Reactivos GPL

Barcelona, España

CE

- hCG LATEX -

hCG LATEX
Agglutination test.

Store at: +2+8ºC.

Presentatión:
Cod. SE017 50 Test.
Cod. SE018 100 Test.

Procedure

Diagnostic reagent for qualitative measurement of hCG (Human chorionic gonadotropin).

Only for *in vitro use in clinical laboratory* (IVD)

TEST SUMMARY
The hCG-latex agglutination is an slide agglutination test for the direct qualitative detection of human chorionic gonadotropin in human urine and serum. Latex particles coated with monoclonal antibodies anti- hCG (Note 1) are agglutinated when mixed with samples containing hCG.

REAGENTS COMPOSITION

Latex **Ref. SE019 - 5 mL**	Latex particles coated with monoclonal antibodies anti-hCG, pH, 8.2. Sodium azide 0.95 g/L.
Control (+) **1 mL**	Human urine with a hCG concentration ≥ 1600 UI/L. Sodium azide 0.95 g/L.
Control (-) **1 mL**	Animal serum. Sodium azide 0.95 g/L.

PRECAUTIONS
Components from human origin have been tested and found to be negative for the presence of HBsAg and HCV, and of antibody to HIV (1/2). However handle cautiously as potentially infectious.

Good laboratory safety practices should be followed when handling laboratory reagents or human samples.

REAGENT PREPARATION AND STABILITY
All the components are ready to use.
Do not use reagents over the expiration date.
Do not freeze; frozen reagents could change the functionality of the test.
If appear particles and turbidity do not use.

All the reagents of the kit are stable up to the end of the indicated month and year of expiry. Store tightly closed at 2-8ºC,. Do not use reagents over the expiration date.

CALIBRATION
The hCG-latex sensitivity is calibrated against the 3rd International Standard of hCG 75/537 from NIBS (U.K.).

SPECIMEN
Urine or fresh serum (Note 2). The first morning urine is recommended as it generally contains the highest hormone concentration.
Urine samples: stable 2 days at 2-8ºC or 3 months at –20ºC.
Serum samples: stable 8 days at 2-8ºC or 3 months at –20ºC.
The samples with particles or fibrin should be centrifuged to eliminate them. Do not use haemolized or lipemic samples.

Discard contaminated specimen.

MATERIAL REQUIRED BUT NOT PROVIDED
Mechanical rotator with adjustable speed at 80-100 r.p.m.

General laboratory equipment

TEST PROCEDURE
1. Allow the reagents and sample to reach room temperature. The sensitivity of the test may be reduced at low temperatures.
2. Place 100 µL of the sample and one drop of each Positive and Negative control into separate circles on the slide test.
3. Shake the hCG-latex reagent gently before using and add a drop of this reagent next to the sample to be tested.
4. Mix both drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Rotate the slide with a mechanical rotator at 80-100 r.p.m. for 2 minutes. False positive results could appear if the test is read later than two minutes.

READING AND INTERPRETATION
Examine macroscopically the presence or absence of visible agglutination immediately after removing the slide from the rotator.
The presence of agglutination indicates a hCG concentration equal or greater than 200 IU/L (Note 3).

QUALITY CONTROL
Positive and Negative controls are recommended to monitor the performance of the procedure, as well as a comparative pattern for a better result interpretation.

Serum controls hCG are recommended for internal quality control. Each laboratory should establish its own Quality Control scheme and corrective actions.

REFERENCE VALUES
Serum: 5–50 IU/L between 0.2 and 1 week of gestational age.
Urine: 50–5000 IU/L between 1 and 2.5 weeks of gestational age.

It is suggested that each laboratory establish its own reference range.

CLINICAL SIGNIFICANCE
hCG is an hormone synthesized by the placenta of pregnant woman that appears in urine and serum relatively soon after implantation of the developing embryo. It may be detected in urine from the third day of the missed period and its concentration increase rapidly, peaking at approximately 10 weeks after the last menstrual period.

Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

REAGENT PERFORMANCE
- *Analytical sensitivity*:
  200 IU/L, under the described assay conditions.
- *Prozone effect:*
  No prozone effect was detected upon 3.4 x 10^6 IU/L.
- *Diagnostic sensitivity:* 98.7 %.
- *Diagnostic specificity:* 100 %.

INTERFERING SUBSTANCES
Interferences:
- Luteinizing Hormone (LH) (4000 UI/L), Thyroid Stimulating Hormone (TSH) (1 UI/mL), Follicle Stimulating Hormone (FSH) (1000 UI/L), hemoglobin (20 g/L), bilirubin (0.02 g/L), do not interfere.
- Other potentially interfering substances are referred to the Technical Report of the kit.

NOTES
1. The monoclonal antibodies used to coat particle latex, only react with the whole hCG molecule. α and β subunits of the same molecule do not react with the latex reagent.
2. The incidence of false positive results using serum as sample is about 4.5 –5%.
3. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

LIMITATIONS OF THE PROCEDURE
- Pituitary hormones such FSH and LH will cross-react immunologically with hCG. When levels of these hormones become abnormally high, false positive results could be obtained.
- A negative result does not exclude a pregnancy process. It is recommended to repeat the test again.
- Urine from patients with trophoblastic disease such as choriocarcinoma or hidatiform mole could cause positive results**.**

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CHEMELEX, S.A.
Pol. Ind. Can Castells. C / Industria 113, Nau J
08420 Canovelles –BARCELONA-
Tel- 34 93 849 17 35 Fax- 34 93 846 78 75