NADAL® Norovirus GI + GII Test (Ref. 920002)

1. Intended Use

The NADAL® Norovirus GI + GII test is a rapid chromatographic immunoassay for the qualitative detection of norovirus genogroups I and II antigens in human faeces specimens to aid in the diagnosis of norovirus infection.

2. Introduction and Clinical Significance

Noroviruses, members of the Caliciviridae family, are a group of more than 40 extremely heterogeneous viruses. Infection is typically characterised by self-limited vomiting and diarrhoea, with symptoms prevailing for 12–60 h.

Noroviruses are divided into five distinguishable genogroups (GI – GV) based on genome sequence similarity; however, only virus strains from genogroups I–II are known to widely infect humans. Further strains in the newly identified genogroup IV have also been detected in human stools. Noroviruses within a genogroup can differ by up to 40% in capsid amino acid sequence and by >50% between genogroups.

3. Principle of the Test

The NADAL® Norovirus GI + GII test is a qualitative lateral flow immunoassay for the detection of norovirus GI and GII antigens in human faeces samples. Antibodies against norovirus GI and GII antigens are pre-coated in the test line region of the membrane. During testing, the sample reacts with particles coated with antibodies against noroviruses GI and GII which are pre-dried on the test strip. The mixture migrates along the membrane by capillary action. In the case of a positive result specific antibodies present on the membrane react with the mixture of conjugates and generate one or two red coloured lines. A green coloured line should always appear in the control line region and serves as verification that sufficient volume of sample has been added, that membrane wicking has occured and as an internal control for reagents.

4. Reagents and Materials Supplied

- 10 NADAL® Norovirus GI + GII test cassettes
- 10 specimen collection tubes
- 1 package insert

5. Additional Required Materials

- Specimen collection containers
- Disposable gloves
- Timer

6. Storage & Stability

Store the test as packaged in the sealed foil pouch either refrigerated or at room temperature (2-30°C). The test is stable through the expiration date printed on the sealed foil pouch. The test must remain in the sealed foil pouch until use. Do not freeze.

7. Warnings and Precautions

- For professional *in-vitro* diagnostic use only.
- Do not use after expiration date.
- The test should remain in the sealed foil pouch until use.
- Do not use the test if the foil pouch is damaged.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Do not eat, drink or smoke in the area where the specimens or test kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- The test should be discarded in a proper biohazard container after testing.
- The test must be carried out within 2 hours of opening the sealed foil pouch.

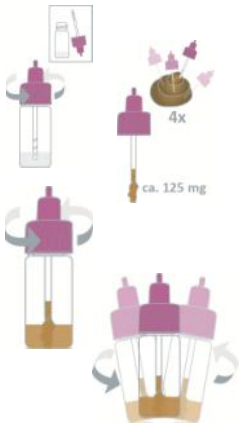
8. Specimen Collection and Preparation

Collect sufficient quantity of feces (1-2 g or 1-2 mL for liquid samples). Stool samples should be collected in clean and dry containers (without preservatives or transport media). Samples can be stored in the refrigerator (2-8°C) for 1-2 days prior to testing. For longer storage (maximum 1 year) samples must be kept frozen at –20°C. In this case, samples should be completely thawed and brought to room temperature prior to testing.

9. Procedure of the Test

To process collected stool samples:

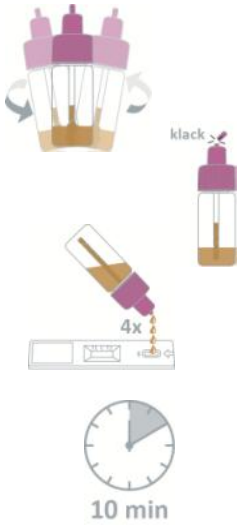
Use a separate specimen collection tube for each sample. Unscrew the tube cap and introduce the applicator stick four times into four different sites of fecal sample to collect approximately 125 mg of the sample. Close the tube containing buffer and stool sample. Shake the tube in order to assure good sample dispersion. For liquid stool samples, aspirate faecal sample with a dropper and add 125 µL of the sample to the specimen collection tube containing buffer.



Test Procedure

Bring tests, stool samples and buffer to room temperature (15-30°C) prior to testing. Do not open foil pouches until ready to perform the assay.

1. Remove the NADAL® Norovirus GI + GII test cassette from the sealed foil pouch and use it as soon as possible.
2. Shake the specimen collection tube to assure good sample dispersion. Break off the tip of the tube cap.
3. Use a separate test cassette for each sample. Dispense 4 drops into the specimen well (S) of the test cassette. Start the timer.
4. Read the result at 10 minutes after dispensing the sample into the specimen well (S).



10. Interpretation of the Results

Positive:

Norovirus GI positive:

One green line develops in the control line region (C) and one red line develops in the test line region (T1) for norovirus GI.

Norovirus GII positive:

One green line develops in the control line region (C) and one red line develops in the test line region (T2) for norovirus GII.

Norovirus GI + GII positive:

In addition to the green control line (C), a red line develops in each test line region (T1 and T2) for norovirus GI and norovirus GII.

Note:

The intensity of the red coloured lines in the test line regions (T1 and T2) may vary depending on the concentration of antigens in the specimen. However, neither the quantitative value nor the rate of increase in antigens can be determined by this qualitative test.

Negative:

One green line develops in the control line region (C). No line develops in each test line region (T1 and T2).

Invalid:

The absence of the green control line (C) regardless of the appearance or absence of the red test lines indicates a failure in the test procedure. The sample should be retested.

Note: Insufficient specimen volume, incorrect procedural techniques or deterioration of reagents are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit and contact your distributor.

11. Quality Control

An internal procedural control is included in the test cassette:

A green line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

12. Limitations

- The NADAL® Norovirus GI + GII test only indicates the presence of norovirus antigens in specimens and should be used for the qualitative detection of norovirus GI and GII antigens in feces specimens only. Neither the quantitative value nor the rate of increase in antigen concentration can be determined by this test.
- An excess of sample can cause wrong results (brown lines appear). Dilute the sample with buffer and repeat the test.
- Some stool samples can decrease the intensity of the control line.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of norovirus infection.
- After one week of infection, the number of parasites in faeces is decreasing, making the sample less reactive. Stool samples should be collected within one week of the onset of symptoms.
- This test provides a presumptive diagnosis of infection caused by norovirus. All results must be interpreted in conjunction with other clinical information and laboratory findings available to the physician.

13. Expected values

Noroviruses are recognized as the most common cause of viral gastroenteritis among adults in the United States. It is estimated that more than 40% of foodborne outbreaks of gastroenteritis are attributable to Noroviruses. These highly contagious viruses can be transmitted by contaminated food, water, or direct person-to-person contact. Norovirus outbreaks have been documented on cruise ships, at daycare centers, schools and among members of the military. Severe illnesses are rare, but unusual complications can occur in the elderly, children and immunocompromised individuals.

14. Performance Characteristics

Sensitivity and specificity

Some stool samples from patients of different hospitals were studied using the NADAL® Norovirus GI + GII test in comparison with another immunochromatographic test (Simple Norovirus Operon). The results show that the NADAL® Norovirus GI + GII test sensitivity is >99% for both Norovirus GI and Norvirus GII. The NADAL® Norovirus GI + GII test specificity is >99% for both Norovirus GI and Norvirus GII.

The samples were confirmed by PCR technique.

Cross-Reactivity

An evaluation was performed to determine the cross-reactivity of the NADAL® Norovirus GI + GII test. No cross-reactivity with common gastrointestinal pathogens which occasionally are present in feces was observed with the NADAL® Norovirus GI + GII test:

Adenovirus	*Escherichia coli*	*RSV*
Astrovirus	*Giardia lamblia*	*Salmonella*
Campylobacter	*Helicobacter pylori*	*Shigella*
Clostridium difficile	*Hepatitis A*	*Staphylococcus aureus*
Cryptosporidium parvum	*Listeria monocytogenes*	*Yersinia*
Enterovirus	*Rotavirus*	

15. References

1. KISSMANN j., et al. “Physical stabilization of Norwalk Virus-like Particles”. Journal of Pharmaceutilca Sciences, VOL.97, NO. 10, OCTOBER 2008.
2. LOBUEA A., et al. “Multivalent norovirus vaccines induce strong mucosal and systemic blocking antibodies against multiple strains”. Vaccine 24 (2006) 5220–5234.

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