Atlas Medical CE

Norovirus Device
One Step *Norovirus* genogroups I and II Antigen Test

IVD *For in-vitro diagnostic use only*

2 30°C Store at 2-30°C

INTENDED USE

The *Norovirus* Device test is a rapid chromatographic immunoassay for the qualitative detection of *Norovirus* genogroups I and II (GI and GII) antigens in human feces specimens to aid in the diagnosis of Norovirus infection.

SYNTHESIS

Noroviruses, members of the Caliciviridae family, are a group of more than 40 extremely heterogeneous viruses. Infection is typically characterized by self-limited vomiting and diarrhea, 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. Additional 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 >50% between genogroups.

PRINCIPLE

The *Norovirus* Device is a qualitative lateral flow immunoassay for the detection of *Norovirus* GI and GII antigen in human feces samples. The membrane is pre-coated with antibodies against *Norovirus* (GI and GII) antigens on the test line region. During testing, the sample reacts with the particle coated with anti-*Norovirus* (GI and GII) antibodies which was pre-dried on the test strip. The mixture then moves upward on the membrane by capillary action. In the case of a positive result the specific antibodies present on the membrane will react with the mixture conjugate and generate a coloured line. A green coloured line always appears in the control line and serves as verification that sufficient volume was added, that proper flow was obtained and as an internal control for the reagents.

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after expiration date.
- The test should remain in the sealed pouch until use.
- Do not use the test if pouch is damaged.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- 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 bag.

STORAGE AND STABILITY

- Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC/36-86ºF).
- The test is stable through the expiration date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.

MATERIALS

Materials provided

- Devices
- Extraction tube with buffer.
- Instructions for use.

Materials required but no provided

- Timer.
- Specimen collection container.
- Disposable gloves.

SPECIMEN COLLECTION AND PREPARATION

Collect sufficient quantity of feces (1-2 g or mL for liquid sample). Stool samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-8ºC/36-46.4ºF) for 1-2 days prior to testing. For longer storage (maximum 1 year) the specimen must be kept frozen at –20ºC/-4ºF. In this case, the sample will be totally thawed, and brought to room temperature before testing.

PROCEDURE

To process collected stool samples (see illustration 1):

Use a separate specimen collection vial for each sample. Unscrew the cap of the vial and introduce the stick four times into the fecal specimen to pick up the sample (approx. 125 mg). Close the vial with the buffer and stool sample. Shake the vial in order to assure good sample dispersion. For liquid stool samples, aspirate the fecal specimen with a dropper and add 125 µL into the specimen collection vial with buffer.

Test Procedure (see illustration 2):

Allow the tests, stool samples and buffer to reach room temperature (15-30ºC/59-86ºF) prior to testing. Do not open pouches until ready to perform the assay.

1. Remove the *Norovirus* Device from its sealed pouch and use it as soon as possible.
2. Shake the specimen collection vial to assure good sample dispersion. Break off the cap of the vial.
3. Use a separate device for each sample. Dispense exactly 4 drops into the specimen well (S). Start the timer.
4. Read the result at **10 minutes** after dispensing the sample.

Illustration 1

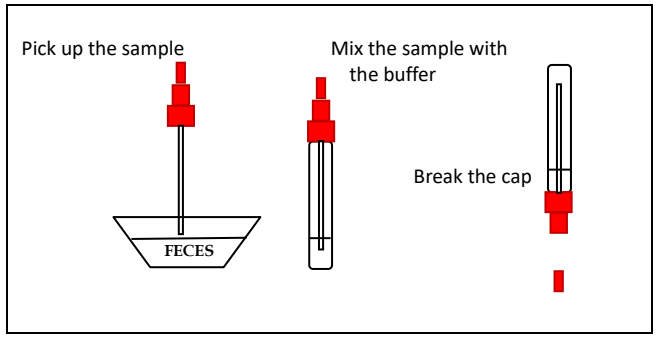
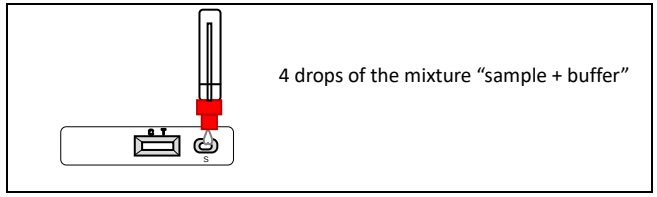
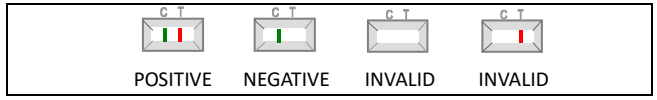


Illustration 2



INTERPRETATION OF RESULTS

Illustration 3



POSITIVE: Two lines appear across the central window, a **red** test line marked with the letter T and a **green** control line marked with letter C.

NEGATIVE: Only one **green** line appears across the control line region marked with the letter C (control line).
INVALID: Total absence of the green control coloured line regardless the appearance or not of the red test line. Note: Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit and contact your local distributor. See illustration 3.

NOTES ON THE INTERPRETATION OF RESULTS

The intensity of the red coloured test line in the result line region (T) will 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

QUALITY CONTROL

Internal procedural controls are included in the test:

- A green line appearing in the control line region (C). It confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS

1. Norovirus Device will only indicate the presence of Norovirus antigens in the specimen (qualitative detection) and should be used for the detection of Norovirus GI and GII antigens in feces specimens only. Neither the quantitative value nor the rate of increase in antigens concentration can be determined by this test.
2. An excess of sample could cause wrong results (brown lines appear). Dilute the sample with the buffer and repeat the test.
3. Some stool samples can decrease the intensity of the control line.
4. 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.
5. After one week of infection, the number of virus in feces is decreasing, making the sample less reactive. Stool samples should be collected within one week of the onset of symptoms.
6. This test provides a presumptive diagnosis of Norovirus infections. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

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 and schools, and among members of the military. Severe illness is rare, but unusual complications can occur in the elderly, in children, and in immunocompromised individuals.

PERFORMANCE CHARACTERISTICS

SENSITIVITY AND SPECIFICITY

It was studied some stool samples from patients of different Hospitals. The result showed using *Norovirus* Device and compared with other immunochromatographic test (Simple *Norovirus,* Operon) were:
The results were >99% of sensitivity and >99%of specificity.
The samples were confirmed by PCR technique.

CROSS-REACTIVITY

It was performed an evaluation to determine the cross reactivity of *Norovirus* Device. There is not cross reactivity with common gastrointestinal pathogens occasionally present in feces:

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

REFERENCES

1. CUKOR G., and BLACKLOW N. R., "Human Viral Gastroenteritis", Microbiological Reviews, Vol. 48 No 2, June 1984, pp. 157-179
2. NEEL K. KRISHNA, B.A, "Identification of Structural Domains Involved in Astrovirus Capsid Biology", Viral Immunol. 2005; 18(1): 17–26.
3. BON, F. et al. "Prevalence of group A rotavirus, human calicivirus, astrovirus type 40 and 41 infections among children with acute gastroenteritis in Dijon, France." J. Clin. Microbiol. 37 No 9 3055-3058 (1999).

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry