**INTENDED USE**

One Step hCG Pregnancy Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.

**SUMMARY AND EXPLANATION**

hCG is a glycoprotein hormone produced by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in urine as early as 8 to 10 days after conception. hCG levels continue to rise very rapidly, frequently exceeding 100mIU/mL by the first missed menstrual period, and peaking in the 100,000-200,000mIU/mL range about 10-12 weeks into pregnancy. The appearance of hCG in urine 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.

One Step hCG Pregnancy Test is a rapid test that qualitatively detects the presence of hCG in urine specimen at the sensitivity of 20mIU/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, One Step hCG Pregnancy Test shows no cross-reactivity interference from the structurally related glycoprotein hormones hFSH, LH, and hTSH at high physiological levels.

**PRINCIPLE OF TEST**

One Step hCG Pregnancy Test is a rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy. The test utilizes a combination of antibodies including a monoclonal hCG antibody to selectively detect elevated levels of hCG. The assay is conducted by adding urine specimen to the specimen well of the test device and observing the formation of pink colored lines. The specimen migrates via capillary action along the membrane to react with the colored conjugate.

Positive specimens react with the specific antibody-hCG-colored conjugate and form a pink colored line at the test line region of the membrane. Absence of this pink colored line suggests a negative result. To serve as a procedural control, a pink colored line will always appear at the control line region if the test has been performed properly.

**REAGENTS**

Coated Antibodies:
- Control region: Goat anti-mouse (IgG) polyclonal antibody
- Test region: Mouse monoclonal anti-hCG antibody A

Labeled Antibodies:
- Colloidal gold conjugate of monoclonal anti-hCG antibody B

**WARNINGS & PRECAUTION**

1) For in vitro diagnostic and professional use only.

2) Check expiration date on package label before use. Do not use test kit beyond the expiry date.

3) Inspect pouch for damage before use. Do not use if pouch is visibly damaged before opening.

4) The test kit should not be reused.

5) The test kit is moisture sensitive and should be used immediately after taking out of the pouch. When handling, avoid touching the test membrane.

6) Urine specimens may be infectious; insure proper handling and dispose of all used reaction devices into a biohazard container.

**MATERIALS PROVIDED**

1) One Step hCG Pregnancy Test Strip
2) Instructions for use

**MATERIALS NEEDED BUT NOT PROVIDED**

1) Clean glass or plastic container for specimens collection
2) Timer

**SPECIMEN COLLECTION**

A fresh urine specimen should be used, no special pre-treatment is necessary. Specimens should be collected in a clean glass or plastic container. The specimen may be refrigerated (2-8°C) and stored up to 2 days. For longer storage, freeze samples at -20°C or below. Refrigerated samples should be allowed to come to room temperature and mixed thoroughly before assaying. Frozen samples should be thawed completely allowed to come to room temperature, and mixed thoroughly before assaying.

**DIRECTIONS FOR USE**

Allow the test and the specimen to equilibrate to room temperature (15-30°C) prior to testing.

1. To begin testing, open the sealed pouch by tearing along the notch. Remove the test kit from the pouch and use it as soon as possible.

2. Immerse the strip vertically into the urine sample with the arrow pointing towards the urine. Do not immerse past the “Mark” Line. Take the strip out after 10 seconds and lay the strip flat on a clean, dry, non-absorbent surface.

3. Wait for the pink colored bands to appear. Depending on the concentration of hCG, positive results may be observed in as little as 40 seconds. For all results, wait 5 minutes to confirm the observation. Do not interpret the result after 30 minutes. It is important that the background is clear before the result is read.

**STORAGE AND STABILITY**

The test kit can be stored at temperatures between 2 to 30°C in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat. The expiration dating was established under these storage conditions.

**QUALITY CONTROL**
Ascorbic Acid 20 mg/ml
Albumin 50 mg/ml
Atropine 20 mg/ml
Caffeine 20 mg/ml
Gentestic Acid 20 mg/ml
Glucose 2 g/dl
Hemoglobin 1 mg/dl

BIBLIOGRAPHY


LIMITATIONS

1. False negative results may occur when the levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a first morning urine should be collected 48 hours later and tested.
2. This test has been developed for testing urine samples only. The performance of this test using other specimens has not been substantiated.
3. Very dilute urine specimens, as indicated by a low specific gravity, may not contain representative levels of hCG. If pregnancy is still suspected, a first morning urine specimen should be collected 48 hours later and tested.
4. Very low levels of hCG (less than 50mIU/mL) are present in urine specimens shortly after ovulation. However, because a significant number of first trimester pregnancies terminate for natural reasons, a test result test is weakly positive should be confirmed by retesting with a first morning urine collected 48 hours later.
5. As with any assay employing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the specimen. Specimens from patients who have received preparations of monoclonal antibodies for diagnosis or therapy may contain HAMA. Such specimens may cause false positive or false negative results.
6. This test provides a presumptive diagnosis for pregnancy. A confirmed pregnancy diagnosis should only be made by a physician after all clinical and laboratory findings have to be evaluated.

PERFORMANCE CHARACTERISTICS

High Dose Effect
Normal urine that were spiked with hCG concentrations of 62,500, 125,000, 250,000, 500,000 and 1,000,000 mIU/mL were used to study the high dose hook effect on One Step hCG Pregnancy Test. It was noticed that both color bands at the test band region and the control region were visible. However, when hCG levels were over 500,000 mIU/mL, the higher the hCG concentration became, the lighter the band at the test region became.

Accuracy
An external clinical evaluation was conducted comparing the results obtained using the One Step hCG Pregnancy Test to another commercially available One Step hCG Pregnancy Test. The study included 40 positive or negative urine samples. The results demonstrated 100% agreement when trained technicians performed comparison testing on the tests. The results are shown in Table 1.

Table 1: Comparison between UMS and Predicate Test - Urine Samples

<table>
<thead>
<tr>
<th>Substance</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>20 mg/ml</td>
</tr>
<tr>
<td>Acetylsalicylic acid</td>
<td>20 mg/ml</td>
</tr>
</tbody>
</table>

Table 2: Sensitivity of One Step hCG Pregnancy Test - Urine Samples

<table>
<thead>
<tr>
<th>hCG added</th>
<th>0</th>
<th>10</th>
<th>20</th>
<th>40</th>
<th>100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative</td>
<td>40</td>
<td>36</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Positive</td>
<td>0</td>
<td>4</td>
<td>40</td>
<td>40</td>
<td>40</td>
</tr>
</tbody>
</table>

Table 3: Specificity of One Step hCG Pregnancy Test

<table>
<thead>
<tr>
<th>hCG conc. in sample (mIU/mL)</th>
<th>Unspiked urine samples</th>
<th>Ureine samples spiked with homologous hormones</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>FSH</td>
<td>LH</td>
</tr>
<tr>
<td></td>
<td>mIU/mL</td>
<td>mIU/mL</td>
</tr>
<tr>
<td>0</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>40</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

Interfering substances
The following substances were also added in negative hCG, 20 mIU hCG/mL and 50 mIU hCG/mL spiked urine samples. None of the substances at the concentrations tested interference in this assay when tested with Urine strip based test kits. The substances and their concentration are shown in Table 4.

Table 4: Interfering substances on hCG Pregnancy Test

<table>
<thead>
<tr>
<th>Substance</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>20 mg/ml</td>
</tr>
<tr>
<td>Acetylsalicylic acid</td>
<td>20 mg/ml</td>
</tr>
</tbody>
</table>