ADVANCED QUALITY ™

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ONE STEP Pregnancy(hCG)Test
(Serum/Plasma/Urine)

FOR IN VITRO DIAGNOSTIC USE

Please read this package insert carefully prior to use and strictly follow the instructions. Reliability of the assay cannot be guaranteed if there are any deviations from the instructions in this package insert.

INTENDED USE

The ADVANCED QUALITY™ ONE STEP Pregnancy (hCG) Test is a rapid, qualitative immunochromatographic assay for the detection of human chorionic gonadotropin (hCG) in serum, plasma or urine that indicates early pregnancy. This test is a rapid test as an aid in the diagnosis of relative symptom; it only provides preliminary analysis results but not critical diagnosis criteria, the obtained results should be analyzed in connection with other clinical information, e.g. clinical symptoms, and alternate test to make final decision. 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 Advanced Quality™ ONE STEP Pregnancy (hCG) Test is a rapid, qualitative test used to detect the presence of hCG in serum, plasma or 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 has a sensitivity of 10mIU/mL hCG for serum and plasma. The test is specific for hCG and does not cross react with related glycoprotein hormones (hFSH, hLH and hTSH) at physiological levels.

PRINCIPLE OF THE PROCEDURE

The Advanced Quality™ ONE STEP Pregnancy (hCG) 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 control line 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

FOR STRIP TEST

1. Test strips individually foil pouched with a desiccant.
2. Package insert.

FOR CARD TEST

1. Test cards individually foil pouched with a desiccant.
2. Plastic dropper.
3. Package insert.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer or stopwatch.
2. Disposable gloves.
3. Sample collection containers.
4. Positive and negative urine controls available from commercial distributors.

STORAGE AND STABILITY

The kit has a 24 month shelf-life from the date of manufacture. Store the unused kits at 2℃–30℃. If stored refrigerated, ensure that the sealed pouch is brought to room temperature (10℃–30℃) before opening for testing. Do not use after the expiration date.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. Handle all specimens as potentially infectious.
3. Sterilize all devices used in this assay prior to disposal.
4. DO NOT use it if the foil pouch is damaged or broken.
5. DO NOT reuse test cassettes and any disposable accessories.
6. DO NOT open foil pouch until specimen is collected and ready to be tested.
7. DO NOT use the kit beyond the expiration date imprinted on the outside of the foil pouch.
8. Operate according to standard safety precautions when dispose biohazardous materials.

SAMPLE COLLECTION AND STORAGE

Urine: Collect 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.

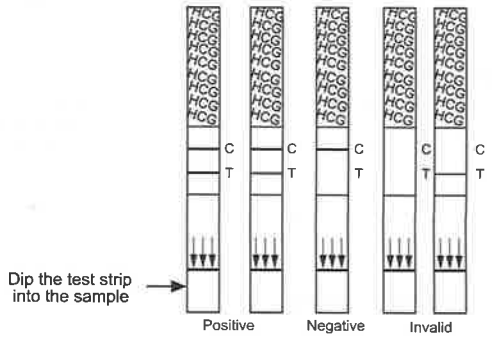
Serum or Plasma: Prepare serum or plasma from a whole blood sample which has been obtained using proper venipuncture technique. Store serum or plasma at 2–8℃ and assay within 24 hours. If the sample cannot be tested within 24 hours, freeze at – 20℃ for no longer than 2 weeks .Frozen samples should be mixed thoroughly after thawing and allowed to reach room temperature before testing. Particulate matter should be allowed to settle prior to sampling urine, serum or plasma.

ASSAY PROCEDURES

Do not open the pouch until you are ready to perform a test, and the single-use test is suggested to be used under low environment humidity (RH≤70%) within 1 hour.

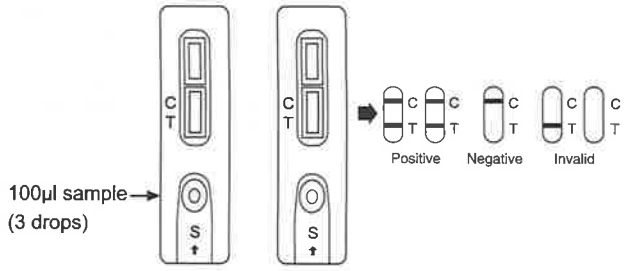
FOR STRIP TEST:

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



FOR CARD TEST:

1. Bring all materials and specimens to room temperature.
2. Remove test card from the sealed foil pouch.
3. Place the test card on a flat dry surface.
4. Using the provided plastic dropper, dispense 100μL sample (3 drops) to the sample well of the test card. Start timing.
5. Read result between 3 to 10 minutes after adding the sample.



INTERPRETATION OF RESULTS

Read results between 3 to 10 minutes

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

Positive: Two (2) pink/purple bands form. In addition to the control band(C), a pink/purple band also appears in the test region (T).

The intensity of the test band (T) may vary from light pink to deep burgundy.

Invalid: There should always be a purplish red control band in the control region regardless of test result. If control band (C) is not seen, the test is considered in valid. Repeat the test using a new test device.

QUALITY CONTROL

SERUM/PLASMA: It is recommended that a positive serum or plasma control, with a level between 10–20 mIU/mL hCG and a negative serum or plasma control, 0 mIU/mL hCG, be used with this test.

URINE: 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 Advanced Quality™ ONE STEP Pregnancy (hCG) Test. Most pregnant patients have urine, serum and plasma 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 Advanced Quality™ ONE STEP Pregnancy (hCG) 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, serum and plasma.

Accuracy:

URINE: Urine samples from normal women (n=61) and pregnant women (n=66) were tested with the Advanced Quality ™ ONE STEP Pregnancy (hCG) 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.

Serum/Plasma: Serum/plasma samples containing no detectable hCG (n=70) and hCG positive serum/plasma (n=154) were tested with the Advanced Quality™ ONE STEP Pregnancy (hCG) Test and the reference laboratory test. A 99.6% correlation was observed between the two tests. No false positive or false negative results were obtained. The accuracy of the Advanced Quality™ test was >99% in serum or plasma.

Specificity:

The specificity of the Advanced Quality™ ONE STEP Pregnancy (hCG) 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 Advanced Quality™ ONE STEP Pregnancy (hCG) 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

Potentially interfering substances were added to hCG free serum/plasma and 10 mIU/mL hCG spiked serum/plasma samples. No interference was found with any of the substances at the following concentrations:

Bilirubin	10 mg/dL
Cholesterol	790 mg/dL
Hemoglobin	250 mg/dL
Triglyceride	1270 mg/dL

LIMITATIONS

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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