5. PROCEDURES

5.1. Preparation of the sample for testing

5.1.1. In the case of broth enrichment specimens, the broth culture should be centrifuged at 1000 x g for 10 minutes to remove cells, if required.

5.1.2. Transfer 0.3 ml broth culture into 0.6 ml Bacterial Specimen Buffer. Place a transfer pipette to the tube and mix tube gently to mix the contents by drawing up and down once. Leave the transfer pipette in the tube.

5.2. Sample preparation

5.2.1. For liquid stools, semi-solid stools use a transfer pipette to add equal volumes of specimen to the tip of the pipette. Expel sample into Bacterial Specimen Buffer contained in the microplate and mix with the contents by drawing up and down once. Leave the transfer pipette in the tube.

5.2.2. For faecal-oral route has also been reported as well as drinking

6. PRECAUTIONS

6.1. The ProSpecT Campylobacter Microplate Assay does not detect the presence of Campylobacter or its absence in a sample. A negative test result does not indicate that Campylobacter SA is not present in the sample. Indeterminate: O.D. readings that are in the indicated indeterminate range. Repeat test results are always negative, the specimen is negative. If the repeat test results are given an O.D. reading that is consistent with the visual interpretation check the sample with a different supplier to confirm the negative result. If the discrepancy between visual and O.D. readings is repeated, the test result is negative. If the repeat test results are suspect or an undetectable level of Campylobacter SA is present in the sample.

7. PERFORMANCE LIMITATIONS

7.1. The ProSpecT Campylobacter Microplate Assay does not detect the presence of Campylobacter jejuni or Campylobacter coli in the sample.

8. SECURITY

8.1. The ProSpecT Campylobacter Microplate Assay is an INB III/IV microplate enzyme immunoassay kit which is intended for detection of Campylobacter Specific Antigen in faecal specimens and broth enriched faecal cultures. ProSpecT Campylobacter Microplate Assay is intended for use in an aid in the diagnosis of Campylobacter infections.

9. ENSUING TESTS

9.1. The ProSpecT Campylobacter Microplate Assay depends on the control reaction performing as expected. See Quality Control section 9.2.

10. DISPOSAL

10.1. Integration of spectrophotometric results: Positive: If a negative test result indicates that the specimen tested is positive for single wavelength or dual wavelength by specimen type is positive and indicates the presence of Campylobacter SA. Negative: O.D. readings that are in the indicated indeterminate range. Repeat test results are always negative, the specimen is negative. Indeterminate: O.D. readings that are in the indicated indeterminate range. Repeat test results are always negative, the specimen is negative. If the repeat test results are given an O.D. reading that is consistent with the visual interpretation check the sample with a different supplier to confirm the negative result. If the discrepancy between visual and O.D. readings is repeated, the test result is negative. If the repeat test results are suspect or an undetectable level of Campylobacter SA is present in the sample. Indeterminate: O.D. readings that are in the indicated indeterminate range. Repeat test results are always negative, the specimen is negative. If the repeat test results are given an O.D. reading that is consistent with the visual interpretation check the sample with a different supplier to confirm the negative result. If the discrepancy between visual and O.D. readings is repeated, the test result is negative. If the repeat test results are suspect or an undetectable level of Campylobacter SA is present in the sample.

11. SECURITY

11.1. The ProSpecT Campylobacter Microplate Assay does not detect the presence of Campylobacter or its absence in a sample. A negative test result does not indicate that Campylobacter SA is not present in the sample.

12. QUALITY CONTROL

12.1. Quality control must be included every time the test is performed. Both Positive and Negative controls should be included with every series of tests. Controls must be used at both the beginning and after every 30 tests. Controls should be checked for substantial reagent failure. The Positive control will not be able to read the test visually and should use a spectrophotometric reader to interpret results. The optical density (OD) of the Positive Control should be 0.150 ± 0.050. Positive results remain indeterminant another specimen should be obtained and tested.

13. RESULTS

13.1. Read the test results by comparing with the reaction columns on the Procedure Card. Positive results remain indeterminant another specimen should be obtained and tested.

14. SPECIMENS

14.1. Read results at either single (96 wells) or dual wavelength by specimen type is positive and indicates the presence of Campylobacter SA. Negative: O.D. readings that are in the indicated indeterminate range. Repeat test results are always negative, the specimen is negative. Indeterminate: O.D. readings that are in the indicated indeterminate range. Repeat test results are always negative, the specimen is negative. If the repeat test results are given an O.D. reading that is consistent with the visual interpretation check the sample with a different supplier to confirm the negative result. If the discrepancy between visual and O.D. readings is repeated, the test result is negative. If the repeat test results are suspect or an undetectable level of Campylobacter SA is present in the sample. Indeterminate: O.D. readings that are in the indicated indeterminate range. Repeat test results are always negative, the specimen is negative. If the repeat test results are given an O.D. reading that is consistent with the visual interpretation check the sample with a different supplier to confirm the negative result. If the discrepancy between visual and O.D. readings is repeated, the test result is negative. If the repeat test results are suspect or an undetectable level of Campylobacter SA is present in the sample.

15. PERFORMANCE LIMITATIONS

15.1. The validity of the results with the ProSpecT Campylobacter Microplate Assay will depend on the quality of the sample as it is expected. See Quality Control section 9.2.

16. REPORTING

16.1. The ProSpecT Campylobacter Microplate Assay does not detect the presence of Campylobacter or its absence in a sample. A negative test result does not indicate that Campylobacter SA is not present in the sample.
identified in 1.5% of the specimens, Salmonella in 1.25% and Shigella in 0.5%. Prevalence rates for E. coli in the United States range from 1.0 to 4.6%. Rates as high as 2.9% were also found in a 4-year study in Betterman.

13. PERFORMANCE CHARACTERISTICS

SENSITIVITY AND SPECIFICITY

The ProSpecT Campylobacter Microplate Assay was evaluated at three geographically distinct clinical sites in the United States and Canada. The sites were a Metropolitan Hospital in Illinois, a large reference laboratory in New Jersey, and a centralized testing laboratory in Ontario, Canada. All specimens were tested by culture and biochemical assays to confirm a positive isolate of Campylobacter. The results at each of the test sites after repeating indeterminate results and discrepant reading results as indicated by the instructions in this Instruction for Use are presented in Table 1.

Table 1. ProSpecT Campylobacter Microplate Assay compared with Culture Assays on direct stool specimens.  

<table>
<thead>
<tr>
<th>Site</th>
<th>ProSpecT</th>
<th>Microplate</th>
<th>Assay</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site 1</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Site 2</td>
<td>99.2%</td>
<td>99.2%</td>
<td>99.2%</td>
<td>99.2%</td>
<td>99.2%</td>
</tr>
<tr>
<td>Site 3</td>
<td>98.5%</td>
<td>98.5%</td>
<td>98.5%</td>
<td>98.5%</td>
<td>98.5%</td>
</tr>
</tbody>
</table>

The inter-assay or run-to-run coefficient of variation (CV) of the ProSpecT Campylobacter Microplate Assay was evaluated by testing laboratory in Ontario, Canada. All specimens were tested at three geographically distinct clinical sites in the United States and Canada. The sites were a Metropolitan Hospital in Illinois, a large reference laboratory in New Jersey, and a centralized testing laboratory in Ontario, Canada. All specimens were tested by culture and biochemical assays to confirm a positive isolate of Campylobacter. The results at each of the test sites after repeating indeterminate results and discrepant reading results as indicated by the instructions in this Instruction for Use are presented in Table 1.

Table 2. Results with Combined Data from three Clinical Trial Sites on direct stool specimens.  

<table>
<thead>
<tr>
<th>Site</th>
<th>ProSpecT</th>
<th>Microplate</th>
<th>Assay</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site 1</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Site 2</td>
<td>99.6%</td>
<td>99.6%</td>
<td>99.6%</td>
<td>99.6%</td>
<td>99.6%</td>
</tr>
<tr>
<td>Site 3</td>
<td>97.5%</td>
<td>97.5%</td>
<td>97.5%</td>
<td>97.5%</td>
<td>97.5%</td>
</tr>
</tbody>
</table>

The specificity of the ProSpecT Campylobacter Microplate Assay was evaluated by selecting one negative and three positive samples with varying levels of antigen. Sensitivity and specificity were 90.0% (55.5 - 99.9%) and 99.4%, respectively.

14. BIBLIOGRAPHY