

Cat.No. 101-0215
 Cat.No. 101-0214

Size 50 tests
 Size 100 tests

PRINCIPLE:

HCG excreted in the urine during pregnancy, is determined qualitatively using a latex agglutination direct reaction. Latex particles, coated with two different monoclonal antibodies, will agglutinate in the presence of HCG-molecule in urine (positive result). When HCG is absent in the urine, no agglutination occurs (negative result).

SAMPLE:

Urine
 Any fresh urine can be used, however, the morning urine is the most suitable because it contains the greatest concentration of HCG. The test should be performed as soon as possible, preferably within 24 hours of sampling.
 Stability up to 72 hours at +2 °C to +8 °C.

REAGENTS:

1. Latex reagent
 Latex particles coated with monoclonal anti-HCG.
2. Positive control
3. Negative control
4. Test slides
5. Mixing sticks

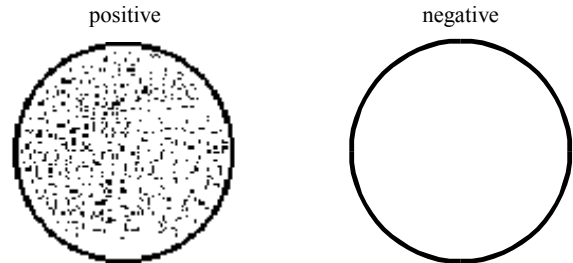
The reagents are stable up to the expiry date when stored at +2 °C to +8 °C. Do not freeze.

PROCEDURE:

Bring the reagents and samples to room temperature and mix the latex reagent well before use. Make sure that the latex reagent is completely in suspension.

Latex reagent	1 drop
Urine	1 drop
Mix the latex reagent and the urine, spread the mixture over the entire test area on the slide. Rock slide gently allowing the mixture to flow slowly over the entire area.	
After 2 minutes or less if agglutination occurs, place the slide under a light source to observe for agglutination.	

INTERPRETATION:



Agglutination within 2 min.

No agglutination within 2 min.

SENSITIVITY:

The test is standardized to detect levels of 300 IU HCG/L urine or higher. A positive reaction is therefore possible 5 days after a missed period. If the test should prove negative, it is recommended to repeat the test after 7 days once again.

NOTE:

1. Do not use reagents from different lots.
2. Use centrifuged urine.
3. Both controls should be run with each series and compared with the unknown specimen to distinguish possible granularity from agglutination.
4. The test is not influenced by hormone preparations employed for diagnostic or therapeutic purposes.
5. High levels of HGC in urine may occur in patients suffering of chorionic epithelioma or hydatid mole, even in the absence of pregnancy. These conditions can lead to false positive results.
6. In cases of extra-uterine pregnancy, toxemia, fetal death or threatened abortion, the excretion of HCG is often decreased. This can lead to false negative results.
7. As with all pregnancy tests the final diagnosis should not be made on the results of a single test, but should be based on a correlation of test results with typical clinical signs and symptoms.
8. The reagents contain sodium azide as preservative. Do not swallow. Avoid contact with skin and mucous membranes.

REFERENCES:

1. Braunstein, G.D. et al., Am.J.Obstet.Gynecol. 126, 6 (1976)
2. Uotila, M., et al., J. of Immul. method 42, 11 (1981)
3. Milstein, C., and Kohler, G., Nature 256, 495 (1975)
4. Horwitz, C.A., et al, J. Repord. Fet. 33,489(1973)