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**ONE-STEP PREGNANCY TEST
URINE/SERUM (DIPSTICK)****INTENDED USE**

One-Step Urine/Serum Combo Pregnancy DipStick Test is a colloidal gold antibody complex based immunoassay designed for the qualitative determination of human chorionic gonadotropin (hCG) in serum or 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 serum and urine increase 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/Serum Combo Pregnancy DipStick 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 or serum, 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.

REAGENTS

One-Step Test Strip Urine/Serum:

Test Strip containing goat polyclonal antibody coated membrane and a pad containing mouse monoclonal IgG (antibody) dye conjugate in protein matrix with 0.1% sodium azide.

MATERIALS AND REAGENTS PROVIDED

1. One-Step Urine/Serum Combo Pregnancy Test Strip:
Test strip containing goat polyclonal antibody coated membrane and a pad containing mouse monoclonal IgG (antibody) dye conjugate in protein matrix with 0.1% sodium azide. Test strip is sealed in a foil pouch containing a desiccant.
2. Product package insert.

MATERIALS REQUIRED BUT NOT PROVIDED

Specimen collection containers and a clock or timer.

STORAGE AND STABILITY

One-Step reaction pack can be stored at room temperature (18 - 30°C) or refrigerated (2 - 8°C). Avoid freezing.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only.

2. **Warning:** the reagents in this kit contain sodium azide that may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build up. Urine specimens should be considered hazardous and handled appropriately.

SPECIMEN COLLECTION⁶**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.

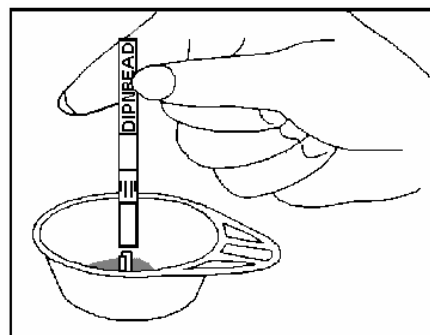
Serum (0.5ml):

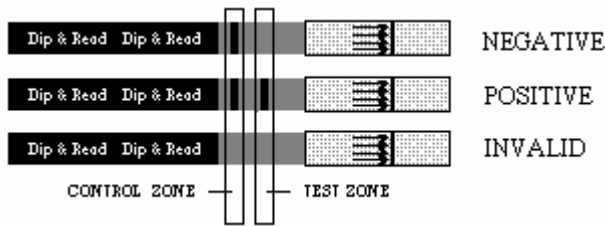
Collect blood aseptically by venipuncture into a clean tube without anticoagulants. Permit blood to form a clot for 20 to 30 minutes at room temperature. Centrifuge to obtain clear serum and transfer the serum into a clean plastic or glass tube. The sample serum can be tested without prior treatment.

Specimens may be refrigerated (2 - 8°C) and stored up to 72 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. Bring device and sample to room temperature (18-30°C).
2. Remove the "test strip" from its foil wrapper by tearing along the "splice".
3. Fill a test tube or a sample collection container with urine or serum sample and hold the strip in a vertical position.
4. Place the test strip into the tube or container containing the sample. The specimen level should not be lower than 150 µl or higher than the "↓↓↓" level indicated on the strip. The strip must be placed in the tube or container so that the words "dip" and "read" are in an upright position.
5. Read results at 5 minutes. Do not interpret results after 5 minutes.

**INTERPRETATION OF RESULTS**



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

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

Invalid: At 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 test strip.

QUALITY CONTROL

Each test strip has its own built-in quality control indicator, the C line. The rose-pink color band appears on C line indicating that the test has been performed correctly. Regardless of the result, the C line should always appear within 5 minutes.

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 serum and urine will appear.⁷ 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.⁷
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.⁸
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.⁸
4. Samples with HCG concentrations less than 25 mIU/mL will be detected as negative.

STANDARDIZATION

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

PERFORMANCE CHARACTERISTICS

1. **Sensitivity:** One-Step Combo 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 Combo 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), 500 mIU/ml hLH, 1000 mIU/ml hFSH and 1000 mIU/ml hTSH all gave negative results.

3. **Menopausal Urines:** A study was performed using urine specimens from 20 postmenopausal women. These specimens were chosen because urine from postmenopausal women frequently interferes with pregnancy tests due to cross reactivity with other gonadotropin hormones. All 20 urine specimens were negative when tested with One-Step Combo Pregnancy Test. Potentially interfering substances were added to urine that had HCG levels of 0 and 25 mIU/ML. In each case, no interference with the expected One-Step Combo Pregnancy Test results was observed.

4. **Accuracy:** *Urine:* A study was performed using a total of 70 positive and negative urine specimens. These specimens were assayed with One-Step Combo Pregnancy Test and a similar commercially available pregnancy test and both tests gave identical results with all 70 samples. An additional 61 tests were assayed by outside laboratories and they too produced identical results when compared with similar pregnancy tests.

Serum: A study was performed using a total of 165 serum specimens. These specimens were assayed with Teco's Combo One-Step and a commercially available test according to the respective package insert procedures. All 165 specimens showed identical results.

5. **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	20 mg/dl	Caffeine	20 mg/dl
Acetylsalicylic Acid	20 mg/dl	Gentescic Acid	20 mg/dl
Ascorbic Acid	20 mg/dl	Glucose	2 g/dl
Atropine	20 mg/dl	Hemoglobin	1 mg/dl

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