**INTENDED USE**

SAS™ Ultra 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. 2 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. 3 Values decline between 10% and 15% of peak concentrations during the 2nd and 3rd trimesters. 4 False results may occur due to certain pathological conditions. See “Limitations of the Procedure.”

**PRINCIPLE OF THE TEST**

SAS™ Ultra hCG is a rapid qualitative test that detects the presence of hCG in serum or urine. The test utilizes a combination of monoclonal and polyclonal antibodies 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 with the aid of the control and sample 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 in plastic or glass vials 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.

**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.

**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 identification.
2. Pipette 3-4 drops (approximately 0.15 mL) of specimen into the round sample well (see “Sample Preparation”). Wait for the colored lines to appear.
3. Read serum results after 5-8 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.

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

**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 (sample) 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 5 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.

1. If no colored line appears in the C (control) area, 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) area, the test is invalid and should be repeated using another device. Colored lines which appear after 30 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.

1. 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.

**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. Leitot cell tumors may also produce hCG as well as other carcinomas. 6

3. Detectable levels of hCG may remain several weeks following normal pregnancy, delivery by caesarean section, spontaneous or therapeutic abortion. 7

4. Estriope pregnancies may produce very low levels of hCG. If suspected, further testing using a quantitative test may be desirable. 7

5. Approximately one third of all conceptions end in natural termination. 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 repeating with a fresh serum or first morning urine specimen collected 48 hours later. 7

6. This test provides a presumptive diagnosis for pregnancy. Physicians should consult 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 with gestational age and between patients. If first morning urine specimen approximates serum hCG levels which are between 5 mIU/mL and 50 mIU/mL within one week of gestational age. SAS™ Ultra hCG can detect hCG levels as low as 10 mIU/mL in serum and 20 mIU/mL in urine.

**PERFORMANCE CHARACTERISTICS**

Accuracy by Comparison

A total of 234 blind clinical samples from suspected pregnant women were studied by different laboratory techniques using hCG reagents provided with SAS™ Ultra hCG and an additional commercial kit. Specimens were tested using 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 sensitivity of SAS™ Ultra hCG compared to the other commercially available kit.

Sensitivity & Specificity

SAS™ Ultra hCG detect concentrations of 10 mIU/mL and greater in serum and 20 mIU/mL and greater in urine. It has been standardized to World Health Organization Second International Standard (S1). The addition of 0.8 (100 mIU/mL), FSH (1000 mIU/mL), and TSH (1000 mIU/mL) to negative (0 mIU/mL) hCG and positive (10 mIU/mL) S1 urine specimen showed no cross-reactivity.

**Interfering Substances**

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

- Acetaminophen 20 mg/mL
- Aspirin 20 mg/mL
- Bacitracin 10 mg/mL
- Atropine 20 mg/mL
- Calcium 20 mg/mL
- Crescentic 20 mg/mL
- Glucose 2 g/L
- Hemoglobin 1 mg/dL

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

**REFERENCES**