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 sample 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.[6] If this condition is suspected, further testing using a quantitative assay 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 sample 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.

EXPECTED VALUES

Negative results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG present. The amount will vary greatly with gestational age and between patients. First morning urine specimens approximate serum hCG levels which are between 5 and 50 mIU/ml within one week of gestational age.[2] The SAS™ Pregnancy Strip test can detect pregnancy as early as one day after a missed menses.

PERFORMANCE CHARACTERISTICS

Accuracy by Comparison

A total of 110 blind clinical samples from suspected pregnant women were studied by different clinics. Samples were assayed with SAS™ Pregnancy Strip and another commercially available membrane test according to assay procedure. Both methods showed 63 negative and 47 positive results. The results demonstrated a 100% overall accuracy of SAS™ Pregnancy Strip compared to the other membrane test.

Sensitivity and Specificity

SAS™ Pregnancy Strip detects hCG concentrations of 25 mIU/ml and greater. The test has been standardized to the World Health Organization Second International Standard (61/6). The addition of LH (300 mIU/ml), FSH (1000 mIU/ml), and TSH (1000 mIU/ml) to negative (0 mIU/ml hCG) and positive (25 mIU/ml hCG) urine showed no cross-reactivity.

Interfering Substances

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

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

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

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SAS™ Pregnancy Strip

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

✔Dipstick format with built-in quality control check.

✔Just dip into urine for 15 seconds and get 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, Ltd.
4919 Golden Quail, San Antonio, Texas 78240 USA

READ ALL THE INSTRUCTIONS
BEFORE BEGINNING THE ASSAY

INTENDED USE

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

SUMMARY AND EXPLANATION

The detection of hCG (human chorionic gonadotropin) in urine and serum 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 rises to 100,000 mIU/ml at 2 to 3 months. A slower rise may be associated with high risk abortions.[2] Values decline to 10% to 15% of peak concentrations during 2nd and 3rd trimesters.[3] False results may occur due to certain pathological conditions. See "Limitations of the Procedure".

PRINCIPLE OF THE TEST

The SAS™ Pregnancy Strip 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 dipping the strip into the urine specimen and observing for the formation of colored bands. The specimen migrates via capillary action along the membrane and reacts with the colored conjugate. Positive specimens react with the specific hCG antibody colored conjugate and form a colored band on the Specimen portion of the membrane. Absence of this colored band suggests a negative result. To serve as a procedural control, a colored band at the Control Zone will always appear regardless of the presence or absence of hCG.

REAGENTS

Test strip containing monoclonal hCG colored conjugate and polyclonal anti-hCG coated on a membrane.

PRECAUTIONS

1. For *In Vitro* diagnostic use only.
2. The test strip should remain in the canister or sealed pouch until ready for use. Once the canister has been opened, the test strips are good for 90 days only. Immediately recap the canister after use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
4. The test strip should be discarded in a proper biohazard container after testing.

5. Do not use test kit beyond expiration date.

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 strip must remain in the canister or "sealed" in the pouch until ready for use. Once the canister has been opened, the test strips are good for 90 days only.

SPECIMEN COLLECTION AND PREPARATION

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. Urine 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 before testing. Urine samples exhibiting visible precipitates should be filtered, centrifuged, or allowed to settle (obtaining clear aliquots) before testing.

PROCEDURE

Materials Provided

Test strip containing monoclonal mouse-hCG colored conjugate and polyclonal anti-hCG antibody coated on membrane.

Materials Required But Not Provided

Specimen collection container

Directions For Use

Allow specimen and/or controls to reach room temperature (15° - 30°C) prior to testing.

1. Remove the test strip from the canister or foil pouch. Immediately recap the canister. Once the canister has been opened, the test strips are good for 90 days only. Record the initial opening date on the canister.
2. Hold the test strip at the top in a vertical position with the arrows pointing downward. Lower the test strip into the urine specimen. Do not immerse the test strip beyond the "Stop Line" (See illustration on page 3).
3. Leave the test strip immersed for at least 15 seconds. Remove and place on a non-absorbent flat surface.
4. Read results after 4 minutes. Do not interpret results after 15 minutes.

INTERPRETATION OF RESULTS

Negative Results

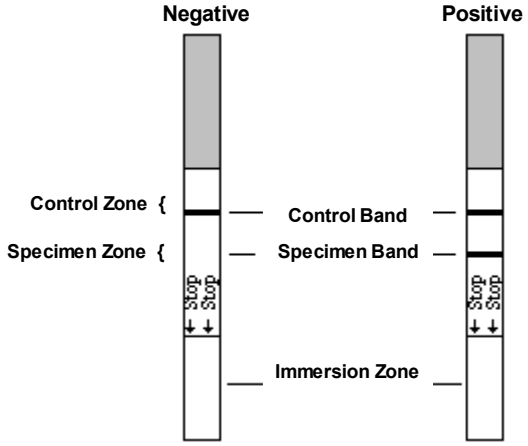
The test is negative if only one band appears in the Control Zone. See illustration below.

Positive Results

The test is positive if two colored bands appear. One colored band will appear in the Specimen Zone and one in the Control Zone. Any colored band in the Specimen Zone should be considered positive. The colored band in the Control Zone may be lighter or darker in color than the band in the Specimen Zone. See illustration below.

Invalid Results

The test is invalid if no band appears in the Control Zone even if a colored band appears in the Specimen Zone. The test should be repeated.



QUALITY CONTROL

Each test strip includes a built in procedural control. Correct procedural technique and test strip performance is confirmed when a colored band appears in the Control Zone of the membrane to assure proper specimen flow. 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.