

QDx Instacheck™ FSH

INTENDED USE

QDx Instacheck™ FSH in conjunction with **QDx Instacheck™ Reader** is a fluorescence immunoassay for quantitative measurement of follicle stimulating hormone (FSH) in human serum/plasma. It is useful as an aid in management and monitoring of concentration of FSH.

INTRODUCTION

Follicle-stimulating hormone (FSH) is synthesized and secreted by gonadotrophs of the anterior pituitary gland. The alpha subunits of LH, FSH, TSH, and hCG are identical, and contain 92 amino acids. FSH has a beta subunit of 118 amino acids (FSHB), which confers its specific biologic action and is responsible for interaction with the FSH-receptor. FSH regulates the development, growth, pubertal maturation, and reproductive processes of the body. FSH and Luteinizing hormone (LH) act synergistically in reproduction.

The most common reason for high serum FSH concentration is in a female who is undergoing or has recently undergone menopause. High levels of Follicle-Stimulating Hormone indicate that the normal restricting feedback from the gonad is absent, leading to an unrestricted pituitary FSH production. If high FSH levels occur during the reproductive years, it is abnormal. Conditions with high FSH levels include: Premature menopause also known as Premature Ovarian Failure, Poor ovarian reserve also known as Premature Ovarian Aging, Gonadal dysgenesis, Turner syndrome, Castration, Swyer syndrome, Certain forms of Congenital adrenal hyperplasia (CAH), Testicular failure.

Most of these conditions are associated with subfertility and/or infertility. Therefore high FSH levels are an indication of subfertility and/or infertility.

PRINCIPLE

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

The more antigens in the sample, the more antigen-antibody complexes are formed. This then leads to stronger intensity of the fluorescence signal, which is processed by instrument for QDx Instacheck™ tests to produce FSH concentration in the sample.

COMPONENTS AND REAGENTS

QDx Instacheck™ FSH consists of a 'Cartridge', a 'Detection Buffer Tube' and an 'ID Chip'.

- The cartridge contains a test strip, the membrane which has anti human FSH at the test line, with chicken IgY at the control line.
- Each cartridge is individually sealed in an aluminum foil pouch containing of a desiccant. 25 sealed cartridges are packed in a box. An ID chip also comes with the box.
- The detection buffer contains anti human FSH-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 is pre-dispensed in a tube. 25 detection buffer tubes are packed in a Styrofoam box with ice-packs for shipping.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only.
- Carefully follow the instructions and procedures described in this 'Instructions for use'.
- Use only fresh samples and avoid direct sunlight.
- Lot numbers of all the test components (cartridge, ID chip and detection buffer) must agree 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 test result(s).
- Do not reuse. A detection buffer tube should be used for processing one sample only. So should a cartridge.
- The cartridge should remain sealed in its original pouch before use. Do not use the cartridge if found damaged or 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 cartridge, detection buffer and sample to be at room temperature for approximately 30 minutes.
- **QDx Instacheck™ FSH** as well as the **QDx Instacheck™ Reader** should be used away from vibration and/or magnetic field. During normal usage, it can be noted that **QDx Instacheck™ Reader** may produce minor vibration.
- Used detection buffer vial, 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.
- **QDx Instacheck™ FSH** will provide accurate and reliable results subject to the following conditions.
 - **QDx Instacheck™ FSH** should be used only in conjunction with **QDx Instacheck™ Reader**.
 - Any anticoagulants other than EDTA, sodium citrate, sodium heparin should be avoided.

STORAGE AND STABILITY

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

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. 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 IFPC-21

Components of QDx Instacheck™ FSH

- **Cartridge Box:**
 - Cartridges 25
 - ID Chip 1
 - Package Insert 1
- **Box containing Detection Buffer Tubes:**
 - Detection Buffer Tubes 25

MATERIALS REQUIRED BUT SUPPLIED ON DEMAND

Following items can be purchased separately from QDx Instacheck™ FSH. Please contact our sales division for more information.

- QDx Instacheck™ Reader REF FPRR010
- Thermal Printer

SAMPLE COLLECTION AND PROCESSING

The sample type for QDx Instacheck™ FSH 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

1. Check the components of QDx Instacheck™ FSH: Sealed Cartridge, Detection Buffer Tube and ID Chip.
2. Ensure that the lot number of the test cartridge matches with that of the ID chip as well as the detection buffer tube.
3. Keep the sealed 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.
4. Turn on the QDx Instacheck™ Reader.
5. Insert the ID chip into the 'ID Chip Port' of the QDx Instacheck™ Reader.
6. Press 'Select' button on the QDx Instacheck™ Reader.
(Please refer to the 'QDx Instacheck™ Reader Operation Manual' for complete information and operating instructions.)

TEST PROCEDURE

[Single mode]

1. Transfer 150 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.
3. Pipette out 75 µL of a sample mixture and load it into the sample well on the cartridge.
4. For scanning the sample-loaded cartridge, insert it into the test cartridge holder of the QDx Instacheck™ Reader. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow has been marked on the test cartridge especially for this purpose.

5. Press 'Select' button on the QDx Instacheck™ Reader to start the scanning process.
6. QDx Instacheck™ Reader will start scanning the sample-loaded test cartridge after 15 min.
7. Read the test result on the display screen of the QDx Instacheck™ Reader.

[Multi mode]

1. Transfer 150 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.
3. Pipette out 75 µL of a sample mixture and load it into the sample well on the cartridge.
4. Leave the sample-loaded test cartridge at room temperature for 15 minutes.
5. For scanning the sample-loaded cartridge, insert it into the cartridge holder of the QDx Instacheck™ Reader. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder. An arrow has been marked on the test cartridge especially for this purpose.
6. Press 'Select' button on the QDx Instacheck™ Reader to start the scanning process.
7. QDx Instacheck™ Reader will start scanning the sample-loaded cartridge immediately.
8. Read the test result on the display screen of the QDx Instacheck™ Reader.

INTERPRETATION OF TEST RESULT

- QDx Instacheck™ Reader calculates the test result automatically and displays FSH concentration of the test sample in terms of mIU/mL.

- The cut-off (reference range)

	Stage	Range (mIU/mL)
Females	Follicular Phase	3-11
	Mid-Cycle	6-21
	Luteal Phase	1-9
	Postmenopausal	22-153
	Males	1-11

- Working range: 1-100 mIU/mL

QUALITY CONTROL

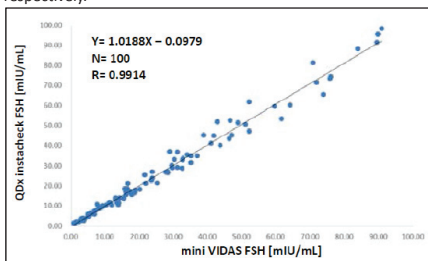
- Quality control tests should be performed as a part of the good testing practice to confirm the expected quality control results and validity of the assay as well as to ensure accuracy of the test results with clinical samples.
- A quality control test should be performed at regular intervals. Before 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 not provided with QDx Instacheck™ FSH. For more information regarding obtaining the control standards, contact the technical section at **Diasys Diagnostics India Private Limited**.
- **Internal Control:** QDx Instacheck™ FSH 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

- Specificity:** There, in test samples, are biomolecules such as D-glucose, bilirubin, hemoglobin, cholesterol, L-ascorbic acid, triglyceride mixture and disease related makers such as hCG, LH, TSH, PRL were added to the test sample(s) at concentrations much higher than their normal physiological levels in blood. **QDx Instacheck™ FSH** test results did not show any significant cross-reactivity with these biomolecules.
- 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 **QDx Instacheck™ FSH**. The inter-assay precision was confirmed by 3 different evaluators with 3 different lots, testing five times each different concentrations.

FSH (mIU/mL)	Intra-assay		Inter-assay	
	Mean	CV (%)	Mean	CV (%)
5	5.05	3.61	5.05	3.45
25	25.75	3.73	25.77	4.02
50	52.32	2.99	52.45	3.16

- Comparability:** The FSH concentrations of 100 clinical samples were quantified independently with **QDx Instacheck™ FSH** 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 $Y = 1.0188X - 0.0979$ and $R = 0.9914$ respectively.



REFERENCES

- Bruni JF, Van Vugt D, Marshall S, Meites J. Effects of naloxone, morphine and methionine enkephalin on serum prolactin, luteinizing hormone, follicle stimulating hormone, thyroid stimulating hormone and growth hormone. *Life Sci.* 1977 Aug 1;21(3):461-6.
- Kim HK, Kee SJ, Seo JY, Yang EM, Chae HJ, Kim CJ. Gonadotropin-releasing Hormone Stimulation Test for Precocious Puberty. *Korean J Lab Med.* 2011 Oct;31(4):244-9.
- Reyes FI, Winter JS, Faiman C. Pituitary-ovarian relationships preceding the menopause. I. A cross-sectional study of serum follicle-stimulating hormone, luteinizing hormone, prolactin, estradiol, and progesterone levels. *Am J Obstet Gynecol.* 1977 Nov 1;129(5):557-64.
- MacNaughton J, Banah M, McCloud P, Hee J, Burger H. Age related changes in follicle stimulating hormone, luteinizing hormone, oestradiol and immunoreactive inhibin in women of reproductive

- age. *Clin Endocrinol (Oxf).* 1992 Apr;36(4):339-45.
- Reddi K, Wickings EJ, McNeilly AS, Baird DT, Hillier SG. Circulating bioactive follicle stimulating hormone and immunoreactive inhibin levels during the normal human menstrual cycle. *Clin Endocrinol (Oxf).* 1990 Oct;33(4):547-57.
- Baird DT, Campbell BK, Mann GE, McNeilly AS. Inhibin and oestradiol in the control of FSH secretion in the sheep. *J Reprod Fertil Suppl.* 1991;43:125-38
- Randolph JF Jr, Sowers M, Bondarenko IV, Harlow SD, Luborsky JL, Little RJ. Change in estradiol and follicle-stimulating hormone across the early menopausal transition: effects of ethnicity and age. *J Clin Endocrinol Metab.* 2004 Apr;89(4):1555-61
- Randolph JF Jr, Sowers M, Gold EB, Mohr BA, Luborsky J, Santoro N, McConnell DS, Finkelstein JS, Korenman SG, Matthews KA, Sternfeld B, Lasley BL. Reproductive hormones in the early menopausal transition: relationship to ethnicity, body size, and menopausal status. *J Clin Endocrinol Metab.* 2003 Apr;88(4):1516-22.

Note: Please refer to the table below to identify various symbols.

	Sufficient for <n> tests
	Read instruction for use
	Use by Date
	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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