RefuAH

**ONE-STEP URINE PREGNANCY CASSETTE**
(CLIA-WAIVED) FOR URINE TEST ONLY

## INTENDED USE

One-Step Urine Pregnancy Cassette is a colloidal gold antibody complex based immunoassay designed for the qualitative determination of human chorionic gonadotropin (hCG) in urine. This test is for professional use in obtaining a visual qualitative result for the early detection of pregnancy.

## INTRODUCTION

Human chorionic gonadotropin **(hCG)** is a glycoprotein hormone secreted by the developing placenta shortly after fertilization. From the onset of pregnancy hCG concentrations in a woman's urine increases rapidly making the hormone a good marker for pregnancy testing. Seven to ten days after conception the hCG concentration reaches 25 mIU/mL and then increases steadily to reach its maximum between the eighth and eleventh week of pregnancy.(1,2,3)
One-Step Urine Pregnancy Test is a qualitative sandwich dye conjugate immunoassay for the determination of human hCG in urine. (4,5) The method employs a combination of monoclonal and polyclonal antibodies to selectively identify hCG in test samples with a high degree of sensitivity. In less than 5 minutes, elevated levels of hCG equal to or greater than 25 mIU/mL can be detected.

## PRINCIPLE

As the test sample, urine diffuses through the absorbent reaction pack, the labeled antibody-dye conjugate binds to the hCG in the specimen forming an antibody-antigen complex. This complex binds to the anti-hCG antibody in the test region (T) and produces a pink-rose color band when hCG concentration is equal to or greater than 25 mIU/mL. In the absence of hCG, there is no line in the test region. The reaction mixture continues flowing through the absorbent device past the test region and control region (C). Unbound conjugate binds to the reagents in the control region, producing a pink-rose color band, demonstrating that the reagents and reaction pack are functioning correctly.

## MATERIALS AND REAGENTS PROVIDED

1. One pouch containing a reaction cassette, a dropper and a desiccant. The desiccant is for storage purposes only, and is not used in the test procedures.
2. Product package insert.

## MATERIALS REQUIRED BUT NOT PROVIDED

1. A clean, dry, plastic or glass container to collect the urine.
2. Timer (watch or clock).
3. Control materials.

## STORAGE AND STABILITY

1. Store at 4°C to 30°C in the sealed pouch up to the expiration date.
2. Keep away from direct sunlight, moisture and heat.
3. DO NOT FREEZE.
4. Preferably open the pouch only shortly before the test.

## WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Discard after the first use. The test cassette cannot be used more than once.
3. Do not use the test kit beyond expiry date.
4. Do not use the kit if the pouch is punctured or not well sealed.
5. Keep out of the reach of children.

## SPECIMEN COLLECTION

**Urine** (0.5ml):
The urine specimen must be collected in a clean dry container either plastic or glass, without preservative. No centrifugation or filtration of urine is required. Specimens collected at any time may be used however the first morning urine generally contains the highest concentration of hormone.

Specimens may be refrigerated (2° - 8°C) and stored up to 48 hours prior to assay. If samples are refrigerated they must be equilibrated to room temperature (18° - 30°C) for 10 minutes before testing. Urine samples exhibiting visible precipitates should be filtered, centrifuged, or allowed to settle and clear aliquots obtained for testing.

## PROCEDURE

1. Equilibrate all materials and reagents to room temperature before testing.
2. Remove the "reaction pack" from its foil wrapper by tearing along the "splice".
3. Fill the dropper with urine and hold the dropper vertically and add four (**4**) full drops approximately 100ul, into the sample well.
4. Wait for the pink lines to appear. Positive results may be read as early as three (**3**) minutes. **It is important that the background is clear before the results are read. Do not interpret results after 5 minutes.**

## INTERPRETATION OF RESULTS

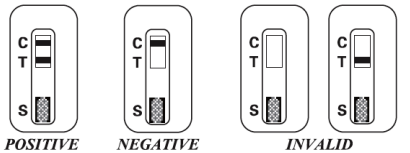
**Positive**: At 3-5 minutes, two pink colored bands appear, one in the control region (C) and one in the test region (T), indicate a positive result and that the specimen contains hCG level of 25mIU/mL or greater.

**Note:** *Early stages of pregnancy may show positive results nearer to 5 minutes due to low concentrations of hCG.*

**Negative**: At 3-5 minutes, only one pink colored band appears in the control region (C) indicating a negative result and that the specimen contains hCG level of less than 25 mIU/mL.

**Invalid**: At 3-5 minutes, if no bands appear, or a test band appears without a control band, the result is invalid and the test should be repeated using a new device.

**Do not interpret results after 5 minutes.**




**NOTE**: Avoid over flooding the device with sample. This will cause erroneous result. If this occurred, it is strongly recommended that the test be repeated. Also, if the flow of the sample is not observed through the viewing window, this is due to an insufficient amount of urine sample dispensed into the sample well.

## QUALITY CONTROL

Each reaction device has its own built-in quality control indicator. After performing the test and no line in either the "T" or "C" region of the reaction device is visible, or only one line appears in the "T ", you may have added the urine in the wrong window or the test device may have deteriorated. Repeat the assay using a new kit. It is strongly recommended that commercial controls should also be used with every new lot as part of the quality control.

## EXPECTED VALUES

Healthy men and healthy non-pregnant women do not have detectable hCG. In approximately 7 days after conception, hCG concentration of 5 - 50 mIU/mL in urine will appear. This level of hCG will reach 100 mIU/mL within 60 to 80 days and follow by a gradual fall to a mean level of about 20,000 mIU/mL after 120 days. (3,8)

## LIMITATIONS

1. Proteinuria, hematuria, gross bacterial contamination, and detergents may cause an increase in hCG in urine.

2. **False positive**: patients with trophoblastic diseases, hydatidiform mole, or choriocarcinoma may yield false positive results. Patients with ovarian and testicular teratomas have also been reported to excrete large quantities of hCG.
3. **False negative**: diluted or low specific gravity urine and conditions that may cause denaturation of hCG (e.g., pH, temperature, contamination with heavy metals, and so forth) may yield false-negative results.
4. Samples with hCG concentrations less than 25 mIU/mL will be detected as negative.

## STANDARDIZATION

One-Step Urine Pregnancy Test has been standardized to World Health Organization First International Reference Preparation (IRP 75 - 537).

## PERFORMANCE CHARACTERISTICS

1. **Sensitivity**:
   One-Step Urine Pregnancy Test detects hCG concentrations equal to or greater than 25 mIU/mL as indicated by the development of a line in the "T" region of the viewing window. Urine from healthy men and non-pregnant women will normally show undetectable levels of hCG when tested on One-Step Urine Pregnancy Test. The test will yield a positive result on the first day of missed menstrual period.
2. **Specificity**:
   Specificity was determined from cross reaction studies with known amounts of Luteinizing Hormone (hLH), Follicle, Stimulating Hormone (hFSH), and Thyroid Stimulating Hormone (hTSH), 300 mIU/mL hLH, 300 mIU/mL hFSH and 1000 mIU/mL hTSH all gave negative results.
3. **Accuracy**:
   The result from One Step hCG Urine Pregnancy Test is compared with that from a commercially available membrane hCG test (Acon). Among 619 urine specimens, both assays identified 375 negative and 244 positive results. In the study, One Step hCG Urine Pregnancy Test showed > 99.5% overall agreement when compared with the other urine membrane hCG test.
4. **Interference Testing**:
   The following substances were added in hCG free and 25 mIU/mL hCG spiked urine samples. None of the substances at concentration tested interfered in the assay.
   - Acetaminophen 20mg/dl
   - Acetylsalicylic acid 20mg/dl
   - Ascorbic acid 20mg/dl
   - Atropine 20mg/dl
   - Caffeine 20mg/dl
   - Albumin 20mg/dl
   - Gentesic acid 20mg/dl
   - Glucose 2mg/dl
   - Hemoglobin 20mg/dl
   - Tetracycline 20mg/dl
   - Ampicillin 20mg/dl

## REFERENCES


1. Cart, K.J., Dufan, M.L., and Vaitukaitis, J.L., J. *Clin. Endocrinol. Metab.*,Vol. 40, 537, (1975).
2. Lenton, E.A., Neal, L.M., Sulaiman, R., *Fertility & Sterility*, Vol. 37, 773, (1982).
3. Batzer, F.R., *Fertility & Sterility*, Vol. 34, 1, (1980).
4. Engvall, E., *Method in Enzymology*, Vol. 70, p. 419-439, (1980).
5. Uotila, M., Ruoslahti, E., and Engvall, E., *J. Immunol. Methods*. Vol. 42, 11, (1981).
6. Dawood, M.Y., Saxeba, B.B., and Landesman, R., Ob. Gyn., Vol. 126, 678, (1976).
7. Tietz. "Clinical Guide to Laboratory Tests" p. 126 - 128, W.B. Saunders Co., Philadelphia, (1990).
8. Tietz. "Fundamentals of Clinical Chemistry" p. 798, W.B. Saunders Co., Philadelphia, (1976).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