Human Chorionic Gonadotropin
hCG Test Cassette (Urine)

INTENDED USE
The Rapid Response™ hCG Test Cassette (Urine) 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 aid in the early detection of pregnancy.

INTRODUCTION
Human chorionic gonadotropin (hCG), a glycoprotein hormone secreted by viable placental tissue during pregnancy, is secreted in urine approximately 20 days after the last menstrual period. 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.

PROCEDURE
Bring tests, specimens, and/or controls to room temperature (15-30°C; 59-86°F) before use. Remove the test from its sealed pouch, carefully tear open on a clean, level surface. Label the device with patient or control identification. For best results the assay should be performed within one hour.

1. Add 3 drops of specimen (approximately 120 μL) directly into the specimen well (S) and start the timer.
2. Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the test area.
3. Wait for the colored band(s) to appear. The result should be read at 3 minutes. Do not interpret the result after 10 minutes.

NOTE: Low hCG concentrations may produce very weak test 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 apparent 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 using the kit immediately and contact your local distributor.

NOTE: The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Although this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.

QUALITY CONTROL

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

LIMITATIONS OF THE TEST

1. The Rapid Response™ hCG Test Cassette (Urine) is for professional in vitro diagnostic use, and should only be used for the qualitative detection of human chorionic gonadotropin.
2. Very dilute urine specimens, exhibiting low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected after a negative result, a first morning urine specimen should be obtained 48-72 hours later and tested.
3. Very low levels of hCG (less than 50 mIU/mL) are present in urine or serum shortly after implantation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result that is weakly positive should be interpreted in conjunction with other clinical and laboratory data.
4. A number of conditions other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasms including testicular tumors, prostate cancer, breast cancer, and lung cancer, cause elevated levels of hCG (>10 000 mIU/mL). Therefore, the presence of hCG in urine as determined by using the Rapid Response™ hCG Test Cassette (Urine) should not be used to diagnose pregnancy unless these clinical conditions have been ruled out.

EXAMPLES

Expected Values

If hCG concentration in pregnant women rises very rapidly after implantation, reaching a peak concentration in excess of 200 mIU/mL about 2-3 months after the last menstrual period. The Rapid Response™ hCG Test Cassette (Urine) has a sensitivity of 20 mIU/mL for urine and is capable of detecting pregnancy as early as 1 day after the first missed menses. Reportedly, a level of 20 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 urine 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.

INTERFERENCE TESTING
The following substances were added to hCG free and urine samples spiked with 20 mIU/mL hCG. None of the substances interfered with the assay at the listed concentrations.

<table>
<thead>
<tr>
<th>Substance</th>
<th>Concentration (mIU/mL)</th>
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</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>20 mg/dl</td>
</tr>
<tr>
<td>Ascorbic Acid</td>
<td>20 mg/dl</td>
</tr>
<tr>
<td>Caffeine</td>
<td>20 mg/dl</td>
</tr>
<tr>
<td>Glucose</td>
<td>2 g/dl</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>1 mg/dl</td>
</tr>
</tbody>
</table>

LITERATURE REFERENCES


GLOSSARY OF SYMBOLS

- CB: Catalog number
- TM: Time Limitation
- CS: Consult instructions for use
- BD: Batch code
- ML: In vitro diagnostic medical device
- Mf: Manufacturer
- NF: Contains sufficient for n= tests
- NR: Do not reuse

Table: Rapid Response™ hCG Test Cassette (Urine) vs. EIA (Urine)

<table>
<thead>
<tr>
<th>Substance</th>
<th>Relative Sensitivity:</th>
<th>Relative Specificity:</th>
</tr>
</thead>
<tbody>
<tr>
<td>EIA</td>
<td>+</td>
<td>% Total</td>
</tr>
<tr>
<td>Rapid Response™ hCG Test Cassette (Urine)</td>
<td>+</td>
<td>% Total</td>
</tr>
</tbody>
</table>

Relative Sensitivity: >99.9% (98.7%-100.0%)*

Relative Specificity: >99.9% (99.8%-100.0%)*

*95% Confidence Interval

SPECIFICITY
The specificity of the Rapid Response™ hCG Test Cassette (Urine) was determined in cross-reactivity studies with known amounts of Luteinizing hormone (LH), Follicle Stimulating Hormone (FSH) and Thyroid Stimulating Hormone (TSH). 300 mIU/mL LH, 1000 mIU/mL FSH and 1000 μIU/mL TSH all gave negative results.

PRODUCT COLLECTION AND STORAGE

- The kit should be stored at 2-30°C (36-86°F) until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.

STORAGE AND STABILITY

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Glossary of Symbols

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