SERATEC®
Gesellschaft für Biotechnologie mbH

SERATEC®
Gesellschaft für Biotechnologie mbH
Ernst-Ruhstrat-Str. 5
D -37079 Göttingen, Germany

Phone: +49 (0)551/504 800 • Fax: +49 (0)551/504 80 80 • e-mail: contact@seratec.com, web: www.seratec.com

SERATEC® hCG Cassette Test

REF SSC

A visual one-step immunoassay for the qualitative detection of human chorionic gonodotropin in urine.
For professional *In Vitro* diagnostic use only.

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 device 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.
The SERATEC® hCG device 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 as active compounds to selectively detect elevated levels of hCG. The immunological specificity of the test kit virtually eliminates cross-reactivity interference from the structurally related glycoprotein hormones hFSH, hLH and hTSH at physiological levels.

PRINCIPLE

The SERATEC® hCG device 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.
This means that hCG **positive** samples result in the formation of **two** colored lines in the test line (T) and control line region (C), whereas hCG **negative** samples only exhibit **one** colored line in the control line region. The appearance of the control line confirms the proper capillary flow and the correct handling of the test device.

STORAGE AND STABILITY

The test kit is to be stored at refrigeration (+2-8°C) or at room temperature (up to 30°C) in the sealed pouch for the duration of the shelf life. Do not use beyond expiration date.

MATERIALS SUPPLIED

- Test devices with disposable pipettes
- One instruction leaflet

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Specimen collection containers

USER QUALITY CONTROL

The test device is standardized to the recent WHO standard (4th IRP 75/589). The appearance of the control line serves as procedural control and indicates proper performance and reactive reagents.
However, good laboratory practices recommends the use of external specimens to ensure proper kit performance. Each day of testing, two levels of commercial controls should be tested with the SERATEC® hCG test devices. 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 test devices have not been adversely affected and are detecting hCG at the stated sensitivity of the test system.

PRECAUTIONS

- For single *in-vitro* diagnostic use.
- For professional use only.
- Urine specimens may be potentially infectious. Proper handling and disposal methods should be established.
- Avoid cross-contamination of samples by using new specimen collection containers and specimen pipettes for each sample.
- Do not use test device if the pouch is damaged
- The components of the test that are of animal origin (e.g. antibodies) do not cause any danger if the test is used according to the instructions.

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.

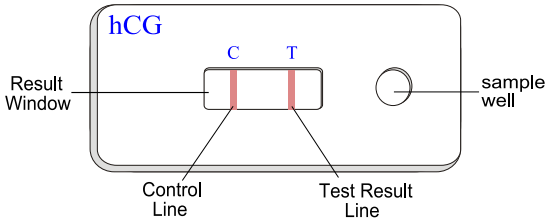
TEST PROCEDURE

1. Review Specimen Collection instructions. Test device, patient's samples, or controls should be brought to room temperature (18–30 °C) prior to testing.

2. Remove the test device from its protective pouch (bring the device to room temperature before opening the pouch to avoid condensation of moisture on the membrane). Label the device with patient or control identifications.

3. Draw the urine sample to the line marked on the pipette (approximately 0.1 mL). Hold the pipette in a straight up and down position - not an angle. Dispense 3 drops (approximately 0.1 mL) of the specimen or control into the sample well. For each sample or control, use a separate pipette and device.

4. 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 5 minutes.



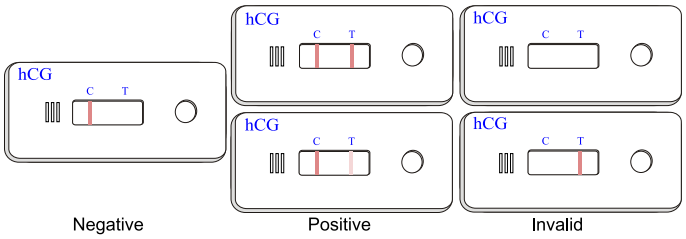
SERATEC®
Gesellschaft für Biotechnologie mbH
Ernst-Ruhstrat-Str. 5
D -37079 Göttingen, Germany
Phone: +49 (0)551/504 800 • Fax: +49 (0)551/504 80 80 • e-mail: contact@seratec.com, web: www.seratec.com

INTERPRETATION OF RESULTS

Negative result:
Only **one** colored line appears in the control region (C). **No apparent** line in the test line region (T) indicates a negative result.

Positive result:
Two red lines indicate a positive result. In addition to the red colored control line (C), a distinct red colored line appears in the test line region (T). The color of the test result line can be less or more intent than that of the control line. Even a weak test result line is a positive result and indicates an elevated hCG level.

Invalid:
A total absence of a colored line in the control line region is an indication of a procedural error and/or a deterioration of test reagents. Add some additional drops of sample to the sample well. If still no colored band appears, the test should be voided.



NOTES ON THE INTERPRETATION OF RESULTS

- Negative test results for patients strongly suspected to be pregnant should be repeated with a sample obtained 48 to 72 hours later, or by performing a quantitative assay. When testing a urine specimen, the first morning urine would contain the highest hCG concentration.
- Borderline samples (those showing a very faint line in the test line 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).
- The shade of red color in the test line region (T) 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 this qualitative test.

LIMITATIONS OF THE PROCEDURE

- A number of conditions other than pregnancy including trophoblastic diseases and certain nontrophoblastic neoplasms cause elevated levels of hCG. These conditions should be kept in mind before an elevated hCG level is considered diagnostic for pregnancy.
- 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, we recommend retesting a first morning urine sample of the patient 48-72 hours later.
- 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.

PERFORMANCE CHARACTERISTICS

The hCG concentration of the the non-clinical samples was adjusted with the WHO Standard 1st International Reference Preparation (IRP 75/537).

Sensitivity

The analytical sensitivity of the SERATEC® hCG device has been set to 20 mIU/ml. At this concentration the test will develop a clear test result line. Additionally, samples containing less than 20 mIU/mL hCG may also produce a faint positive result. The upper detection limit is at least 300 IU/ml hCG. At this concentration the test shows no detectable prozone effect.
To evaluate the sensitivity of the SERATEC® hCG device 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 device. The results are summarized in Table 1.

Table1

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

SPECIFICITY

Specificity of the SERATEC® hCG device 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 device 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.

Acetamionophen	0.2 mg/mL
Acetylsalicylic Acid	0.2 mg/mL
Ascorbic Acid	0.2 mg/mL
Atropine	0.2 mg/mL
Caffeine	0.2 mg/mL
Gentesic Acid	0.2 mg/mL
Glucose	20 mg/mL
Hemoglobin	10 µg/mL

Triglycerides and cholesterol in lipemic samples with concentrations of 23 and 3 mg/ml, respectively, did not interfere with the test result.

No cross reactivity was observed when testing the following structurally related hormones at the following concentrations: TSH (1 mIU/ml), FSH (1000 mIU/mL), LH (300 mIU/mL). These concentrations are considerably higher than the physiologically expected values.

STANDARDIZATION

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

SUGGESTED READING

1. Batzer, F.R. Fertility & Sterility, Vol. 34, 1, 1980
2. Catt, K.J., Dufan, M.L., Vol 40, 537, 1975
3. Braunstein, G.D. et al., Am. J. Obster. Gynecol., Vol 126, 678, 1976
4. Lenton, E.A., Neal, L.M., Sulaiman, R., Fertility & Sterility, Vol. 37, 773, 1982
5. Batzer, F.R., Fertility & Sterility, Vol. 34, 1, 1980
6. Wilcox, A.J. et al, N. Eng.J. Med, Vol 319, 189, 1988.

Symbols

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

Rev. june 2009

CE