

SAS™ Pregnancy Serum/Urine

READ ALL INSTRUCTIONS
BEFORE BEGINNING THE ASSAY

INTENDED USE

SAS™ Pregnancy Serum/Urine is a visual and rapid test for the qualitative determination of human chorionic gonadotropin (hCG) in serum or urine to aid in the early detection of pregnancy. This test is for professional use only.

SUMMARY AND EXPLANATION

The detection of hCG (human chorionic gonadotropin) in serum and urine has proven valuable in the presumptive diagnosis of pregnancy. The developing placenta secretes this glycoprotein hormone after fertilization. The hCG hormone doubles approximately every 2.2 days during the 1st trimester.¹ Detectable levels start at 5 mIU/mL during the first week of gestation and rise to 100,000 mIU/mL at 2 to 3 months. A slower rise may be associated with high risk abortions.² Values decline between 10% and 15% of peak concentrations during the 2nd and 3rd trimesters.³ False results may occur due to certain pathological conditions. See "Limitations of the Procedure."

PRINCIPLE OF THE TEST

SAS™ Pregnancy Serum/Urine is a rapid qualitative test to detect the presence of hCG in serum or urine. The test utilizes a combination of monoclonal and polyclonal antibody reagents to selectively detect elevated levels of hCG in serum or urine. The assay is conducted by the addition of a serum or urine specimen into the test device sample well and observing for the formation of colored lines. The specimen migrates via capillary action along the membrane and reacts with the colored conjugate. A positive specimen reacts with the hCG-specific antibody colored conjugate and forms a colored line in the T (test) window. Absence of this colored line suggests a negative result. To serve as a control for the procedure, a colored line in the C (control) window will always appear regardless of the presence or absence of hCG.

REAGENTS

Test device containing monoclonal mouse-hCG colored conjugate and hCG antibody coated on a membrane.

PRECAUTIONS

1. For *In-Vitro* diagnostic use only.
2. The test device should be discarded in a proper biohazard container after testing.
3. Do not use kit beyond the expiration date.
4. The test device should remain in the sealed pouch until ready for use.

STORAGE AND STABILITY

The test kit is to be stored at room temperature (15° - 30°C) for the duration of the shelf-life. The test device must remain "sealed" in the pouch until ready for use.

SPECIMEN COLLECTION AND PREPARATION

Urine - The urine specimen must be collected into a clean, dry container, either plastic or glass. Specimens collected at random may be used; however, the first morning urine generally contains the highest concentration of hormone. A urine sample exhibiting visible precipitates should be filtered, centrifuged, or allowed to settle (obtaining clear aliquots) before testing. Gross hematuria may prevent an accurate reading of test results by masking the positive line.

Serum - Blood should be collected aseptically into a clean tube without anticoagulants. Allow clot to form by leaving the tube for 20 to 30 minutes at

room temperature. Centrifuge to acquire a clear specimen. If serum shows cloudiness or is highly viscous, it should be diluted with equal parts of saline before testing. Hemolyzed specimens may require a fresh specimen for accurate results. Lipemic specimens may be centrifuged for a short period of time.

Specimen Storage – Specimens may be refrigerated (2° - 8°C) and stored up to 72 hours prior to assay. If specimens are refrigerated, they must be equilibrated to room temperature (15° - 30°C) before testing. Serum specimens can be frozen at -20°C for 3 months. Frozen specimens must be thawed and mixed before testing.

PROCEDURE

Materials Provided

1. Test device containing monoclonal mouse-hCG colored conjugate and hCG antibody coated on a membrane.
2. Disposable specimen dropper.

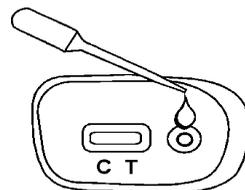
Materials Required But Not Provided

Specimen collection container

Directions For Use

The pouch must be at room temperature before opening to avoid condensation of moisture on the membrane. Allow specimen and/or controls to reach room temperature prior to testing.

1. Remove the test device from the protective pouch and place it on a flat surface. Label the device with patient or control identifications.
2. Dispense 4 drops (approximately 0.15 mL) of specimen into the round sample well (see illustration below). Wait for colored lines to



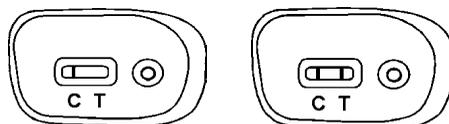
- appear.
3. Read results at 4 minutes. Positive results may be observed in as short as 30 seconds depending on the concentration of hCG. The presence of the control line is not indicative of the test being completed. Wait the entire 4 minutes for the completion of the test. READ UNDER DIRECT LIGHT TO AVOID INTERFERENCE OF SHADOWS IN THE T AND C WINDOWS.

INTERPRETATION OF RESULTS

Negative Results

The test is negative if a colored line appears only in the C (control) window (See illustration).

Positive Results



The test is positive if one colored line appears in the T (test) window and one colored line appears in the C (control) window (See illustration). Any colored line in the T (test) window should be considered positive. Colored lines may be lighter or darker than each other. Specimens with hCG levels near the threshold of the test may develop color (faint lines) overtime after the 4 minute reading. In such cases another test should be performed with a new specimen in 48-72 hours. A line that appears after 15 minutes should be ignored.

Invalid Results

The test is invalid if no colored line appears in the C (control) window even if a colored line appears in the T (test) window.

Serum - If no colored line appears in the C (control) window or the migration of specimen is slow or incomplete, add 1 to 2 drops of additional serum or add 1 to 2 drops of deionized water or saline into the sample well and wait an additional 4 minutes. If a colored line still does not appear in the C (control) window, the serum could be too viscous. Dilute the serum 1:1 with saline or deionized water and repeat the test using another device. Dilution with saline or deionized water to specimens of low levels of hCG will dilute sample lines. Care needs to be taken in reading the assay correctly.

Urine - If no colored line appears in the C (control) window, add 1 to 2 additional drops of urine and wait an additional 4 minutes. If a colored line still does not appear in the C (control) window, the test is invalid and should be repeated using another device.

QUALITY CONTROL

Each test device includes a built-in control for the procedure. Correct procedural technique and test device performance is confirmed when a colored line appears in the C (control) window of the device to assure proper specimen flow. Serum controls should be used when testing serum and urine controls should be used when testing urine. Negative and positive controls for hCG should be tested according to federal, state and local authorities. Quality control should be performed on each lot received. SAS™ controls should be utilized with the SAS™ test kit to ensure proper Q/C testing.

LIMITATIONS OF THE PROCEDURE

1. False negative results may occur when levels of hCG are below the sensitivity level of the test. When pregnancy is still suspected, a fresh serum or a first morning urine specimen should be collected 48 hours later and tested.
2. Elevated levels of hCG may be found in trophoblastic disease, choriocarcinoma, and embryonal cell carcinoma. Islet cell tumors may also produce hCG as well as other carcinomas.⁴
3. Detectable levels of hCG may remain several weeks following normal pregnancy, delivery by cesarean section, spontaneous or therapeutic abortion.⁵
4. Ectopic pregnancies may produce very low levels of hCG. A negative test therefore does not exclude ectopic pregnancy.⁶ If this condition is suspected, further testing using a quantitative test may be desirable. Abnormally high levels of hCG may be seen in molar pregnancies. Samples from abnormal pregnancies are beyond the intended use for qualitative hCG tests.
5. Approximately one third of all conceptions end in natural termination.⁷ This may produce positive results when testing early in the pregnancy, followed by negative results after the natural termination. Low positive results may be confirmed by retesting with a fresh serum or first morning urine specimen collected 48 hours later.
6. This test provides a presumptive diagnosis for pregnancy. Physicians should evaluate all clinical and laboratory findings before making a definitive diagnosis.
7. A viscous specimen (high specific gravity) may exhibit a slower flow rate, therefore requiring more time for the test to be completed.
8. A high dose "hook effect" may occur where the intensity of sample line decreases as the concentration of hCG increases. If a "hook effect" is suspected, dilution of specimens may increase color intensity of the sample line.⁸
9. This test is designed to be a qualitative test only and does not correlate directly to quantitative hCG tests. The intensity of color in a positive line should not be evaluated as "quantitative or semi quantitative".
10. Sensitive immunoassays may demonstrate false positive results with specimens containing heterophilic antibodies. Assays may also exhibit false-positive or false negative results with specimens containing human anti-mouse antibodies. These specimens may come from patients receiving preparations of mouse monoclonal antibodies for diagnosis or therapy or have been exposed to mice. If the qualitative interpretation is inconsistent with the clinical evaluation, results should be confirmed by an alternate hCG method.

EXPECTED VALUES

Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present. The amount will vary with gestational age and between patients. SAS™ Pregnancy Serum/Urine can detect hCG levels as low as 25 mIU/mL in serum or urine.

PERFORMANCE CHARACTERISTICS

Accuracy by Comparison

A total of 284 blind clinical samples from suspected pregnant women were studied by different clinics. Samples were assayed with Sure-View™ Serum/Urine hCG and another commercially available serum & urine test according to assay procedure. Both methods showed 26 positive and 82 negative results in serum testing and 77 positive and 99 negative results in urine testing. The results demonstrated a 100% overall accuracy of SAS™ Pregnancy Serum/Urine compared to the other commercially available test.

Sensitivity & Specificity

SAS™ Pregnancy Serum/Urine detects hCG concentrations of 25 mIU/mL and greater in serum and urine. It has been standardized to World Health Organization Third International Standard (75/537). The addition of LH (300 mIU/mL), FSH (1000 mIU/mL), and TSH (1000 µIU/mL) to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) serum/urine showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) serum/urine samples.

Acetaminophen	20 mg/dL
Acetylsalicylic Acid	20 mg/dL
Ascorbic Acid	20 mg/dL
Atropine	20 mg/dL
Caffeine	20 mg/dL
Gentisic Acid	20 mg/dL
Glucose	2 g/dL
Hemoglobin	1 mg/dL

None of the substances at the concentration tested interfered in the assay.

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