Intended Use

The Rotavirus/Adenovirus Ag Rapydtest® is a lateral flow immunoassay for the qualitative detection and differentiation of rotavirus and adenovirus antigens in faecal specimens. This device is intended to be used as a screening test and as an aid in the diagnosis of infection with rotavirus and adenovirus.

Performance Characteristics

Clinical Performance

<table>
<thead>
<tr>
<th>REFERENCE TEST</th>
<th>POSITIVE</th>
<th>NEGATIVE</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>POSITIVE</td>
<td>36</td>
<td>0</td>
<td>36</td>
</tr>
<tr>
<td>NEGATIVE</td>
<td>2</td>
<td>69</td>
<td>71</td>
</tr>
<tr>
<td>TOTAL</td>
<td>38</td>
<td>69</td>
<td>107</td>
</tr>
</tbody>
</table>

Clinical Performance of rotavirus specimens: 107 faecal samples collected from subjects with symptomatic diarrhoea and non-diarrhoea symptoms were tested with the Rotavirus/Adenovirus Ag Rapydtest® and with a reference rapid test. Comparison for all subjects is shown in the table.

Relative Sensitivity: 100%
Relative Specificity: 97.2%
Overall Agreement: 98.1%

<table>
<thead>
<tr>
<th>REFERENCE TEST</th>
<th>POSITIVE</th>
<th>NEGATIVE</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
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<td>10</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>NEGATIVE</td>
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<td>95</td>
<td>97</td>
</tr>
<tr>
<td>TOTAL</td>
<td>12</td>
<td>95</td>
<td>107</td>
</tr>
</tbody>
</table>

Clinical Performance of adenovirus specimens: samples collected from subjects with symptomatic diarrhoea and non-diarrhoea symptoms were tested with the Rotavirus/Adenovirus Ag Rapydtest® and with a reference rapid test. Comparison for all subjects is shown in the table.

Relative Sensitivity: 100%
Relative Specificity: 97.9%
Overall Agreement: 98.1%
Reagents and Materials Provided
1. Individually sealed foil pouches containing:
   a. One cassette test device.
   b. One desiccant.
2. Stool collection devices, each containing 2ml of extraction buffer.
4. One package insert (instruction for use).

Specimen Collection and Handling
Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

Procedure for Stool Sample Collection

Test Procedure

Do not read results after 20 minutes. To avoid confusion, discard the test device after interpreting the result.

Interpretation of Assay Result

1. Negative Result:
   If only the C band is developed, the test indicates that the level of rotavirus Ag and adenovirus Ag in the specimen is undetectable. The result is negative.

2. Positive Result:
   In addition to the presence of the C band, if the R band is developed, the test indicates that the specimen contains rotavirus Ag. The result is rotavirus Ag positive.
   In addition to the presence of the C band, if the A band is developed, the test indicates that the specimen contains adenovirus Ag. The result is adenovirus Ag positive.
   In addition to the presence of the C band, if both the R band and the A band are developed, the result indicates the specimen contains both rotavirus Ag and adenovirus Ag. The result is both rotavirus Ag and adenovirus Ag positive.

3. Invalid
   If no C band is developed, the test is invalid regardless of any colour development in the R band or A band as indicated below. Repeat the assay with a new device.

References