TSH
QUANTI CARD

Fluorescence immunoassay (antigen-antibody) for quantitative measurement of Thyroid Stimulating Hormone (TSH) in Human Serum/ Plasma

INTRODUCTION
Thyroid Stimulating Hormone (TSH) secreted by anteriorpituitary is a glycoprotein and regulates thyroid functions. Detection of serum TSH is one of the indicators of diagnostics and efficacy evaluation of hyperthyroidism and hypothyroidism, differentiate primary and secondary hypothyroidism, monitor treatment efficacy of hyperthyroidism and hypothyroidism, diagnose subclinical hyperthyroidism, screen neonatal hypothyroidism, and diagnose pituitary TSH tumor in labs.

INTENDED USE
TSH Quanti Card is a sensitive immunoassay for the quantitative determination of Thyroid Stimulating Hormone (TSH) in human serum/ plasma with i-Quant Analyzer.

PRINCIPLE (ANTIGEN-ANTIBODY REACTION)
TSH Quanti Card is based on principle of fluorescence sandwich immunoassay technology. The test uses anti TSH antibody immobilized on a nitrocellulose strip. When a sample is added to the cartridge, TSH antigen from the sample will form a complex with another specific TSH antibodies conjugated to fluorochrome. On addition of assay buffer, this complex migrates through the nitrocellulose strip by capillary action. When the complex meets the line of the corresponding specific antibody immobilized on nitrocellulose membrane, the fluorescence signal is produced. This signal is interpreted and the result is displayed on iQuant Analyzer in form of results.

KIT PRESENTATION & MATERIALS PROVIDED
TSH Quanti Card Test kit contains following components to perform the assay:

S. No.	Component	10 Test Pack Cat No.: IR371010	25 Test Pack Cat No.: IR371025	50 Test Pack Cat No.: IR371050
1.	TSH Quanti Card	10 Nos.	25 Nos.	50 Nos.
2.	Assay Buffer	1 No.	1 No.	2 Nos. x 25 Tests
3.	Instruction Manual	1 No.	1 No.	1 No.

MATERIAL REQUIRED, BUT NOT PROVIDED
iQuant Analyzer
Micropipette & Microtips
Stop Watch

STORAGE AND STABILITY
TSH Quanti Card should be stored at 2-8ºC in the coolest & driest area available. Expiry date on the kit indicates the date beyond which kit should not be used. The kit should not be frozen & must be protected from exposure to humidity and direct sunlight.

DESCRIPTION OF SYMBOLS USED
The following are graphical symbols used in or found on J. Mitra diagnostic products and packing. These symbols are the most common ones appearing on medical cartridges and their packing. They are explained in more detail in the British and European Standard EN ISO 15223-1:2016.

	Manufactured By	IVD	In vitro diagnostic medical device
Σ	No. of tests		See Instruction for use
LOT	Lot Number Batch Number	8ºC 2ºC	Temperature Limitation
	Manufacturing Date		Caution, see instruction for use
	Expiry Date	REF	Catalogue Number
	Do not use if package is damaged		Keep away from sunlight
	Single use only		

WARNING FOR USERS
CAUTION: ALL THE SAMPLES TO BE TESTED SHOULD BE HANDLED AS THOUGH CAPABLE OF TRANSMITTING INFECTION. NO TEST METHOD CAN OFFER COMPLETE ASSURANCE THAT HUMAN BLOOD PRODUCTS WILL NOT TRANSMIT INFECTION.

1. The use of disposable gloves and proper biohazardous clothing is STRONGLY RECOMMENDED while running the test.
2. In case there is a cut or wound on hands, DO NOT PERFORM THE TEST.
3. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
4. Tests are for in vitro diagnostic use only and should be run by competent person only.
5. Do not pipette by mouth.
6. All materials used in the assay and samples should be disposed off in accordance with established safety procedures.
7. Wash hands thoroughly with soap or any suitable detergent, after the use of the kit. Consult a physician immediately in case of accident or contact with eyes, in the event that contaminated material are ingested or come in contact with skin puncture or wounds.
8. Spills should be decontaminated promptly with Sodium Hypochlorite or any other suitable disinfectant.
9. Assay Buffer contains Sodium Azide as a preservative. If it is to be disposed off through a sink or other common plumbing systems, flush with generous amounts of water to prevent accumulation of potentially explosive compounds. In addition, consult the manual guideline "Safety Management No. CDC-22", Decontamination of Laboratory Sink Drains to remove Azide salts" (Centre for Disease Control, Atlanta, Georgia, April 30, 1976).
10. Follow standard biosafety guidelines for handling & disposal of potentially infectious material.

PRECAUTIONS
In order to obtain reproducible results, the following instructions must be followed:

1. Do not use the kit beyond the expiry date.
2. Do not mix reagents from different batches.
3. Do not open the foil pouch until it attains room temperature.
4. Do not re-use the test device.
5. Use separate pipette tips for each sample in order to avoid cross-contamination of samples which could cause erroneous results.
6. Follow the given test procedure and storage instructions strictly to get accurate results.
7. Do not paste any sticker or write anything on the QR-Code as this will lead to erroneous result.
8. Do not temper the QR-Code as this will lead to erroneous result.

Important Note: TSH Quanti Card is only operational in conjunction with i-Quant Analyzer.

SAMPLE / SPECIMEN COLLECTION AND STORAGE
1. Collect the whole blood in a clean container (containing EDTA, sodium fluoride or heparin) by using standard venipuncture technique and the serum should be separated from the red cells. Fresh serum samples are preferred for testing.
2. If specimens cannot be tested immediately, they should be refrigerated at 2-8ºC. For storage for more than 3 days, freeze the specimen at -20ºC or below.
3. Frozen samples shall be thawed only once and repeated freezing and thawing of samples is not recomended.
4. Specimens containing precipitate or particulate matter may yield inconsistent test results. Such specimens must be centrifuged and the clear supernatant should only be used for testing.
5. The use of hemolytic, lipaemic, icteric or bacterially contaminated specimens should be avoided as it may lead to erroneous results.

BEFORE YOU START
The Assay Buffer Solution provided in the kit has closed nozzle and screw cap with pin (outside). Before using Assay Buffer, keep the vial vertically straight and tap down gently on the working platform, so that Assay Buffer comes down at the bottom of the vial. To orifice/puncture the closed nozzle, follow the instruction as illustrated below:

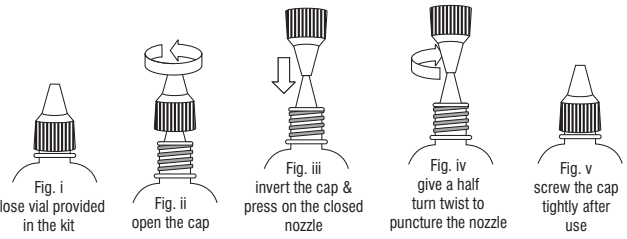

Fig. i close vial provided in the kit
Fig. ii open the cap
Fig. iii invert the cap & press on the closed nozzle
Fig. iv give a half turn twist to puncture the nozzle
Fig. v screw the cap tightly after use

TEST PROCEDURE
Reliable and reproducible results will be obtained when the assay procedure is carried out with a complete understanding of the instruction manual instructions and with adherence to good laboratory practice.

i) Bring the complete kit and specimen to be tested to Room Temperature prior to testing. **RT 20-30ºC**

Ii) Remove the test cartridge from foil pouch prior to use and place it on a flat and dry surface. The test should be performed immediately after removing the test cartridge from foil pouch.

iii) Label the test cartridge with patient's name or identification number. **DO NOT write on QR Code.**

iv) Add **100µl of Serum/ Plasma sample** in the sample well 'S'. **Care should be taken to avoid any spillage on the QR Code.**

v) Wait for 30 minutes at Room Temp. (20-30ºC).

vi) Add 1 drop of assay buffer in buffer well 'B' of the cartridge. Screw cap the vial after use.

Note: Always add sample in sample well(S) and Assay buffer in buffer well(B). Dispose off the microtip considering it bio hazardous.

vii) Allow the reaction to occur for 15 minutes at Room Temperature (20-30°C). In the meantime enter the patient's details in the iQuant analyzer testing window and select the TSH test from the pop down menu in the testing window of the i Quant analyzer.

viii) After 15 minutes, insert the test cartridge into the iQuant analyzer with arrow (←) marked side on the top of the cartridge facing towards the iQuant analyzer.

ix) Press the "RUN" icon on the iQuant analyzer test window.

x) Note down the TSH value displayed on the result window of the iQuant analyzer. The result is automatically calculated by iQuant using the stored built-in graphics for this test in µIU/ml.

xi) Discard the TSH Quanti Card immediately after reading results at 15 minutes considering it to be potentially infectious.
Note: Do not read results before & after 15 minutes.

MEASURING RANGE

The measuring range of TSH Quanti card is 0.40 - 40.0 µIU/ml. Samples showing results as >40.0 µIU/ml should be diluted in normal saline to get the actual value of the sample. For calculation of the concentration this dilution factor has to be taken into account.

Detection Limit: 0.4 µIU/ml

Each laboratory should establish its own range of normal value. The values given below are only indicative.

Distribution of normal values ranges from 0.5µIU/ml to 5.5 µIU/ml.

PERFORMANCE CHARACTERISTICS OF TSH QUANTI CARD

1. Precision

Intra-Assay: Within-run and between-run precision have been determined by testing 10 replicates of 3 different samples with TSH concentration (0.5 µIU/ml, 2µIU/ml & 5µIU/ml respectively) on the same lot on same day. The C.V (%) is ≤ 10%.

Inter-Assay: The inter-assays were performed with 10 replicates of 3 different samples with TSH concentration (0.5 µIU/ml, 2µIU/ml & 5 µIU/ml respectively) of three different lots on 10 sequential days. The C.V (%) is ≤10%.

2. Accuracy

The TSH concentration of 780 clinical specimen were quantified independently with TSH Quanti Card and commercially available certified kit. The following results were obtained:

Slope : 0.99300
Y-Intercept : 0.0028
R^2 : 0.9969

3. Sensitivity

The analytical sensitivity of TSH Quanti Card is 0.4 µIU/ml.

4. Specificity

No significant interference was observed with TSH Quantification when other biomolecules; LH (300 mIU/ml, FSH (200 mIIU/m and hCG (2,00,000 mIU/ml) were added to the test specimen with much higher level in normal blood.

LIMITATIONS AND INTERFERENCES

1. The test procedure, precautions and interpretation of results for this test must be strictly followed.
2. As with all diagnostic tests, the test result must always be correlated with clinical finding and laboratory data available.
3. Any modification to the above procedure and / or use of other reagents will invalidate the test procedure.
4. Technical / procedural errors as well as the presence of additional substances in blood samples may interfere with product performance and may cause erroneous results.
5. The test has been developed for testing Human serum/ plasma samples only.

LIMITED EXPRESSED WARRANTY DISCLAIMER

The manufacturer limits the warranty to the test kit, as much as that the test kit will function as an in-vitro diagnostic assay within the limitations and specifications as described in the product instruction-manual, when used strictly in accordance with the instructions contained therein. The manufacturer disclaims any warranty expressed or implied including such expressed or implied warranty with respect to merchantability, fitness for use or implied utility for any purpose. The manufacturer's liability is limited to either replacement of the product or refund of the purchase price of the product and in no case liable to claim of any kind for an amount greater than the purchase price of the goods in respect of which damages are likely to be claimed. The manufacturer shall not be liable to the purchaser or third parties for any injury, damage or economic loss, howsoever caused by the product in the use or in the application there of.

TROUBLE SHOOTING

PROBLEM	POSSIBLE CAUSE	SOLUTION
1. Unexpected low Test Result	a) Use of hemolysed sample.	Use fresh serum/plasma sample & repeat the test by taking proper volume of Sample.
	b) Less volume sample taken than recommended.	
	c) Use of old sample or sample storage not proper.	Repeat the test with fresh sample.
	d) Test result read before prescribed /recommended time.	Read result at 15 minutes Only.
	e) Kit and samples not brought to R.T.	Bring the kit & samples to R.T. at list 30 minutes prior to testing.
	f) Less volume of assay buffer used.	Use 1 drop of Assay Buffer.
2. Unexpected high test results	a) High volume of sample used.	Use 100ul sample, using calibrated pipette.
	b) Result read beyond prescribed time.	Read results at 15 minutes only.
3. Test Result do not match with other Elisa or CLIA method	a) Result on Elisa or CLIA kit can be more or less than actual value due to improper calibration of instrument.	Recheck the sample after proper calibration of instrument.
	b) Procedural error.	Check the procedure and perform test again as per kit product insert.
		Retest the sample on standard ELISA or CLIA kit to confirm the correct value of the sample.

REFERENCES

1. IOSR Journal of Dental and Medical Sciences(IOSR-JDMS) e-ISSN: 2279-0853, p-ISSN: 2279-0861. Volume 13, Issue 1, Ver. VIII (Feb. 2004), PP 10-14.
2. Statistical estimationof the minimal detectable concentration("sensitivity") for radioligand assays. Anal Biochem 1987; 90:1-12
3. Klee GG, "Symposium on Sensitive TSH Assays – Part II: Sensitive Thyrotropin Assays: Analytic and Clinical Performance Criteria," Mayo Clin Proc, 1988, 63:1123-32.
4. Rosenfeld L and Blum M, "Immunoradiometric Assay for Thyrotropin (TSH) Should Replace the RIA Method in the Clinical Laboratory," Clin Chem, 1986, 32:232-3, (letter).
5. Martinez M, Derksen D, and Kapsner P, "Making Sense of Hypothyroidism. An Approach to Testing and Treatment," Postgrad Med, 1993, 93(6): 135-8, 141-5.

For in-vitro diagnostic use only, not for medicinal use

VER-01 R-03

J. MITRA & CO. PVT. LTD.
A 180-181, Okhla Indl. Area, Phase-1, New Delhi-110 020, INDIA
Ph: +91-11-47130300, 47130500, 26818971-73
e-mail: jmitra@jmitra.co.in Internet: www.jmitra.co.in

MN/THQ/056
Rev. Dt.: Mar.-19