INTENDED USE
SAS™ Pregnancy Serum/Urine 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 placenta secretes this glycoprotein hormone after fertilization and its levels are proportional to the number of gestational age and between patients. SAS™ Pregnancy Serum/Urine hCG and another commercially available serum & urine test according to federal, state and local authorities. Quality control should be performed on each lot received.

Materials Provided
1. Test device containing monoclonal mouse-hCG colored conjugate and hCG antibody coated on a membrane.
2. Disposable specimen dropper.

Materials Required But Not Provided
1. Serum or urine specimen into the test device sample well and observing the formation of colored lines. The specimen migrates via capillary action along the membrane and reacts with the hCG colored conjugate. A positive specimen reads with the hCG-specific antibody colored conjugate and forms a colored line in the T (test) window. This suggests a positive result. To serve as a control for the procedure, a colored line in the C (control) window will always appear regardless of the presence or absence of hCG.

Dilution with saline or deionized water to specimens of low levels of hCG can be frozen at -20°C. Values decline with gestational age and between patients. SAS™ Pregnancy Serum/Urine can be stored 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 or serum. If urine specimen is too concentrated it may require a fresh specimen for accurate results. Laminar specimens may be centrifuged for a short period of time.

To Order:
Fax: 210-699-6545

Performance Characteristics

Accuracy by Comparison
A total of 284 blind clinical samples from suspected pregnant women were studied. SAS™ Pregnancy Serum/Urine was compared to the gold standard hCG immunoassay and another commercially available assay & urine test according to federal, state and local authorities. Quality control should be performed on each lot received.

Interfering Substances
The following interferin substances were added to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) serum/urine samples.

Acetaminophen 20 mg/dL
Acetylsalicylic Acid 20 mg/dL
Ascorbic Acid 20 mg/dL
Caffeine 20 mg/dL
Carnitine 20 mg/dL
Glucose 2 g/dL
Hemoglobin 1 mg/dL
None of the substances at the concentration tested interfered in the assay.

REFERENCES

To Order:
Phone: 1-800-275-2326 70 by phone
Fax: 210-699-5454
Rev. 03-07

EXCEPTED VALUES:
Positive results are expected in healthy non-pregnant women and healthy men. Healthy pregnant women have hCG crossed. The amount will vary with gestational age and between patients. SAS™ Pregnancy Serum/Urine can be stored at room temperature as low as 25 mIU/mL in serum or urine.

Sensitivity & Specificity:
SAS™ Pregnancy Serum/Urine detects hCG concentrations of 25 mIU/mL and above, where hCG has been standardized to World Health Organization Third International Standard (75:537). The addition of LH (200 mIU/mL), FSH (1000 mIU/mL), and TSH (1000 µIU/mL) to negative (0 mIU/mL hCG) and positive (25 mIU/mL hCG) serum/urine samples showed no cross-reactivity.