hCG
Urine/Serum

COMBO TEST

CAT. SM/2003

The hCG Combo Test is an immunochromatographic assay designed for qualitative determination of human chorionic gonadotropin (hCG) in urine or serum for early detection of pregnancy.

SUMMARY AND EXPLANATION OF THE TEST

Human chorionic gonadotropin is a glycopeptide hormone produced by the placenta during pregnancy. The appearance and rapid rise in the concentration of hCG in the woman's urine and serum makes it a good pregnancy marker. Usually, concentration of hCG in urine and serum is at least 20 mIU/ml as early as seven to ten days after conception. The concentration increases steadily and reaches its maximum between the eighth and eleventh weeks of pregnancy.

The hCG Combo Test is an immunochromatographic assay which utilizes both conventional and monoclonal antibodies to selectively identify hCG in urine or serum.

PRINCIPLES OF THE TEST

The immunochromatographic device contains a unique set of dye-conjugated and immobilized monoclonal and polyclonal antibodies used to produce a distinctive visual pattern indicating elevated concentration of hCG (≥20 mIU/ml) in the test sample, in approximately five minutes.

In the test procedure, the liquid sample is allowed to migrate through the absorbent area. If hCG is present, labeled antibody-dye conjugate binds it, forming an antibody-antigen complex. As the reaction mixture continues to flow along the test membrane, the complex binds to the anti-hCG antibody in the test (T) zone of the membrane, and produces a pink-rose color band. Unbound conjugate binds to the reagents immobilized in the control (C) zone producing a pink-rose color band, demonstrating proper performance of the test.

REAGENTS AND MATERIALS PROVIDED

1. Testing Device. Contains dye-conjugated and membrane-immobilized anti-hCG antibodies, in a protein matrix with sodium azide.
2. Sample Dropper. Sealed in the foil pouch with the Testing Device.
3. Positive Control, 1.0 ml. Contains hCG in a buffered protein solution with sodium azide, in a dropper vial. (optional)
4. Negative Control, 1.0 ml. Buffered protein solution with sodium azide, in a dropper vial. (optional)

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection container.
2. Centrifuge capable of 1000 *g* (for centrifuging whole blood specimens).
3. Clock or timer.

STORAGE CONDITIONS

Store the kit below 28°C; do not freeze. Optional liquid components require refrigeration (4°C). Refer to individual expiration dates of components for stability.

PRECAUTIONS

1. Do not use test kit components after the expiration dates.
2. Dispose of all used test components in a proper biohazard container.
3. If specimens or test components have been stored in a refrigerator, allow them to warm to room temperature before performing the test.
4. Human specimens should be handled as if capable of transmitting infectious agents.

SPECIMEN COLLECTION AND STORAGE

Urine

First morning urine usually contains the highest concentration of hCG and is therefore the best sample when performing the urine test. However, randomly collected urine specimens may be used. Collect a urine specimen in a clean glass, plastic, or wax coated container. Do not use preservatives. If the test is not run immediately following collection of the sample specimen, but is to be run within 48 hours following collection, the specimen should be refrigerated (2-8°C), and brought back to room temperature (15-28°C) before testing. If testing is delayed more than forty-eight hours, the specimen should be frozen. A frozen specimen should not be used if stored more than two weeks. Prior to testing, the frozen specimen must be completely thawed, thoroughly mixed, and brought to room temperature.

Serum

Collect blood aseptically by venipuncture into a clean tube without coagulants. Permit blood to form a clot for twenty to thirty minutes at room temperature. Centrifuge to obtain clear supernatant and transfer it into a clean plastic or glass tube.

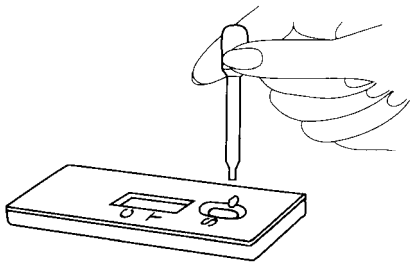
QUALITY CONTROL

The use of controls is recommended to verify proper kit performance. Quality control reagents (optional kit components) should be tested according to quality control requirements established by the testing laboratory.

Use controls in the same procedure as specimens.

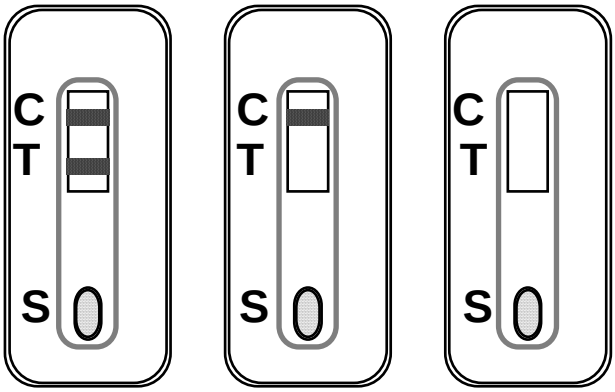
TEST PROCEDURE

NOTE: Bring test components and specimens to room temperature prior to testing.



1. Remove a Testing Device from the foil pouch by tearing at the "notch" and place it on a level surface.
2. Holding a Sample Dropper vertically, add exactly four drops of urine or serum specimen to the sample well marked "S".
3. Read results at five minutes.

INTERPRETATION OF RESULTS



1. **Positive** (pregnancy). Two pink-rose bands appear: one in the test region (T) and in the control region (C). A positive result indicates presence of hCG at ≥20 mIU/ml.
2. **Negative** One rose-pink band appears in the control region (C), with no band in the test region (T). A negative result indicates that concentration of hCG is below the detection level.
3. **Invalid** There is no distinct color band visible both in the test region and in the control region, or there is a visible band only in the test region and not in the control region. The result is invalid due to deterioration of the test or improper test procedure. Repeat the test with a new Testing Device.

LIMITATIONS OF THE TEST

1. The hCG Combo Test is for *in vitro* diagnostic use only.
2. Besides pregnancy, elevated concentrations of hCG may be found in patients with both gestational and non-gestational trophoblastic diseases. These conditions should be ruled out in the interpretation of hCG levels to establish a diagnosis of pregnancy.
3. Although Test is very accurate in detecting pregnancy, a low incidence of false results can occur. Consult with a physician if you obtain unexpected or inconsistent results.
4. A normal pregnancy cannot be distinguished from an ectopic pregnancy based on hCG levels alone. Also, a spontaneous miscarriage may cause confusion in interpreting the test results.
5. As with all diagnostic tests, a definitive diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
6. A negative result from a urine or serum specimen collected from a woman in very early pregnancy may be due to an unusually low concentration of hCG. In such cases, the test should be repeated on a fresh specimen obtained approximately two days later.
7. A urine sample may be too diluted and thus may not contain a representative concentration of hCG. If a negative result is obtained with a urine specimen and pregnancy is still suspected, obtain a first morning urine specimen and re-test.

PERFORMANCE CHARACTERISTICS

Sensitivity

The hCG Combo Test will detect hCG in urine or serum at concentrations 20 mIU/ml or greater. This sensitivity level has been confirmed with hCG standards (20, 50, 100, 1000, 450,000, and 900,000 mIU/ml) in urine and serum. Occasionally, specimens containing less than 20 mIU/ml hCG can also give positive results.

Specificity

Related hormones potentially cross-reactive with anti-hCG were added to hCG-free serum and urine samples in the following concentrations: LH: 50, 100, 300, and 500 mIU/ml; FSH: 50, 100, 500, and 1000 mIU/ml; TSH: 100, 500, and 1000 mIU/ml. In addition, these concentrations of LH, FSH and TSH were added to urine and serum samples containing hCG at 20 and 450,000 mIU/ml. In all cases the results of hCG testing were not affected by added glycoprotein hormones (no cross reactivity of Test was detected).

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