EN

REF F-RAC-01G

STANDARD F

Rota/Adeno Ag FIA

STANDARD™ F Rota/Adeno Ag FIA

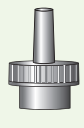
PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

SD BIOSENSOR

KIT CONTENTS

Test device
(individually in a foil pouch with desiccant)

Extraction buffer tube



Filter cap

Sterile swab

Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

- STANDARD F Analyzer
- Timer

SPECIMEN COLLECTION AND PREPARATION

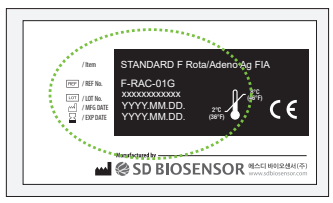
■ Feces

1. Fecal specimen should be collected in a clean and dry container and collected at any time of the day may be used.
2. Urine should be excluded from the fecal specimen.
3. Fresh fecal specimen should be used for this test. Do not use any transport media to store and transport fecal specimen.
4. Fecal specimen stored at 25±2°C (73.4-80.6°F) can be used for up to 24 hours.
5. Fecal specimen stored at -40±2°C (-40±3.6°F) can be used within 1 week.
6. Fecal specimen stored at 4±2°C (35.6-42.8°F) can be used up to 48 hours.

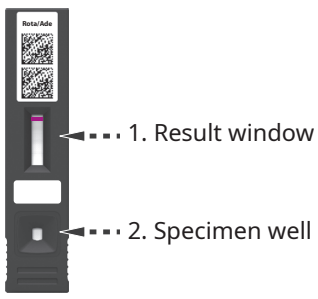
TEST PROCEDURE

■ Preparation

1. Allow test device and collected specimen to room temperature (15-30°C/59-86°F) prior to testing.
2. Carefully read instructions for use before using the STANDARD F Rota/Adeno Ag FIA.
   * Check the valid expiry date at the back of the foil pouch. Do not use if the expiry date has passed.
3. Check the condition of the test device and desiccant before use.



Foil pouch



Test device

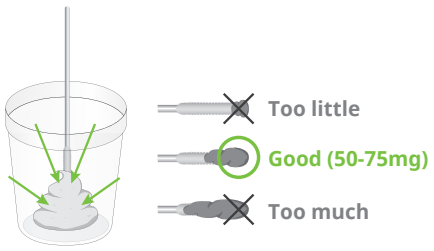
Desiccant

The violet-line on the membrane of unused test device will disappear after use.

Before Use **After Use**

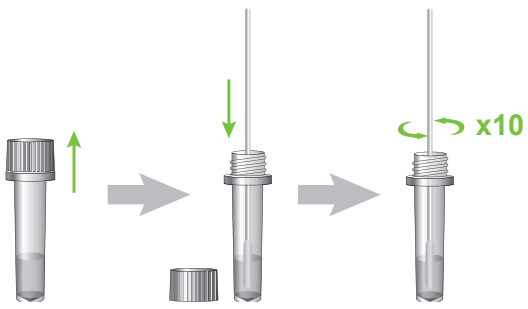
Do not write on the barcode or damage the barcode of the test device.

■ Specimen Preparation

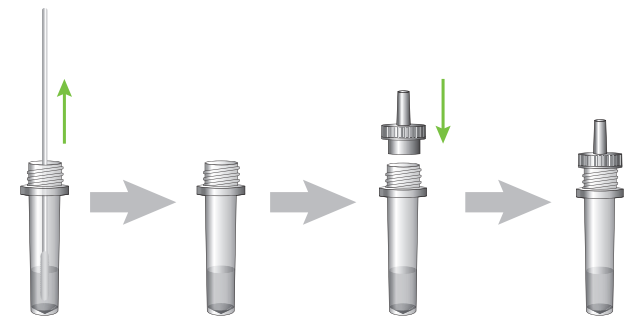


1. Collect a random fecal specimen in a clean and dry container.
2. Randomly pierce 3-4 different sites of the fecal specimen using the sterile swab. For watery specimen, soak the sterile swab completely.

- Excessive or lack amount of fecal specimen may induce an erroneous test result.
- Do not scoop fecal specimen as it may lead to an invalid test result.



3. Open the extraction buffer tube and insert the swab into the tube.
4. Swirl the swab at least 10 times to dissolve the specimen in the extraction buffer.



5. Remove the swab from the tube and dispose it.
6. Place the filter cap onto the extraction buffer tube and tighten securely.

- Do not use the extraction buffer tube without the filter cap.
- Use of unfiltered specimen mixture may lead to an invalid test result.

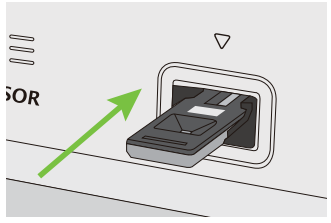
■ Analysis of specimen

'STANDARD TEST' mode — **STANDARD F100, F200 and F2400 analyzer**

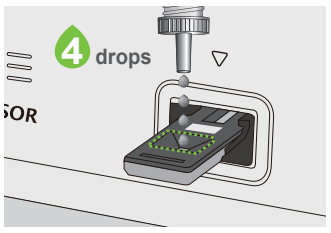
1. Take the test device out of the foil pouch and place it on a flat and dry surface. Write patient information on the label of test device.

STANDARD F2400 analyzer	'Workplace' → 'Run Test' → Scan or type patient ID and/or operator ID
STANDARD F100 and F200 analyzer	'Standard Test' mode → Insert patient ID and / or operator ID on the analyzer

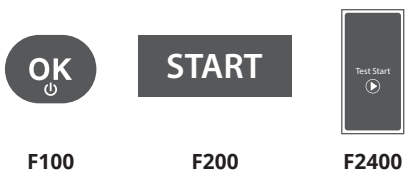
2. Insert the test device to the test slot of the analyzer. Once it is inserted, the analyzer will read the barcode data and check the validity of the test device.



3. Apply 4 drops of specimen mixture to the specimen well of the test device.



4. After applying the specimen, immediately press the **'TEST START'** button.



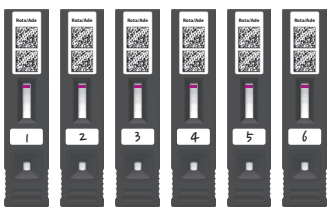
F100 **F200** **F2400**

5. The analyzer will automatically display the test result after 15 minutes.

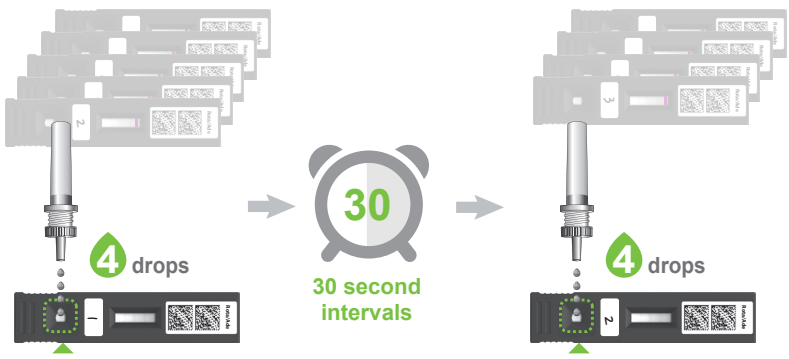
'READ ONLY' mode — **STANDARD F100 and F200 analyzer**

1. Take the test device out of the foil pouch and place it on a flat and dry surface. Write a specimen information on the label of test device.
2. Prepare extracted specimens.

3. Prepare test devices depending on the workload.



4. Apply 4 drops of extracted specimen into test devices in sequence at about 30 seconds intervals.



5. Incubate the test device for 15 minutes outside of the analyzer.

6. Select the 'Read Only' mode on the screen, and insert test devices in sequence.

7. The analyzer will automatically scan and display the test result immediately after specimen type selection.

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INTERPRETATION OF TEST RESULTS

Result		Interpretation
Rotavirus Positive (COI ≥ 1.0)	Adenovirus Negative (COI < 1.0)	Positive for Rotavirus
Rotavirus Negative (COI < 1.0)	Adenovirus Positive (COI ≥ 1.0)	Positive for Adenovirus
Rotavirus Positive (COI ≥ 1.0)	Adenovirus Positive (COI ≥ 1.0)	Positive for Rotavirus and Adenovirus
Rotavirus Negative (COI < 1.0)	Adenovirus Negative (COI < 1.0)	All Negative
COI value is not displayed with an 'Invalid' message.		Invalid

The test result of a specimen is given either as Positive (+) / Pos (+) or Negative (-) / Neg (-) with a COI (cut off index) value. The COI is a numerical representation of the measured fluorescence signal.

Positive results should be considered in conjunction with the clinical history and other data available to the physician.

EXPLANATION AND SUMMARY

■ Introduction

Rotavirus is the commonest virus cause acute diarrhea. It is most common in infants and young children. Children who get rotavirus infected may have severe watery diarrhea, often with vomiting, fever, and abdominal pain. However, older children and adults also can get sick from rotavirus. Adenovirus is the second most common cause of diarrhea following rotavirus. Adenoviruses cause various clinical diseases such as Common cold, Sore throat, Bronchitis, etc. Adenoviruses mainly implicated respiratory, ocular and the gastrointestinal systems of humans. Particularly, Enteric adenovirus types 40 and 41 cause gastroenteritis. Symptoms may include loss of appetite and dehydration (loss of body fluids), which can be especially dangerous for infants and young children. STANDARD F Rota/Adeno Ag FIA provides significantly fast, easy and accurate system to detect the specific antigens to rotavirus and adenovirus in human fecal specimen. It is essential for the reliable clinical diagnosis to identify Rotavirus/Adenovirus infection and enables supportive definite diagnosis of them.

■ Intended use

STANDARD F Rota/Adeno Ag FIA is a fluorescent immunoassay for the qualitative detection of the presence of Rotavirus and/or Adenovirus antigens in fecal specimens. STANDARD F Rota/Adeno Ag FIA should be used with STANDARD F Analyzers manufactured by SD BIOSENSOR.

■ Test principle

STANDARD F Rota/Adeno Ag FIA is based on immunofluorescence technology with STANDARD F Analyzer to detect antigen of Rotavirus and Adenovirus. STANDARD F Rota/Adeno Ag FIA has two test lines (R : which is coated with monoclonal anti-Rotavirus / A : which is coated with monoclonal anti-Adenovirus), and one control line which is coated with anti-rabbit-IgG. The patient's specimen is applied into the specimen well of the test device and the specimen migrates through the membrane. If antigen of Rotavirus (Adenovirus) is present, it will react with europium conjugated polyclonal anti-Rotavirus (monoclonal anti-Adenovirus) in the conjugation pad and form antibody-antigen fluorescence particle complexes. These complexes move along to the membrane to be captured by the anti-Rotavirus (Adenovirus) on the each test line and make fluorescence signal. The intensity of the fluorescence light generated on the membrane is scanned by the STANDARD F Analyzer manufactured by SD BIOSENSOR. STANDARD F Analyzer can analyze the presence of the analyte in the clinical specimen by processing the results using pre-programmed algorithms and display the test result on the screen.

KIT STORAGE AND STABILITY

Store the kit at 2-8°C(36-46°F) and 10-90% RH.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Do not re-use the test kit.
3. Do not use the test kit if the pouch is damaged or the seal is broken.
4. Do not use the extraction buffer of another lot.
5. Do not smoke, drink or eat while handling specimen.
6. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents.
7. Wash hands thoroughly after the test is done.
8. Clean up spills thoroughly using an appropriate disinfectant.
9. Handle all specimens as if they contain infectious agents.
10. Observe established precautions against microbiological hazards throughout testing procedures.
11. Dispose of all specimens and materials used to perform the test as bio-hazard waste. Laboratory chemical and bio-hazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
12. Silica gel in foil pouch is to absorb moisture and keep humidity from affecting products. If the moisture indicating silica gel beads change from yellow to green, the pouch should be discarded.
13. Immediately use the test device after taking out of foil pouch.
14. Do not write on the bar code or damage the bar code of the test device.
15. Store the STANDARD F Rota/Adeno Ag FIA at 2-8°C / 36-46°F.

PERFORMANCE CHARACTERISTICS

■ Clinical sensitivity and specificity

164 clinical specimens are tested internally and the test result shows the 100% (13/13) sensitivity for Rotavirus positive specimen and 100% (2/2) for Adenovirus positive specimen. The specificity is 100% (149/149) for Rotavirus and Adenovirus negative specimen.

1) Clinical sensitivity

Rotavirus positive specimen		Confirmed result		
		Positive	Negative	Total
STANDARD F Rota/Adeno Ag FIA	Positive	13	0	13
	Negative	0	0	0
	Total	13	0	13

Sensitivity for Rotavirus: 13/13 (100%)

Adenovirus positive specimen		Confirmed result		
		Positive	Negative	Total
STANDARD F Rota/Adeno Ag FIA	Positive	2	0	2
	Negative	0	0	0
	Total	2	0	2

Sensitivity for Adenovirus: 2/2 (100%)

2) Clinical specificity

Rotavirus and Adenovirus negative specimen		Confirmed result		
		Positive	Negative	Total
STANDARD F Rota/Adeno Ag FIA	Positive	0	0	0
	Negative	0	149	149
	Total	0	149	149

Specificity for Rotavirus: 149/149 (100%)

Specificity for Adenovirus: 149/149 (100%)

LIMITATION OF TEST

1. The test should be used for the detection of Rotavirus and Adenovirus antigens in human fecal specimens.
2. Neither the quantitative value nor the rate of concentration for Rotavirus and Adenovirus antigens can be determined by this qualitative test.
3. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
4. A negative test result may occur if the level of extracted antigen in a specimen is below the sensitivity of the test or if a poor quality specimen is obtained.
5. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
6. The test result must always be evaluated with other data available to the physician.

QUALITY CONTROL

■ Calibration

The calibration set test of STANDARD F analyzer should be conducted according to the analyzer's manual.

[When to use calibration set]

1. Before using the analyzer for the first time.
2. When you drop the analyzer.
3. Whenever you do not agree with the final result.
4. When you want to check the performance of an analyzer and test device.

[How to use calibration set]

Calibration set test is a required function that ensures optimal performance by checking the internal analyzer optics and functions.

1. Select the 'Calibration' in main menu.
2. The specific calibration set is included with the analyzer.
3. Insert the CAL-1 for white calibration, CAL-2 for UV LED calibaration, and CAL-3 for RGB LED calibration in sequence.

STANDARD F analyzer automatically calibrate and identify the optical performance through measuring the membrane of the test device whenever the test is conducted in 'Standard Test' mode. If 'EEE' message displays on the screen, it means that the analyzer has a problem, so check with test device. Contact the SD BIOSENSOR local distributor if the 'EEE' message still appears.

■ Internal quality control

1. The internal procedural control zone is on the membrane of the test device. STANDARD F analyzers read the fluorescence signal of the internal procedural control zone and decide whether the result is valid or invalid.
2. The invalid result denotes that the fluorescence signal is not within the pre-set range. If the screen of STANDARD F analyzer shows 'Invalid', turn off and turn on the analyzer again and re-test with a new test device.

BIBLIOGRAPHY

1. Murphy TV, Gargiullo PM, Massoudi MS, Nelson DB, Jumaan AO, Okoro CA, et al. Intussusception among infants given an oral Rotavirus vaccine. N Engl J Med 2001;344:564-72.
2. CDC. Prevention of rotavirus gastroenteritis among infants and children. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2006;55(No. RR-12).
3. Parashar UD, Gibson CJ, Bresee JS, Glass RI. Rotavirus and severe childhood diarrhea. Emerg Infect Dis 2006;12:304–6.
4. Parashar UD, Burton A, Lanata C, et al. Global mortality associated with rotavirus disease among children in 2004. J Infect Dis 2009;200 Suppl 1:S9–15.
5. Bon F, Fascia P, Dauvergne M, Tenenbaum D, Planson H, Petion AM, et al. Prevalence of group A rotavirus, human calicivirus, astrovirus, and adenovirus type 40 and 41 infections among children with acute gastroenteritis in Dijon, France. J Clin Microbiol 1999;37: 3055-8.