of rotavirus in faecal specimens. Strains may be further
offer a rapid, sensitive and specific method for the detection
gastroenteritis in young children throughout the world3,4,5,6,7.
Human serotypes of Group A rotavirus are a major cause of
elderly populations8,9,10. The virus is commonly associated with
outbreaks in nosocomial infections in paediatric wards and neonatal nurseries.
The laboratory diagnosis of rotavirus infections plays an important
role in patient management and effective management and control of outbreaks. At present human serotypes of rotavirus do not grow readily in cell culture systems, hence they are difficult to isolate from faecal specimens. However, the laboratory diagnosis of rotavirus infections relies on direct detection of the virus in viral antigens in faecal specimens. This can be performed using electron microscopy to detect the virus or viral antigens, or by polyethylene glycol precipitation or RNase A of the rotavirus genome3,15,16,17. These procedures are technically demanding and require specific equipment which limits their application.3

2 SUMMARY

Rotavirus are non-enveloped RNA viruses of subfamily
symmetry consisting of a spherical inner core and two outer
capsid shell’. At least seven serogroups (A-G) within the genus
Rotavirus have been identified11,12.

Human serotypes of Group A rotavirus are a major cause of
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3 PRINCIPLE OF THE TEST

The ProSpecT Rotavirus test is an immunocapture assay for the detection
and quantitation of Group A rotavirus in human faecal samples, as an aid in the diagnosis of acute gastroenteritis caused by Group A rotavirus.

4 SYMBOl DEFINITIONS

4.1 The ProSpecT Rotavirus test is a qualitative enzyme immunoassay
for the detection of rotavirus (Group A) in human faecal samples,
and control of outbreaks. At present human serotypes of rotavirus
and control of outbreaks. At present human serotypes of rotavirus
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5 KIT CONTENTS, PREPARATION FOR USE AND STORAGE

The ProSpecT Rotavirus Microplate Assay includes sufficient reagents to perform 
96 Tests.

6 PRECAUTIONS

6.1 The Positive Control contains inactivated bovine rotavirus
in phosphate buffered saline solution. Store at 4°C or<br>

The Colour Substrate should be stored in<br>
and used from the light protected brown bottle. The colour<br>
substrate should be used within 30 minutes of addition of<br>
using the light protected brown bottle. The colour<br>
substrate should be used within 30 minutes of addition of<br>
using the light protected brown bottle. The colour

7 COLLECTION OF Fecal SPECIMENS

Fecal specimens should be collected as soon as possible following the onset of symptoms. Peak excretion levels of rotavirus in faeces from patients with gastroenteritis is reported to occur 3-5 days after the onset of the symptoms. Fecal specimens for direct testing should be collected into containers that do not contain media, preservatives, animal<br>
materials, oxidising agents, or detergent. As all of these additives may reduce the sensitivity of the test. If rectal swabs are collected they must contain sufficient faecal material to contain a 10% suspension of faeces to testing. (See Section 8). Specimens should be tested within 48 hours of collection, if not, test results may be uninterpretable.

8 PROCEDURE

8.1 Transfer faecal specimen to a polypropylene microtube containing the<br>

8.4 Add 2 drops (or 100 µl) of each diluted specimen to the<br>

9 QUALITY CONTROL

At least one Positive and one Negative Control must be included in each test batch. 10

10 RESULTS

10.1 The microfluidic device would be read photographically within 30 minutes. For professional use only.

11 PERFORMANCE

11.1 The sensitivity of the ProSpecT Rotavirus Microplate Assay depends on the control reactions being performed as expected. See Quality Control Section 8. The ProSpecT Rotavirus Microplate Assay may be adversely affected if a combination of<br>

12 EXPECTED VALUES

Prospects of detecting rotavirus of different species or
areas of rotavirus in faecal specimens. Strains may be further
offer a rapid, sensitive and specific method for the detection
gastroenteritis in young children throughout the world3,4,5,6,7.
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PreciseT Rotavirus test was evaluated in clinical studies performed at three centres in the UK. Studies were conducted on faecal specimens taken from patients presenting with gastroenteritis. The results of the PreciseT Rotavirus test were compared with Electron Microscopy (EM) and a commercial enzyme immunoassay (EIA) for the direct detection of rotavirus in faecal specimens.

A total of 201 faecal specimens were tested. The results of these studies are shown in Table 13.1.

**CLINICAL PERFORMANCE**

The PreciseT Rotavirus test, when read photometrically, showed a correlation of 99.5% (199/201) with Electron Microscopy and 99.0% (199/201) with a commercial EIA. The overall sensitivity and specificity of the PreciseT Rotavirus test, when compared to EM, was 100% (77/77) and 92.9% (222/229) respectively. The relative sensitivity and relative specificity when compared to the commercial EIA was 98.7% (77/78) and 99.0% (222/223) respectively (see Table 13.1). The same specimens were also interpreted visually and the data is presented in Table 13.2.

### Table 13.1 Comparison of PreciseT Rotavirus (photometric determination) with Electron Microscopy and EIA

<table>
<thead>
<tr>
<th>Method</th>
<th>EM</th>
<th>EIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive Rotavirus</td>
<td>92</td>
<td>92</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>100%</td>
<td>98.7%</td>
</tr>
<tr>
<td>Specificity</td>
<td>98.4%</td>
<td>98.4%</td>
</tr>
<tr>
<td>95% Confidence intervals</td>
<td>(95%-100%)</td>
<td>(93%-100%)</td>
</tr>
<tr>
<td>Correlation</td>
<td>99.0%</td>
<td>99.2%</td>
</tr>
<tr>
<td>95% Confidence intervals</td>
<td>(94%-100%)</td>
<td>(97%-100%)</td>
</tr>
</tbody>
</table>

### Table 13.2 Comparison of PreciseT Rotavirus (visual interpretation) with Electron Microscopy and EIA

<table>
<thead>
<tr>
<th>Method</th>
<th>EM</th>
<th>EIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive Rotavirus</td>
<td>90</td>
<td>90</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>100%</td>
<td>98.7%</td>
</tr>
<tr>
<td>Specificity</td>
<td>98.4%</td>
<td>98.4%</td>
</tr>
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</tr>
<tr>
<td>95% Confidence intervals</td>
<td>(94%-100%)</td>
<td>(97%-100%)</td>
</tr>
</tbody>
</table>

### Table 13.3 Premodification of the ProSpecT Rotavirus test

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Negative Control</th>
<th>Positive Control</th>
<th>Positive faecal specimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status</td>
<td>Mean</td>
<td>%CV</td>
<td>Mean</td>
</tr>
<tr>
<td>Negative Control</td>
<td>0.06</td>
<td>4.8</td>
<td>0.06</td>
</tr>
<tr>
<td>Positive Control</td>
<td>1.00</td>
<td>5.7</td>
<td>1.10</td>
</tr>
<tr>
<td>Positive faecal specimen</td>
<td>0.06</td>
<td>4.8</td>
<td>0.06</td>
</tr>
<tr>
<td>Positive faecal specimen</td>
<td>0.06</td>
<td>4.8</td>
<td>0.06</td>
</tr>
<tr>
<td>Positive faecal specimen</td>
<td>0.06</td>
<td>4.8</td>
<td>0.06</td>
</tr>
</tbody>
</table>

### CROSS-REACTIVITY

The following micro-organisms were tested and shown to be negative in the PreciseT Rotavirus test. Cross-reaction tests were performed either on clinical specimens for which the microbial status had been determined, or on laboratory cultures of known organisms, containing approximately 10^7-10^8 viable organisms/ml. The source of micro-organisms is referenced in the key below:

**Viruses**
- Adenovirus 1, 2, 3, 5, 7, 11, 14, 22, 40, 41
- Coxsackie A and B4
- Echovirus 9, 11, 18, 22, 32
- Polio virus types 1, 2, 3
- Small round structured viruses (including Calichi virus)

**Bacteria**
- Aeromonas spp
- Campylobacter jejuni
- Clostridium perfringens (toxin)
- Corynebacterium spp
- Enteropathogenic E. coli
- Lactobacillus spp
- Listeria monocytogenes
- Pseudomonas aeruginosa
- Salmonella enteritidis
- Staphylococcus aureus
- Streptococcus pneumoniae
- Stomatococcus macedonicus
- Trichuris trichiura

**Staphylococcus aureus**
- [protein A producing Cowan strain]

**Streptococcus group A**
- [viridans strain]

**Stomatococcus macedonicus**
- [viridans strain]

**Protozoa**
- Cryptosporidium spp
- Entamoeba histolytica
- Giardia lamblia
- Other micro-organisms
  - [amebae]
  - [amoebae]

**Key**
- * micro-organisms present and tested in faeces
- † binary material
- ‡ micro-organisms grown on solid culture media
- § micro-organisms tested both in faeces and in broth culture

All other micro-organisms were tested in broth culture.