ImmunoScience INDIA

ImmunoQuick

LH

Rapid One Step LH Test – Device

A test for detection of LH Surge (Ovulation) by urine

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

OVERVIEW

luteinizing hormone (LH) is a glycoprotein hormone produced by pituitary gland. In women, LH helps control the menstrual cycle. It also triggers the release of an egg from the ovary. LH levels quickly rise just before ovulation this elevation of LH is called as “LH Surge”. Hence, LH Surge detection plays an important role in ovulation monitoring.

INTENDED USE

The One Step LH Test is an immunoassay for the fast detection of LH Surge in urine. 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. This line serves as an internal functional check and must be formed in every test. In case of LH surge, the intensity of test band will be equal to or more than intensity of control band. Very weak test line or absence of test line denotes negative results for LH surge.

CONTENTS OF KIT

1. Test Device with desiccant & plastic dropper.
2. Package Insert

OPTIONAL MATERIAL REQUIRED

1. Stop Watch
2. Sample container
3. Disposable Gloves

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 off 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 direct or consequential arising out of or related to an incorrect diagnosis,

PI/LH/01-22/VER-2

SPECIMEN COLLECTION

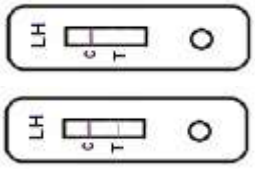
A urine specimen must be collected in a clean and dry container. A first morning urine specimen is preferred since it generally contains the highest concentration of LH. However, urine specimens collected at any time of the day may be used.

TEST PROCEDURE

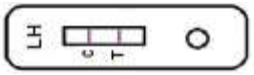
1. Allow the Test Device, components and urine sample to reach room temperature (20°C to 30°C) before opening the foil pouch.
2. Remove the Test Device, Desiccant Pouch & Dropper. Check the color of the Desiccant. It should be blue, if it has turned colorless or pink, discard the test & use another test. Once Opened, the test must be used immediately.
3. Place the device on plain surface and add two drops (i.e. approximately 60 µl) of urine sample in well ‘S'.
4. Start the timer.
5. Read the result at 5 minutes. Do not read the result after 10 minutes.

INTERPRETATION OF RESULTS

Negative: Very faint or no colored band appears at test A colored line appears at control side ‘C' only.



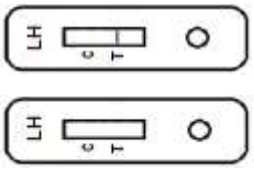
Positive: A distinct clearly visible colored lines appears at control side ‘C' and at test side ‘T',



Invalid: The test should be considered invalid 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:

The intensity of the color in the test line region (T) will vary depending on the concentration of LH present in the specimen. However, neither the quantitative value nor the rate of increase in LH can be determined by this qualitative test. Depending on the concentration of LH in the specimen, positive results may appear as early as 30 seconds. Negative results must be confirmed only at the end of five minutes.

LIMITATIONS

1. False negative results may occur when the levels of LH are below the sensitivity level of test.
2. A number of conditions, including trophoblastic disease and non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer and lung cancer cause elevated levels of hCG/LH. Therefore, the presence of LH in urine should not be used to diagnose.
3. This test is not reusable.

PERFORMANCE CHARACTERISTICS

Total 183 samples were evaluated for specificity & sensitivity. sensitivity was found to be 100% (51/51) 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, FHS, TSH, Albumin, glucose, Bilirubin, caffeine, Ketone, Nitrite positive samples.

Lowest detection limit: 20 mIU/ml

Sample	ImmunoQuick LH Test		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. This product is utilized outside the control of manufacturer and distributors. The various factors including storage temperature, environmental conditions and procedure error may affect the results.

REFERENCES

1. Batzer FR. "Hormonal evaluation of early pregnancy", Fertil. Steril. 1980; 34(1): 1-13
2. Catt KJ, ML Dufau, JL Vaitukaitis "Appearance of hCG in pregnancy plasma following the initiation of implantation of the blastocyte", J. Clin.Endocrinol. Metab.1975;40(3):537-540
3. Braunstein GD,J Rasor, H.Danzer, D Adler, ME Wade "Serum human chorionic gonadotropin levels throughout normal pregnancy", Am. J. Obstet.Gynecol.1976;126(6): 678-681
4. Lenton EA, LM Neal, R Sulaiman "Plasma concentration of human chorionic gonadotropin from the time of implantation until the second week of pregnancy", Fertil. Steril. 1982; 37(6): 773-778
5. Steier JA, P Bergsjo, OL Myking "Human chorionic gonadotropin in maternal plasma after induced abortion, spontaneous abortion and removed ectopic pregnancy", Obstet. Gynecol. 1984; 64(3): 391- 394.
6. Dawood MY, BB Saxena, R Landesman "Human chorionic gonadotropin and its subunits in hydatidiform mole and choriocarcinoma", Obstet.Gynecol. 1977;50(2): 172-18

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

ImmunoScience India Private Limited
Gat No. 41, Kusgaon, Shivapur-Velhe Road,
Tal- Bhor, Pune, Maharashtra (India) -412205.