

## Early Pregnancy Testing



Qualitative rapid immunoassay tests based on the SAS™ colloidal gold technology for the determination of Human Chorionic Gonadotropin (hCG) in serum or urine (a visual method)

- SAS™ One-Step Pregnancy
- SAS™ Serum/Urine hCG
- SAS™ Ultra hCG Serum/Urine
- SAS™ Pregnancy Strip

**CLIAwaived.com™**

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# SAS™ One-Step Pregnancy



- CLIA Classification: Waived
- Simple to run with built-in control
- Results within 4 minutes
- Room temperature storage
- 24-month shelf life

Description	Cat. No.	Test/Kit	Specimen	Application/Shelf Life	Sensitivity, Specificity	CLIA/CPT Code	Results/Minutes
<b>SAS™ One-Step Pregnancy</b>	087430	30	Urine	Detects hCG in urine (Shelf Life: 24 mos.)	25 mIU/mL, >99%	Waived/81025	4
<b>Urine Control Set</b>	087413	25 mIU, 250 mIU, Negative, 3 Vials/Pk (NOTE: For use with 087525, 087430, 087730, 087750, 087731, and 087751)					

# SAS™ Serum/Urine hCG



- CLIA Classification: Waived for urine and non-waived for serum tests
- Simple to run with built-in control
- Results within 4 minutes
- Room temperature storage
- 21-month shelf life

**NOTE:** Listed in College of Pathologist (CAP) surveys and American Proficiency Institute (API)

Description	Cat. No.	Test/Kit	Specimen	Application/Shelf Life	Sensitivity, Specificity	CLIA/CPT Code	Results/Minutes
<b>SAS™ Serum/Urine hCG</b>	087730	30	Serum/Urine	Detects hCG in serum or urine (Shelf Life: 21 mos.)	25 mIU/mL, >99%	<b>Serum:</b> Non-waived/84703	4
	087750	50				<b>Urine:</b> Waived/81025	
<b>Serum Control Set</b>	087712	25 mIU, 250 mIU, Negative, 3 Vials/Pk (NOTE: For use with 087730, 087750, 087731, and 087751)					

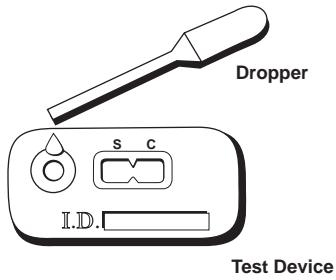
# SAS™ Ultra hCG Serum/Urine



- Waived for urine and non-waived for serum tests
- Simple to run with built-in control
- Results within 4–8 minutes
- Room temperature storage
- 18-month shelf life

Description	Cat. No.	Test/Kit	Specimen	Application/Shelf Life	Sensitivity, Specificity	CLIA/CPT Code	Results/Minutes
<b>SAS™ Ultra hCG Serum/Urine</b>	087731	30	Serum/Urine	Detects hCG in serum or urine (Shelf Life: 18 mos.)	<b>Serum:</b> 10 mIU/mL & <b>Urine:</b> 20 mIU/mL, >99%	<b>Serum:</b> Non-waived/84703	<b>Serum:</b> 5-8, <b>Urine:</b> 4
	087751	50				<b>Urine:</b> Waived/81025	
<b>Serum Control Set</b>	087715	10 mIU, 250 mIU, Negative, 3 Vials/Pk (NOTE: For use with 087731, and 087751)					

## Test Procedure



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 to 4 drops (approximately 0.15 mL) of specimen into the round sample well (see illustration). Wait for colored lines to appear.

## Test Results



Minutes/  
Urine



Minutes/  
Serum



Minutes/Ultra  
Serum

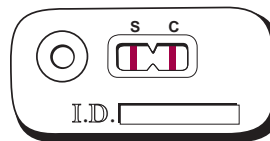
### SAS™ One-Step Pregnancy and SAS™ Serum/Urine hCG—

Read serum and urine results after 4 minutes and no later than 15 minutes.

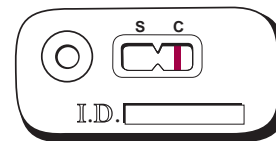
**SAS™ Ultra hCG Serum/Urine**—Read serum results after 5–8 minutes and no later than 15 minutes, and urine results after 4 minutes and no later than 15 minutes.

Positive results may be observed in as short as 30 seconds depending on the concentration of hCG.

The test is negative if a colored line only appears in the C (control) area. The test is positive if one colored line appears in the C (control) area and one line appears in the S (specimen) area.



Positive



Negative

(See package insert for detailed instructions.)



High quality  
early pregnancy  
tests

# SAS™ Pregnancy Strip



- CLIA Classification: Waived
- Simple to run with built-in quality control check
- Results within 4 minutes or less
- No pipetting or counting drops
- Room temperature storage
- 24-month shelf life

Description	Cat. No.	Test/Kit	Specimen	Application/Shelf Life	Sensitivity, Specificity	CLIA/CPT Code	Results/Minutes
SAS™ Pregnancy Strip	087525	25	Urine	Detects hCG in urine (Shelf Life: 24 mos.)	25 mIU/mL, >99%	Waived/81025	4
Urine Control Set	087413	25 mIU, 250 mIU, Negative, 3 Vials/Pk (NOTE: For use with 087525, 087430, 087730, 087750, 087731, and 087751)					

## Test Procedure



1. Dip test strip into the urine specimen.  
NOTE: Do not immerse the test strip beyond the "Stop Line."
2. Leave the test strip immersed for at least 15 seconds.
3. Read results.

(See package insert for detailed instructions.)

## Test Results

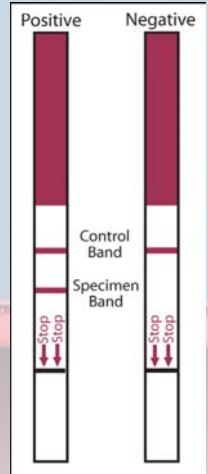


Read results after 4 minutes but no later than 30 minutes.

The test is negative if only one band appears in the Control Zone.

The test is positive if two colored bands appear. One colored band will appear in the Specimen Zone and one in the Control Zone.

Each test strip includes a built in procedural control. Correct procedural technique and test strip performance is confirmed when a colored band appears in the Control Zone of the membrane to assure proper specimen flow.



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