REFERENCES

1. Schwartz S, Berger P, and Wick G: Epitope-selective monoclonal antibody based immunoradiometric assay of predictable specificity for differential measurement of choriogonadotropin and its subunits, *Clin Chem* 31:1322-1328, 1985.
2. Kaplin LA, Pesce AJ. *Clinical Chemistry Theory, Analysis, & Correlation*, 2nd Edition, Missouri, 1989, C.V. Mosby Co., p. 944.
3. Braunstein GD, Rasor J, Adler D, Danzer H, Wade ME: Serum human chorionic gonadotropin levels through normal pregnancy. *Am J Obstet Gynecol*, 126: 678-681, 1976.
4. Jacobs DS, et al: *Laboratory Test Handbook*, 2nd Ed., Ohio, 1990, Lexi-Comp Inc., pp. 224, 305-307.
5. 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.
6. Thorneycroft IH: When you suspect ectopic pregnancy. *Diagnosis* January: 67-82, 1976.
7. Wilcox EG, Weinberg CR, O'Connor JF, et al: Incidence of early loss of pregnancy. *N Eng J Med* 319: 189-194, 1988.
8. Fernando SA, Wilson, GS: Studies of the hook effect in the one-step sandwich immunoassay. *J Immunol Meth* 15:47-66, 1992.
9. 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.
10. 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.

SAS #70-PI-OSP
Revised 10-07

Authorised Representative:
T-MED
Olympus House
Calleva Park, Aldermaston
Berkshire RG7 8SA, UK

CE

SAS™ One-Step Pregnancy

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

✓One step test with built-in quality control check

✓Just add 3-4 drops of urine and read results in 4 minutes or less

✓Greater than 99% Accuracy

✓Sensitive to 25 mIU/ml hCG

✓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

SA Scientific™

SA Scientific, Inc.
4919 Golden Quail, San Antonio, Texas 78240 USA

READ ALL INSTRUCTIONS
BEFORE BEGINNING THE ASSAY

INTENDED USE

SAS™ One-Step Pregnancy is a visual and rapid test for the qualitative determination of human chorionic gonadotropin (hCG) in 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 first 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™ One-Step Pregnancy is a rapid qualitative test to detect the presence of hCG in urine. The test utilizes a combination of monoclonal and polyclonal antibody reagents to selectively detect elevated levels of hCG in urine. The assay is conducted by the addition of a 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 of the membrane. 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 testing.
3. Do not use kit beyond 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

The urine specimen must be collected into a clean, dry container, either plastic or glass. A specimens collected at random may be used; however, the first morning urine generally contains the highest concentration of hormone. The urine specimen may be refrigerated (2° - 8°C) and stored up to 72 hours prior to assay. If the specimen is refrigerated, it must be equilibrated to room temperature (15º - 30ºC) before testing. A urine sample exhibiting visible precipitates should be filtered, centrifuged, or allowed to settle (obtaining clear aliquots) before testing.

PROCEDURE

Materials Provided

1. Test device containing monoclonal hCG colored conjugate and polyclonal anti-hCG coated on membrane.
2. Disposable specimen dropper.

Materials Required But Not Provided

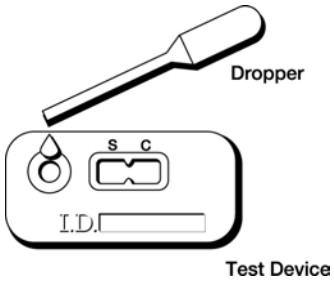
Specimen collection container

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 to 4 drops (approximately 0.15 ml) of urine into the round sample well (see illustration). Wait for colored lines to appear.

3. Read 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.



Test Device

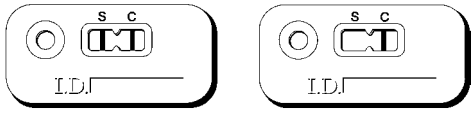
INTERPRETATION OF RESULTS

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 C (control) area and one colored line appears in the S (specimen) area. Any colored line in the S (specimen) area should be considered positive. Colored lines may be lighter or darker than each other.



Positive Negative

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. 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 at the C (control) area, the test is invalid and should be repeated using another test device. Colored lines that 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. 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™ Urine Controls should be utilized with the SAS™ One Step Pregnancy 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 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 a normal pregnancy, delivery by cesarean section, spontaneous or therapeutic abortion.[5]
4. Ectopic pregnancies may produce very low levels of hCG.[6] If this condition is suspected, further testing using a quantitative test may be desirable.
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 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 semiquantitative”.
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.[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.[2] SAS™ One-Step Pregnancy can detect pregnancy as early as one day after a missed menses.

PERFORMANCE CHARACTERISTICS

Accuracy by Comparison

A total of 176 blind clinical samples from suspected pregnant women were studied by different clinics and laboratories. Samples were assayed with SAS™ One-Step Pregnancy and another commercially available one-step membrane test according to assay procedure. Both methods showed 99 negative and 77 positive results. The results demonstrated a 100% overall accuracy of SAS™ One-Step Pregnancy compared to the other commercially available test. A sensitivity of 100% and a specificity of 100% were obtained.

Sensitivity & Specificity

SAS™ One-Step Pregnancy detects hCG concentrations of 25 mIU/ml and greater. It has been standardized to World Health Organization Second International Standard (61/6). 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) urine samples showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances

were added to hCG negative urine and 25mIU/ml hCG positive 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
Bilirubin	2 mg/dl
Triglycerides	450 mg/dl

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