CE

Beta-Clear™ HCG
Device.
Cat N°: HCG-210020
One step test for the determination of human chorionic gonadotropin (HCG).

► INTRODUCTION

One-step pregnancy test is a rapid, self-performing, qualitative, two-site sandwich immunoassay for the determination of human chrorionic gonadotropin (HCG), a marker for pregnancy, in urine/serum specimens.

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Human chorionic gonadotropin (HCG) is a glycoprotein hormone secreted by variable placental tissue during pregnancy. The levels of HCG rise rapidly reaching peak levels after 60-80 days.

The appearance of HCG soon after conception and its rapid rise in concentration makes it an ideal marker for the early detection and conformation of pregnancy. However elevated HCG levels are frequently associated with trophoblastic and non-trophoblastic neoplasms and hence these conditions should be considered before a diagnosis of pregnancy can be made.

HCG one-step pregnancy test detects the presence of HCG in urine/serum specimens, qualitatively, at concentrations as low as 10 mlU/ml.

►PRINCIPLE

One-step pregnancy test utilizes the principle of Immunochromatography, a unique two-site immunoassay on a membrane. As the test sample flows trough the membrane assembly of the dipstick, the colored anti-HCG-colloidal gold conjugate complexes with the HCG in the sample. This complex moves further on the membrane to the test region where it is immobilized by the anti-HCG coated on the membrane leading the formation of a pink colored band, which confirms a positive test result. Absence of this colored band in the test region indicates a negative test result. The unreacted conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the anti-mouse antibodies coated on the membrane at the control region, forming a pink band. This control band serves to validate the test results.

►REAGENTS AND MATERIALS SUPPLIED

Each individual pouch contains:

1. Device: Membrane predisposed with anti-HCG antisera – colloidal gold conjugate and anti-HCG antisera and anti-mouse antisera at the respective regions.
2. Disposable plastic dropper.
3. Desiccant pouch.

►SPECIMEN COLLECTION AND PREPARATION (Urine)

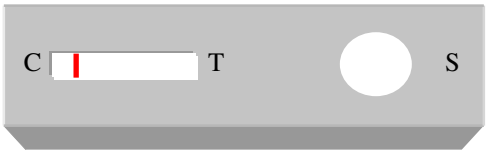
Though random urine specimens can be used, first morning urine specimen is preferable as it contains the highest concentration of HCG. Specimens should be collected in clean glass or plastic containers. If testing is not immediate, the urine specimens may be stored at
2 – 8°C for up to 72 hours. Turbid specimen should be centrifuged or allowed to settle and only the clear supernatant should be used for testing.

►SPECIMEN COLLECTION AND PREPARATION (Serum)

No special preparation of the patient is necessary prior to specimen collection by approved techniques. Though fresh serum/plasma is preferable, serum/plasma specimens may be stored at 2-8°C for up to 24 hours, in case of delay in testing. Do not use haemolysed specimens.

►TEST PROCEDURE AND INTERPRETATION OF RESULTS

1. Bring the sealed pouch to room temperature, open the pouch and remove the device. Once opened, the device must be used immediately.
2. Dispense two drops of urine/serum specimen into the sample well "S" using the dropper provided. Refrigerated specimens must be brought to room temperature prior to testing.
3. At the end of five minutes (for urine samples) or 15 minutes (for serum samples), read the results as follow:



Negative: Only one colored band appears on the controls region "C".

Positive: In addition to the control band, a distinct colored band also appears on the test region "T".

4. The test should be considered invalid if no band appears. Repeat the test with a new device.
5. Although, depending on the concentration of HCG in the specimen, positive results may start appearing as early as 30 seconds, negative results must be confirmed only at the end of five minutes (urine) / fifteen minutes (serum).

►STORAGE AND STABILITY

The sealed pouches in the test kit may be stored between 4 - 30° C till the duration of the shelf life as indicated on the pouch.

►NOTE

1. For in vitro diagnostic use only.
2. NOT FOR MEDICINAL USE
3. Do not use beyond expire date.

►LIMITATIONS OF THE TEST

1. A number of conditions other than pregnancy including trophoblastic and non-trophoblastic neoplasms such as hydatidiform choriocarcinoma etc. cause elevated levels of HCG. Such clinical conditions must be ruled out before a diagnosis of pregnancy can be made.
2. Highly dilute urine specimens and specimens from very early pregnancy may not contain representative levels of HCG. If pregnancy is still suspected, repeat the test with first morning urine after 48-72 hours after the initial test.
3. As with all diagnostic tests, the results must be correlated with clinical findings.

►PERFORMANCE CHARACTERISTICS

1. Sensitivity:

HCG one-step pregnancy test detects the presence of HCG in urine/serum specimens, qualitatively, at concentrations as low as 10 mlU/ml. Concentrations of about 100 mlU/ml of HCG are reached by the first missed menstrual period in normal pregnancy. Thus HCG one step pregnancy test is able to detect pregnancy at very early stages.

2. Specificity:

Normally men and non-pregnant women do not have detectable levels of HCG by the HCG one step pregnancy test. Homologous hormones and other potentially interfering substances spiked beyond peak physiological concentrations did not cross-react with HCG one step pregnancy test.

3. Accuracy:

The results obtained by HCG one step pregnancy test correlated very well when run in parallel with other commercially available tests for pregnancy, using known positive and negative specimens.

►WARRANTY

This product is designed to perform as described on the label and the package insert, the manufacturer disclaims any implied warranty of use and sale for any other purpose.

►REFERENCES

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SYMBOLS USED ON THE

	**Consult instructions for use**
	**Storage temperature**
	**Use by**
LOT	**Batch code**
REF	**Catalogue number**
I V D	**In vitro diagnostic medical device**
CARD	**Test Device**
PIPETTE	**Disposable Plastic Dropper**
	**Manufactured By**
	**Date of Manufacture**
	**Contains sufficient <n> tests**

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