VITASSAY

# Norovirus

Rapid test for the qualitative detection of norovirus genogroups I and II (GI and GII) in human stool samples.

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CE IVD EN

Vitassay

**For professional *in vitro* diagnostic use only.**

## INTENDED USE

**Vitassay Norovirus** is a rapid one step immunochromatographic assay for the qualitative detection of norovirus genogroups I and II (GI and GII) in human stool samples.

Simple, non-invasive and highly sensitive screening assay to make a presumptive diagnosis of norovirus (GI and GII) infection.

## NTRODUCTION

Noroviruses are a group of no enveloped single-stranded positive-sense RNA viruses classified in the family *Caliciviridae*.

Norovirus can infect humans via multiple routes, including the oral route, transmitted through contact with fecal matter or aerosolized vomitus from infected people, as well as contaminated surfaces, food, or water.

After incubation period 12 to 48h, Norovirus illness is characterized by projectile vomiting, no bloody diarrhea, nausea, abdominal cramps, and low-grade fever. Some persons might experience only vomiting or diarrhea. In healthy individuals, the duration of symptoms is usually not longer than 48 h, and the disease is self-limiting in most patients. However, young children and the elderly are at increased risk for more-severe and prolonged illness leading hospitalization, while the disease is increasingly recognized as an important cause of chronic gastroenteritis for immunocompromised patients.

Although Norovirus can be detected in rectal swabs and vomitus, whole-stool samples are the preferred clinical specimen for the detection of Norovirus because they contain a higher quantity of virus.

## PRINCIPLE

**Vitassay Norovirus** is a qualitative immunochromatographic assay for the detection of norovirus genogroups I and II (GI and GII) in human stool samples.

The test line zone of the nitrocellulose membrane is pre-coated with monoclonal antibodies against norovirus.

During the process, the sample reacts with the antibodies against Norovirus (GI and GII), forming conjugates. The mixture moves upward on the membrane by capillary action. If the sample is positive, antibodies present on the membrane (test line) capture the conjugate complex and a red line will be visible. Although the sample is positive or negative, the mixture continues to move across the membranes and the green control line always appears.

The presence of this green line (in the control zone (C)) indicates that sufficient volume is added; proper flow is obtained and serves as an internal control for the reagents.

## PRECAUTIONS

- For professional *in vitro* use only.
- Do not use after expiration date.
- Do not use the test if its pouch is damaged.
- Specimens should be considered as potentially hazardous and handle in the same manner as an infectious agent. A new test must be used for each sample to avoid contaminations errors. Single use device.
- Tests should be discarded in a proper biohazard container after testing.
- Reagents contain preservatives. Avoid any contact with the skin or mucous membrane. Consult safety data sheet, available on request.
- Components provided in the kit are approved for use with the **Vitassay Norovirus**. Do not use any other commercial kit component.
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, goggles and mask. Do not eat, drink or smoke in the working area.

## STORAGE AND STABILITY

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC/35.6-86ºF) on the sealed pouch.

The test is stable until the expiration date printed.

The test must remain in the sealed pouch until use.

Do not freeze.

## MATERIALS

| MATERIAL PROVIDED | MATERIAL REQUIRED BUT NOT PROVIDED |
|---|---|
| ▪ **25** tests/kit **Vitassay Norovirus.**<br>▪ Instructions for use.<br>▪ **25** vials with diluent for the sample dilution. | ▪ Specimen collection container.<br>▪ Disposable gloves.<br>▪ Timer. |

## SPECIMEN COLLECTION

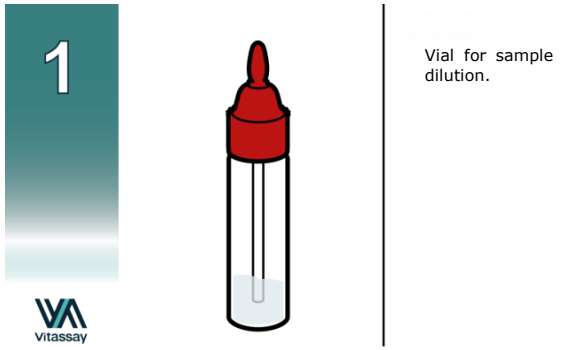
Collet sufficient quantity of feces: 1-2g or mL for liquid samples. Stool samples should be collected in clean and dry containers.

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

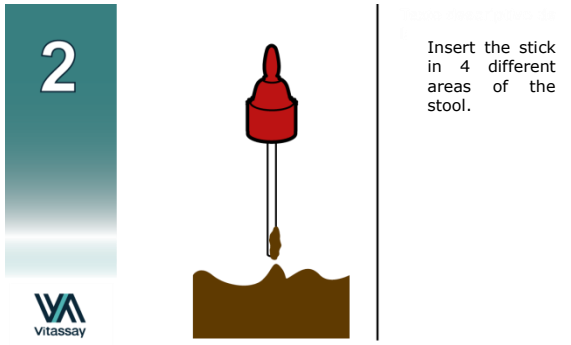
specimen must be kept frozen at -20ºC (-4ºF). Samples must be brought to room temperature before testing.

## SPECIMEN PREPARATION

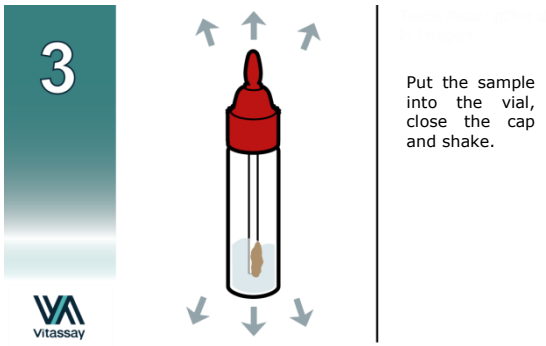
1. Remove the cap of the vial with diluent for the sample dilution (figure 1).
2. Use the stick to collect sufficient sample quantity. For solid stool, insert the stick in 4 different areas of the stool sample, taken approx. 125mg, (figure 2), and add it into the vial with diluent for the sample dilution. For liquid stool, take 125µL of the sample using a micropipette and transfer it into the vial with diluent for the sample dilution.
3. Close the vial with the diluent and stool sample. Shake vigorously the vial in order to assure good sample dispersion (figure 3).




Vial for sample dilution.




Insert the stick in 4 different areas of the stool.



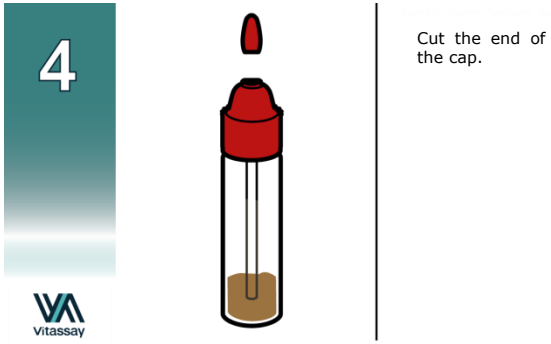

Put the sample into the vial, close the cap and shake.

## PROCEDURE

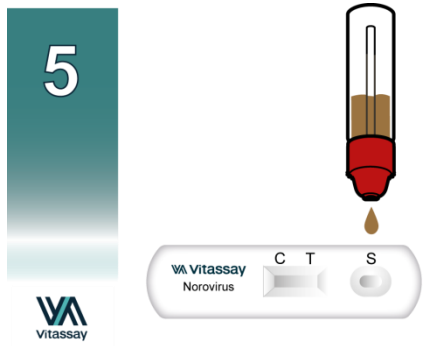
Allow the test, stool sample, controls and diluent to reach room temperature (15-30ºC/59-86ºF) prior to testing. Do not open pouches until the performance of the assay.

1. Shake the vial with the sample to obtain a good sample dilution.
2. Remove the **Vitassay Norovirus** from its sealed bag just before using it.
3. Take the vial containing the diluted sample, cut the end of the cap (figure 4) and dispense 4 drops in the circular window marked with the letter S (figure 5).
4. Read the results at **10 minutes**. Do not read the results later than 10 minutes.

If the test does not run due to solid particles, stir the sample added in the sample window with the stick. If it does not work, dispense a drop of diluent until seeing the liquid running through the reaction zone.




Cut the end of the cap.




Dispense 4 drops in the circular window marked with the letter S.

## INTERPRETATION OF THE RESULTS

| | | |
|---|---|---|
|  | **NEGATIVE**<br>Only one **green** line in the control zone **(C)**. | There is no norovirus presence. No infection caused by norovirus. |
|  | **POSITIVE**<br>In addition to the **green** line (**control line C**), a **red** line appears (**test line T**). | There is presence of norovirus. Infection caused by norovirus. |
| **ANY OTHER RESULTS** | | Invalid result, we recommend repeating the assay using the sample with another test. **Note:** Wrong procedural techniques or deterioration of the reagents are mostly the main reasons for control line failure. If the symptoms or situation persist, discontinue using the test kit and contact your local distributor. |

**Notes:** The intensity of the red colored test line in the result line zone (T) will vary depending on the concentration of antigens in the specimen.

## QUALITY CONTROL

Internal procedural control is included in **Vitassay Norovirus**. Green line appearing in the results window is an internal control, which confirms sufficient specimen volume and correct procedural technique.

## LIMITATIONS

- **Vitassay Norovirus** must be carried out within 2 hours of opening the sealed bag.
- An excess of stool sample could cause wrong results (brown bands appear). Dilute the sample with the diluent and repeat the test.



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- The intensity of test line may vary depending on the concentration of antigens.
- The use of other samples different from human samples has not been established.
- The quality of **Vitassay Norovirus** depends on the quality of the sample; Proper fecal specimens must be obtained.
- Positive results determine the presence of norovirus (GI and/or GII) in fecal samples. A positive result should be followed up with additional laboratory techniques (biochemical methods or PCR) to confirm the results. A confirmed infection should only be made by a physician after all clinical and laboratory findings have been evaluated and must be based in the correlation of the results with further clinical observations.
- Negative results should not be considered as conclusive; it is possible that the concentration of antigens is lower than the detection limit value. If symptoms or situation still persist, a norovirus determination should be carried out with another technique (for example: PCR).

## EXPECTED VALUES

Noroviruses are the leading cause of epidemic and sporadic cases of acute gastroenteritis worldwide and a leading cause of foodborne disease.

The majority of Norovirus outbreaks occur in health care settings (including long-termcare facilities and hospitals), where the virus is predominantly spread from person to person. In addition, noroviruses have also been identified in over 58% of the reported foodborne outbreaks in which an etiologic agent was determined. In the most recent disease burden estimates in the United Satetes (US), noroviruses causes 570 to 800 deaths, 56,000 to 71,000 hospitalizations, 400,000 emergency room visits, and 1.7 to 1.9 million outpatient visits anually. In pediatric populations in industrialized countries where a rotavirus vaccine has been introduced, norovirus are rapidly replacing rotavirus as the most common cause of medically attended acute gastroenteritis.

In countries that belong to temperate latitudes, most infections occur in the fall and winter and at least 70% of outbreaks are reported in semiclosed communities such as long-term-care facilities, schools, hospitals, and cruise ships.

## PERFORMANCE CHARACTERISTICS

### Clinical sensitivity and specificity

An evaluation with fecal samples was performed using **Vitassay Norovirus** and these results were compared with a commercial available immunochromatographic test (Simple Norovirus, Operon) and confirmed by PCR.

Results were as follows:

| | | Simple Norovirus | | |
|---|---|---|---|---|
| | | Positive | Negative | Total |
| **Vitassay Norovirus** norovirus GI | Positive | 2 | 0 | 2 |
| | Negative | 0 | 48 | 48 |
| | Total | 2 | 48 | 50 |

| **Vitassay Norovirus** (norovirus GI) **vs Simple Norovirus** | | | |
|---|---|---|---|
| Sensitivity | Specificity | PPV | NPV |
| >99% | >99% | >99% | >99% |

| | | PCR | | |
|---|---|---|---|---|
| | | Positive | Negative | Total |
| **Vitassay Norovirus** norovirus GI | Positive | 2 | 0 | 2 |
| | Negative | 0 | 48 | 48 |
| | Total | 2 | 48 | 50 |

| **Vitassay Norovirus** (norovirus GI) **vs PCR** | | | |
|---|---|---|---|
| Sensitivity | Specificity | PPV | NPV |
| >99% | >99% | >99% | >99% |

| | | Simple Norovirus | | |
|---|---|---|---|---|
| | | Positive | Negative | Total |
| **Vitassay Norovirus** norovirus GII | Positive | 10 | 0 | 10 |
| | Negative | 0 | 48 | 48 |
| | Total | 10 | 48 | 58 |

| **Vitassay Norovirus** (norovirus GII) **vs Simple Norovirus** | | | |
|---|---|---|---|
| Sensitivity | Specificity | PPV | NPV |
| >99% | >99% | >99% | >99% |

| | | PCR | | |
|---|---|---|---|---|
| | | Positive | Negative | Total |
| **Vitassay Norovirus** norovirus GII | Positive | 8 | 0 | 8 |
| | Negative | 2 | 48 | 50 |
| | Total | 10 | 48 | 58 |

| **Vitassay Norovirus** (norovirus GII) **vs PCR** | | | |
|---|---|---|---|
| Sensitivity | Specificity | PPV | NPV |
| 80% | >99% | >99% | 96% |

The results showed that **Vitassay Norovirus** has a high sensitivity and specificity to detect norovirus (GI and GII).

### Cross reactivity

No cross reactivity was detected against gastrointestinal pathogens that are occasionally present in feces:

| | | |
|---|---|---|
| *Adenovirus* | *Hepatitis A* | *Salmonella typhi* |
| *Astrovirus* | *Giardia lamblia* | *Shigella boydii* |
| *Campylobacter coli* | *Helicobacter pylori* | *Shigella dysenteriae* |
| *Campylobacter jejuni* | *Listeria monocytogenes* | *Shigella flexneri* |
| *Clostridium difficile* | *Rotavirus* | *Shigella sonnei* |
| *Cryptosporidium parvum* | *RSV* | *Staphylococcus aureus* |
| *Enterovirus* | *Salmonella enteritidis* | *Yersinia enterocolítica* |
| *Escherichia coli O111* | *Salmonella paratyphi* | |
| *Escherichia coli O157:H7* | *Salmonella typhimurium* | |

## REFERENCES

1. JAN VLNJÉ. "Advances in Laboratory Methods for Detection and Typing of Norovirus". Journal of Clinical Microbiology 53:373-381. 2015.

## SYMBOLS FOR IVD COMPONENTS AND REAGENTS

| | | | |
|---|---|---|---|
| IVD | *in vitro* diagnostic device | | Keep dry |
| | Consult instructions for use | | Temperature limitation |
| | Use by | | Manufacturer |
| LOT | Batch code | Σ n | Contains sufficient for <n> test |
| DIL | Sample diluent | REF | Catalogue number |



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