hCG CARD

Pregnancy Test
Qualitative Determination of CG
in Urine and in Serum

20 tests	**REF 4003**
50 tests	**REF 4024**
100 tests	**REF 4051**

PRINCIPLE

hCG card is a rapid, qualitative one-step assay for the detection of human chorionic gonadotropin (hCG) in serum and urine.
The method employs a unique combination of monoclonal-dye conjugate and polyclonal solid phase antibodies to identify hCG in the test samples with a high degree of specificity.
In less than 5 minutes, levels of hCG as low as 25 mIU/ml are detected. As the test sample flows through the absorbent device, the labelled antibody-dye conjugate binds to the hCG forming an antibody-dye-antigen complex. This complex binds to the anti-hCG antibody in the positive reaction zone and produces a pink-rose colour band when hCG concentration is ≥ 25 mUI/ml. In the absence of hCG, there is no line in the positive reaction zone. The reaction mixture continues flowing through the absorbent device past the reactive zone and control zone. Unbound conjugates binds to the reagents in the control zone, producing a pink-rose colour band, demonstrating that the reagents are functioning correctly.

REAGENTS

Components of the kit:	REF 4003	REF 4024	REF 4051
Cards	**20**	**50**	**100**
Pipette	**20**	**50**	**100**

STABILITY: the test card should be stored at 4-30°C. Do not freeze.

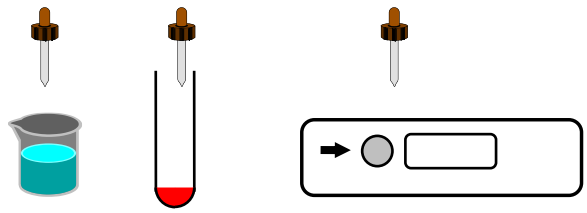
SAMPLE

Urine for optimal detection of early pregnancy, a specimen of the first voided in the morning is preferable since it contains the highest concentration of hCG.
STABILITY: urine may be refrigerated at 2-8°C for 24 hours.
If testing is delayed more than 24 hours, the specimen should be frozen. The frozen specimen must be completely thawed and allowed to return to room temperature prior to testing. Avoid repeated freezing and thawing.

Serum collected under standard laboratory conditions avoiding hemolysis. In the event of cloudiness, high viscosity dilute with an equal volume of saline before testing.
STABILITY: serum may be refrigerated at 2-8°C for 48 hours.

ASSAY PROCEDURE

1. Bring all specimens and cards to room temperature before the assay.
2. Remove the requested number of cards from the sealed pouch.
3. Label each card with the patient's name.
4. Dispense, holding the pipette vertically, **3 full drops (100 µl)** of urine to the sample well (➡).

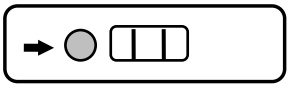


urine **serum** **3 drops (100 µl)**

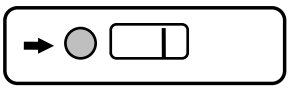
5. Read the results at 5 to 10 minutes.

INTERPRETATION OF RESULTS

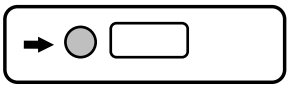
Two band:	**positive,** hCG presence within the test sensitivity limit.
One band:	**negative,** hCG presence inferior to the test sensitivity limit.
No band:	**inconclusive:** procedure performed non correctly or with expired card or not correctly stored. Repeat the test or obtain a fresh specimen 48 hours later and retest.



POSITIVE: 2 pink bands



NEGATIVE: 1 pink band



INCONCLUSIVE: no band

REFERENCE VALUES

hCG concentration in urine increases from 5 to 50 mIU/ml in the first week of pregnancy and it increases up to 100.000-200.000 at 9th month of pregnancy. High levels of hCG indicates pregnancy. Patients with trophoblastic disease give positive results.

CHARACTERISTICS

Sensitivity: ≥ 25 mIU/ml hCG.
Specificity: the following concentration of homologous hormones do not interfere with test: hLH 300 mIU/ml, hFSH 1000 mIU/ml and hTSH 1000 mIU/ml. Urine from menopausal women, tested with hCG card gave negative result.
Precision: Intra-assay: 100%; **Inter-assay:** 100%.

INTERFERENCES

The following concentration of substances do not interfere with the test: acetominophen 20 mg/dl, albumin 1.5 g/dl, ascorbic acid 20 mg/dl, gentesic acid 20 mg/ml, atropine 20 mg/dl, bilirubin 30 mg/ml, caffeine 20 mg/ml, hemoglobin 30 mg/ml, glucose 2 g/dl, ampicillin 20 mg/ml and tetracycline 40 mg/ml.

LIMITATION OF THE TEST AND NOTES

1. (*) Dangerous reagents are marked by an asterisk. Refer to MSDS.
2. A normal pregnancy cannot be distinguished from an ectopic pregnancy on the basis of hCG levels only.
3. Samples with high levels of RF may yield non-specific positive results during testing.
4. hCG levels may remain detectable for several weeks after normal, delivery, delivery by cesarean section, spontaneous abortion or therapeutic abortion.
5. The presence of hydroxyethyl-cellulose in the composition of catheter lubricant may give false positive at the concentration equal o higher than 0.1%.

REFERENCES

Batzer F.R. Fertility & Sterility, Vol. 34,1,1980.
Catt K.J., Dufan M.L., Vaitukaitis J.L., Journ. Clin. Endocr. Metab., Vol. 40,537,1975.

IVD CE

Issue 02 - Mar 2015 RR/MS

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