ImmunoScience INDIA

ImmunoQuick

FSH

Rapid Test for Detection of FSH – Device

A rapid immunochromatographic test for detection of FSH in urine

For Self - Testing &*In-Vitro* Diagnostic Use Only **Store at 4°C to 30°C**

OVERVIEW

Follicle stimulating hormone (FSH) is a member of the glycoprotein hormone family that includes luteinizing hormone (LH), thyroid stimulating hormone, and chorionic gonadotropin. FSH is made by pituitary gland, a small gland located underneath the brain. FSH plays an important role in sexual development and functioning. In women, FSH helps control the menstrual cycle and stimulates the growth of eggs in the ovaries.

INTENDED USE

The test for Detection of FSH is a rapid chromatographic immunoassay for the qualitative detection of follicle stimulating hormone (FSH) in urine. This helps to detect Elevated (peak) levels of FSH in urine an indicator for the ovulation.
This test is for healthcare professional and home use.

PRINCIPLE

The Rapid test for detection of FSH is an immunoassay for the detection of FSH in urine. The device contains a strip which contains colloidal gold particles coated with monoclonal anti-FSH antibodies. The Strip also contains NCM coated with two separate lines of FSH specific antibodies and control line specific antibodies. If a sample is applied, the colloidal gold particles dissolve in the liquid sample. If the sample contains the FSH hormone, then it will be bind to the monoclonal antibodies marked with colloidal gold particles. The dissolved gold particles are transported through the membrane due to the capillary forces effective in the special membrane. In the area of the T-line, the anti-FSH antibodies immobilized there form the complex of FSH and colloidal gold. A pink-purple line is formed depending on the FSH concentration. The surplus colloidal gold particles are then bonded in the area of the C-line by the control antibodies immobilized there, so that a pink –purple line also becomes visible in this area. This line serves as an internal functional check and must be formed in every test. In case of Ovulation, the intensity of test band will be strong and clearly visible. Very weak test line or absence of test line denotes negative results for ovulation

CONTENTS OF KIT

1. Test Device with desiccant
2. Plastic Dropper.
3. Package Insert.

OPTIONAL MATERIAL REQUIRED

1. StopWatch

PRECAUTIONS/KIT STORAGE AND STABILITY

1. Please read all the information in this package insert before performing the test .Pay particular attention to the position of the Control and Test lines.
2. Do not use after the expiration date printed on the foil pouch.
3. Store in the sealed pouch in a dry place in between temperature 4°C to 30°C.Do not freeze.
4. Do not use if pouch is torn or damaged.
5. Do not open the foil pouch until you are ready to start the test.
6. Keep out of the reach of children.

WARNINGS

1. Do not reuse the test.
2. Follow the instruction to get accurate results.
3. Use appropriate personal protective equipment.
4. Dispose hygienically in domestic waste.
5. Do not touch the membrane.
6. Treat urine samples and used test as potentially infectious. Avoid contact with skin.
7. For in vitro diagnostic use. Not to be takeninternally.
8. Do not eat the desiccant in thepackage.
9. Do not mix the specimen sample or interchange the differentspecimen.
10. The manufacturer and distributor of this product shall not be liable for any loses, liability, claims, costs or damages whether direct or consequential arising out of or related to incorrect diagnosis.

SPECIMEN COLLECTION

A second morning urine specimen is considered best ovulation monitoring. Do the test in between 10 am to afternoon (2 pm). However, urine specimens collected at any time of the day may be used.

TEST PROCEDURE

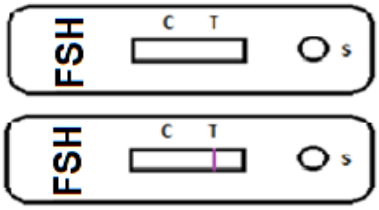
1. Allow the Test device and samples to reach room temperature (20°C to 30°C) before opening the pouch.
2. Add two drops (Approx.60µl) of Urine in sample well by using dropper.
3. Start the timer.
4. Read the result at 5 minutes. Do not read the result after 10 minutes.

INTERPRETATION OF RESULTS

1. If colored line appears at control region 'C', and no band or the weak band appears at 'T' then sample is FSH negative.

Positive: A distinct clearly visible colored line appears at control region 'C' and at the test region 'T' with intensity of test line 'T' is same or greater than 'C', then specimen is FSH positive

Invalid: Test should be considered invalid and repeat the test using fresh test if
No line appears at control side 'C' and line appears only at test side 'T'.
No line appears at control side 'C' and test side 'T'.



NOTE:

Intensity of the color in the test line region (T) will vary depending on the levels of the FSH in the specimen. However, neither the quantitative value nor the rate of increase in level of antibody in the specimen can be determined by this qualitative test. Positive results may appear as early as two minutes. Negative results must be confirmed only at the end of 5 minutes.

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LIMITATIONS

1. False negative results may occur when the levels of LH are below the sensitivity level of test.

PERFORMANCE CHARACTERISTICS

Total 190 samples were evaluated for specificity& sensitivity. sensitivity was found to be 100% (50/50) and relative specificity was found 100% (132/132).

The Positive predictive value (PPV) and Negative Predictive value (NPV) for the test was 100 %.

No cross reactivity found with HCG, FSH, TSH, Albumin, glucose, Bilirubin, caffeine, Ketone, Nitrite positive samples.

Lowest detection limit: 4.0mIU/ml

Sample	Rapid Test For Detection of FSH - Device		Reference		Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
	Positive	Negative	Positive	Negative				
Positive	51	0	51	0	100	-	100	-
Negative	0	100	0	100	-	100	-	100
Cross reactivity	0	32	0	32	No cross reactivity observed			
Total	51	132	51	132	-			

DISCLAIMER

The all precautions shall be taken to ensure the diagnostic ability and accuracy of this product.Thisproduct is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results.

IVD	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
LOT	Lot Number
	Store at 4°C to 30°C
	Single Use
	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
	Read package insert before use

MANUFACTURED BY

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