

SAS™ Rota Test

CLIA
NON-WAIVED



▶ **CPT Code:**
87425

▶ **Sensitivity:**
>98%

▶ **Specificity:**
>98%

▶ **Specimen:**
Stool

SAS™ Rota Test is a rapid lateral-flow, membrane-based immunoassay for the qualitative detection of rotavirus antigen in human fecal specimens. SAS™ Rota Test aids in the diagnosis of acute gastroenteritis caused by rotavirus infection.

- CLIA Classification: Non-waived
- Simple to run—results within 15 minutes.
- Buffer and extraction tubes are provided in kit.
- Room temperature storage.
- 18-month shelf life.



CLIAwaived.com™

CLIAwaived.com - 4332 Corte de la Fonda - San Diego, CA 92130

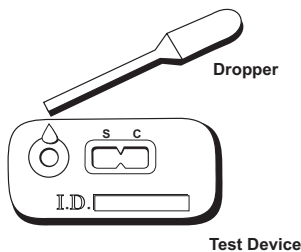
Toll Free : (888) 882-7739 - Phone (858) 481-5031

FAX: (801) 720-7568 - www.cliawaived.com

SAS™ Rota Test

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.



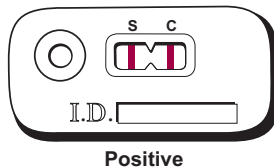
1. Remove the test device from the protective pouch and place it on a flat surface. Label the device with patient or control identifications.
2. Using a swab, add 30-50 mg of stool sample to tube containing the extraction buffer provided.
3. Dispense 4 drops (approximately 150µL) of the supernatant into the round sample well (see illustration). Wait for colored lines to appear.

Test Results

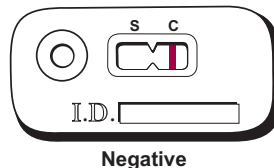


Read results after 15 minutes and no later than 30 minutes. Positive results may be observed in as short as 30 seconds depending on the concentration of the antigen.

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.)

Product No.
069020
20-Test Kit

Product No.
069101
Control
(2 × 1 mL,
2 Vials/Pk)

Description	Cat. No.	Test/ Kit	Specimen	Application/Shelf Life	Sensitivity, Specificity	CLIA/ CPT Code	Results/ Minutes
SAS™ Rota Test	069020	20	Stool	Detects wide range of Rotavirus serotypes (Shelf Life: 18 mos.)	>98%, >98%	Non-waived/ 87425	15
Control Set	069101	2 × 1 mL, 2 Vials/Pk (NOTE: For use with 069020)					

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