hCG-Latex CE

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For *in vitro* diagnostic use only			

hCG-Latex

Determination of human Chorionic Gonadotropin

SLIDE TEST

PRINCIPLE

hCG-Latex Test is a rapid slide agglutination procedure, developed for the direct detection of human Chorionic Gonadotropin (hCG) in urine.
The assay is performed by testing a suspension of latex particles coated with monoclonal anti-hCG antibodies against unknown samples[1]. The presence or absence of a visible agglutination, indicates the presence or absence of hCG in the sample tested.

REAGENT COMPOSITION

R — **hCG-Latex Reagent**. Suspension of polystyrene latex particles coated with monoclonal anti-hCG antibodies in a buffered saline solution. Contains 0.95 g/L of sodium azide.

CONTROL + — Human urine with a hCG concentration ≥ 1600 IU/L. Contains 0.95 g/L of sodium azide.

CONTROL - — Animal serum. Contains 0.95 g/L of sodium azide.

Precautions: Components of different human origin have been tested and found to be negative for the presence of antibodies anti-HIV 1+2 and anti-HCV, as well as for HBsAg. However, the controls should be handled cautiously as potentially infectious.
Warning: The reagents in this kit contain sodium azide. Do not allow to contact with skin or mucous membranes.

PACKAGING CONTENTS

REF 2610005, kit 50 tests.
hCG-Latex Reagent, 1x0.5 mL Positive control, 1x0.5 mL Negative control, 3 Test cards and 1x50 disposable pipettes.

REF 2610015, kit 100 tests.
hCG-Latex Reagent, 1x0.5 mL Positive control, 1x0.5 mL Negative control, 3 Test cards and 2x50 disposable pipettes.

STORAGE AND STABILITY

Store at 2-8ºC. Do not freeze. Frozen reagents could change the functionality of the test.
Reagent and Controls are stable until the expiry date stated on the label.

REAGENT PREPARATION

Reagent and Controls are ready to use.

SAMPLES

Urine collected in plastic or glass containers at any time of the day. The use of the first morning urine is recommended as it generally contains the highest concentration of hormone. Samples with turbidity should be centrifuged before testing.
The samples may be stored at 2-8ºC up to two days or for longer periods at –20ºC.

MATERIAL REQUIRED

- Mechanical rotator, adjustable at 100 r.p.m.
- Laboratory alarm clock.

PROCEDURE

Qualitative Test

1. Bring the test reagents and samples to room temperature (Note 1).
2. Resuspend the antigen vial gently. Aspirate dropper several times to obtain a thorough mixing.
3. Place 2 drop (100 µL) of the urine under test into one of the circles on the card (Note 2). Dispense 1 drop of positive control and 1 drop of negative control into two additional circles.
4. Add 1 drop of hCG-Latex Reagent to each circle next to the sample to be tested.
5. Mix the contents of each circle with a disposable pipette while spreading over the entire area enclosed by the ring. Use separate pipettes for each mixture.
6. Rotate the slide slowly by means of a mechanical rotator (100 r.p.m.) for a period of **2 minutes** (Note 3).
   Observe immediately under a suitable light source for any
7. degree of agglutination.

Reading

Nonreactive: Smooth suspension with no visible agglutination, as shown by negative control.

Reactive: Any degree of agglutination visible macroscopically (Note 4).

QUALITY CONTROL

Positive and negative controls should be run daily following the steps outlined in the Qualitative Test, in order to check the optimal reactivity of the reagent.
The positive control should produce clear agglutination. If the expected result is not obtained, do not use the kit.

EXPECTED VALUES

Urine may contain 50 – 5000 IU/L between 1 and 2.5 weeks of gestational age.
Negative results are expected in healthy non-pregnant women and healthy men.
In normal pregnancies a positive reaction is therefore possible 2-4 days after a missed period. If the first test should prove negative, it should be repeated a few days later, unless menstruation occurs.

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CLINICAL SIGNIFICANCE[2-5]

Human Chorionic Gonadotropin is a glycoprotein hormone produced by the placental tissue of pregnant women, being present in serum and urine. In normal pregnancy, hCG may be detected at 7-10 days after implantation of the developing embryo, reaching maximum levels of 120.000 IU/L at 10-12 weeks of the gestation period. It is for this reason that, hCG has been considered an excellent indicator for the early detection of pregnancy.
Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

ANALYTICAL PERFORMANCES

- The minimum detectable unit (analytical sensitivity) is of approximately 200 UI/L, referred to the 3rd International Standard of hCG 75/537 from NIBS (U.K.).
- Diagnostic specificity : 99.0%
- Prozone effect: No prozone effect was detected up to 250.000 IU/L.
- Results obtained with this reagent did not show significant differences when compared with reference reagents.
- The hemoglobin (<20 g/L) and the bilirubin (<2 mg/dL), do not interfere. Luteinizing Hormone (LH) does not interfere at concentrations $\leq$ 4 IU/L, being this concentration 20-30 fold more elevated than the maximum LH concentration found in the urine of women in the menopause period. Other substances may interfere[6].

LIMITATIONS OF THE PROCEDURE

- Urine from patients with trophoblastic disease such as choriocarcinoma or hydatiform mole could cause positive results[7].
- High hCG concentrations may result in either week or negative results (prozone effect).

NOTES

1. The sensitivity of the test may be reduced at low temperatures. The best results are achieved at 15-25ºC.
2. Press the pipette between the thumb and index finger with the open edge downwards, holding it at 3-4 cm from the welded edge, in a way that the fingers form an right angle with the pipette. Insert the open tip into the sample and reduce the pressure to fill up the pipette. Place the pipette in vertical position over the slide and press slightly again allowing to fall down two drops of urine (100 µL).
3. Samples with a high hCG concentration agglutinate in a few seconds and it is not necessary to wait the 2 minutes prescribed. When testing either negative or low hCG concentration samples, the time interval of 2 minutes should be accomplished.
4. The intensity of the agglutination is not an indication of the hCG concentration in the samples tested.

SOURCES OF ERROR

- Bacterial contamination of controls and specimens as well as freezing and thawing of the hCG-Latex Reagent may lead to false positive results.
- Traces of detergent in the test cards may give false positive results. Wash used cards first under tap water until reactants are removed and then with distilled water. Allow to dry in air, avoiding the use of organic solvents as they may impair the special finish on the slide.
- The hCG-Latex Reagent must not be used beyond its expiry date because a prolonged storage can affect the sensitivity of the suspension.

REFERENCES

1. Schwartz, S, Berger, P. and Wick, G The Antigenic surface of Human Chorionic Gonadotropin as mapped by murine monoclonal antibodies. Endocrinology. 118(1): 189 (1986).
2. Batzer, F.R. Fertil. Steril. 34(1): 1 (1980).
3. Catt, K.J., Dufau, M.L. and Vaitukaitis, J.L. J. Clin. Endocrinol. Metab. 40(3) : 537 (1975).
4. Braunstein, G.D., Rasor, J. Danzer, H., Adler, D. and Wade, M.E. Am. J. Obstet. Gynecol. 126(6): 678 (1976).
5. Lenton, E.A., Neal, L.M. and Sulaiman, R. Fertil. Steril. 37(6): 773 (1982).
6. Young, D.S. Effects of Drugs on Clinical Laboratory Tests. 4th Edition. AACC Press (1995).
7. Dawood, M.Y., Saxena, B.B. and Landesman, R. Obstet. Gynecol. 50(2): 172 (1977).

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