SERATEC®
Gesellschaft für Biotechnologie mbH

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SERATEC® hCG Dip Stick Test

REF HCG-S1

A Rapid One Step, Visual Test for the Qualitative Detection of Human Chorionic Gonadotropin in Urine

INTENDED USE

For the rapid determination of human chorionic gonadotropin (hCG) in urine. The test kit is used to obtain a visual, qualitative result and is intended for professional use.

SUMMARY

Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after fertilization. In normal pregnancy, hCG can be detected in serum or urine as early as 7 days following conception (1-4). The concentration of hCG continues to rise rapidly, frequently exceeding 100 mIU/mL by the first missed menstrual period (2-5) and peaking in the 30,000 - 100,000 mIU/mL range by 10 - 12 weeks into pregnancy. The appearance of hCG soon after conception and its subsequent rise in concentration during early gestational growth makes it an excellent marker for the early detection of pregnancy.

Elevated serum hCG levels comparable to those observed in early pregnancy may also be associated with trophoblastic or non-trophoblastic neoplasms such as hydatidiform mole, choriocarcinoma; therefore, the possibility of such diseases should be ruled out before a positive hCG result is considered diagnostic for pregnancy.

The SERATEC® hCG dip stick test is a rapid lateral flow test for the detection of hCG at a level of more than 20 mIU/mL.

The test utilizes monoclonal antibodies to selectively detect elevated levels of hCG in urine. The immunological specificity of the test kit virtually eliminates cross reactivity interference from structurally related glycoprotein hormones hFSH, hLH and hTSH at physiological levels.

PRINCIPLE

The SERATEC® hCG dip stick test is a chromatographic immunoassay (CIA) for the rapid qualitative determination of hCG in urine specimens. The membrane was pre-coated with anti-alpha hCG capture antibody on the test band region and goat anti-mouse on the control band region. During testing, the urine or serum specimen is allowed to react with the colloidal gold particles which have been coated with anti-beta hCG monoclonal antibody. The mixture then moves upward on the membrane chromatographically by capillary action. For a positive result, a colored band with a specific antibody-hCG-antibody-colloidal gold particle complex will form on the membrane in the test band region. The absence of a colored band in the test band region indicates a negative result. To serve as a procedural control, a colored band at the control region will always appear regardless of the presence of hCG.

REAGENTS AND MATERIALS SUPPLIED

- Dip stick test, single sealed (25 test / Box)

STORAGE AND STABILITY

The test kit is to be stored at refrigeration (2-8 °C) or room temperature (up to 30 °C) in the sealed pouch for the duration of the shelf life.

PRECAUTIONS

- FOR IN VITRO USE ONLY
- Do not use kit beyond expiration date
- Open pouch immediately before use

SPECIMEN COLLECTION

The urine specimen must be collected in a clean, dry container. Specimens collected at anytime may be used, however, the first morning urine generally contains the highest concentration of hormone. Urine specimens may be refrigerated (2-8°C) and stored up to 72 hours prior to assay. If samples are refrigerated, they must be equilibrated to room temperature before testing. Urine samples exhibiting visible precipitates should be filtered, centrifuged or allowed to settle and clear aliquots obtained for testing.

ASSAY PROCEDURE

Material Provided:

- dip stick test

Materials required but not provided:

- Specimen collection container

USER QUALITY CONTROL

A procedural control is included in the test. A colored band appearing on the control region of the membrane indicates proper performance and reactive reagents.

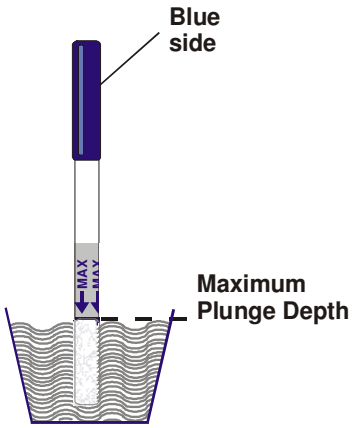
Good laboratory practices include the use of external specimens to ensure proper kit performance. Each day of testing, two levels of commercial controls should be tested on the SERATEC® hCG dip stick tests. The two levels of controls should consist of a negative control and a positive control containing low levels of hCG. The use of the low level positive control will assure that the dip stick tests have not been adversely affected and are detecting hCG at the stated sensitivity of the test system.

TEST PROCEDURE

1. Review Specimen Collection instructions. Dip stick tests (inside the closed pouch!), patient's samples, or controls should be brought to room temperature (18 - 30°C) prior to testing.

2. Open the pouch and take the strip by seizing it at the blue side.

3. Immerse the white side of the strip up to the mark into the urine sample with the arrow pointing towards the urine



4. Wait for at least 20 seconds, then remove the test and put it with the marked side facing to you on a dry underlay.

5. Wait for colored bands to appear. Depending on the concentration of hCG, positive results may be observed in as short as 40 seconds. However, to confirm negative results, the complete reaction time (5 min) is required. Do not interpret results after 10 minutes.

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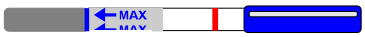
INTERPRETION OF RESULTS



NEGATIVE (=not pregnant): Only one colored band appears on the control region (C). No apparent band on the patient test region (T).

POSITIVE: In addition to a pink colored control band, a distinct pink colored band will also appear in the patient test region (T).

INVALID: A total absence of color in both regions is an indication of procedure error and/or that the test reagent deterioration has occurred. It should be noted that the control band may be faint when the color of the test band is intense. This should be considered valid.

NOTES ON THE INTERPRETATION OF RESULTS

- Negative test results in patients suspected to be pregnant should be retested with a sample obtained 48 to 72 hours later, or by performing a quantitative assay. When testing with a urine specimen, the first morning specimen would contain the highest hCG concentration.
- Borderline samples (those showing a very faint line in the test region) that later test negative may be attributed to falling hCG levels following a spontaneous or induced abortion. Natural termination occurs in 22% of clinically unrecognized pregnancies (6). Conversely, borderline samples that subsequently show color intensity greater than the reference band may be attributed to rising hCG levels.
- The shade of pink on the (T) test band region will vary depending on the concentration of hCG present. However, neither the quantitative value nor the rate of increase in hCG can be determined by a qualitative test.

LIMITATIONS OF THE PROCEDURE

- A number of conditions other than pregnancy including trophoblastic disease and certain nontrophoblastic neoplasms cause elevated levels of hCG. These diagnoses should be considered if appropriate to the clinical evidence.
- If a urine specimen is too dilute (i.e. low specific gravity) it may not contain representative levels of hCG. If pregnancy is still suspected, first morning urine should be obtained from the patient 48-72 hours later and tested.
- As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
- Immunologically interfering substances such as those in antibody therapy treatments may invalidate the test result.

EXPECTED VALUES

Healthy men and healthy non-pregnant women do not have detectable hCG by the SERATEC® hCG test. hCG levels of 100 mIU/mL can be reached on the day of the first missed menstrual period. hCG levels peak about 8-10 weeks after the last menstrual period and then decline to lower values for the remainder of the pregnancy. Following delivery, hCG levels rapidly decrease and usually return to normal within days after parturition.

PERFORMANCE CHARACTERISTICS

SENSITIVITY

The analytical sensitivity of the SERATEC® hCG dip stick test has been set at 20 mIU/mL (calibrated according to the 4th IRP) as indicated by the development of a colored band in the window of the test region of the test. Additionally, samples containing less than 20 mIU/mL hCG may also produce a faint positive result.

To evaluate the sensitivity of the SERATEC® hCG dip stick test at low levels of hCG the following experiments were carried out: Urine samples from five known non-pregnant subjects were spiked with hCG to the concentrations of 0, 10, 20, 40, 100 mIU/mL. A total of 100 of these samples were blind labelled and tested with the SERATEC® hCG dip stick test. Results are summarized in Table 1.

Table1

hCG (mIU/mL)	0	10	20	40	100
samples	20	20	20	20	20
negative	20	5	0	0	0
positive	0	15	20	20	20

SPECIFICITY

Specificity of the SERATEC® hCG dip stick test was determined from cross reaction studies with known amounts of Luteinizing Hormone (hLH), Follicle Stimulating Hormone (hFSH), and Thyroid Stimulating Hormone (hTSH). 300 mIU/mL hLH, 1000 mIU/mL hFSH and 1000 µIU/mL hTSH all gave negative results.

ACCURACY

102 randomly selected urine samples were analyzed by the SERATEC® hCG dip stick test procedure in parallel with a commercially available one step hCG test. The results indicated complete agreement (57 positive samples and 45 negative samples).

INTERFERENCE TESTING

The following substances were added to hCG free and 20 mIU/mL hCG spiked urine samples. None of the substances at the concentration tested interfered with the assay.

compound	concentration
Paracetamol, Atropine, caffeine, Acetylsalicylic acid, ascorbic acid and gentisic acid	0.2 mg/mL
Glucose	20 mg/mL
Hemoglobin	10 µg/mL

STANDARDIZATION

The SERATEC® hCG dip stick test has been standardized to the World Health Organization Forth International Reference Preparation (IRP75/589).

REFERENCES

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Symbols

	Please read user instructions first!
	For single use only
	Expiry date
	Storage temperatur
IVD	In vitro diagnostic medical device
LOT	Lot number

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