

DeTec

hCG Pregnancy Test Device

CLIA Waived

For the Early Diagnosis of Pregnancy

A Rapid, Visual, One Step Test
For the Qualitative Detection of
Human Chorionic Gonadotropin
In Urine

For *in Vitro* Diagnostic

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INTENDED USE

DeTec hCG Test Device is a rapid and sensitive immunoassay for the qualitative determination of human chorionic gonadotropin (hCG) in urine. This test kit is intended for the early diagnosis of pregnancy and is CLIA waived.

SUMMARY AND EXPLANATION

Human chorionic gonadotropin (hCG) is a glycoprotein hormone synthesized by the placenta and released in blood and urine soon after the implantation of a fertilized ovum in the chorionic tissue. It is the principal signal and a specific marker of the pregnancy (3,5). Use of monoclonal antibodies to the beta-subunit of hCG is an important development which provides the feasibility to manufacture new generations of immunoassays with consistent specificity and high sensitivity to detect hCG (16).

PRINCIPLES

DeTec hCG Test Device is a colored solid-phase immunoassay for qualitative detection of elevated levels of hCG in urine for the early pregnancy diagnosis. It is based on a sandwich immunometric assay that utilizes a unique combination of monoclonal and polyclonal antibodies to selectively identify hCG with a high degree of sensitivity. hCG test device contains a strip with a sample pad and a membrane area. The former contains mouse anti-hCG monoclonal antibody conjugated with colloid gold. The latter is coated with goat anti-mouse IgG at the control zone and goat anti-hCG antibody at the test zone. During the test, the urine is sucked up through sample pad by capillary action, and hCG in the urine sample binds to the gold conjugate, moving chromatographically toward the membrane. The immobilized goat anti-hCG antibody at the test zone catches the resulting complex, forming an antibody-hCG-gold conjugate complex. The appearance of a purple band in the test zone resulted from the complex shows a positive result, which indicates presence of hCG and suggests a pregnancy. Absence of this band, on the other hand, displays a negative result, i.e. no detectable hCG in the urine sample. The appearance of a purple band in the control zone demonstrates proper performance and validity of the reactive reagent.

REAGENTS AND MATERIALS SUPPLIED

Each DeTec hCG Test Device kit contains enough reagents and materials for 25 tests.

1. Test device (x 25): Each device contains a strip with a membrane coated with goat anti-hCG antibody and a samples pad with mouse anti-hCG monoclonal antibody conjugated and 0.05% sodium azide as a preservative.
2. Instruction Booklet (x 1).

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collecting container.
- Timer.
- Digital single channel pipettes. (Optional)

STORAGE

The test kit can be stored at room or refrigerated temperature (2-30°C; 36-86°F) in sealed pouch with desiccant.

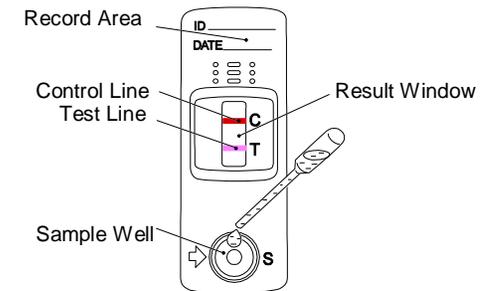
PRECAUTION

1. For in vitro diagnostic use only.
2. Do not use test strip beyond expiration date.
3. Do not open protective pouch until you are ready to do the test, and always bring it to room temperature prior to assay.
4. Handle all patient samples as if they are capable of transmitting disease.

SPECIMEN COLLECTION

Use a clean, dry container to collect urine. Urine collected over a 24-hour period may be used (5). Urine specimens may be refrigerated (2-8°C; 36-46°F) and stored up to 72 hours prior to testing. Those having been subjected to repeated freezing and thawing should not be used. The specimens with visible precipitates should be filtered, centrifuged or allowed to settle down. Take only the clear supernatants for testing.

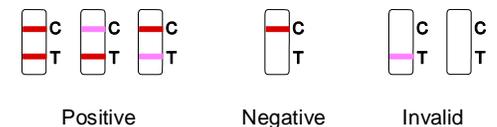
ASSAY PROCEDURES



Test devices, together with collected urine specimens, and any controls or related materials should be brought to room temperature (15-30°C; 59-86°F) prior to assay.

1. Remove the test device from its protective pouch.
2. Place the device on a clean level surface.
3. Use supplied dropper to dispense 3 free –dropping-down drops (about 110-150 µl) of specimen into the sample well marked by the arrow. Don't add more than 4 drops. If you use digital pipette, add 140 µl of specimen. Use a separate pipette and device for different specimen or control.
4. Wait for about 5 minutes to observe the result.

INTERPRETATION OF RESULTS



Positive

Negative

Invalid

1. **Negative:** Only one purple band appears in the control line zone, none in the test line zone. A 5-minute observation time is required to confirm negative and to exclude pregnancy.
2. **Positive:** In addition to a band in the control line zone, a distinct purple band also appears in the test line zone. Depending on the hCG level, one band may be lighter than or same as the other. The best time for observation is between 2.5 to 3 minutes, although a positive result may develop as early as 25 seconds.
3. **Invalid:** After five minutes if neither a control band nor a test band appears, or only test band appears, the test should be voided. It generally results from improper testing procedures or deterioration of reagents. The specimen should be tested again on a new device.

Notes: Do not read results after 5 minutes. This is important because specimens containing low level of hCG and the abnormal reaction condition may show color development over time.

QUALITY CONTROL

The device contains an internal control. The appearance of a colored band in the control window indicates proper performance and validity of the reactive reagents. This product has passed a rigorous quality control examination. However, use of control specimens does ensure proper laboratory practice. For this purpose, we recommend the use of the hCG controls (catalog No: PC50U for positive, NC50U for negative).

LIMITATIONS

1. The concentration of hCG at a very early stage of pregnancy could be too low to be detected. If a pregnancy is still suspected, the first morning urine should be collected 48 hours later and tested again.
2. Extremely high levels of hCG may exist in certain pregnancies and trophoblastic diseases, resulting in falsely low hCG readings caused by the high-dose "hook effect" (12).
3. Although the presence of hCG is suggestive of a pregnancy, it does not differentiate between a normal intrauterine pregnancy and that in an ectopic site. A suspected ectopic pregnancy may be further evaluated using recommended procedures (10).
4. hCG levels may remain detectable for several weeks after spontaneous abortions (15).
5. A normal pregnancy cannot be distinguished from medication with injected hCG for induction of ovulation.
6. There is large number of reports about secretion of hCG or its subunits by neoplasms and tumor (7, 17). Elevated hCG levels could be related to both gestational and nongestational trophoblastic diseases, such as choriocarcinoma and hydatidiform mole, a gonadal teratoma, or carcinoma with ectopic secretion of hCG. Such possibilities should be ruled out before pregnancy is diagnosed.

7. It has been recommended that a pregnancy test is an important medical indication of a pregnancy (6,14). However, it is important to emphasize that the information obtained from this kit can only be used together with other clinical and laboratory procedures, and that the diagnosis should be made only by a physician.

PERFORMANCE CHARACTERISTICS

Sensitivity

DeTec hCG pregnancy test device detects urinary hCG concentrations of 20 mIU/ml or greater (WHO 3rd IS 75/537).

Accuracy

364 randomly selected urine specimen, 189 positive and 175 negative, were analyzed by the hCG test in parallel with a commercially available quantitative visual hCG test. The result shows complete agreement.

Specificity

The amount of the following substances added to the specimen will not interfere with DeTec hCG testing.

hLH	200	mIU/ml
hFSH	1000	mIU/ml
hTSH	1000	μIU/ml
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	2000	mg/dl
Hemoglobin	1	mg/dl
Protein	2000	mg/dl
PH	5 to 9	

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