The HCG Rapid Test Device (Urine/Serum) is a rapid visual immunoassay for the qualitative, presumptive detection of human chorionic gonadotropin in human urine specimens. This kit is intended for use as an in the early detection of pregnancy.

INTRODUCTION

Human chorionic gonadotropin (hCG), a glycoprotein hormone secreted by viable placental tissue during pregnancy, is a glycoprotein that can be detected in urine specimens as early as 10 days after missed menstruation. hCG levels rise rapidly, reaching peak levels after 60-80 days. The appearance of hCG in urine soon after conception and its rapid rise in concentration makes it an ideal marker for the early detection and confirmation of pregnancy. However, elevated hCG levels are frequently associated with trophoblastic and non-trophoblastic neoplasms and hence these conditions should be considered before a diagnosis of pregnancy can be made.

PRINCIPLE

The HCG Rapid Test Device (Urine/Serum) determines hCG through visual interpretation of color development. Anti-hCG antibodies are immobilized on the test region (T) of the membrane and anti-mouse antibodies on the control region (C). During testing, hCG, if present in the specimen, will bind to anti-hCG antibodies conjugated to colored particles and precoated onto the sample pad. As the specimen migrates along the strip by capillary action and interacts with reagents on the membrane, the complex will be captured by anti-hCG antibodies at the test region. Excess colored particles are captured at the internal control region.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results the assay should be performed within one hour.
2. Add 3 drops of specimen (approximately 120 µL) directly into the specimen well (S) and start the timer. As the test begins to work, color will migrate across the result area in the center of the device.
3. Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the test region (T).
4. Wait for the colored bands to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.

NOTE: Low hCG concentrations may produce very weak T lines after a prolonged period of time. Therefore, do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

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

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue the use immediately and contact your local distributor.

LIMITATIONS OF THE TEST

Internal procedural controls are included in the test. The appearance of a colored band in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique. External controls are not supplied with the kit. It is recommended that positive and negative controls be tested as a laboratory practice to confirm the test procedure and to verify proper test performance.

SAFETY INFORMATION

For professional in vitro diagnostic use only.

INTENDED USE

The HCG Rapid Test Device (Urine/Serum) is intended for use with human urine or serum specimens only.

Although urine specimens from any time of day can be used, first morning urine specimens are preferred as they contain the highest concentration of hCG.

1. The HCG Rapid Test Device (Urine/Serum) is for professional in vitro diagnostic use only. It is not intended for use in the diagnosis of non-trophoblastic tumors, including testicular tumors, prostate cancer, breast cancer and lung cancer, cause elevated levels of hCG (>100 mIU/mL). Therefore, the presence of hCG in urine as determined by using the HCG Rapid Test Device (Urine/Serum) test kit may not be used to diagnose pregnancy unless these conditions have been ruled out.
2. hCG concentrations are below the minimum detectable level of the test, a false negative result may be obtained. If pregnancy is suspected after a negative result, a first morning urine specimen should be collected 48-72 hours later and tested. If pregnancy is suspected and the test continues to produce negative results, see a physician for further diagnosis.
3. As with all diagnostic tests, a confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

EXPECTED VALUES

hCG concentration in pregnant women rises very rapidly after implantation, reaching a peak concentration in excess of 200 mIU/mL about 2-3 weeks after the last menstrual period. The HCG Rapid Test Device (Urine/Serum) has a sensitivity of 20 mIU/mL for urine/serum and is capable of detecting pregnancy as early as 1 day after the first missed menstrual period.

Reportedly, a level of 25 mIU/mL or more, is present 7-10 days after conception or 4-5 days prior to the first missed menses. Test results which appear as very light bands in the test region are not definitive for the diagnosis of pregnancy. It is strongly recommended that an additional urinary/serum specimen be obtained after 48-72 hours and tested again. Patients suspected to be pregnant but showing negative test results should be re-tested with first morning specimens obtained 48-72 hours later.

QUALITY CONTROL

The specificity of the HCG Rapid Test Device (Urine/serum) was determined in cross reactivity studies with known antibodies to Luteinizing Hormone (hLH), Follicle Stimulating Hormone (hFSH) and Thyroid Stimulating Hormone (hTSH). 300 mIU/mL hLH, 1000 mIU/mL hFSH and 1000 µIU/mL hTSH all gave negative results.

EXPECTED VALUES

Table: HCG Rapid Test Device vs. EIA (Urine)

<table>
<thead>
<tr>
<th>Relative Sensitivity</th>
<th>Relative Specificity</th>
<th>Overall Agreement</th>
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<tbody>
<tr>
<td>&gt;99.9% (97.2-100.0%)</td>
<td>&gt;99.9% (98.8-100.0%)</td>
<td>&gt;99.9% (98.5-100.0%)</td>
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<td></td>
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<td>99.9% (98.6-101.0%)</td>
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Glossary of Symbols

<table>
<thead>
<tr>
<th>Catalog number</th>
<th>Temperature limitation</th>
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<tr>
<td>Consult instructions for use</td>
<td>Batch code</td>
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<tr>
<td>Use in vitro diagnostic device</td>
<td>Life for use</td>
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<tr>
<td>Made in China</td>
<td>Contains sufficient for x2 tests</td>
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<tr>
<td>Authorized representative in the European Community</td>
<td>CE marking according to IVD Medical Devices Directive 98/79/EC</td>
</tr>
</tbody>
</table>

DISTRIBUTED BY

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