

## TECO DIAGNOSTICS

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## ONE-STEP PREGNANCY DIPSTICK TEST

### INTENDED USE

For the rapid determination of human chorionic gonadotropin (hCG) in human urine. The test strip is used to obtain 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<sup>1,2,3</sup>.

One-Step Pregnancy Dipstick Test is a qualitative, sandwich dye conjugate immunoassay that employs a unique combination of monoclonal and polyclonal antibodies to selectively identify hCG in test samples with a high degree of sensitivity.<sup>4,5</sup> In less than 5 minutes, elevated levels of hCG as low as 25 mIU/mL can be detected.

### PRINCIPLE

The test strip in the device consists of a conjugate pad containing mouse monoclonal anti-hCG antibody dye-conjugated to Colloidal Gold, and a nitrocellulose membrane strip containing a test (T) line that is captured with rabbit anti-hCG antibody, and a control (C) line containing goat anti-mouse antibody, which should be bound to the conjugated monoclonal antibody regardless of the presence of hCG. As the test sample diffuses through the absorbent test strip, 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 (T) zone and produces a pink-rose color band when hCG concentration is greater than 25 mIU/ml. In the absence of hCG or the hCG level is below the detectable level, there is no line in the test zone. The reaction mixture continues flowing through the absorbent device past the test zone and control zone. Unbound conjugate binds to the reagents in the control zone, producing a pink-rose color band, demonstrating that the reagents and test strip are functioning correctly.

### MATERIALS AND REAGENTS PROVIDED

1. One-Step Dipstick Pregnancy Test Strip: Test strip contains polyclonal antibody coated membrane and a pad contains 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 bag and a dropper.
2. Product package insert

### MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection container
2. Timer or watch

### STORAGE AND STABILITY

One-Step reaction pack can be stored at 4-30°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, always flush with large volumes of water to prevent azide build up.

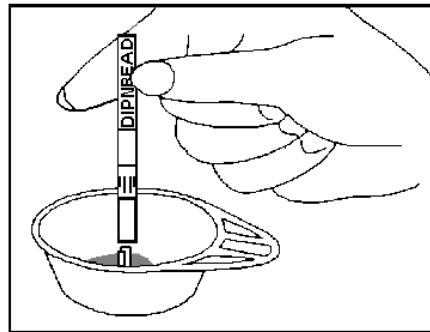
### SPECIMEN COLLECTION<sup>6</sup>

1. The urine specimen must be collected in a clean dry container either plastic or glass, without preservative. Specimens collected at any time may be used, however the first morning urine generally contains the highest concentration of hormone.
2. Urine 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(15-30°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.

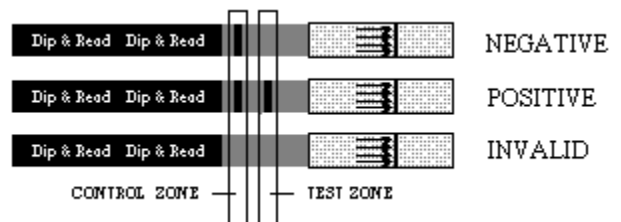
### ASSAY PROCEDURE

*Refrigerated specimens or other materials should be equilibrated to room temperature(15-30°C) prior to testing.*

1. Open the foil pouch at the notch and remove test strip.
2. Fill a test tube or a urine cup with specimen and place the strip in vertical position. The specimen level should not be lower than 150 µl or higher than the "↓↓↓" level indicated on the strip.
3. Read results at 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 device.

**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.

**PERFORMANCE CHARACTERISTICS**

1. Sensitivity and Specificity:

One-Step Pregnancy Dipstick Test detects Urinary hCG concentrations greater than 25 mIU/ml as indicated by the development of two lines on the test strip.

Urine from healthy men and non-pregnant women will normally show undetectable levels of hCG when tested on One-Step Pregnancy Dipstick Test. The test will yield a positive result on the first day of missed menstrual period.

Specificity of the One-Step Dipstick Pregnancy Test 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.

2. 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 Dipstick 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 Dipstick Pregnancy Test results was observed.

3. Standardization:

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

4. Accuracy:

A study was performed using a total of 150 positive and negative urine specimens. These specimens were assayed with One-Step Dipstick Pregnancy Test and our Visual Pregnancy Test and it 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.

**Chemical analytes:**

DESCRIPTION	CONCENTRATION
Acetoacetic Acid	2,000 mg/ml
Acetaminophen	20 mg/ml
Acetylsalicylic Acid	20 mg/ml
Ascorbic Acid	20 mg/ml
Benzocgonine	10 mg/ml
Caffeine	20 mg/ml
Cannabinol	10 mg/ml
DMSO	5%
EDTA	80 mg/ml
Ephedrine	20 mg/ml
Ethanol	1%
Gentisic Acid	20 mg/ml
Methadone	10 mg/ml
Methanol	10%
Phenothiazine	20 mg/ml
Phenylpropanalamine	20 mg/ml
Salicylic Acid	20 mg/ml
$\beta$ -hydroxybutyrate	2,000 mg/ml
Uric acid	20 mg/ml

**Biological analytes:**

DESCRIPTION	CONCENTRATION
Albumin (Serum)	2,000 mg/ml
Bilirubin	1,000 mg/ml
Hemoglobin	1,000 mg/ml
Glucose	2,000 mg/ml
pH	5-9

**Bacteria:**

DESCRIPTION	CONCENTRATION
<i>E. Coli</i>	108 CFU/ML
<i>Group B streptococcus</i>	2.5x 108 CFU/ML
<i>Chlamydia trachomatis</i>	104 CFU/ML

**REFERENCES**

- Catt, K.J., Dufan, M.L., and Vaitukaitis, J.L., J. *Clin.Endocrinol. Metab.*, Vol. 40, 537, (1975).
- Lenton, E.A., Neal, L.M., Sulaiman, R., *Fertility & Sterility*, Vol. 37, 773, (1982).
- Batzer, F.R., *Fertility & Sterility*, Vol. 34, 1, (1980).
- Engvall, E., *Method in Enzymology*, Vol. 70, pp. 419-439, (1980).
- Uotila, M., Ruoslahti, E., and Engvall, E., *J. Immunol. Methods*. Vol. 42, 11, (1981).
- Dawood, M.Y., Saxeba, B.B., and Landesman, R., *Ob. Gyn.*, Vol. 126, 678, (1976).

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