One Step Assay
Rapid Visual Results
For Qualitative In Vitro Diagnostic Use

INTENDED USE
The Pregnancy Urine Dip-Strip Test is a qualitative immunoassay for the detection of human chorionic gonadotropin (hCG) in human urine for the early detection of pregnancy. It is for health care professional use only and not for self testing.

SUMMARY AND EXPLANATION OF THE TEST
This pregnancy test is based on the detection of the human chorionic gonadotropin (hCG) in urine. hCG is a hormone produced by the placenta. In normal subjects, hCG in urine provides an early indication of pregnancy. The Pregnancy Urine Dip-Strip Test uses a monoclonal antibody specific to hCG in a one-step lateral flow chromatographic immunoassay to accurately detect hCG at the level close to or greater than 25 mIU/ml (WHO 3rd IS 75/537).

PRINCIPLE OF THE PROCEDURE
This assay is a one-step lateral flow chromatographic immunoassay. The test strip includes: 1) a conjugate pad containing mouse monoclonal anti-hCG antibody conjugated to colloidal gold and 2) nitrocellulose membrane containing a test line (T line) and a control line (C line).

The T line is coated with an anti-hCG capture antibody. When an adequate amount of specimen is applied to the sample pad of the device, hCG in the specimen binds to sites on the antibody-gold conjugate in the conjugate pad and migrates along the membrane strip. If the specimen contains hCG at a level close to or greater than 25 mIU/ml, enough of the hCG will bind to the capture antibody coated on the T line to form a burgundy-colored band. If the specimen does not contain hCG or the hCG level is below the detectable level, the T line will not develop.

The C line is coated with goat anti-mouse antibody, which should bind to the gold-antibody conjugate and forms a burgundy-colored line regardless of the presence of hCG.

REAGENTS AND MATERIALS SUPPLIED

- 50 test strips each sealed in a pouch with desiccant.
- 1 package insert (Instructions for Use).

MATERIAL REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer

STORAGE AND STABILITY
Store the kit at room temperature 15-30°C (59-86°F). Each device may be used until the expiration date printed on the label if it remains sealed in its foil pouch.

Do not freeze and/or expose the kit to temperatures over 30°C (86°F).

SPECIMEN COLLECTION
1. Each urine specimen must be collected in a clean container.
2. Specimens may be kept at 15-30°C (59-86°F) for 8 hours, at 2-8°C for up to 3 days and at -20°C or lower for prolonged storage. Do not mix stored samples.

PRECAUTION
1. The instructions must be followed exactly to obtain accurate results.
2. This test is for professional in vitro diagnostic use only.
3. Do not open the sealed pouch unless ready to conduct the assay.
4. Do not use expired devices.
5. Dispose of all specimens and used assay materials as potentially biohazardous.

ASSAY PROCEDURE
1. Refrigerated specimens and other test materials including device, must be equilibrated to room temperature before testing.
2. Remove a dip-strip from the pouch. Label the test and sample container (not provided), accordingly.
3. Hold the dip strip vertically from the handle end. Dip the sample pad in the specimen for about 10 seconds. Keep the specimen surface at the level indicated by the arrow sign on the test.
4. Remove the test from specimen, place it on a flat, dry surface.
5. Strong positive results may be observed in 2-3 minutes. Weak positive results may take a longer time, up to 5 minutes, to develop.

INTERPRETATION OF RESULTS

IMPORTANT: Do not interpret the results after 7 minutes. The T Line should always be interpreted independently of the C Line.

**POSITIVE**
- C (control) line appears
- T (test) line appears

**NEGATIVE**
- C line appears
- T line does not develop

**INVALID**
- No band is visible in the control region within 5 minutes, repeat the assay with a new device.

Positive:
If both C line and T line appear in the viewing area, the test indicates that hCG was detected in the specimen.

Samples with positive results should be confirmed with a more specific method before a positive determination is made.

Negative:
If only the C line appears, the test indicates that the hCG level in the specimen is not detectable and the result is negative. If pregnancy is suspected, repeat the test after 2 to 3 days with a new device and fresh sample.

Invalid:
If no band is visible in the control region within 5 minutes, repeat the assay with a new test device.

QUALITY CONTROL

- **Built-in Control**
  The Pregnancy Urine Dip-Strip Test contains a built-in control feature, the C line. The appearance of the burgundy C line indicates that the test has been performed correctly; specifically an adequate volume of specimen has been absorbed and capillary flow has occurred. The C line should always appear regardless of the presence of hCG. If the C line does not develop within 5 minutes, the result is invalid. In this case, review the procedure and repeat test with a new device.

- **External Quality Control**
  Good Laboratory Practice recommends using external controls, positive and negative, to assure the proper performance of the assay.
LIMITATIONS

1. This kit is not intended for any use other than early detection of pregnancy.
2. HCG may be detectable in some conditions other than normal pregnancy, that should be ruled out when diagnosing pregnancy.
   - Low titer elevations of hCG can occur in normal, non-pregnant subjects.
   - Ectopic pregnancy cannot be distinguished from normal pregnancy from hCG measurements alone.
   - Positive hCG levels may be detectable for several weeks following delivery or abortion.
3. The results must be evaluated with other data by a physician before diagnosing pregnancy.

EXPECTED VALUES

This test is capable of detecting hCG at a level as low as 25 mIU/ml (WHO 3rd IS 75/537) or the first day of a missed period and no sooner. In normal subjects, hCG in urine provides an early indication of pregnancy. In a 28 day cycle with ovulation occurring at day 14, hCG can be detected in urine in minute quantities around day 23, or 5 days before the expected menstruation. The hormone concentration doubles approximately every 2 days and peaks between 7-12 weeks after the first day of the last menstrual period with a mean concentration of 50,000 mIU/ml. Concentrations as high as 100,000 mIU/mL have been reported in normal pregnancies during the first trimester.

PERFORMANCE CHARACTERISTICS

1. Sensitivity
   The Pregnancy Urine Dip-Strip Test will display positive results with specimens containing hCG at the level close to or greater than 25 mIU/ml.
   The test is standardized to the WHO 3rd IS 75/537.

2. Accuracy
   - Samples studied
     Pooled urine specimens from forty healthy non-pregnant humans were spiked with hCG to concentrations of 0, 15, 20, 25, 30, 35, 50, 100 mIU/ml with 5 replicates each. All specimens were blind labeled.
   - Comparison studies
     Comparison studies on the Pregnancy Urine Dip-Strip Test with a legally marketed device were performed in-house and in a clinical reference laboratory. Positive and negative results were compared. The correlation of the results in the comparison study was 100%.
   - Physician’s Office Laboratory (POL) Studies
     The device was evaluated at three POL sites by persons with diverse educational backgrounds and work experiences. The results from all three POL sites agreed 100%.

3. Specificity
   The α subunit of hTSH, hLH, and hFSH is similar to or greater than that of hCG, which may cause cross reactivity between those hormones. High physiological concentrations of hTSH (up to 1,000 µIU/ml), hLH (up to 300 mIU/ml), and hFSH (up to 1,000 mIU/ml) spiked in hCG positive (spiked to 25mIU/ml) and negative specimens were tested, separately, in the Pregnancy Urine Dip-Strip Test, and did not affect the expected results in that study.

4. Interfering Substances
   The following analytes spiked in urine pools containing 0, or 25mIU/ml hCG (WHO 3rd IS) were tested, separately, in the Pregnancy Urine Dip-Strip Test, and did not affect the expected results.
## Chemical Analytes

<table>
<thead>
<tr>
<th>Description</th>
<th>Concentration</th>
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</thead>
<tbody>
<tr>
<td>Acetoacetic Acid</td>
<td>2,000 mg/dL</td>
</tr>
<tr>
<td>Acetaminophen</td>
<td>20 mg/dL</td>
</tr>
<tr>
<td>Acetylsalicylic Acid</td>
<td>20 mg/dL</td>
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<tr>
<td>Ascorbic Acid</td>
<td>20 mg/dL</td>
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<tr>
<td>Benzyliccaine</td>
<td>10 mg/dL</td>
</tr>
<tr>
<td>Caffeine</td>
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<tr>
<td>Cannabinoide</td>
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<tr>
<td>DMSO</td>
<td>5%</td>
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<tr>
<td>EDTA</td>
<td>80 mg/dL</td>
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<tr>
<td>Ephedrine</td>
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<tr>
<td>Ethanol</td>
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<tr>
<td>Gentamic Acid</td>
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<tr>
<td>Methadone</td>
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</tr>
<tr>
<td>Methanol</td>
<td>10%</td>
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<tr>
<td>Phenothiazine</td>
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<tr>
<td>Phenytoinamide</td>
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</tr>
<tr>
<td>Salicylic Acid</td>
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<tr>
<td>ß-Hydroxybutyrate</td>
<td>2,000 mg/dL</td>
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<tr>
<td>Uric Acid</td>
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## Biological Analytes

<table>
<thead>
<tr>
<th>Description</th>
<th>Concentration</th>
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<tbody>
<tr>
<td>Albumin (serum)</td>
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<tr>
<td>Bilirubin</td>
<td>1,000 µg/dL</td>
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<tr>
<td>Hemoglobin</td>
<td>1,000 µg/dL</td>
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<tr>
<td>Glucose</td>
<td>2,000 mg/dL</td>
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<tr>
<td>pH</td>
<td>5-9</td>
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</table>

## Bacteria

<table>
<thead>
<tr>
<th>Description</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>E. Coli</td>
<td>10^8 CFU/mL</td>
</tr>
<tr>
<td>Group B strepococcus</td>
<td>2.5x 10^8 CFU/mL</td>
</tr>
<tr>
<td>Chlamydia trachomatis</td>
<td>10^8 IFU/mL</td>
</tr>
</tbody>
</table>

## REFERENCES