

**READ ALL INSTRUCTIONS BEFORE
BEGINNING THE ASSAY**

SAS™ Ultimate hCG

FOR THE RAPID QUALITATIVE DETERMINATION
OF HUMAN CHORIONIC GONADOTROPIN (hCG)
IN SERUM OR URINE TO AID ON THE EARLY
DETECTION OF PREGNANCY

- ✓ One Step test with built-in quality control check
- ✓ Just add 3-4 drops of serum or urine
- ✓ Sensitive to 10 mIU/ml hCG in serum
and 20 mIU/ml hCG in urine
- ✓ For early pregnancy detection
- ✓ Room Temperature Storage

FOR *IN-VITRO* DIAGNOSTIC USE ONLY

Store at 15°C to 30°C

For Technical Assistance Call 800-272-2710
Outside the USA Call 210-699-8800

CLIA Complexity
Urine-Waived
Serum-Moderate



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INTENDED USE

SAS™ Ultimate hCG 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. This glycoprotein hormone is secreted by the developing placenta after fertilization. The hCG hormone doubles approximately every 2.2 days during the 1st trimester.¹ Detectable levels start at 5mIU/mL during the first week of gestation and rise to 100,000mIU/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™ Ultimate hCG 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 S (specimen) area. Absence of this colored line suggests a negative result. To serve as a control for the procedure, a colored line in the C (control) area will always appear regardless of the presence or absence of hCG.

REAGENTS

Test device containing monoclonal 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 use.
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 in 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 hCG colored conjugate and hCG antibody coated on a membrane.
2. Disposable specimen dropper.

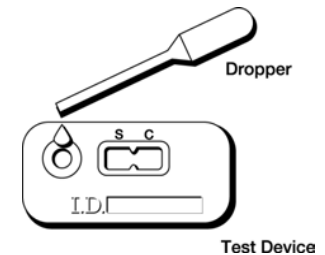
Materials Required But Not Provided

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 3-4 drops (approximately 0.15mL) of specimen into the round sample well (see illustration). Wait for colored lines to appear.



3. Read **serum** results after 7 minutes and no later than 15 minutes and **urine** results after 4 minutes and no later than 15 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.

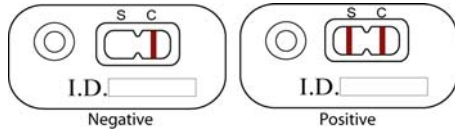
INTERPRETATION OF RESULTS

Negative Results

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

Positive Results

The test is positive if one colored line appears in the S (specimen) area and one colored line appears in the C (control) area. Any colored line in the S (specimen) area 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) over time after the 4 minute reading for urine and after 7 minute reading for serum. 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) area even if a colored line appears in the S (specimen) area.

Serum - If no colored line appears in the C (control) area or the migration of specimen is slow or incomplete, add 1 to 2 drops of deionized water or saline into the sample well and wait an additional 7 minutes. If a colored line still does not appear in the C (control) area, 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.

Urine - If no colored line appears in the C (control) area, 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) area, the test is invalid and should be repeated using another device. Colored lines, which appear after 15 minutes, are not diagnostic and should be ignored.

QUALITY CONTROL

Internal Controls

The appearance of a Control Line in the C region of the device is a positive procedural control. Correct procedural technique, specimen flow and device performance is confirmed when a colored line appears in the C (control) area of the membrane. If the colored line fails to appear in the C (control) area, the test result is invalid.

A clear background is an internal negative procedural control. The background color should be white to light pink and should not interfere with the reading of the test result. If a more intensely red background color appears, it may interfere with the ability to read the test result, therefore the test should be repeated.

External Control

Urine controls should be used when testing urine. Serum controls should be used when testing serum. 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. SASTM controls should be utilized with the SASTM Ultimate hCG test kit to ensure proper Q/C testing.

LIMITATIONS OF THE PROCEDURE

- 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.
- Elevated levels of hCG may be found in trophoblastic disease, choriocarcinoma, and embryonic cell carcinoma. Islet cell tumors may also produce hCG as well as other carcinomas.⁴
- Detectable levels of hCG may remain several weeks following a normal pregnancy, delivery by caesarean section, spontaneous or therapeutic abortion.⁵
- Ectopic pregnancies may produce very low levels of hCG.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.
- 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.
- This test provides a presumptive diagnosis for pregnancy. Physicians should evaluate all clinical and laboratory findings before making a definitive diagnosis.
- A viscous specimen (high specific gravity) may exhibit a slower flow rate, therefore requiring more time for the test to be completed.
- 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
- 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 semiquantitative".
- Sensitive immunoassays may demonstrate false positive results with specimens containing heterophilic antibodies. Assays may also exhibit false-positive or false negative 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.^{9,10}

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. First morning urine specimens approximate serum hCG levels, which are between 5 mIU/ml and 50 mIU/ml within one week of gestational age. SASTM Ultimate hCG can detect hCG levels as low as 10mIU/mL in serum and 20mIU/mL in 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 SASTM Ultimate 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 SASTM Ultimate hCG compared to the other commercially available test.

Sensitivity and Specificity

SASTM Ultimate hCG detects hCG concentrations of 10mIU/mL and greater in serum and 20mIU/mL and greater in urine. It has been standardized to World Health Organization Second International Standard (61/6). The addition of LH (300mIU/mL), FSH (1000mIU/mL), and TSH(1000 μ IU/mL) to negative (0mIU/mL hCG) and positive (10mIU/mL hCG) serum/urine showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to negative (0mIU/mL hCG) and positive (10mIU/mL hCG) serum samples:

Acetaminophen	20 mg/dL	Gentisic Acid	20 mg/dL
Acetylsalicylic Acid	20 mg/dL	Glucose	2 g/dL
Ascorbic Acid	20 mg/dL	Hemoglobin	1 mg/dL
Atropine	20 mg/dL	Bilirubin	2 mg/dL
Caffeine	20 mg/dL	Triglycerides	450 mg/dL

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

REFERENCES

- Schwartz S, Berger P, and Wick G: Epitope-selective monoclonal antibody based immunoradiometric assay of predictable specificity for differential measurement of choriongonadotropin and its subunits, *Clin Chem* 31:1322-1328, 1985.
- Kaplin LA, Pesce AJ. *Clinical Chemistry Theory, Analysis, & Correlation*, 2nd Edition, Missouri, 1989, C.V. Mosby Co., p. 944.
- Braunstein GD, Razor J, Adler D, Danzer H, Wade ME: Serum human chorionic gonadotropin levels through normal pregnancy. *Am J Obstet Gynecol*, 126: 678-681, 1976.
- Jacobs DS, et al: *Laboratory Test Handbook*, 2nd Ed., Ohio, 1990, Lexi-Comp Inc., pp. 224, 305-307.
- Steier JA, Bergso p, Myking OL: Human chorionic gonadotropin in maternal plasma after induced abortion, spontaneous abortion, and removed ectopic pregnancy. *Obstet Gynecol* 64: 391-394, 1984.
- Thorneycroft IH: When you suspect ectopic pregnancy. *Diagnosis* January: 67-82, 1976.
- Wilcox EG, Weinberg CR, O'Connor JF, et al: Incidence of early loss of pregnancy. *N Eng J Med* 319: 189-194, 1988.
- Fernando SA, Wilson, GS: Studies of the hook effect in the one-step sandwich immunoassay. *J Immunol Meth* 15:47-66, 1992.
- Primus FJ, Kelly EA, Hansen HJ, Golde, et al: "Sandwich"-type immunoassay of carcinoembryonic antigen in patients receiving murine monoclonal antibodies for diagnosis and therapy. *Clin Chem* 34: 261-4: 1988.
- Schroff, RW, Foon KA, Beatty SM, et al: Human anti-mouse immunoglobulin responses in patients receiving monoclonal antibody therapy. *Cancer Res* 45: 879-85: 1985.

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