CORMAY hCG Latex

AGGLUTINATION TEST FOR DETECTION OF HUMAN CHORIONIC GONADOTROPIN (hCG)

Kit name	Kit size	Cat. No
CORMAY hCG Latex 50	50 tests	6-265
CORMAY hCG Latex 100	100 tests	6-266

INTRODUCTION
Human chorionic gonadotropin (hCG) is a glycoprotein produced by trophoblast. hCG appears in serum and urine of pregnant woman within several days after an implantation. hCG concentration rinses to 10th week of pregnancy, then decreases to the labor. Urine testing for hCG presence is a basic pregnancy test.

METHOD PRINCIPLE
Latex particles coated with monoclonal antibodies anti-hCG are agglutinated when mixed with samples containing hCG.

REAGENTS
Package

	CORMAY hCG Latex 50	CORMAY hCG Latex 100
hCG-Latex	1 x 2.5 ml	1 x 5 ml
hCG-Control (+) (red cap)	1 x 1 ml	1 x 1 ml
hCG-Control (-) (blue cap)	1 x 1 ml	1 x 1 ml
Stirrers	1 x 25 pcs.	2 x 25 pcs.
Slides (6 circles each)	1 x 9 pcs.	2 x 9 pcs.

Reagent preparation and stability
The reagents are ready to use.
The reagents when stored at 2-8°C are stable up to expiry date printed on the package. Do not freeze.

Concentrations in the test

latex particles coated with monoclonal antibodies anti-hCG	50 mmol/l
human urine solution	150 mmol/l
animal serum solution	150 mmol/l
sodium azide	< 0.1 %

Warnings and notes
- Product for in vitro diagnostic use only.
- The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.
- 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.
- The reagents contain sodium azide (< 0.1%) as a preservative. Avoid contact with skin and mucous membranes.
- 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.
- False positive results could be obtained in case of: use serum as a sample (4.5-5%), high level FSH and LH in the sample, use urine from patient with trophoblastic disease.
- A negative result does not exclude a pregnancy process.
- Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.

ADDITIONAL EQUIPMENT
- mechanical rotator with adjustable speed at 80-100 r.p.m.
- general laboratory equipment.

SPECIMEN
Urine or fresh serum. 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 7 days at 2-8ºC or 3 months at –20ºC.
Samples with turbidity should be centrifuged before testing.
Do not use highly hemolized or lipemic samples. It is recommended to perform the assay with freshly collected samples.

PROCEDURE
The test is recommended for the qualitative manual assay.

Qualitative method
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. Swirl the hCG-Latex reagent gently before using and add one drop (50 µl) next to the sample 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.

REFERENCE VALUES

0.2 – 1 week of gestational age	5-50 IU/l (serum)
1 – 2.5 week of gestational age	50-5000 IU/l (urine)

It is recommended for each laboratory to establish its own reference ranges for local population.

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.

PERFORMANCE CHARACTERISTICS
- **Analytical sensitivity:** 200 IU/l.
- **Prozone effect:** no prozone effect up to 3.4 x 10^6 IU/l.
- **Diagnostic sensitivity:** 98.7 %.
- **Diagnostic specificity:** 100%.
- **Interferences:**
  LH up to 4000 IU/l, TSH up to 1 IU/ml, FSH up to 1000 IU/l, haemoglobin up to 20 g/l, bilirubin up to 0.02 g/l do not interfere with the test.

WASTE MANAGEMENT
Please refer to local legal requirements.

LITERATURE

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.

Date of issue: 03. 2011.

MANUFACTURER

PZ CORMAY S.A.
ul. Wiosenna 22,
05-092 Łomianki, POLAND
tel.: +48 (0) 22 751 79 10
fax: +48 (0) 22 751 79 14
http://www.pzcormay.pl

03/11/03/11