

1. INTENDED USE

The Biokits hcG Urine Rapid Test is an in-vitro diagnostic, immunochromatographic assay for the qualitative detection of human chorionic gonadotropin (hCG) in human urine.

2. INTRODUCTION

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the developing placenta shortly after fertilization. hCG appears in urine early in pregnancy and increases rapidly during the first trimester. Detection of hCG in urine is widely used for the early diagnosis of pregnancy. The Biokits hcG Urine Rapid Test provides a rapid qualitative result to aid in the early detection of pregnancy.

3. PRINCIPLE OF THE TEST

The Biokits hcG Urine 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). hCG present in the urine specimen binds to colloidal gold-conjugated anti-hCG antibodies and migrates along the nitrocellulose membrane by capillary action. The antigen-antibody complexes are captured by immobilized anti-hCG antibodies at the test line region, producing a visible colored line when hCG 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 hCG concentration, thereby confirming proper sample flow, reagent integrity, and test validity.

4. KIT COMPONENTS

Each kit contains:

1. Individually pouched hcG Urine 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. 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. Use a fresh urine specimen whenever possible.
4. Avoid contamination of the urine specimen.
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 provide an hCG concentration.
2. hCG levels below 25 mIU/mL may not be detected.
3. Very early pregnancy may result in false-negative results.
4. Diluted urine specimens may reduce sensitivity; first-morning urine is recommended when possible.
5. Clinical interpretation should consider patient history and confirmatory testing when required.

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.

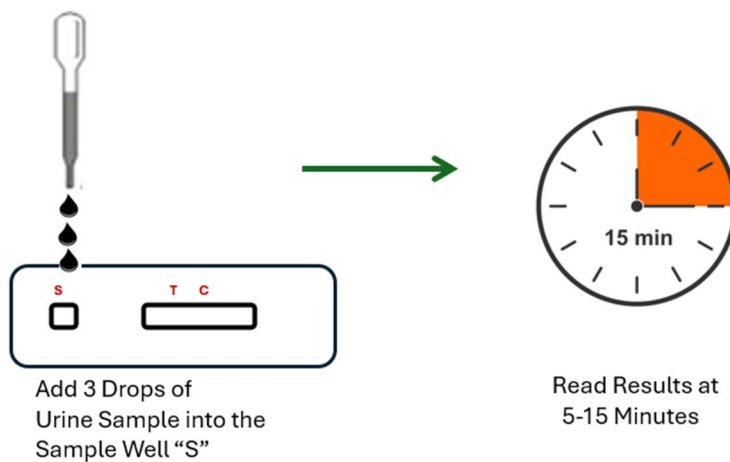
9. REFERENCES

1. Cole LA. *The utility of six over-the-counter (home) pregnancy tests*. Clinical Chemistry. 2011;57(5):661–666.
2. World Health Organization. *Laboratory diagnosis of pregnancy*.

SPECIMEN COLLECTION AND STORAGE

Category	Details
Accepted Specimens	✓ Human Urine
Collection	<ul style="list-style-type: none"> ✓ 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	<ul style="list-style-type: none"> ✓ 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



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

RESULT INTERPRETATION

