CHRONOLAB

CE
IVD

hCG-Latex

Slide agglutination

Qualitative determination of human chorionic gonadotropin (hCG)

PACKAGING

Ref.: 101-0214	Cont.: 100 tests
Ref.: 101-0215	Cont.: 50 tests
Ref.: 101-0533	Cont.: 100 tests (latex only)

Store at 2- 8ºC.

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.

PRINCIPLE OF THE METHOD

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

REAGENTS

Latex	Latex particles coated with monoclonal antibodies anti-hCG. Preservative
Control + Red cap	Human urine with a hCG concentration ≥ 1600 UI/L. Preservative
Control - Blue cap	Animal serum. Preservative

PRECAUTIONS

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

CALIBRATION

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

STORAGE AND STABILITY

All the kit components are ready to use, and will remain stable until the expiration date printed on the label, when stored tightly closed at 2 - 8º C and contaminations are prevented during their use. Do not freeze: frozen reagents could change the functionality of the test.
Reagents deterioration: Presence of particles and turbidity.

ADDITIONAL EQUIPMENT

- Mechanical rotator with adjustable speed at 80 - 100 r.p.m.
- Vortex mixer.
- Pippetes 50 µL.

SAMPLES

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 - 8º C or 3 months at –20º C.
Serum samples: stable 7 days at 2 - 8º C or 3 months at –20º C.
Samples with turbidity should be centrifuged before testing.
Do not use highly hemolized or lipemic samples.

PROCEDURE

1. Allow the reagents and samples 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 controls into separate circles on the slide test.
3. Mix the hCG-latex reagent vigorously or on a vortex mixer before using and add one drop (50 µL) next to the samples to be tested.
4. Mix the drops with a stirrer, spreading them over the entire surface of the circle. Use different stirrers for each sample.
5. Place the slide on 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 assay procedure, as well as a comparative pattern for the results interpretation. All result different from the negative control result, will be considered as a positive.

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.
Each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

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

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) and bilirrubin (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.

BIBLIOGRAPHY

1. Pesce AJ et al. Methods in Clinical Chemistry Ed Mosby; 487 – 495.
2. Choriogonadotropin Testing: I/LA 10-A Vol.16 No.14 NCCLS 12/1996.
3. John F O'Connor et al. Endocrin Reviews 1994 Vol 15 nº5 .
4. England TE et al. Journal of Clinical Ligand Assay 1995; Vol 18 nº1: 58-60.
5. Edward W et al. Am J Obst and Gynec 1969; 104/6: 865-870.
6. Hogan WJ et al. Obst and Gynec 1967; 29/4: 585-589.

CHRONOLAB SYSTEMS, S.L., C/Diputación 260, 08007 Barcelona, SPAIN
Tel. +34 617722466, www.chronolab.com, e-mail: comercial@chronolab.es