INTRODUCTION

The determination of blood level of thyroid stimulating hormone (TSH or thyrotropin) is recognized as an important measurement in the assessment of the thyroid function[1,2]. TSH is secreted by the anterior lobe of the pituitary gland, and induces the production and release of triiodothyronine (T3) and thyroxine (T4) by the thyroid gland which are primarily responsible for body metabolism[3]. TSH is a glycoprotein with a molecular weight of approximately 28,000 daltons, consisting of two chemically different subunits, alpha (89 amino acids) and beta (115 amino acids)[4,5]. 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 by the anterior pituitary gland is regulated by thyrotropin-releasing hormone (TRH) produced by the hypothalamus. Blood levels of TRH and TSH are inversely related to those of the thyroid hormones. When the level of thyroid hormone in blood increases, lesser amount of TRH is released by the hypothalamus, so that less TSH is secreted by the anterior pituitary gland. 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 level of these hormones[6,7,8].

PRINCIPLE

QDx Instacheck™ TSH WB is an immunoassay system based on antigen-antibody reaction and fluorescence technology.

When a human blood sample is processed with the detection buffer in the sample mixing tube, the fluorochrome-labeled detector antibodies (anti-TSH) in the detection buffer bind with TSH in the test sample.

When this processed test sample is loaded into the sample well on the cartridge as per the prescribed test procedure, it migrates through the nitrocellulose matrix of the test strip.

The fluorochrome-labeled detector antibody-analyte (TSH) complexes get captured on to the capture antibodies (anti-TSH) which have been immobilized at the test line on the test strip.

As a result, the complexes of the capture antibody-analyte (TSH)-detector antibody get accumulated at the test line on cartridge membrane.

Thus, more the TSH in the test sample, more the complexes that get accumulated at the test line on the cartridge membrane.

Upon inserting the sample-loaded cartridge in the instrument for **QDx Instacheck™ tests**, the laser light illuminates the cartridge membrane thereby triggering fluorescence from the fluorochrome-labeled complexes of TSH.

Intensity of the fluorescence is scanned and converted into an electric signal. The on-board microprocessor computes the TSH concentration based on a pre-programmed calibration.

The computed and converted result is displayed by the instrument for **QDx Instacheck™ tests** quantitatively in terms of µIU/mL.

COMPONENTS AND REAGENTS

QDx Instacheck™ TSH WB consists of 'cartridges', '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, 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. 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.
- 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 Instacheck™ 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 WB** will provide accurate and reliable results subject to the below conditions.
  - **QDx Instacheck™ TSH WB** should be used only in conjunction with 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 (months)	Note
Cartridge	4 - 30 °C.	20	Disposable
Detector vial	4 - 30 °C.	20	Unopened
	4 - 30 °C.	1	Opened
Detector diluent	4- 30 °C.	20	Unopened
	4- 30 °C.	3	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 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**

Components of QDx Instacheck™ TSH WB

- **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 WB**. 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 WB** is human whole blood.

- It is recommended to test the sample within 24 hours after collection.

TEST SETUP

1. Check the components of **QDx Instacheck™ TSH WB**: Sealed cartridges, detector vials, detector diluent, sample mixing tubes and ID chip.
2. Ensure that the lot number of the cartridge 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 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 1,600 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 100 µL of detection buffer using a pipette to a sample mixing tube.
5) Add (50 µL of human whole blood/ 30 µL of control) of the sample using a pipette to the detection buffer in the sample mixing tube
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 100 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 15 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) The test procedure is same with "Multi mode 1)-7)
2) 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.
3) Press the 'Select' or Tab the 'START' button on the instrument for **QDx Instacheck™ tests** to start the scanning process.
4) 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 15 minutes.
5) Read the test result on the display screen of the instrument for **QDx Instacheck™ tests**.

INTERPRETATION OF TEST RESULT

- **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 WB** is 1.0-100 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 WB**. For more information regarding obtaining the control standards, contact the technical section at **Diasys Diagnostics India Private Limited**.
- **Internal Control**: **QDx Instacheck™ TSH WB** 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 instrument for **QDx Instacheck™ tests** indicating that the test should be repeated.

PERFORMANCE CHARACTERISTICS

1. **Specificity:** There, in test samples, are biomolecules such as luteinizing hormone (1,000 mIU/mL), follicle stimulating hormone (1,000 mIU/mL), and human chorionic gonadotropin (200,000 mIU/mL) were added to the test sample(s) at concentrations much higher than their normal physiological levels in blood. **QDx Instacheck™ TSH WB** test results did not show any significant cross-reactivity with these biomolecules.

2. **Interference**: Study of interference from glucose, hemoglobin, bilirubin, L-ascorbic acid and cholesterol with **QDx Instacheck™ TSH WB** showed following results[11].

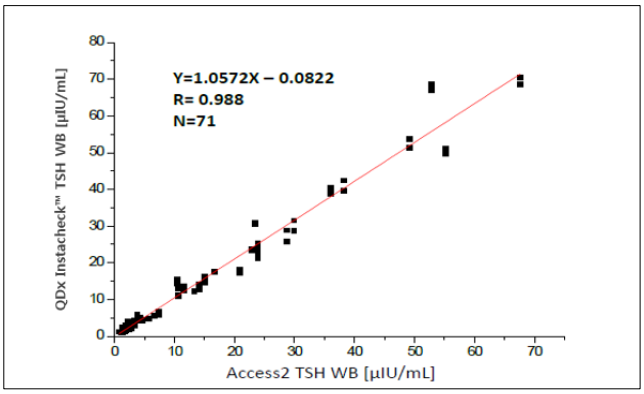
Interfering Substance	Concentration added	Interference (%)
D-Glucose	60 mM/L	< 2.4
Hemoglobin	2000 mg/L	< 6.0
Bilirubin	0.4 mM/L	< 6.8
L-Ascorbic acid	0.2 mM/L	< 3.7
Cholesterol	13 mM/L	< 4.5

3. **Prozone/Hook Effect:** No prozone/hook effect was observed with **QDx Instacheck™ TSH WB** at TSH concentrations up to 2,500 µIU/mL.

4. **Precision**: The intra-assay precision was calculated by one evaluator, who tested different concentration of control standard ten times each with three different lots of **QDx Instacheck™ TSH WB.** The inter-assay precision was confirmed by 2 different evaluators with 3 different lots, testing two times each different concentrations during 6 days.

TSH Concentration (µIU/mL)	Intra-assay		Inter-assay	
	Mean (µIU/ml)	CV (%)	Mean (µIU/ml)	CV (%)
3.5	3.59	11.04	3.57	12.1
16.0	16.19	4.4	16.26	4.6
32.0	33.0	4.6	32.84	4.2

5. **Comparability:** TSH concentrations of 71 clinical samples were quantified independently with **QDx Instacheck™ TSH WB** and Access® 2 (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 = 1.0572X – 0.0822 and *R* = 0.998 respectively.



REFERENCES

1. Marshaal, J.C.: Clinic. In Endocrinol. Metab, 1975, 4:545.Burger, H. G., Patel, Y. C. Thyrotropin releasing hormone-TSH.
2. 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. Laboratory Support for the Diagnosis and Monitoring of Thyroid Disease. Laurence M. Demers, Ph.D., F.A.C.B. and Carole A. Spencer Ph.D.,F.A.C.B., 2002 by the National Academy of Clinical Biochemistry.
10. Reference intervals for thyroid hormone in pregnant Chinese women. Panesar NS, Li CY and Rogers MS., Ann Clin Biochem 2001;38:329-32.
11. Interference Testing in Clinical Chemistry; Approved Guideline Second Edition. Robert J. McEroe, PhD, Mary F. Burritt, PhD, Donald M. Powers, PhD, Douglas W. Rheinheimer, MT, Brian H. Wallace, PhD, Clinical and Laboratory Standards Institute.

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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