ImmunoScience INDIA

ImmunoQuick

LH + FSH

Fertility Monitoring Test – Device

A rapid qualitative test for detection of Best fertile period by urine

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

OVERVIEW

The ability to identify the precise time of ovulation is important for women who want to plan conception or practice contraception. Detection and monitoring of ovulation has long been practiced by women pursuing or avoiding pregnancy

INTENDED USE

Fertility Monitoring Test is a rapid chromatographic immunoassay for the qualitative detection of FSH and LH in urine.

This test is for healthcare professional and home use only.

PRINCIPLE

Principle for FSH

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.

Principle for LH

The device contains a strip which contains colloidal gold particles coated with monoclonal anti-LH antibodies. The Strip also contains NCM coated with two separate lines of LH 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 LH hormone in high quantity (During LH surge), then it will be bonded 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-LH antibodies immobilized there form the complex of LH and colloidal gold. A pink-purple line is formed depending on the LH 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.

CONTENTS OF KIT

1. Test Device with desiccant
2. 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 taken internally.
8. Do not eat the desiccant in the package.
9. Do not mix the specimen sample or interchange the different specimen.
10. The manufacturer and distributor of this product shall not be liable for any loses, liability, claims, costs or damages whether director cons sequential rising out for related to an incorrect diagnosis.

SPECIMEN COLLECTION

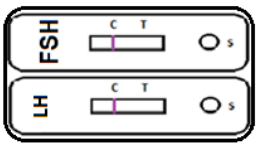
A second morning urine specimen is considered best ovulation monitoring. Do the test in between 10 am to afternoon (2 pm). However, urine specimens collected at any time of the day may be used.

TEST PROCEDURE

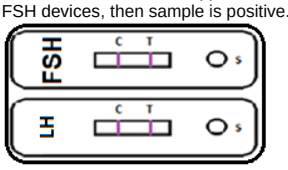
1. Bring the kit components to room temperature before testing.
2. Open the pouch and retrieve the test and desiccant pouch. Check the color of the desiccant. It should be blue, if it has turned colorless or pink, discard the test and use another test. Once opened, the test must be used immediately.
3. Keep the device on plain surface & add two drops (Approx. 60µl) urine sample in sample port “S” of LH & FSH device.
4. Start the timer.
5. Read the result at 5 minutes. Do not read the result after 10 minutes.

INTERPRETATION OF RESULTS

Negative for fertile period: If only colored line appears at control region 'C' with absence colored line at test region of both or any one of LH & FSH device, then sample is negative.



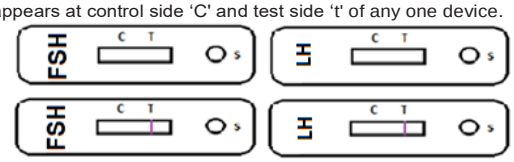
Positive for fertile period: A distinct colored line appears at control region ‘C’ and at the test region ‘T’ of both LH & FSH devices, then sample is positive.



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' of any device.

No line appears at control side ‘C' and test side ‘t' of any one device.



NOTE:

intensity of the color in the test line region (T) will vary depending on the levels of the antibody in the specimen. However, neither the quantitative value nor the rate of increase in level of CRP in the specimen can be determined by this qualitative test. Positive results may appear as early as five minutes. Negative results must be confirmed only at the end of 15 minutes.

LIMITATIONS

1. As with all diagnostic tests, the test result must always be correlated with clinical findings.
2. The results of test are to be interpreted within the epidemiological, clinical and therapeutic context. When it seems indicated, reference correlation should be considered.
3. Any modification to the above procedure and / or uses of other reagents will invalidate the test procedure.

PERFORMANCE CHARACTERISTICS

Total 190 samples were evaluated for specificity& sensitivity. sensitivity was found to be 100% (50/50) and relative specificity was found 100% (108/108).

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: LH: 5.0 mIU/ml, FSH: 4.0 mIU/ml

Sample	Fertility Monitoring Test		Reference		Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
	Positive	Negative	Positive	Negative				
Positive	50	0	50	0	100	-	100	-
Negative	0	100	0	100	-	100	-	100
Cross reactivity	0	8	0	8	No cross reactivity observed			
Total	50	108	50	108	-			

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.

	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
	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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