

One Step hCG Pregnancy Urine Test Cassette

Cat. No: 100-10

A rapid one step test for the qualitative detection of human chorionic gonadotropin (hCG) in urine.

For professional in vitro diagnostic use only.

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 7 to 10 days after conception. hCG levels continues 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.^{7,8,9,10} 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, hLH 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) In vitro diagnostic use for professional use only.
- 2) Do not use test kit beyond the expiry date.
- 3) The test device should not be reused.
- 4) 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
- 2) Disposable pipette
- 3) 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. Draw the urine sample using the pipette provided, and dispense 3-4 drops (approx. 0.2 mL) onto the sample well of the cassette (see diagram).
3. Wait for the pink colored bands to appear. Depending on the concentration of hCG in the test specimen, positive results may be observed in as soon as 40 seconds. However, to confirm negative results, the complete reaction time of 5 minutes is required. It is important that the background is clear before the result is read.

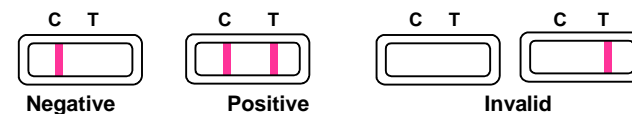
Note: A low hCG concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

Negative: Only one pink colored band appears on the control region. No apparent band on the test region.

Positive: Distinct pink color bands appear on the control and test regions. The color intensity of the test bands may vary since different stages of pregnancy have different concentrations of hCG hormone.

Invalid: No line appears in the control zone "C", the test should be voided since an improper test procedure may have been performed or deterioration of reagents may have occurred. This is due to the internal control built in which a distinct control region (C) line should always appear. Repeat the test using a new device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



STORAGE AND STABILITY

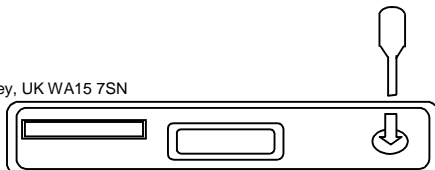
The test kit can be stored at temperatures between 2 to 30°C in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat. The expiration dating was established under these storage conditions.

QUALITY CONTROL

A pink line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

External controls should be used to assure that the reagents are working properly and that the assay procedure is followed correctly. It is recommended that a control be tested at regular intervals as good laboratory testing process.

Users should follow the appropriate federal, state, and local guidelines concerning the running of external quality controls.



| | | Predicate | | Subtotal |
|-------------------|---|-----------|----|----------|
| | | + | - | |
| IND (Cassette) | + | 51 | 1 | 52 |
| | - | 0 | 48 | 48 |
| Subtotal | | 51 | 49 | 100 |

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 specimen 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 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, 1,000,000, and 2,000,000 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 rest 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 100 positive or negative urine samples. The

results demonstrated 99% agreement when trained technicians performed comparison testing on the tests. The results are shown in Table 1.

Table 1: Comparison between IND vs. Predicate Urine cassette Format – Urine Samples

Percent Accuracy = 99%
Discrepant Results = 1%

Sensitivity

One Step hCG Pregnancy test detects urine hCG concentrations greater than 20 mIU/ml as indicated by the appearance of a color band at the test region. Additionally, samples containing less than 20 mIU/mL hCG may also produce a positive result. To evaluate the sensitivity of One Step hCG Pregnancy test at low levels of hCG the following experiments were carried out. Urine samples from 120 known non-pregnant subjects were spiked with hCG to the concentrations of 0, 10, 15, 20, 40, 100 mIU/ml. A total of twenty samples at each concentration were performed and blindly labeled and tested. The results are summarized in Table 2.

Table 2: Sensitivity of One Step hCG Pregnancy Test – urine Samples

| hCG added | 0 | 10 | 15 | 20 | 40 | 100 |
|-----------|----|----|----|----|----|-----|
| # Samples | 20 | 20 | 20 | 20 | 20 | 20 |
| Negative | 20 | 20 | 18 | 1 | 0 | 0 |
| Positive | 0 | 0 | 2 | 19 | 20 | 20 |

Specificity

Specificity of One Step hCG Pregnancy test was determined from cross reaction studies with known amounts of luteinizing hormone (LH), follicle stimulating hormone (FSH), and thyroid stimulation hormone. Samples of urine with different hCG concentrations were mixed individually with 300 mIU LH/mL, 1000 mIU FSH/mL, and 1000 µIU TSH/mL and gave expected results. The results were done in-house by trained technicians in a two day process. The results, which have been pooled together due to little variance are shown in Table 3.

Table 3: Specificity of One Step hCG Pregnancy Test

| hCG conc. in sample (mIU/mL) | Unspiked urine samples | Urine samples spiked with homologous hormones | | |
|------------------------------|------------------------|---|------------|-------------|
| | | FSH | LH | TSH |
| | | 1000 mIU/ml | 300 mIU/ml | 1000 µIU/ml |
| 0 | - | - | - | - |
| | - | - | - | - |
| 20 | + | + | + | + |
| | + | + | + | + |

| | | | | |
|-----|---|---|---|---|
| | + | + | + | + |
| 100 | + | + | + | + |
| | + | + | + | + |

Interfering substances

The One-Step hCG Pregnancy test was checked for possible interference from visibly hemolyzed, lipemic and icteric samples. Human hemoglobin, bilirubin or albumin was spiked into urine samples with different concentration of hCG and tested using unspiked samples as controls. No significant interference was observed in 20 sample testing results that were either positive or negative for hCG. The results, which have been pooled together due to little variance are shown in Table 4.

Table 4: Non-Specific Interference on hCG Pregnancy Test

| Sample No | Unspiked samples | Urine samples spiked with (mg/mL) | | | |
|-----------|------------------|-----------------------------------|-----------|---------|-----|
| | | Hemoglobin | Bilirubin | Albumin | 100 |
| 1 | - | - | - | - | - |
| 2 | - | - | - | - | - |
| 3 | - | - | - | - | - |
| 4 | - | - | - | - | - |
| 5 | - | - | - | - | - |
| 6 | - | - | - | - | - |
| 7 | - | - | - | - | - |
| 8 | - | - | - | - | - |
| 9 | - | - | - | - | - |
| 10 | - | - | - | - | - |
| 11 | + | + | + | + | + |
| 12 | + | + | + | + | + |
| 13 | + | + | + | + | + |
| 14 | + | + | + | + | + |
| 15 | + | + | + | + | + |
| 16 | + | + | + | + | + |
| 17 | + | + | + | + | + |
| 18 | + | + | + | + | + |
| 19 | + | + | + | + | + |
| 20 | + | + | + | + | + |

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 cassette based test kits. The substances and their concentration are shown in Table 5.

Table 5: Interfering substances on hCG Pregnancy Test








| Substance | Concentration |
|----------------------|---------------|
| Acetaminophen | 20 mg/ml |
| Acetylsalicylic acid | 20 mg/ml |
| Ascorbic Acid | 20 mg/ml |
| Albumin | 100 mg/ml |
| Atropine | 20 mg/ml |
| Bilirubin (urine) | 2 mg/ dl |
| Caffeine | 20 mg/ml |
| Gentestic Acid | 20 mg/ml |
| Glucose | 2 g/dl |

| | |
|------------|---------|
| Hemoglobin | 1 mg/dl |
|------------|---------|

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GRAPHICAL SYMBOLS USED

| | | | |
|--|-----------------------------|---|--------------|
|  | Storage temperature |  | Lot number |
|  | In vitro diagnostic device |  | Expiry date |
|  | Read instruction before use |  | Manufacturer |
| | |  | Do not reuse |

