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Pregnancy Combo II Test (Cassette)

REF
R24-618

IVD

For Qualitative In Vitro Diagnostic Use

INTENDED USE

The Pregnancy Combo II Test is a qualitative immunoassay for the detection of human chorionic gonadotropin (hCG) in human urine or serum at a cut off level of 10 mIU hCG/ml. It is for health care professional investigational use only and not for self testing or diagnosis of pregnancy.

SUMMARY AND EXPLANATION OF THE TEST

This pregnancy test is based on the detection of the human chorionic gonadotropin (hCG) in urine and serum. HCG is a hormone produced by the placenta. In normal subjects, hCG in urine and serum provides an early indication of pregnancy. The Pregnancy Combo Test uses a mouse monoclonal antibody specific to hCG in a one-step lateral flow chromatographic immunoassay to detect hCG at the level close to or greater than 10 mIU/ml (WHO 3rd IS 75/537).

PRINCIPLE OF THE PROCEDURE

This assay is a one-step lateral flow chromatographic immunoassay. The test strip in the device consists of a conjugate pad containing mouse monoclonal anti-hCG antibody conjugated to colloidal gold, and a nitrocellulose membrane strip containing a test line (T line) and a control line (C line).

When an adequate amount of specimen is applied to the sample pad of the device, hCG in the specimen binds to sites on the anti-hCG antibody-gold conjugate in the conjugate pad to form a complex and migrates along the membrane strip. If the specimen contains hCG at a level close to or greater than 10 mIU/ml, the complex will bind to the capture antibody coated on the T line to develop a burgundy-colored band. If the specimen does not contain hCG or the hCG level is below the detectable level, the T line will not develop.

The C line is coated with goat anti-mouse antibody, which should bind to the gold-antibody conjugate and forms a burgundy colored line regardless of the presence of hCG.

REAGENTS AND MATERIALS SUPPLIED

- 25 test devices, each sealed in a foil pouch with a dropper pipette.
- 1 package insert (Instructions for Use).

MATERIAL REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer

STORAGE AND STABILITY

Store the kit at room temperature 15-30°C (59-86°F). Each device may be used until the expiration date if it remains sealed in its foil pouch.

Do not freeze and/or expose the kit to temperatures over 30℃ (86°F).

15°C 30°C

SPECIMEN COLLECTION

1. Each urine specimen must be collected in a clean container.
2. Each serum specimen must be collected following standard clinical procedure.
3. Specimens may be kept at 15-30°C (59-86°F) for 8 hours, at 2-8°C for up to 3 days and at -20°C or lower for prolonged storage. Do not mix specimens.

PRECAUTION

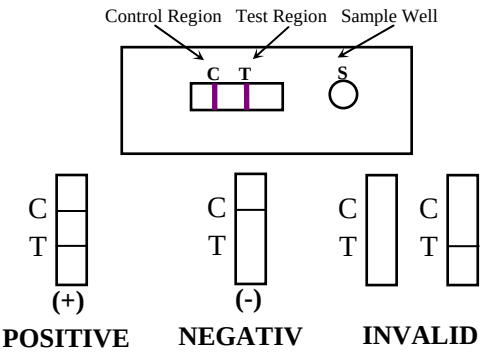
1. The instructions must be followed exactly to obtain accurate results.
2. This test is for professional in vitro diagnostic use only.
3. Do not open the sealed pouch, unless ready to conduct the assay.
4. Do not use expired devices.
5. Dispose of all specimens and used assay materials as potentially biohazardous.

ASSAY PROCEDURE

1. Refrigerated specimens and other test materials including devices, **must be equilibrated to room temperature before testing**.
2. Remove the test device from its pouch and place it on a flat surface.
3. Holding the dropper vertically, add four drops of the specimen to the sample well.
4. Strong positive results may be observed in 2-3 minutes. Weak positive results may take a longer time, up to 5 minutes.

INTERPRETATION OF RESULTS

***IMPORTANT*: Do not interpret the results after 7 minutes. The T Line should always be interpreted independently of the C Line.**



Positive:

If both the C line and T line appear, the test indicates that hCG is present in the specimen at the level close to or higher than 10 mIU/ml.

Negative:

If only the C line appears, the test indicates that the hCG level in the specimen is not detectable and the result is negative. If pregnancy is suspected, repeat the test after 2 to 3 days with new devices and fresh samples.

Invalid:

If no line is visible in the control region within 5 minutes, repeat the assay with a new test device.

QUALITY CONTROL

- **Built-in Control Features**

  The Pregnancy Combo II Test contains built-in control feature, the C line. The appearance of the burgundy C line indicates that the test has been performed correctly, in particular that an adequate volume of specimen has been absorbed and capillary flow has occurred. The C line should always appear. If the C line does not develop within 5 minutes,

the result is invalid. In this case, review the whole procedure and repeat test with a new device.

- **External Quality Control**
  Good Laboratory Practice recommends using external controls, positive and negative, to assure the proper performance of the assay.

LIMITATIONS

1. This kit is not intended for any use other than early detection of pregnancy.
2. HCG may be detectable in some conditions other than normal pregnancy, which should be ruled out when diagnosing pregnancy.
   - Low titer elevations of hCG can occur in normal, non-pregnant Subjects.
   - Ectopic pregnancy cannot be distinguished from normal pregnancy from hCG measurements alone.
   - Positive hCG levels may be detectable for several weeks following delivery or abortion.
3. The results must be evaluated with other data by a physician before diagnosing pregnancy.

EXPECTED VALUES

Immunospec test is capable of detecting hCG at the level as low as 10 mIU/ml (WHO 3rd IS 75/537) or the first day of a missed period and no sooner. In normal subjects, hCG in urine and serum provides an early indication of pregnancy. In a 28-day cycle with ovulation occurring at day 14, hCG can be detected in urine and serum in minute quantities around day 23, or 5 days before the expected menstruation. The hormone concentration doubles approximately every 2 days and peaks between 7-12 weeks after the first day of the last menstrual period with a mean concentration of 50,000 mIU/ml. Concentrations as high as 100,000 mIU/mL have been reported in normal pregnancies during the first trimester.

PERFORMANCE CHARACTERISTICS

The performance characteristics of this product have not been established.

REFERENCES

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