

STANDARD F

Norovirus Ag FIA

REF F-NRV-01

STANDARD™ F Norovirus Ag FIA

PLEASE READ BACK PAGE CAREFULLY BEFORE YOU PERFORM THE TEST



EXPLANATION AND SUMMARY

[Introduction]

Norovirus is the dominant cause of outbreaks of acute gastroenteritis in humans and results in about 685 million cases of disease and 200,000 deaths globally a year. Especially, those under the age of five are most often affected and result in about 50,000 deaths in the developing countries. Norovirus infection commonly occurs in winter months and a person usually develops symptoms of nausea, vomiting, watery diarrhea and abdominal pain after 12 to 48 hours of symptoms incubation. Because of the rapid transmission of the norovirus, early detection is important to prevent the outbreak of norovirus infection. STANDARD F Norovirus Ag FIA provides a significantly fast, easy and accurate system to detect the specific antigens to norovirus in the human fecal specimen. It is essential for the reliable clinical diagnosis of norovirus infection and proper treatment decisions.

[Intended use]

STANDARD F Norovirus Ag FIA is a rapid, qualitative immunoassay to detect norovirus Ag in the human fecal specimen. The test is for *in vitro* diagnostic use and is intended as an aid to early diagnosis of norovirus infection. This is intended for professional use, only for an initial screening test.

[Test principle]

STANDARD F Norovirus Ag FIA is based on the immunofluorescence technology with STANDARD F Analyzer manufactured by SD BIOSENSOR to detect of norovirus antigen in human fecal specimens. After applying the sample mixture to the test device, the complex will be formed on the membrane as the result of the antigen-antibody reaction. The intensity of the fluorescence light is scanned and converted into an electric signal which is proportional to the intensity of fluorescence light produced on the membrane. STANDARD F analyzers can calculate the concentration of the analyte in the clinical specimen based on a pre-programmed calibration and display the test result on the screen.

[Kit contents]

- ① Test device ② Extraction buffer tube ③ Filter cap ④ Sterile swab ⑤ Instructions for use

[Materials required but not provided]

- STANDARD F Analyzer
- Timer

KIT STORAGE AND STABILITY

Store the kit at 2-30°C /36-86°F, out of direct sunlight. Kit materials are stable until the expiration date printed on the outer box. Do not freeze.

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.

SPECIMEN COLLECTION AND PREPARATION

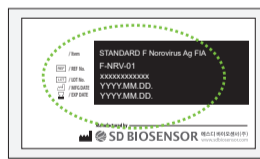
[Feces]

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 in this test. Do not use any transport media to store and transport the fecal specimen.
4. Fecal specimen may be stored at room temperature (15-30°C/59-86°F) for up to 1 day or at 2-8°C/ 36-46°F for up to 2 days prior to testing.

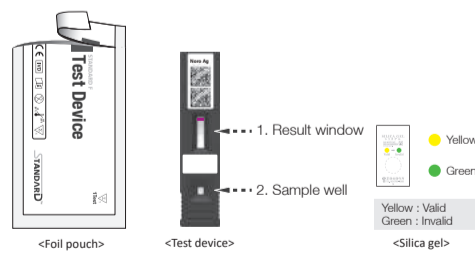
TEST PROCEDURE

[Preparation]

1. Allow test device and collected sample to room temperature (15-30°C / 59-86°F) prior to testing.
2. Carefully read instructions for using the STANDARD F Norovirus Ag FIA.
3. Check the expiry date at the back of the foil pouch. Use another lot, if expiry date has passed.

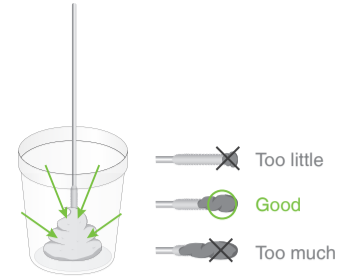


4. Open the foil pouch, and check the test device and the silica gel pack in the foil pouch.



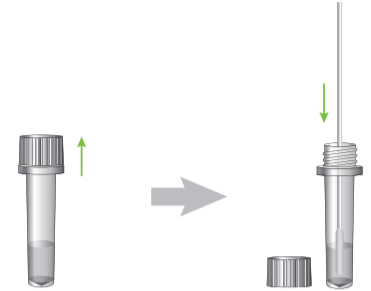
[Collection of sample]

1. Poke the 4 different areas of the feces sample using the sterile swab to collect a portion of feces (about 40-70mg). In case of liquid sample, soak the sterile swab completely in the liquid fecal sample.



• The amount of fecal swab may affect the results. It is required to follow the swab amount of feces as shown in the picture above. Excessive fecal amount may induce a false positive result and slow migration.

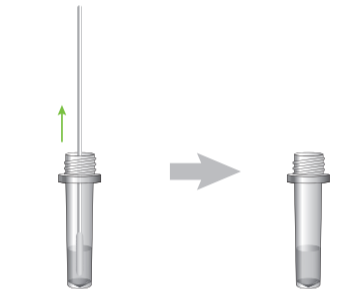
2. Take off the top of an Extraction buffer tube and insert the swab into the tube.



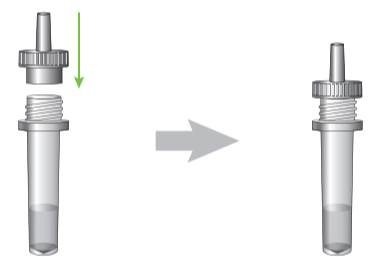
3. Swirl the swab at least ten times into the Extraction buffer tube to dissolve the sample.



4. Remove the swab and dispose of the used swab in accordance with your biohazard waste disposal protocol.



5. Tightly press down the filter cap onto the tube.



• Do not use the extraction buffer tube without the filter cap. It affects the result value.

[Analysis of sample]

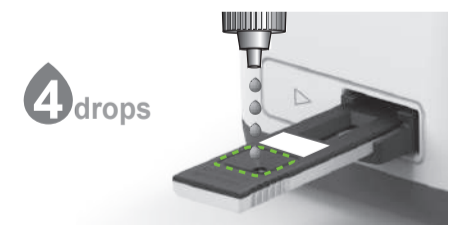
- Using a 'STANDARD TEST' mode
- Applying STANDARD F100, F200 and F2400 analyzer

1. Prepare a STANDARD F Analyzer and select the 'Standard Test' mode according to the analyzer's manual. In case of STANDARD F2400 analyzer, go to the 'Workplace' in the main screen. And select the 'Run Test'.
2. In case of STANDARD F200 and F2400 analyzer, input patient ID and/or operator ID on the analyzer.
3. Take the test device out of the foil pouch.



4. Insert the test device to the test slot of the analyzer. When inserting the test device to the analyzer, the analyzer will read the barcode data, and check the test device is valid. Select the sample type on the sample selection screen.

5. Apply 4 drops of mixed sample to the sample well in the test device holding the prepared extraction buffer tube upside down.



6. After applying the sample, immediately press the 'TEST START' button.



7. The analyzer will automatically display the test result within 15 minutes.

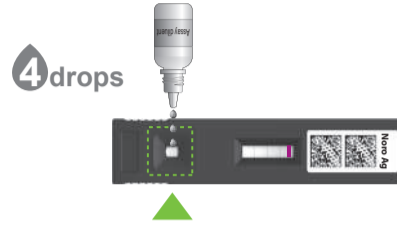


• Using a 'READ ONLY' mode

- Applying 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 sample information on the label of test device.

2. Apply 4 drops of mixed sample to the sample well in the test device holding the prepared extraction buffer tube upside down.



3. Stay the test device for 15 minutes outside of the analyzer for incubation.



4. To preparing the test with STANDARD F Analyzer, set the 'READ ONLY' mode following the instructions in the manual.

5. Insert the test device to the test slot of the analyzer. The analyzer automatically reads the barcode information of the the test device and outputs the resulting values based on the test information.



INTERPRETATION OF TEST RESULTS

[STANDARD F100, F200, F2400 analyzers]

Result	COI (Cutoff index) value	Interpretation
Positive	COI ≥ 1.0	Positive for Norovirus
Negative	COI < 1.0	Negative for Norovirus
Invalid	COI value is not displayed	Retest should be performed with a new test device and a new patient sample



• The test result of a sample is given either as Positive(+)/Pos(+) or Negative(-)/Neg(-) with a COI(cutoff index) value. The COI is a numerical representation of the measured uorecence signal.

LIMITATION OF TEST

1. The test should be used for the detection of norovirus in human fecal specimens.
2. Neither the quantitative value nor the rate of norovirus concentration 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 antibody in a sample 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.

BIBLIOGRAPHY

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Product Disclaimer

Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the SD BIOSENSOR and distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

Warning

The SD BIOSENSOR and distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect of consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.



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