Test procedure for RIDA®QUICK Norovirus

Remove the required number of test cassettes after all kit components and stool specimens have reached room temperature (20 - 25°C).

1. First add 0.5 ml (approx. 12 - 14 drops) of Reagent A (blue) and then 0.5 ml (approx. 12 - 14 drops) of Reagent B (yellow) in the graduated reaction vial.

2. Add 50 mg or 50 µl of stool specimen to the vial using the Pasteur pipette included in the kit. Mix well after sealing the reaction vial tightly.

3. Place the reaction vial containing the homogenized sample (stool) in the reaction vial holder (reagent tray) and allow the contents to settle for 5 minutes at room temperature.

4. Using the microliter pipette included in the test kit, apply 150 µl of the supernatant to the application field on the test cassette. The test cassette should be placed on a horizontal surface for this.

5. Read the results after 15 minutes.

Interpretation

<table>
<thead>
<tr>
<th>Result</th>
<th>Symbol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>✓</td>
</tr>
<tr>
<td>Negative</td>
<td>✗</td>
</tr>
<tr>
<td>Invalid</td>
<td>❌</td>
</tr>
<tr>
<td>Invalid</td>
<td>❌</td>
</tr>
</tbody>
</table>

Order number:
RIDA®QUICK Norovirus N1402 25 determinations

RIDA®QUICK Norovirus
Innovative rapid test in new design

- Progress in reliability at simplified work flow
- Highly sensitive detection of Noroviruses from both human pathogenic genogroups (GG I and GG II) in one specimen
- None additional sample dilution necessary
- Lateral flow technology makes it possible to perform rapid one-site screening and to store the test kit at room temperature (2 - 25 °C)
- The kit contains all materials needed for near-patient testing
- Reliable results in only 15 minutes
Information on Noroviruses

Noroviruses are a major cause of gastroenteritis world-wide with an estimated 23 million cases a year only in the USA. They are frequently involved in outbreaks in community settings, such as nursing homes, hospitals, day care centers and prisons, and on cruise ships. Outbreaks caused by Noroviruses are reported more often than outbreaks caused by bacterial pathogens and they have a considerable impact on public health. The RIDA®QUICK Norovirus test, which is based on monoclonal antibodies, makes it possible to determine Norovirus antigens in stool samples quickly and reliably and therefore speeds up patient management. The quick test is an easy and sensitive method for determining the antigens of both Genogroups I and II of the Norovirus. It is particularly suitable for use on small sample series.

Timely diagnosis

The most useful measures are early diagnosis followed by the appropriate hygiene interventions. For instance, diagnosis within three days instead of four days of the first case reduces outbreak duration by seven days (Lopman BA et al. 2004, Emerg Infect Dis 10: 1827-1834).

Diagnostics

Immunological tests like the RIDA®QUICK Norovirus rapid test are simple and easy to perform. High specific results are read visually in 15 minutes. The results help to investigate acute gastroenteritis events and to prevent further expanding of them. This near-patient test is equally suitable for microbiology laboratories, nursing homes and even for cruise ship operators, as there is no need for special laboratory equipment. All components needed for safe performance are provided with the kit, which can be stored also at room temperature.

Test quality

In a validation study, RIDA®QUICK Norovirus was performed with 75 stool samples (fresh and frozen asserved stool specimen) in comparison to real time RT-PCR for Noroviruses of both genogroups (GG I and GG II). The results are shown in the table below.

<table>
<thead>
<tr>
<th>real time RT-PCR</th>
<th>positive</th>
<th>negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>RIDA®QUICK Norovirus</td>
<td>positive: 23, negative: 1</td>
<td></td>
</tr>
<tr>
<td>negative: 2, positive: 49</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

RIDA®QUICK Norovirus

<table>
<thead>
<tr>
<th></th>
<th>Sensitivity: 92.0 %</th>
<th>Specificity: 98.0 %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PPV: 95.8 %</td>
<td>NPV: 96.0 %</td>
</tr>
</tbody>
</table>

Kit components

Point of diagnosis

Outbreak duration

Day 1

Day 2

Day 3

Day 4

Stop