

# BIOCARD™ HCG

19.06.2007

BIOCARD™ HCG is an immunochromatographic test for the rapid detection of hCG in urine.  
Cat.no. 3-008-00G

BIOCARD™ HCG is a disposable immunochromatographic testing device for the qualitative assay of human chorionic gonadotropin (hCG) in urine for laboratory and professional use.

## INTRODUCTION

Human chorionic gonadotropin (hCG) is a glycoprotein hormone produced by the placenta. In normal pregnancy hCG appears in serum and urine soon after conception. The concentration of the hormone increases rapidly and therefore it serves well as an indicator of pregnancy. The level of urinary hCG is about 100 mIU/ml at the time of the first missed menstrual period. The highest values (100.000 - 200.000 mIU/ml) can be demonstrated towards the end of the first trimester.

## PRINCIPLE OF THE TEST

The BIOCARD™ HCG test is based on immunochromatography. The test device includes a chromatographic membrane with two stationary antibody zones, rehydratable mobile dyed antibody against hCG and a filter.

Testing is performed by adding a few drops of urinary sample into the sample window of the BIOCARD™ HCG testing device. The sample flows through a filter after which it is absorbed into the membrane where it comes into contact with the different reagent zones. In the first zone it rehydrates the dyed antibody against hCG. The hormone in the specimen reacts with the dyed antibody thus forming a dyed hCG-antibody complex. This complex migrates further in the membrane towards the stationary anti - hCG zone. The stationary antibody captures the dyed hCG-antibody complex under formation of an intensively coloured line in the test result window ( test line ).

The excess of the dyed antibody not captured by the test line will be captured by the second stationary antibody, which reacts with the immunoglobulin part of the dyed antibody, leading to the formation of a second intensively coloured line, this time in the control window (control line), indicating proper performance of the test. If the specimen does not include hCG-hormone or if its level is very low, the dyed hCG-antibody complex will not be formed and the dyed antibody will freely pass the stationary

antibody in the test indicator zone and will later be captured by the control indicator zone, leading to the formation of a coloured line only in the control indicator window.

The sensitivity of the BIOCARD™ HCG test has been adjusted so that it will detect urinary hCG at a level equal or higher than 25 mIU/ml (referenced to the World Health Organization 3rd. International Standard 1986, Chorionic Gonadotropin 75/537.). This level is normally reached in approx. 10 days after conception.

## MATERIALS PROVIDED

BIOCARD™ HCG Cat.no 3-008-00G  
20 disposable BIOCARD™ HCG tests  
single-packed in foil pouches  
20 disposable pipettes  
Instructions for use

Materials needed but not provided with the kit: sample collection cup and timer.

## STABILITY AND STORAGE

BIOCARD™ HCG tests shall be stored at +2...+30 °C in original unopened pouches. Each test unit contains a drying agent. Test units shall be used without delay after opening the pouch. The shelf life of BIOCARD™ HCG is two years from the date of manufacture. The expiry date is indicated on the package.

## COLLECTION OF SAMPLES AND STORAGE

The concentration of hCG is highest in the first urine of the morning. Therefore in the very beginning of pregnancy it is recommended to use such a specimen. However, if this is not possible any other sample can be used.

The urinary samples can be stored at room temperature (+15...+30 °C) for up to 8 hours and refrigerated (+2...+8 °C) for up to four days. At -20 °C, the samples can be stored for up to 4 months.

## EXPECTED VALUES

Urine from healthy men and non-pregnant women should not contain detectable levels of hCG. Concentration of 25 mIU/ml, the cut-off value of the

BIOCARD™ HCG test is normally reached in about 10 days after conception. By the end of the first trimester of pregnancy levels of up to 200.000 mIU/ml can be reached.

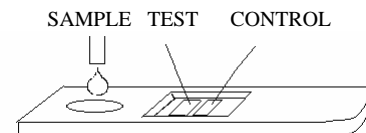
## CONTROLS

Good laboratory practice recommends routine use of controls to ensure proper performance of the test. Performance of BIOCARD™ HCG can be checked by means of known positive and known negative urinary samples. A positive sample shall give a positive reaction when tested according to the instructions of use and a negative sample shall give a negative result.

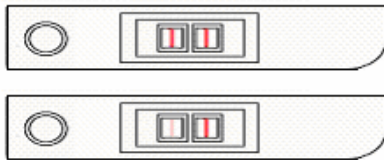
Note: Standards and controls which contain fragmented hCG may give discrepant results when tested by different hCG-assay methods.

## TEST PROCEDURE AND INTERPRETATION OF THE RESULTS

- Bring the specimens to room temperature.
- Remove the test device from the pouch (one device for each specimen) and place the device on the bench. Do not touch the device during the 5-minute testing time.
- Hold the pipette in a vertical position and pipette dropwise 3 free-falling drops (totally approx. 110 microliters) of urine sample in the sample window of the device. Use the disposable pipette provided with the kit (one pipette for each specimen).

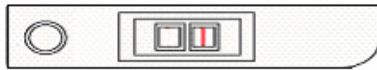


- Read the result after about 5 minutes after having applied the specimen. If a definite red line is formed in the test indicator window and in the control indicator window, the test result is positive, that is, the concentration of hCG in the sample matches or is higher than 25 mIU/ml.



POSITIVE

If a definite red line is formed only in the control indicator window, the test result is negative, that is, the hCG-concentration in the sample is lower than 25 mIU/ml.



NEGATIVE

Note: you can read a positive result as soon as the two red lines are distinctly visible. In most cases a positive result is interpretable in one to two minutes.

If the test line is extremely faint, which may indicate that the concentration of hCG is just below the cut-off level of 25 mIU/ml, repeat the testing with a new sample taken 2 days later.

Read the test result within 15 min after having applied the sample. A positive result will remain unchanged for several hours but after a long reaction time a faint test line may appear although the concentration of hCG is below the cut-off level.

#### INVALID TEST RESULT

If no coloured control line is formed in the control indicator window the test device is damaged and so the test result shall be rejected. In such a case repeat the test with a new test unit.

#### PERFORMANCE CHARACTERISTICS

##### Accuracy

90 urine samples were analyzed at three hospitals parallel with BIOCARD™ HCG (Cat.no. 3-008-00G) and the other commercial kit used at the location. The results were as follows:

	Other commercial kit	
	+	-
BIOCARD™ HCG	68	0
Cat.no. 3-008-00G	1	21

When 93 urine specimens were evaluated using the BIOCARD™ HCG test and another commercially available kit, the results were as follows:

	BIOCARD™ HCG	
	+	-
Other commercial kit	49	0
	0	44

When 16 urine specimens were evaluated using the BIOCARD™ HCG test and Delfia hCG, the results were as follows:

	BIOCARD™ HCG	
	+	-
Delfia hCG	16	0
	0	0

#### Sensitivity and specificity

The overall sensitivity and specificity calculated from the above mentioned results are 99,3% and 100%, respectively.

hCG-negative urine specimens with added glycoprotein hormones (LH 400 mIU/ml and FSH (600 mIU/ml) gave negative results when tested with BIOCARD HCG.

#### Interfering substances

When the following substances were added to a negative and positive specimen (60 mIU/ml) they did not affect the test result:

Compound:	Concentration (mg/dl)
Asetamnophen	20
Asetoacetic acid	1500
Asetone	1250
Asetylsalsilyc acid	20
Albumin	1400
Ampicillin	40
Askorbic acid	40
Biotin	30 µg/dl
Caffeine	40
Codeine	5 µg/ml
Cortisol	150 ng/ml
Creatinine	200
DHEAS	10
Estrone	25 ng/ml
Estradiol	25 ng/ml
Estriol	25 ng/ml
Ethanol	4000
Hemoglobin	30 g/l
Hydroxybutyric acid	100
Glucose	20 g/l
Oxalic acid	5000
Progesterone	50 ng/ml
Phenobarbital	10 µg/ml
Salsilyc acid	1500
Secobarbital	10 µg/ml
Sodium carbonate	1500
Sodium chloride	5000
Tetracycline	40
Urea	3500
Uric acid	10

#### PRECAUTIONS AND LIMITATIONS

If instructions for use are not carefully followed, false results may appear.

BIOCARD™ HCG tests shall be used only for *in vitro* detection of hCG in urine according to the instructions of use.

General laboratory procedures and precautions shall be followed in handling and disposal of samples and used testing material.

Do not reuse BIOCARD™ HCG test units. Do not use expired tests or tests from a lot not showing proper performance when tested with the controls. Do not use a test unit from a pouch which has been damaged during storage.

When assessing whether a woman is pregnant or not, instead of relying solely on the test result given by the BIOCARD™ HCG it is necessary to take into consideration all the patient information which may influence pregnancy.

At the very beginning of pregnancy the concentration of hCG in urine is below 25 mIU/ml and BIOCARD™ HCG will give a negative result. In case a urinary sample is too dilute, the amount of hCG may not be representative and this may lead to a negative test result at an early stage of pregnancy.

Apart from pregnancy, an elevated level of hCG and a positive test result can be caused by trophoblastic and non-trophoblastic neoplasms, which should to be taken into consideration when interpreting a positive BIOCARD™ HCG test result.

#### Manufacturer:

Ani Biotech Oy, Tiilitie 3,  
01720 VANTAA, FINLAND  
<http://www.anibiotech.fi>  
e-mail: [info@anibiotech.fi](mailto:info@anibiotech.fi)  
tel. +358-20-155 7518

