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SERATEC® COMBO Pregnancy Test

REF HCG-C2

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

INTENDED USE

For the rapid determination of human chorionic gonadotropin (hCG) in urine and serum specimens. 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) using sufficiently sensitive test methods. 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. After this the hCG concentration declines until it reaches values at about one tenth of the maximum for the remainder of the pregnancy. Following delivery, hCG levels rapidly decrease and usually return to normal within several weeks after parturition. The appearance of hCG in both, serum and urine, soon after conception and its subsequent rise in concentration during early gestational growth makes it an excellent marker for the early detection of pregnancy.
Healthy men and healthy non-pregnant women do not exhibit detectable hCG levels with the SERATEC® COMBO hCG test. However, 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® COMBO 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® COMBO hCG device is a chromatographic immunoassay (CIA) for the rapid qualitative determination of hCG in serum or urine. The membrane of the test is precoated with anti-alpha hCG capture antibody on the test line region and goat anti-rabbit antibodies on the control line region. A glass fibre pad downstream of the membrane contains dried anti-beta-hCG antibody that has been labelled with gold-conjugate. It can bind to hCG if present in the sample. The pad also contains gold-conjugated rabbit-antibodies that are a part of the control reaction.
During testing the dried components are mobilized by the liquid and move upwards by capillary action. In the presence of hCG the colored hCG-antibody-cold-conjugate complex is captured by the immobilized anti-hCG-antibody on the membrane (sandwich complex) resulting in a red-colored line in the test line region. Independent on the presence of hCG the gold labelled rabbit-antibody will bind in the control line region to form the red-colored control line.
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 and serum 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

Reliable test results can be expected on the first day of the missed period.

Urine samples

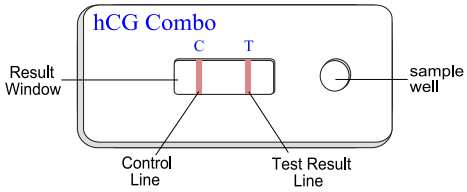
The urine specimen must be collected in a clean, dry container. Specimens collected at anytime may be used, however, the first morning urine generally contains the highest concentration of hormone. Urine specimens may be refrigerated (2-8°C) and stored up to 72 hours prior to assay. If samples are refrigerated, 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.

Serum samples

No special preparation of the patient specimen is required. Limited sample studies indicated that a plasma sample prepared from EDTA can be used instead of serum. Serum not assayed immediately must be stored in the refrigerator (2-8°C, up to 72 hours) or frozen (-20°C, for up to 3 months). Do not freeze and thaw sample repeatedly. Grossly hemolyzed samples should not be used.

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 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 the colored lines to appear in the test area. 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.

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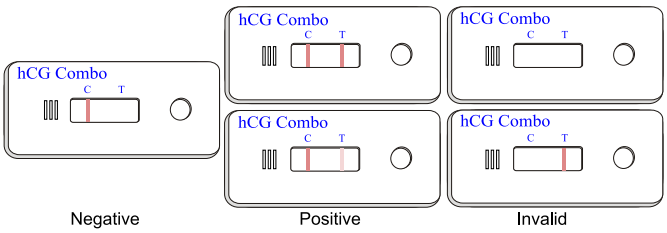
INTERPRETATION OF RESULTS

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® COMBO 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:

A. Urine
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® COMBO hCG device. The results are summarized in the following table .

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

B. Serum
Pooled serum samples from five known non-pregnant subjects were tested under the same conditions as the urine samples. The results are summarized in the following table.

hCG added (mIU/mL)	0	10	20	40	100
samples	20	20	20	20	20
negative	20	16	0	0	0
positive	0	4	20	20	20

Accuracy

A. Urine
100 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 (60 positive samples and 40 negative samples).

B. Serum
100 randomly selected serum samples were analyzed by the SERATEC® COMBO hCG device test procedure in parallel with another commercially available pregnancy test. Here also the results indicated complete agreement (66 positive samples and 34 negative samples).

Interference testing/Cross reactivity

The following substances were added to hCG free and 20 mIU/mL hCG spiked urine samples. At the concentration tested none of the substances 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.

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
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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

Rev. june 2009

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