Introduction

Human chorionic gonadotropin (hCG), a glycoprotein hormone secreted by the placenta during pregnancy, is excreted 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.

Materials

- Individually packed test strips
- Package insert
- Materials Provided
- Materials Required but Not Provided
- Specimen collection container
- Centrifuge
- Timer

Precautions

- For professional in vitro diagnostic use only
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Damage may allow contamination of the specimen
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious and handled observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to testing. Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe standard precautions for hand hygiene and disease transmission hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

Storage and Stability

- The kit should be stored at 2-30°C (36-84°F) until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

Specimen Collection and Storage

- The Rapid Response hCG Test Strip (Urine) is intended for use with human urine 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.
- Turbid specimens should be centrifuged, filtered, or allowed to settle and only the clear supernatant should be used for testing.
- Urine specimens must be collected in clean, dry containers. Ensure that the volume of specimen collected is sufficient to submerge the dip region of the strip.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C (36-46°F) for up to 48 hours. For long term storage, specimens should be kept below -20°C (-4°F).
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed before testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

Procedure

Bring tests, specimens, and/or controls to room temperature (15-30°C; 59-86°F) before use. 1. Remove the test from its sealed package and use as soon as possible. For best results, the assay should be performed within one hour. 2. Hold the strip by the end, where the product name is printed. To avoid contamination, do not touch the strip membrane. 3. Holding the strip vertically, dip the test strip in the urine specimen for at least 10-15 seconds. Do not immerse past the maximum line (MAX) on the test strip.
4. As the test begins to work, color will migrate across the membrane.
5. After the test has finished running, remove the strip from the specimen and place it on a non-absorbent flat surface. Start the timer and wait for the colored band(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.

Interpretation of Results

Postive: 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 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. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
- Insufficient specimen volume, incorrect operating procedure or performing expired tests are the most likely reasons for control band failure.

Quality Control

- Internal procedural controls are included in the test. The appearance of a colored band in the control region is considered a positive result. These controls are processed under the same conditions as the test strip.
- 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

- The Rapid Response hCG Test Strip (Urine) is for professional in vitro diagnostic use, and should only be used for the qualitative detection of human chorionic gonadotropin.
- Very dilute urine specimens, exhibiting low specific gravity, may not contain representative levels of hCG. If pregnancy is suspected after a negative result, a first morning urine sample should be obtained 48-72 hours later and tested.
- Very low levels of hCG (<50 mIU/mL) are present in urine or serum shortly after implantation. However, because a significant number of first trimester pregnancies terminate naturally, a false negative result is not an unusual outcome, which appear as very light bands in the test region.

Performance Characteristics

- The specificity of the Rapid Response hCG Test Strip (Urine) was determined in cross-reactivity studies with known amounts of Luteinizing Hormone (LH), Follicle Stimulating Hormone (FSH) and Thyroid Stimulating Hormone (TSH). 390 mIU/mL LH, 1000 mIU/mL FSH and 1000 mIU/mL TSH all produced negative results.

Interference Testing

The following substances were added to hCG free urine and urine samples spiked with Btntx Inc. hCG. None of the substances interfered with the assay at the listed concentrations.

<table>
<thead>
<tr>
<th>Substance</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caffeine</td>
<td>2 g/dL</td>
</tr>
<tr>
<td>Glycine</td>
<td>20 mg/dL</td>
</tr>
<tr>
<td>Lactose</td>
<td>20 mg/dL</td>
</tr>
<tr>
<td>Glucose</td>
<td>2 g/dL</td>
</tr>
<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>
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</tr>
<tr>
<td>Glucose</td>
<td>2 g/dL</td>
</tr>
</tbody>
</table>

LITERATURE REFERENCES


Glossary of Symbols

- Database: Catalog number
- Code: Temperature limitation
- Instructions: Consult instructions for use
- Batch code: In vitro diagnostic medical device
- User: Manufacturer
- Contains sufficient for <n> tests: Do not reuse

Expec T Values

Urine hCG concentration in pregnant women rises very rapidly after implantation, reaching a peak concentration in excess of 200 IU/mL about 2-3 months after the last menstrual period. The Rapid Response hCG Test Strip (Urine) has a sensitivity of 20 mIU/mL for urine and is capable of detecting pregnancy within 2-4 days of 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 later and tested. Patients suspected to be pregnant but showing negative test results should be re-tested with a first morning specimen obtained 48-72 hours later.