HCG-LATEX

Latex agglutination slide test for qualitative determination of Human Chorionic Gonadotrophin (hCG) in human urines.

**REF 085100 (100 tests)**

R1 4.2 mL  
R2 0.5 mL  
R3 0.5 mL

**CLINICAL SIGNIFICANCE (1)**

Human chorionic gonadotrophin (hCG) is a glycoprotein hormone secreted by the developing placenta beginning shortly after fertilisation. At the time of the first missed menstrual period, hCG concentrations in serum and urine are about 100 mIU/mL and double in concentration every 1.2 to 2 days. Peak levels of over 100,000 mIU/mL hCG are seen late in the first trimester of pregnancy. The early appearance of hCG in urine following conception has made it the marker of choice for the early detection of pregnancy.

**PRINCIPLE (2) (3)**

The Direct Pregnancy test is based upon the latex agglutination reaction between latex particles coated with anti-hCG antibodies and hCG present in the test specimen. The presence of hCG in the urinary specimen results in an agglutination which is visually differentiated from the non-agglutinating negative control.

**REAGENTS COMPOSITION**

1. HCG-LATEX Reagent sufficient for 100 slide tests. The latex reagent should be well shaken to ensure homogeneity.
2. Positive hCG control urine (human origin).
3. Negative hCG control urine (human origin).
   -- Reusable agglutination slide and disposable stirring pipettes.

**REAGENTS PREPARATION**

Reagents are ready for use.

**MATERIAL REQUIRED BUT NOT PROVIDED**

1. Basic medical analysis laboratory equipment.

**STABILITY AND STORAGE**

Store at 2-8°C away from light

**DO NOT FREEZE THE LATEX REAGENT.**

- When free from contamination, stored in the original vial and used as described in this technical data sheet, reagents are stable until expiry date stated on the label of the kit.
- Discard any reagent if contaminated or do not demonstrate the correct activity with controls.

**SAFETY CAUTIONS**

BIOLABO reagents are designated for professional, in vitro diagnostic use.

- Use adequate protections (overall, gloves, glasses).
- Do not pipette by mouth.
- In case of contact with skin and eyes, thoroughly wash affected areas with plenty of water.
- Reagents contain sodium azide (concentration < 0.1%) which may react with copper and lead plumbing. Flush with plenty of water when disposing.
- Control reagents contain human urine. This material should be handled as potentially infectious.
- For further information, Material Safety Data Sheet is available upon request.
- Waste disposal: Respect legislation in force in the country. All specimens should be handled as potentially infectious, in accordance with good laboratory practices using appropriate precautions. Respect legislation in force in the country.

**SPECIMEN COLLECTION AND HANDLING**

Urinés must be collected without preservative in plastic or glass containers.

First morning urine usually contains the highest concentration of hCG, however urine collected at any time during the day may be used. Cloudy urine should be centrifuged before testing.

THE TEST IS FOR URINE ONLY. DO NOT USE SERUM OR PLASMA.

The sample may be stored at 2-8°C for 72 hours before performing the test.

For longer periods of time, urine must be frozen (once only). Frozen specimens should be totally thawed and brought to room temperature before testing.

**INTERFERENCES**

Urine hCG levels of greater than 200 mIU/ml are required for positive results.

A number of conditions other than pregnancy, including trophoblastic diseases, chorionic epithelioma, hydatidiform mole and certain non-trophoblastic neoplasms, can result in elevated urine hCG levels leading to false positive results. These diagnoses should be considered if consistent with the clinical evidence. Excretion of hCG is often decreased in cases of extra uterine pregnancy, toxemia of pregnancy or threatened abortion. Such circumstances can lead to false negative results. Soaps and detergents may interfere with the agglutination of the reagents.
QUALITY CONTROL
Positive and Negative hCG control urine included in this kit.
External quality control program.
It is recommended to control in the following cases:
• At least once a run.
• At least once within 24 hours.
• When changing vial of reagent.
If control is not correct, apply following actions:
1. Repeat the test with the same control.
2. If control is still not correct, try again with a new vial of control(s).
3. If control is still not correct, try again with a new vial of reagent.
4. If control is not correct, please contact BIOLABO technical support or
   your local Agent.

EXPECTED VALUES
Healthy men and healthy non-pregnant females do not have hCG
levels detected by this method.
Urine hCG levels of 200 mIU/mL can be reached a few days after
missed menstruation.

PERFORMANCES CHARACTERISTICS
The sensitivity of the Direct Monoclonal Pregnancy Latex Test Kit has
been set to 200 mIU/mL when calculated against the WHO Second
International Standard.
Accuracy of at least 99% is obtained under actual clinical conditions
when compared against standard quantitative hCG methods.

MANUAL PROCEDURE
QUALITATIVE METHOD
1. Allow each component to reach to room temperature before use.
2. Place one drop of the Negative hCG Control onto a circle of the
   agglutination slide.
3. Place one drop of the Positive hCG Control onto an adjacent circle of
   the agglutination slide.
4. Using the pipette-stirrers provided, place one drop of the
   specimen(s) onto the remaining circle(s) of the agglutination slide.
5. Shake and re-suspend the Pregnancy latex reagent.
6. Add one drop to each of the test circles of the agglutination slide.
7. Stir with individual pipette-stirrers and spread mixture over entire
   area of the test circle.
8. Gently rock the agglutination test slide for two minutes and observe
   the test circles for agglutination. Interpret results at two minutes.
   Extended incubation may result in evaporation and erroneous results
   (false positive).
9. At the end of the test rinse the test slide with distilled water and dry.

INTERPRETATIONS OF RESULTS
Positive result occurs when HCG level is ≥ 200 mIU/mL

Positive:
Agglutination
appears within
2 minutes

Negative:
No agglutination
appears within
2 minutes

Negative result occurs when HCG level is ≤ 200 mIU/mL

Urine samples containing high concentrations of hCG will agglutinate
within few seconds.

REFERENCES
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(5) Lenton, E.A. Neal, L.M. Sulaiman, R. Fertility and Sterility, Vol 37, 773
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