

FORETEL

SLIDE TEST FOR PREGNANCY

SUMMARY

Human chorionic gonadotropin (hCG), a hormone produced by viable placental tissue during pregnancy, is excreted in urine approximately 20 days after the last menstrual period. The levels of hCG rise rapidly reaching peak levels after 60-80 days and then the hCG levels fall suddenly and eventually plateau out.

The hCG molecule consists of two combined dissimilar subunits namely, alpha and beta. The alpha subunit is practically identical to the alpha subunit of leutenising hormone (LH), follicle stimulating hormone (FSH), thyroid stimulating hormone (TSH) and the pituitary glycoprotein hormone. The beta subunit of hCG, by virtue of its unique amino acid sequence and content, confers biological and immunological specificity to the entire hCG molecule.

The appearance of hCG in urine soon after conception and its rapid rise in concentration makes it an ideal marker for detection and confirmation of pregnancy. However, elevated hCG levels are frequently associated with trophoblastic and non-trophoblastic neoplasms; these conditions should be considered before a diagnosis of pregnancy can be made.

FORETEL slide test for pregnancy employs monoclonal antibodies specific to the beta subunit of hCG.

REAGENTS

1. Anti-beta human chorionic gonadotropic antibody (mouse monoclonal). The antibodies are adjusted to provide a sensitivity of about 0.3 IU/ml of hCG.
2. Suspension of polystyrene latex particles to which hCG has been chemically coupled.

Each batch of reagents undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity and performance.

REAGENT STORAGE AND STABILITY

1. Store the reagent at 2-8°C. DO NOT FREEZE.
2. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial label.

PRINCIPLE

FORETEL slide test for pregnancy utilises the principle of latex agglutination inhibition. The urine specimen to be tested is first mixed with the antibody reagent containing antibodies directed against the beta subunit of hCG. Then hCG coupled latex reagent is added and the mixture is allowed to react. When the urine specimen is from a non-pregnant woman and does not contain hCG, the anti-beta hCG monoclonal antibodies will be free to react with latex coupled hCG causing agglutination. When the urine is from a pregnant woman and contains at least 0.3 IU/ml of hCG, the anti-beta hCG monoclonal antibodies will be neutralised and will not react with the latex coupled hCG antigen. Hence no agglutination will be observed.

NOTE

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. The reagents contain Sodium Azide 0.1% as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
3. The reagents can be damaged due to microbial contamination or on exposure to extreme temperatures. It is recommended that the performance of reagents should be verified by testing with known positive and negative urine controls.
4. Use reagents of the same lot numbers. Do not interchange reagents of different lot numbers.
5. Do not interchange vial droppers.
6. Shake the latex antigen vial well before use to disperse the latex particles uniformly and improve test readability.
7. Only a clean and dry glass slide must be used. Clean the slide with distilled water and wipe dry. Do not use detergents, soaps or organic solvents to clean the slide.

SAMPLE COLLECTION AND PREPARATION

Qualitative Method

Though random urine specimens can be used, first morning urine specimen is preferable. Specimens should be collected in clean glass or plastic containers free of detergents. Specimens should be tested immediately preferably within 12 hours of collection. Should a delay in testing occur, add thimerosal (0.001%) or sodium azide (0.01%) to the specimen and store at 2-8°C upto 72 hours. Do not use grossly contaminated specimens and if the specimen is cloudy or bloody, centrifuge at 1000 rpm (125 g) for one minute and use clear supernatant for testing.

Semi Quantitative Method

Specimens collected over a 24 hour period should be pooled in a clean detergent free container and refrigerated at 2-8°C. Thimerosal (0.001%) or sodium azide (0.01%) are recommended as urine preservatives.

MATERIAL PROVIDED WITH THE KIT

Reagent Pack

Anti-beta human chorionic gonadotropic antibody (mouse monoclonal), hCG latex antigen.

Accessories Pack

Glass slide with three reaction circles, Pipettes for dispensing urine specimen, Mixing sticks, Rubber teats.

ADDITIONAL MATERIAL REQUIRED

Positive and negative urine controls, Isotonic saline, A high intensity direct light source, Stopwatch.

TEST PROCEDURE

Bring all reagents and samples to room temperature before use.

Qualitative Method

1. Place one drop of urine (specimen or control) on the glass slide using a disposable pipette provided with the kit. Deliver the drop vertically.
2. Add one drop of Anti-beta hCG antibody to the drop of urine on the slide. Deliver the drop vertically.
3. Using a mixing stick, mix the antibody and urine uniformly over the entire circle for 30 seconds.
4. Add one drop of latex reagent to the mixture. Mix uniformly over the entire circle. Do not let the dropper tip touch the liquid on the slide.
5. Immediately start a stopwatch. Rock the slide gently back and forth, observing for agglutination macroscopically at three minutes.

Semi Quantitative Method

1. Measure and record the total volume of patient urine collected over a 24 hour period.
2. Using isotonic saline, prepare progressive dilutions from an aliquot of collected urine specimen (1:2, 1:4, 1:8, and so on).
3. Perform the qualitative test procedure using each dilution as specimen.

INTERPRETATION OF RESULTS

Qualitative Method

Agglutination is a negative test result indicating the absence of detectable levels of hCG.

No agglutination is a positive test result indicating the presence of detectable levels of hCG.

Semi Quantitative Method

No agglutination in the highest urine dilution corresponds to the amount of hCG/ml. To calculate the concentration of hCG in the specimen, use the following formula, $hCG = S \times D$

where, S = sensitivity of the test i.e., 0.3 IU/ml

D = highest dilution of urine showing no agglutination.

For determining 24 hour hCG concentration, use the following formula, $hCG\ 24\ hours = S \times D \times V$

where, V = volume of 24 hours urine specimen.

REMARKS

1. Patient specimens, in pathological conditions such as hydatidiform mole or choriocarcinoma or testicular tumor, may contain hCG and produce a positive test result not necessarily indicating a pregnancy.
2. Values of hCG greater than 250 IU/ml, 110 days after L.M.P., suggest the presence of pathological condition such as a hydatidiform mole or choriocarcinoma.
3. Use only urine as test specimen. Do not use serum.
4. It is recommended that the results of the tests should be correlated with clinical findings to arrive at the final diagnosis.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

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