

<b>Procedure</b>	<b>SAS™ hCG -ULTRA Serum Control Set</b>
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<b>Prepared by</b>	<b>Date Adopted</b>	<b>Supercedes Procedure #</b>

<b>Review Date</b>	<b>Revision Date</b>	<b>Signature</b>

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**INTENDED USE**

SAS™ hCG-ULTRA Serum Controls are intended to be used to monitor the performance and accuracy of SAS™ Serum/Urine hCG-ULTRA pregnancy test kits. These controls are for professional use only.

**SUMMARY AND EXPLANATION**

The use of known controls in the laboratory is invaluable. It is important to verify testing procedures to confirm the validity of the results reported. Testing with the SAS™ hCG-ULTRA Serum Controls will provide assurance that SAS™ Serum/Urine hCG-ULTRA pregnancy kits are performing properly.

**REAGENTS AND MATERIALS**

1. 10 mIU/mL hCG Positive Serum Control - contains normal human serum and sodium azide 0.2%.
2. 250 mIU/mL hCG Positive Serum Control - contains normal human serum and sodium azide 0.2%.
3. Negative Serum Control - contains sodium azide 0.2%.

**PRECAUTIONS**

1. For *In Vitro* diagnostic use only.
2. Refer to the SAS™ Serum/Urine hCG-ULTRA package insert for specific precautions.
3. Do not use controls if they are cloudy or if precipitates are observed in the vials. This may be an indication of reagent instability or deterioration.

4. These controls contain 0.2% of sodium azide which may react with lead and copper plumbing to form explosive metal azides. Drains should be flushed thoroughly with water after disposing of controls to prevent azide buildup.
5. Do not use controls beyond the expiration date.
6. Specimens and controls should be considered potentially hazardous and handled in the same manner as an infectious agent.

## **STORAGE**

SAS<sup>TM</sup> hCG-ULTRA Serum Controls are to be stored refrigerated (2° - 8°C) for the duration of shelf-life. The controls must be equilibrated to room temperature (15° - 30°C) before use.

## **PROCEDURE**

1. Allow the controls to reach room temperature prior to testing. The controls are ready to use. No dilution is required.
2. The controls are used in place of the specimen and should be tested according to the SAS<sup>TM</sup> Serum/Urine hCG-ULTRA package insert.

## **INTERPRETATION OF RESULTS**

### **Positive Results**

The 10 mIU/ml hCG and the 250 mIU/ml hCG Positive Serum Controls should produce positive result.

### **Negative Results**

The Negative Serum Control should produce a negative result.

### **Invalid Results**

See the "Invalid Results" section from the SAS<sup>TM</sup> Serum/Urine hCG-ULTRA package insert. The test should be repeated.

## **LIMITATIONS OF THE PROCEDURE**

1. These controls are formulated for use as quality control specimens in the reagent verification of SAS<sup>TM</sup> Serum/Urine hCG-ULTRA pregnancy test kits. See the SAS<sup>TM</sup> Serum/Urine hCG-ULTRA package insert for guidelines in procedure and interpretation.
2. Refer to the SAS<sup>TM</sup> Serum/Urine hCG-ULTRA package insert for further limitations.

## **EXPECTED VALUES**

The 10 mIU/ml hCG and the 250 mIU/ml hCG Positive Serum Controls should produce positive results. The Negative Serum Control should produce a negative result. If the desired result is not achieved, it may be an indication of the following:

1. The test kit is not performing properly.
2. The test was not performed correctly according to the package insert.

Invalid results should be analyzed to determine probable causes and to provide solutions for corrective actions.

## **PERFORMANCE CHARACTERISTICS**

SAS<sup>TM</sup> hCG-ULTRA Serum Controls have been designed to produce correct results in SAS<sup>TM</sup> Serum/Urine hCG-ULTRA pregnancy test kits. These controls have been tested with SAS<sup>TM</sup> Serum/Urine hCG-ULTRA pregnancy test kits and were found to produce satisfactory results.