READ ALL INSTRUCTIONS BEFORE BEGINNING THE ASSAY

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. 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. Values decline between 10% and 15% of peak concentrations during the 2nd and 3rd trimesters. 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°C - 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

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 (15º - 30º 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.

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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 minutes 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.

LIMITATIONS OF THE PROCEDURE

Negative Results

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

Sensitivity and Specificity

SAS™ 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(100 mIU/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
- Acetylsalicylic Acid 20 mg/dL
- 1 mg/dL
- Caffeine
- Gentisic Acid 20 mg/dL
- Glucose 20 mg/dL
- Bilirubin 2 mg/dL
- Triglycerides 450 mg/dL

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

REFERENCES


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. SAS™ 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 SAS™ 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 SAS™ Ultimate hCG compared to the other commercially available test.

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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.

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. SAS™ controls should be utilized with the SAS™ Ultimate hCG test kit to ensure proper Q/C testing.