Cat: BKLH-01

BioKits LH Rapid Test

(Urine)

BioKits DIAGNOSTICS SOLUTIONS

1. INTENDED USE

The Biokits LH Rapid Test is an in-vitro diagnostic, immunochromatographic assay for the qualitative detection of Luteinizing Hormone (LH) in human urine to aid in the identification of the LH surge associated with ovulation.

2. INTRODUCTION

Luteinizing Hormone (LH) is a glycoprotein hormone secreted by the anterior pituitary gland and plays a key role in the regulation of the female reproductive cycle. A rapid rise in LH concentration, known as the LH surge, typically precedes ovulation by approximately 24–36 hours. Detection of this surge is widely used to determine the fertile period. The Biokits LH Rapid Test provides a rapid qualitative result to assist in ovulation prediction.

3. PRINCIPLE OF THE TEST

The Biokits LH Rapid Test is a lateral-flow immunochromatographic assay with a two-line detection system consisting of a test line (T) and a control line (C). LH present in the urine specimen binds to colloidal gold-conjugated anti-LH antibodies and migrates along the nitrocellulose membrane by capillary action. The hormone–antibody complexes are captured by immobilized anti-LH antibodies at the test line region, producing a visible colored line when urinary LH concentrations are ≥ 25 mIU/mL. The control line is coated with polyclonal antibodies and reacts with a colored control conjugate, producing a visible line independent of LH concentration, thereby confirming proper sample flow, reagent integrity, and test validity.

4. KIT COMPONENTS

Each kit contains:

1. Individually pouched LH Test Devices with desiccant
2. Disposable droppers (if applicable)
3. Instructions for Use (IFU)

5. KIT STORAGE AND STABILITY

1. Store at 2–30°C. Do not freeze.
2. Protect from direct sunlight and humidity.
3. Use the device immediately after opening the foil pouch.
4. Do not use if the pouch is damaged or the seal is broken.
5. Do not mix components from different lots.
6. Use before the expiry date printed on the packaging.

6. PRECAUTIONS

1. For In-Vitro Diagnostic Use Only.
2. Do not reuse the test device.
3. Avoid excessive fluid intake prior to urine collection, as this may dilute LH concentration.
4. Use a clean, dry container for urine collection.
5. Do not eat, drink, or smoke in the testing area.
6. Dispose of all used materials as per biomedical waste regulations.
7. Ensure the test device and specimen are at room temperature before testing.

7. LIMITATIONS

1. This test is qualitative and does not measure the exact LH concentration.
2. LH levels below 25 mIU/mL may not be detected.
3. LH surge patterns may vary between individuals and cycles.
4. Certain medical conditions or medications affecting hormonal balance may influence results.
5. Results should be interpreted in conjunction with menstrual cycle history.

8. SAFETY INFORMATION

1. Handle all specimens as potentially infectious.
2. Clean spills thoroughly with suitable disinfectants.
3. Dispose of used test components according to biomedical waste disposal guidelines.
4. Do not pipette by mouth.

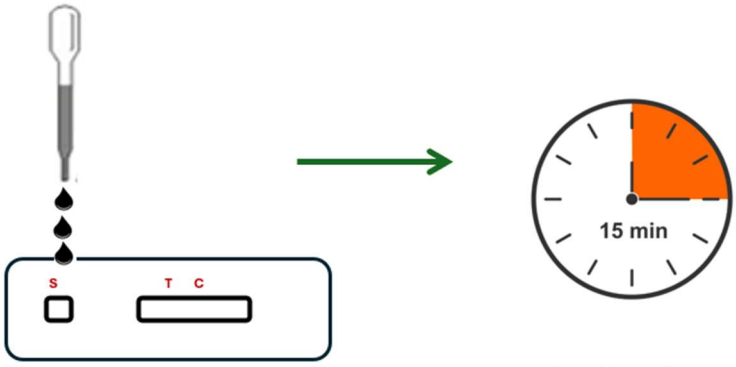
9. REFERENCES

1. World Health Organization. *Laboratory diagnosis of ovulation and fertility assessment.* WHO Technical Guidelines.
2. Cole LA. *Utility of urinary LH testing in ovulation prediction.* Clinical Chemistry.

SPECIMEN COLLECTION AND STORAGE

Category	Details
Accepted Specimens	✓ Human Urine
Collection	✓ Collect a **fresh urine specimen** in a clean, dry container. ✓ **First-morning urine is preferred**, as it contains the highest concentration of hCG, especially in early pregnancy.
Storage	✓ Test the urine specimen **as early as possible** after collection. ✓ If testing is delayed, store urine at **2–8°C for up to 48 hours**. ✓ Bring refrigerated specimens to **room temperature** before testing ✓ **Do not freeze** urine specimens.

TEST PROCEDURE

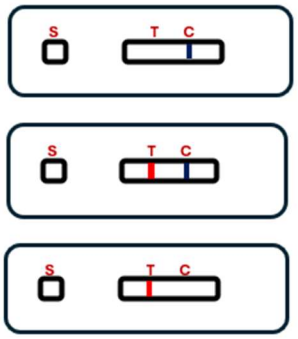


Add 3 Drops of Urine Sample into the Sample Well "S"

Read Results at 5-15 Minutes

Note: **Do not read results after 15 min- it may give incorrect results !**

RESULT INTERPRETATION



Negative – LH is lesser than 25 mIU/ml

LH Reactive - higher than 25 mIU/ml

Invalid Test Pattern

M/s: **ubio Biotechnology Systems Pvt Ltd. Plot No: 15A, Biotechnology Zone, KINFRA Hitech Park, Kalamaserry, Cochin, Kerala - 683503, INDIA.**

Symbols Used Instructions to use | Do Not reuse | Storage temperature | Away from direct sunlight | Store dry | No of tests | IVD | For *In-Vitro* diagnostic use | REF | Product code | Manufactured site | Manufactured date | Use before | LOT | Lot number