MAI hCG Rapid Test (Urine)

Labgene biotech

INTENDED USE

The "MAI" one step urine hCG pregnancy rapid test is a rapid immunochromatography assay for the qualitative detection of human chorionic gonadotropin (hCG) in urine samples to aid in the early detection of pregnancy.

ORDER INFORMATION AND MATERIALS PROVIDED

Cat No.	Test Devices	Dropper & Silica Gel
LG025-10T	10	01 in an individual pouch
LG025-25T	25	
LG025-30T	30	
LG025-40T	40	
LG025-50T	50	
LG025-100T	100	

*IFU: O1 in an individual carton box

INTRODUCTION

MAI one step urine hCG pregnancy test is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in both urine and serum as early as 7 to 10 days after conception (1-4). hCG levels continue to rise very rapidly, frequently exceeding 100 mIU/ml by the first missed menstrual period (2-4), and peaking in the 100,000-200,000 mIU/ml range about 10-12 weeks into pregnancy. The appearance of hCG in both urine and serum soon after conception, and its subsequent rapid rise in concentration during early gestational growth, make it an excellent marker for the early detection of pregnancy. The hCG (Pregnancy Test) rapid test device is a rapid test that qualitatively detects the presence of hCG in urine specimen at the sensitivity of 25 mIU/mL. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of hCG in urine. At the level of claimed sensitivity, the test device showed no cross-reactivity interference from the structurally related glycoprotein hormones FSH, LH and TSH at high physiological levels.

PRINCIPLE

When a specimen sample is dispensed into the sample well, it flows through the filter efficiently. The hCG hormone if present in the specimen sample, forms a complex with the anti-hCG antibodies conjugated to the colloidal gold nanoparticles. The conjugate complex binds to the immobilized anti-hCG antibodies in the Test area. The mouse IgG conjugate complexes migrate out of the Test area and are later captured in Control area. Visible pinkish-red bands will appear in the Test and Control area. If a band is present in both test and control area, the test result is read as positive. If a band is present only in the Control area, the test result is read as negative. If no band is present in the Control area, the test is invalid and another test must be run using a fresh device, regardless of the presence or absence of band in the Test area.

MATERIALS NEEDED BUT NOT PROVIDED

- Specimen collection container
- Timer

PRECAUTIONS

- "MAI" hCG Pregnancy rapid test is for in-vitro diagnostic use only.
- Do not use after expiration date.
- Do not use if pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Humidity and temperature can adversely affect results.
- The used test should be discarded according to local regulations.

STORAGE AND STABILITY

- Store as packaged in the sealed pouch either at room temperature or refrigerated (2°C-30°C).
- DO NOT FREEZE.
- The test device is stable through the expiration date printed on the sealed pouch.
- The test device must remain in the sealed pouch until use.

SPECIMEN COLLECTION AND PREPARATION

- 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 hCG; however, urine specimens collected at any time of the day may be used.
- Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.
- Urine specimen may be stored at 2°C to 8°C for up to 72 hours prior to testing.
- For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

PROCEDURE

1. Allow test device, specimen, to reach room temperature (15°C- 30°C) prior to testing.
2. Place the test device on a clean and level surface.
3. Hold the dropper vertically and transfer 2 drops of sample (approximately 60-70 µL) to the specimen well (s) of the test device, and start the timer.
4. Read the result in 5 minutes. Read results as shown under interpretation of Results
5. NOTE: Strong positive specimens may produce positive result in as little as 1 minute.

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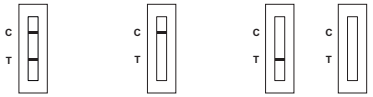
⚠ Do not read results after 10 minutes. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF RESULTS

POSITIVE: Two distinct colored lines appear. One line should be in the control line region (C) and another line should be in the test line region (T).

NEGATIVE: Only one colored line appears in the control line region (C). No apparent colored line appears in the test line region (T).

INVALID: No visible band appears at the control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



Positive पॉजिटिव | Negative नेगेटिव | Invaild अमान्य

LIMITATIONS

- Since hCG found to be elevated in certain conditions other then pregnancy. Those conditions should be ruled out before confirming diagnosis of pregnancy.
- In case of a very early pregnancy the test may show negative or a very faint line due to very low hCG concentration. The test can be repeated after 3-4 days using fresh urine sample.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- For accurate and reliable results, the test procedure must be followed as per instruction provided in the product pack insert.
- Healthy pregnant women have hCG present in their urine and serum specimens. The amount of hCG will vary greatly with gestational age and between individuals. The "MAI" hCG One Step Pregnancy Test Device (Urine) has a sensitivity of 25 mIU/mL, and is capable of detecting pregnancy as early as 1 day after the first missed menses.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity studies were carried out in-house on fresh as well as frozen samples, from low risk as well as high risk groups.

hCG Samples	Positive	Negative	Total
Positive	50	00	50
Negative	00	50	50
Total	50	50	100

Relative Sensitivity: 100.00%, Relative Specificity: 100.00%, Overall agreement: 100.00%

REFERENCES

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MAI™ One step urine HCG pregnancy test

ISO 13485 | IVD

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