**SAS™ Pregnancy Serum/Urinary**

READ ALL INSTRUCTIONS BEFORE BEGINNING THE ASSAY

**INTENDED USE**

SAS™ Pregnancy Serum/Urinary 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. The developing placentae secretes this glycoprotein hormone after fertilization. The test is performed from 10 to 20 days after the last menstrual period or 1 to 2 days after the date of ovulation. 1 Detection levels start at 5 mIU/mL during the first week of pregnancy, and rise to 100,000 mIU/mL at 2 to 3 months. A slower rate may be associated with early pregnancy. 2 Values decline between 15% 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™ Pregnancy Serum/Urinary 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 test is completed 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 test window as suggested by the procedure. A negative specimen in the C (control) window will always appear regardless of the presence or absence of hCG.

**REAGENTS**

Test device containing monoclonal mouse- hCG 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 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**

**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. High concentrations may require a fresh specimen for accurate results. Lipemic specimens may be centrifuged for a short time. A specimen may be frozen for 3 months. Frozen specimens must be thawed and mixed before testing.

**Specimen Storage** – Specimens may be refrigerated (2° - 8°C) and stored for approximately 72 hours prior to assay. If specimens are refrigerated, they must be allowed to equilibrate to room temperature (15° - 30°C) before testing. Serum specimens can be kept at room temperature for 2 to 3 days. However, for specimens containing more than 10 mIU/mL hCG, specimen dilution will be required. If serum contains more than 10 mIU/mL hCG, specimen dilution will be required. If serum contains more than 100 mIU/mL hCG, sample dilution will be required. If serum contains more than 1000 mIU/mL hCG, sample dilution will be required. If serum contains more than 10,000 mIU/mL hCG, sample dilution will be required.

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**Urine** - 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 presence of hCG. If hCG is suspected to be present in the urine specimen, it is recommended that a fresh specimen be collected and tested.

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