

## ONE-STEP PREGNANCY DIPSTICK



[CLIA-WAIVED FOR URINE TEST ONLY]

### 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

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 strip 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. Specimen collection container
2. Timer or watch

### 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 first use. The test strip 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 COLLECTIONS

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.

### ASSAY PROCEDURE

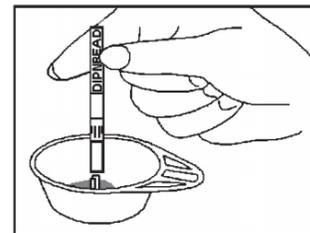
1. Equilibrate all materials and reagents to room temperature before testing.

2. Open the foil pouch at the notch and remove test strip.
3. Immerse the strip into the urine with the arrow pointing towards the urine. Take the strip out after 3 seconds and lay the strip flat on a clean, dry, non-absorbent surface (such as the mouth of the urine container).

**IMPORTANT:** Do not allow the urine level to exceed the MAX (marker line); otherwise the test will not perform correctly.

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.**

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



### INTERPRETATION OF RESULTS

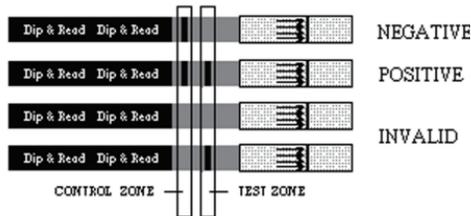
**Positive:** At 3-5 minutes, two pink colored bands appear, one in the control region (C) and one in the test region (T), indicate a positive result and that the specimen contains hCG level of 25mIU/mL or greater.

*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.**



## EXPECTED RESULTS

Negative results are expected in healthy non-pregnant women and healthy men. Although the hCG levels in normal early pregnant women are variable, One Step Strip Urine HCG Test is capable of detecting pregnancy as early as 1 day after the first missed menses.

## 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.

## LIMITATIONS

- As it is with any diagnostic procedure, a confirmed pregnancy diagnosis should only be made by a physician after evaluating all clinical and laboratory findings.
- If a urine sample is too dilute (i.e., low specific gravity) it may not contain a representative level of hCG. If pregnancy is still suspected, another urine specimen should be collected 48 hours later and tested.
- Low concentration of hCG in a very early pregnancy can give a negative result. In this case, another specimen should be obtained at least 48 hours later and tested.
- Elevated levels of hCG can be caused by a few conditions other than pregnancy. Therefore, the presence of hCG in urine specimen should not be used to diagnose pregnancy unless these conditions have been ruled out.
- A normal pregnancy cannot be distinguished from an ectopic pregnancy based on hCG levels alone. Also, spontaneous miscarriage may cause confusion in interpreting test results.
- Sterility treatments, based on hCG may cause false results. Consult your physician.

## PERFORMANCE CHARACTERISTICS

- Sensitivity:** One-Step Pregnancy Dipstick 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 Pregnancy Test. The test will yield a positive result on the first day of missed menstrual period.
- 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.
- Accuracy:** The result from One Step Dipstick Pregnancy Test is compared with that from a commercially available Urine membrane hCG test (Acon). Among 619 urine specimens, both assays identified 375 negative and 244 positive results. In the study, One Step Dipstick Pregnancy Test showed > 99.5% overall agreement when compared with other urine membrane HCG test.
- 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
Gentestic acid	20mg/dl
Glucose	2mg/dl
Hemoglobin	20mg/dl
Tetracycline	20mg/dl
Ampicillin	20mg/dl

## REFERENCES

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