INTENDED USE

IMMUNOQUICK® NOROVIRUS is a rapid chromatographic immunoassay for the qualitative detection of Genogroup 1 and Genogroup 2 Norovirus antigens in stool specimens.

INTRODUCTION

Noroviruses (NoV) are a genetically diverse group of single stranded RNA, nonenveloped viruses belonging to the Caliciviridae family. For decades they were called "small round structured viruses" (SRSV) or "Norwalk-like viruses" until recently when their taxonomy was investigated using modern molecular techniques. Initially four antigenic types of SRSV were recognized, but more recently three genogroups have been identified with the genus Norovirus. Genogroup 1 and Genogroup 2 are associated with human infections whilst Genogroup 3 is associated with bovine and porcine infection.

Noroviruses are a major cause of acute gastroenteritis worldwide, often causing explosive outbreaks in institutions. They are highly contagious, with an incubation of as few as ten particles being able to cause infection. Transmission occurs through ingesting contaminated food and water and by person-to-person spread. Transmission is predominantly faecal-oral but may be airborne due to aerosolisation of vomitus, which typically contains abundant infectious virus particles. Outbreaks may involve several routes of transmission. The illness is acute, usually mild, although it has caused fatalities among the frail elderly, and self-limiting and follows an incubation period of 24-48 hours although cases can occur within 12 hours of exposure. The ability of Noroviruses to cause outbreaks in institutions has become a major public health issue. Outbreaks of Norovirus infection can be associated with restaurants and institutions as diverse as nursing homes, hospitals and elite sporting camps. Infections in infants, elderly or frail patients can be fatal if left untreated.

The symptoms of Norovirus illness usually include nausea, vomiting, diarrhea, and some stomach cramping. Sometimes people also have a low-grade fever, chills, headache, muscle aches, and a general sense of tiredness. The illness often begins suddenly, and the infected person may feel very sick. In most people the illness is self-limiting with symptoms lasting for about 1 or 2 days. In general, children experience more vomiting than adults.

TEST PRINCIPLE

IMMUNOQUICK® NOROVIRUS is a qualitative, lateral flow immunoassay for the detection of Norovirus antigens in stool. The assay uses Genogroup 1 and Genogroup 2 specific monoclonal antibodies coated on the test membrane. During testing, the stool specimen reacts with the conjugate antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with Genogroup 1 and 2 antibodies on the membrane and generates a colored line at the level of the T1 and T2 zone respectively. The presence of a colored line in T1 region indicates a positive result for Genogroup 1 and in T2 region for Genogroup 2 respectively, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control reaction zone (C) indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIAL PROVIDED

- Test devices conditioned in individuals pouches.
- Swabs.
- Tubes.
- Vial of diluent (10mL).
- Instruction for use.

MATERIAL REQUIRED BUT NOT PROVIDED

- Micropipette.
- Clock or timer.
- Centrifuge.

STORAGE AND STABILITY

IMMUNOQUICK® NOROVIRUS should be stored between 2- 30°C. Test is sensitive to humidity as well as to heat. It is stable until expiration date printed on the bag. Cassettes must be kept in their bags until use. DO NOT FREEZE. Do not use beyond expiration date, indicated on the kit and the aluminum bags.

PRECAUTIONS

- For in vitro diagnostic use only.
- Samples and reagents should be brought to room temperature before running the test.
- Do not use the test beyond the expiry date. Use of the test beyond the expiry date may lead to incorrect results.
- Do not pipet samples or reagents by mouth.
- Follow the product insert instructions carefully.
- Do not split the specimens into the reaction zone.
- Avoid cross-contamination of specimens by using a new extraction tubes and specimen pipette for each specimen.
- Remove the test cartridge from its sealed pouch just before running the test, due to humidity sensitive of the test.
- Do not eat, drink or smoke when operating samples or reagents.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Avoid splashes and aerosol formation.
- Humidity and temperature can adversely affect results.
- The test is intended for single use only, do not reuse.
- Handle all specimens as if they contained infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens and contaminated devices.

SAMPLE COLLECTION AND HANDLING

- Testing should be performed immediately after the specimens have been collected. For prolonged periods of storage, the specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing.
- Specimens should not be frozen and thawed repeatedly.
- In case of shipment of samples, regulatory rules related to shipment of samples of human origin should be followed.

TEST PROCEDURE

The specimens and tests should be brought to room temperature for at least 15-30 min at room before testing.

1. Specimen extraction

- Add 0.8 mL of diluent into the tube.
- Using the swab, collect the stool specimens as per below picture (about 25 to 50 mg or 25 to 50 µL. In the case of liquid feces).
- Thoroughly mix specimen with diluent using a vortex.
- The resultant supernatant is used as sample.

- Optimum specimen quantity (25 to 50 mg)
- Insufficient specimen quantity
- Too much specimen quantity
2. Reaction
- Remove the test device from the foil pouch, and place it on a clean and flat surface.
- Transfer 80µL of supernatant of the extracted specimen into the sample well.
- Read the test result at 15 minutes. Do not interpret test result after 20 minutes.

RESULTS INTERPRETATION

POSITIVE: The presence of two color lines at T1 and C zones within the result window indicates a positive result. Presence of Norovirus genogroup I in the sample has been detected. The presence of two color lines at T2 and C zones within the result window indicates a positive result. Presence of Norovirus genogroup II in the sample has been detected.

NEGATIVE: The presence of only control line in the control reaction zone (C) and no line at the level of the Test zone T1 and T2 indicates a negative result.

INVALID: If no control line appears in the result window after performing test, the result is considered invalid. The instructions may not have been followed correctly or the strip may have been deteriorated. It is recommended that the specimen be re-tested with a new device.

QUALITY CONTROL

An internal control of procedure is integrated into the test (control line (C)). That makes it possible to control that the volume of supernatant is sufficient and that the procedure was followed correctly.

LIMITATIONS OF PROCEDURE

- This test should be used for the detection of Norovirus antigens in human stool only.
- IMMUNOQUICK® NOROVIRUS will only indicate the presence of Norovirus antigens in the specimen and should not be used as the sole criteria for the Norovirus infection diagnosis.
- Stool sample from infant under one year old can produce a false positive result.
- As with all diagnostic tests, result must be considered together with other clinical information available to the physician.
- If the test result is negative and clinical symptoms persist, additional follow-up testing using other clinical methods is suggested. A negative result at any time does not preclude the possibility of Norovirus infection.
- In case of migration issue when using a sample with high amount of feces or high viscosity, centrifuge the diluted specimen at 3000xg for 10 minutes.

PERFORMANCES

1. Reactivity: IMMUNOQUICK® NOROVIRUS detects two genogroups of Norovirus:
   - Genogroup I, including genotypes 1, 4, 8, and 11.
   - Genogroup II including genotypes 1, 2, 3, 4, 5, 6, 7, 12, 13, 14, and 15.

2. Cross reactivity: No cross-reactivity was shown with Rotavirus, Adenovirus, Sapovirus and Astrovirus.

3. Detection threshold: The minimum detectable sensitivity of IMMUNOQUICK® NOROVIRUS is about 1 x 10⁻⁸ copies or 6.25ng/mL of VLP (virus like particle) from genogroup I.1 and II.4.

4. Sensitivity specificity: A comparison study with the RT-PCR method was performed.

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<thead>
<tr>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Positive predictive value</th>
<th>Positive predictive value</th>
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<tr>
<td>Tp / (Tp + Fn)</td>
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<td>Tp / (Tp + Fn)</td>
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<td>95.65%</td>
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BIBLIOGRAPHY


SYMBOLS

Attention, see instructions for use
LOD Lot number
In vitro diagnostic use only
Manufacturer
Store between -2-30°C
Do not reuse
Tests per kit
Catalog number
Expiry
Diluent

IFU_1150010_BR_V02201803R01