

# ONE STEP Pregnancy (hCG) Test

(Urine)

FOR IN VITRO DIAGNOSTIC USE ONLY

## INTENDED USE

THE PREGNANCY TEST IS A RAPID, QUALITATIVE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF HUMAN CHORIONIC GONADOTROPIN (HCG) IN URINE THAT INDICATES EARLY PREGNANCY. THE TEST IS INTENDED FOR HEALTHCARE PROFESSIONAL AND HOME USE.

## SUMMARY

Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after fertilization. In normal pregnancy, hCG is detected in urine and serum soon after conception and levels of 5-50 mIU/ml are seen within one week of implantation (1-4). At the time of the first missed menstrual period, hCG concentration in urine and serum are about 100 mIU/ml (2-5). HCG levels increase rapidly during the first 10 weeks of pregnancy, with peak levels of 100,000-200,000 mIU/ml reached at the end of the first trimester (1-4). The appearance of hCG in the urine and serum soon after conception and its subsequent rise in concentration during early gestational growth, make it an excellent marker for the early detection of pregnancy.

Elevated urine and serum hCG levels comparable to those observed in early pregnancy may also be associated with trophoblastic or non-trophoblastic neoplasm, such as hydatidiform mole, and chorio-carcinoma. (6-7) The possibility of such diseases should therefore be ruled out before a positive hCG result is considered diagnostic for pregnancy. Lower levels of the hCG hormone may be associated with placental insufficiency, threatened spontaneous abortion and ectopic pregnancy.

The Pregnancy Test is a rapid, qualitative test used to detect the presence of hCG in urine. The use of specific antibody reagents ensures a highly sensitive and specific test. The test has a sensitivity of 25 mIU/ml hCG for urine, which is sufficient to detect pregnancy the first day of the missed period. The test is specific for hCG and does not cross react with related glycoprotein hormones (hFSH, hLH and hTSH) at physiological levels.

## PRINCIPLE

The Pregnancy Test is a sandwich immunoassay (8-9). The plastic card supports a membrane which has been coated with reagents necessary to detect the presence of hCG and provide a positive control so the user can determine if the test result is valid. The sample is applied to the card and reacts initially with the specific, anti- hCG monoclonal antibody/colloidal gold conjugate on the test membrane. This mixture moves along the membrane, by capillary action, and reacts with a specific anti-hCG in the test region. If hCG is present in the sample, the result is the formation of a colored band in the test region. If there is no hCG in the sample, the area will remain white. The sample continues to flow to the control region and forms a pink to purple color, indicating the test is working and the result is valid.

## REAGENTS AND MATERIALS SUPPLIED

1. 25 Test strips per canister
2. Package insert

## MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer
2. Positive and negative urine controls available from commercial distributors.

## WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. Do not use the kit beyond the expiration date imprinted on the outside of the foil pouch.
3. Do not open foil pouch until specimen is collected and ready to be tested.
4. Handle all specimens as potentially infectious.

## STORAGE AND STABILITY

The test device can be stored under refrigeration and room temperature (2-30°C) and will be stable until the expiration date. Do not use after the expiration date.

## SAMPLE COLLECTION

Collect the urine specimen in a clean, dry glass or plastic container. Urine specimens can be collected at any time of the day. It is not

necessary to obtain a first morning specimen, however concentrations of hCG may be higher in this specimen.

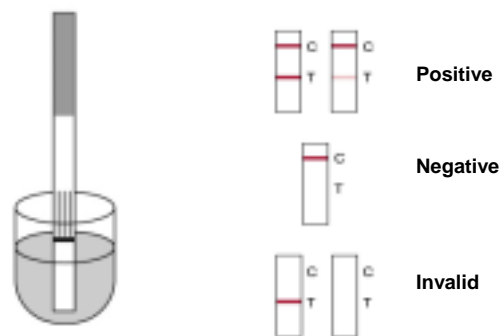
The sample can be refrigerated up to 72 hours prior to testing. A refrigerated sample must be allowed to warm to room temperature and mixed before testing.

## BEFORE TESTING

1. Bring all reagents and specimens to room temperature.
2. Prepare at least 100µl of specimen in a microtiterwell or other container, and label specimen ID number.
3. Remove the test strips to be used from the pack and seal container immediately to prevent the rest of the strips from absorbing moisture.

## ASSAY PROCEDURES

1. Dip the test strip into the urine sample with the arrows pointing toward the specimen.
2. The urine level should reach the maximum line marked on the strip, but must not exceed the maximum line.
3. Hold the strip in the urine until a reddish color appears at the lower edge of the test membrane (approximately 10 seconds).
4. Withdraw the strip and place it face up on a clean, dry surface.
5. Read the result between 3 to 10 minutes after adding the sample.



## READING THE TEST RESULTS

Read results between 3 to 10 minutes

## Do not interpret the result after 15 minutes.

**Negative:** One (1) pink/purple band forms in the control region. No band is found in the test region.

**Positive:** Two (2) pink/purple bands form. In addition to the control band, a pink/purple band also appears in the test region. The intensity of the test band may vary from light pink to deep burgundy.

**Invalid:** If there are no pink/purple bands in the control region, the test result is invalid. Retest the sample using a new device.

## QUALITY CONTROL

It is recommended that a positive urine control, with a level between 25-150 mIU/ml hCG and a negative urine control, 0 mIU/ml hCG, be used.

A procedural control is incorporated into the test device to indicate the volume of sample is sufficient and that it has been added to the correct well, and that the flow of sample is complete and the colloidal gold has dissolved.

## EXPECTED VALUES

Results of tests on healthy, non-pregnant women are negative using the Pregnancy Test. Most pregnant patients have urine and serum hCG levels of 100 mIU/ml or greater the day of the first missed menstrual period. This level of hCG is clearly detected using this test. Peak hCG levels are reached about 8 weeks later. Following delivery, hCG levels rapidly decrease and usually return to non pregnant levels within days. Elevated hCG has also been seen in patients with chorio-carcinoma and non trophoblastic neoplasm. (6,7)

## PERFORMANCE CHARACTERISTICS

### Sensitivity:

The Pregnancy Test detects urine hCG concentrations of 25 mIU/ml. A total of 180 tests were performed, at the three hCG concentrations.

hCG specimens were prepared at the following concentrations using hCG free urine; 0 mIU/ml, 25 mIU/ml and 600,000 mIU/ml. All tests were negative with the hCG negative urine and positive with the 25 mIU/ml and 600,000 mIU/ml samples.

**Hook Effect:**

There was no hook effect at hCG levels up to 600,000 mIU/ml in urine.

**Accuracy:**

The accuracy of the Pregnancy Test was determined by comparing with the results of a reference laboratory test, as follows:

Urine samples from normal women (n=61) and pregnant women (n=66) were tested with the Pregnancy Test and the reference laboratory test. A 100% correlation was observed between the two tests. No false positive or false negative results were obtained. The accuracy of the InTec test was >99% in urine.

**Specificity:**

The specificity of the Pregnancy Test was determined from cross reaction studies with known amounts of Luteinizing Hormone (hLH), Follicle Stimulating Hormone (hFSH), and Thyroid Stimulating Hormone (hTSH). Samples containing 300 mIU/ml hLH, 1000 mIU/ml hFSH and 1000 mIU/ml hTSH all gave negative results.

**STANDARDIZATION**

The sensitivity of the Pregnancy Test was established using urine standards calibrated to the WHO 3rd IS 75/537 and the WHO 1st IRP 75/537 respectively.

**INTERFERENCE TESTING**

Potentially interfering substances were added to hCG free and 25 mIU/ml hCG spiked urine samples. No interference was found with any of the substances at the following concentrations:

Acetaminophen	20 mg/dl	Acetylsalicylic Acid	20 mg/dl
Ascorbic Acid	20 mg/dl	Atropine	20 mg/dl
Caffeine	20 mg/dl	Gentisic Acid	20 mg/dl
Glucose	2 g/dl	Hemoglobin	1 mg/dl

**LIMITATIONS OF THE TEST**

1. A number of conditions, other than pregnancy, including trophoblastic disease and certain non-trophoblastic neoplasm cause elevated levels of hCG. These conditions should be considered with appropriate clinical evidence.
2. A dilute urine specimen may not contain sufficient levels of hCG to give a positive result. If pregnancy is still suspected, a first morning urine should be obtained from the patient 24-48 hours later and retested.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

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