is affinity purified and is specific to the capsid protein of Rotavirus.

2. Using a swab, add a sufficient stool sample (30-50mg) to the tube containing the Sure-Vue® Extraction Buffer.

3. Rub the swab meticulously against the inner wall of the tube to release the fecal material. 

The gold standard for detecting Human Rotavirus depends on electron microscopy4 since existing tissue culture methods are unreliable. The Sure-Vue® Rota Test offers a fast, simple method for the detection of Rotavirus and Rotavirus antigens.

PRINCIPLE OF THE TEST
The Sure-Vue® Rota Test utilizes a pair of Rotavirus-specific antibodies in an immunochromatographic sandwich assay. An extract is first prepared by suspension of the specimen in the provided extraction buffer solution. The buffer containing the extracted specimen is then added to the device’s sample well. The reaction between a positive sample and the colored particle-conjugated antibody will form a complex that migrates along the membrane. An immobilized capture antibody will form a complex. An internal control line C (control) area is built-in to confirm specimen flow and test device performance is confirmed when a colored line appears in the C (control) area of the membrane. If the colored line fails to appear in the C (control) area, the test result is invalid.

MATERIALS AND REAGENTS PROVIDED
1. 25 test devices contain a test strip with a monoclonal anti-Rotavirus antibody, colored conjugate, and polyclonal antibody coated on a membrane. The monoclonal antibody

STORAGE INSTRUCTIONS
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 in the sealed pouch until ready for use.

SPECIMEN COLLECTION & PREPARATION
Specimens should be collected as soon as possible after the onset of symptoms. It is recommended that the specimen be collected during the acute phase of gastroenteritis, because a large number of viral particles and viral antigens are excreted during this period.

The specimen should be collected in a clean, dry container, either plastic or glass. Do not collect specimens in containers having media, animal serum, detergents or preservatives, as these may interfere with the assay. If necessary, a sample can be collected from a soiled diaper of young children and neonates. Do not freeze samples unless a delay in testing is expected. In this case, quickly freeze samples using dry ice, and keep sample frozen at -20°C or colder until ready for testing. Note: Thick or mucoid specimens may fail to flow properly on the Sure-Vue® Rota Test causing an inconclusive test result (see Alternate Test Procedure).

TEST PROCEDURE
1. Allow the pouch (test device), specimen and/or controls to reach room temperature (15° - 30°C) prior to testing.

2. Using a swab, add a sufficient stool sample (30-50mg) to the tube containing the Sure-Vue® Extraction Buffer. Rub the swab carefully against the inner wall of the tube to release the fecal material. Squeeze swab in flexible tube to remove excess liquid.

3. Centrifuge the tube containing the sample for 1-2 minutes.

4. Dispense 150µl of the supernatant into the round sample well of the device (see illustration below). Wait for colored lines to appear.

5. The test is positive if two colored lines appear. One colored line will appear in the T (test) area and one in the C (control) area. If this result is observed in as short as 30 seconds depending on the concentration of antigen. Do not interpret results after 30 minutes.

6. Wear disposable gloves while handling samples and wash hands after handling. 

7. Read results at 15 minutes. Some positive results may be observed in as short as 30 seconds depending on the concentration of antigen. Do not interpret results after 30 minutes.

8. Avoid microbial contamination of reagents or incorrect results may occur. Contamination of samples could cause false results.

9. Avoid splashing or the generation of aerosols.

10. Do not mix or interchange lots of Sure-Vue® Rota Test devices or reagents.

11. Do not use kit or materials beyond expiration date.

12. Extraction buffer contains sodium azide which may react with lead and copper plumbing to form explosive metal azides. Azide build-up may be avoided by flushing drains with large volumes of water after disposal.

13. Avoid microbial contamination of reagents or incorrect results may occur. Contamination of samples could cause false results.

14. Use separate pipettes or pipette tips for each sample, control and reagent.

15. Do not re-use test devices or kit materials.

16. Avoid the mishandling of reagents and controls. Azide build-up may be avoided by flushing drains with large volumes of water after disposal.

17. All specimens, reagents, and controls should be handled as an aid in the diagnosis of acute gastroenteritis caused by Rotavirus infection. This test is for professional use only.

SUMMARY AND EXPLANATION
Rotavirus is the major cause of life-threatening diarrhea (gastroenteritis) in children younger than 2 years1-2. Rotavirus gastroenteritis is ubiquitous, it occurs in all parts of the world1,2. These double stranded RNA viruses cause epidemic and endemic gastroenteritis in pediatric as well as geriatric patients1. It afflicts more than 130 million infants and children annually, causing 1 million deaths3.

The Sure-Vue® Rota Test is a rapid, membrane-based immunogold assay for the qualitative detection of Rotavirus antigens in feces as an aid in the diagnosis of acute gastroenteritis caused by Rotavirus infection. This test is for professional use only.

READ ALL INSTRUCTIONS BEFORE BEGINNING THE ASSAY
INTENDED USE
Sure-Vue® Rota Test is a rapid, membrane-based immunogold assay for the qualitative detection of Rotavirus antigens in feces as an aid in the diagnosis of acute gastroenteritis caused by Rotavirus infection. This test is for professional use only.

STORAGE INSTRUCTIONS
1. Pipette 0.5 ml of Sure-Vue® Extraction Buffer to the Extraction Tube.

2. Using a swab, add a sufficient stool sample (30-50mg) to the tube containing the Sure-Vue® Extraction Buffer.

3. Rub the swab meticulously against the inner wall of the tube to release the fecal material. Squeeze swab in flexible tube to remove excess liquid.

4. Centrifuge the tube containing the sample for 1-2 minutes.

5. Dispense 150µl of the supernatant into the round sample well of the device (see illustration below). Wait for colored lines to appear.

INTERPRETATION OF RESULTS
Positive Results
The test is positive if two colored lines appear. One colored line will appear in the T (test) area and one in the C (control) area. Any colored line in the T (test) area should be considered positive. Colored lines may be lighter or darker than each other.

Invalid Results
The test is invalid if no colored line appears in the C (control) area, even if a colored line appears in the T (test) area. If this occurs, add 1 to 2 additional drops of sample and wait for 5 minutes. If a colored line does not appear in the C (control) area, the test is invalid and should be repeated. Colored lines, which appear after 30 minutes, are not diagnostic and should be ignored.

QUALITY CONTROL
Internal Controls
Each test device includes internal procedural controls. The appearance of a Control Line in the C region of the test device is a positive procedural control. Correct procedural technique, specimen flow and test device performance is confirmed when a colored line appears in the C (control) area of the membrane. If the colored line fails to appear in the C (control) area, the test result is invalid.
A clear background is an internal negative procedural control. The background color should be white to light pink and should not interfere with the reading of the test result. If a more intensely red background color appears, it may interfere with the ability to read the test result, therefore the test should be repeated.

The procedural controls do not test for the presence or absence of Rotavirus. A positive control containing inactivated Rotavirus can be used as a control.

**External Controls**

It is recommended that when a new shipment of product is received, negative and positive controls for Rotavirus should be tested and the appropriate results obtained (See NCCLS C24-A for guidance on appropriate quality control practices).

**LIMITATIONS OF THE PROCEDURE**

1. Sure-Vue® Rota Test is highly sensitive and specific for Rotavirus antigen. The monoclonal antibody in this test will detect human Rotaviruses, but cannot be used to differentiate types.
2. The test is highly dependent on the collection and preparation of the clinical specimen. Care should be taken to adhere to proper procedures.
3. A negative result does not exclude the possibility of Rotavirus infection in the patient. False negative results may occur due to low concentration levels of the Rotavirus antigen below the sensitivity level of the test, improper or inadequate sampling, or improper handling of the specimen.
4. Co-infection with bacterial pathogens is possible. Therefore, bacteriological tests should be performed in parallel with this test to rule out bacteriological etiology.

**EXPECTED VALUES**

Rotavirus infection is seasonal and is the most frequent cause of gastroenteritis in children between 6 months and 3 years of age. Among young children hospitalized for gastroenteritis, it is expected that up to 50% of patient specimens will test positive for Rotavirus. The prevalence of Rotavirus infection will vary based on many factors such as age, geographic location, method of sample collection, sample handling and transportation, and the general health environment of the patient population under study. Normal healthy individuals tested should be negative for Rotavirus. Some infected individuals may show symptoms or only minor symptoms, and these patients may test negative.

**PERFORMANCE CHARACTERISTICS**

The Sure-Vue® Rota Test was tested in laboratories and hospitals in the United States and Japan for the direct testing of patient stool samples. A total of 185 samples were tested, and the results compared to the Meridian Premier Rotaclone® EIA test, and to electron microscopy (EM).

**EXPECTED VALUES**

Rotavirus infection is seasonal and is the most frequent cause of gastroenteritis in children between 6 months and 3 years of age. Among young children hospitalized for gastroenteritis, it is expected that up to 50% of patient specimens will test positive for Rotavirus. The prevalence of Rotavirus infection will vary based on many factors such as age, geographic location, method of sample collection, sample handling and transportation, and the general health environment of the patient population under study. Normal healthy individuals tested should be negative for Rotavirus. Some infected individuals may show symptoms or only minor symptoms, and these patients may test negative.

**PERFORMANCE CHARACTERISTICS**

The Sure-Vue® Rota Test was tested in laboratories and hospitals in the United States and Japan for the direct testing of patient stool samples. A total of 185 samples were tested, and the results compared to the Meridian Premier Rotaclone® EIA test, and to electron microscopy (EM).

**EXPECTED VALUES**

Rotavirus infection is seasonal and is the most frequent cause of gastroenteritis in children between 6 months and 3 years of age. Among young children hospitalized for gastroenteritis, it is expected that up to 50% of patient specimens will test positive for Rotavirus. The prevalence of Rotavirus infection will vary based on many factors such as age, geographic location, method of sample collection, sample handling and transportation, and the general health environment of the patient population under study. Normal healthy individuals tested should be negative for Rotavirus. Some infected individuals may show symptoms or only minor symptoms, and these patients may test negative.

**PERFORMANCE CHARACTERISTICS**

The Sure-Vue® Rota Test was tested in laboratories and hospitals in the United States and Japan for the direct testing of patient stool samples. A total of 185 samples were tested, and the results compared to the Meridian Premier Rotaclone® EIA test, and to electron microscopy (EM).

**EXPECTED VALUES**

Rotavirus infection is seasonal and is the most frequent cause of gastroenteritis in children between 6 months and 3 years of age. Among young children hospitalized for gastroenteritis, it is expected that up to 50% of patient specimens will test positive for Rotavirus. The prevalence of Rotavirus infection will vary based on many factors such as age, geographic location, method of sample collection, sample handling and transportation, and the general health environment of the patient population under study. Normal healthy individuals tested should be negative for Rotavirus. Some infected individuals may show symptoms or only minor symptoms, and these patients may test negative.

**PERFORMANCE CHARACTERISTICS**

The Sure-Vue® Rota Test was tested in laboratories and hospitals in the United States and Japan for the direct testing of patient stool samples. A total of 185 samples were tested, and the results compared to the Meridian Premier Rotaclone® EIA test, and to electron microscopy (EM).