outbreaks 5,7,8 in the United States. Groups at particular risk or death in immunologically deficient patients6. Infection with Cryptosporidium specimens for microscopic examination. as well as to routine procedures used to collect and transport the host intestinal tract. The antigen is specific to produced by organisms as they multiply within Cryptosporidium in HIV-infected persons10, day-care centres1,2,11,12 and waterborne transmission. Acute symptoms of cryptosporidiosis patients, children and caretakers in child day-care centres, animal handlers and travellers6. Acute symptoms include diarrhoea, fever, malaise, and respiratory problems lasting from several days to months. The disease is most severe and often leads to persistent infection or death in immunocompromised patients.6. Infection with Cryptosporidium may also be asymptomatic. The Cryptosporidium antigen has been found associated with Cryptosporidium infections and have been used as the standard control antigen. The Cryptosporidium antigen (CA) detected by this kit is derived from Cryptosporidium host antigens as they multiply within the host intestinal tract. The antigen is specific to Cryptosporidium and has not been found to cross-react with other enteric parasites. The antigen is stable in transport media and intestinal tract as well as to routine procedures used to collect and transport specimens for microscopic examination.

3 PRINCIPLE OF THE TEST

Cryptosporidium Cryptosporidium Assay is a solid phase immunosorbent assay for the detection of CA.

5 KIT CONTENTS, PREPARATION FOR USE AND STORAGE

The ProSpecT Cryptosporidium Cryptosporidium Assay includes sufficient reagents to perform 75 or 300 tests. Use of the kit beyond the time limit specified may affect results.

The expiration date of each kit is stated on the package label. The kit remains stable for 18 months after the expiration date.

Before use, bring all reagents to room temperature (20 - 25°C) and mix gently. Remove the unused reagents from the refrigerator or refrigerator at any time.

All reagents, except the Wash Buffer, are supplied at working strength. Reagents are supplied ready from the 96-well microplate and need no further dilution. The Wash Buffer is supplied in a bottle in which it is provided. If an unused bottle becomes wet, a drop of incorrect volume will form around the neck of the bottle. Discard the bottle to the foil pouch with desiccant. RESEAL the required number of wells from a strip and return the unused strips to a microplate strip holder.

9 QUALITY CONTROL

The value of results with the ProSpecT Cryptosporidium Cryptosporidium Assay may be affected as expected. See Quality Control, section 9. A negative result on one hospital or clinic does not exclude the possibility of the presence of Cryptosporidium, and may occur when the antigen level in the sample is below the detection level of the test. Correlation between the amount of antigen in a sample and clinical manifestations is not established.

As with all microbiological diagnostic tests, results should be interpreted by the clinician in conjunction with clinical findings and/or other laboratory results. Proper collection and processing are essential to achieve reliable results. Optimal specimen collection from specimens tested as soon after collection as possible. See Collection of Specimen, section 7. The performance characteristics of this kit have been classified in high complexity.

12 EXPECTED VALUES

The presence of Cryptosporidium infection varies in different populations and geographic areas. In the U.S., the incidence of Cryptosporidium infection is higher in children than in adults. Cryptosporidium infection is uncommon in industrialized countries but higher in developing areas. Cryptosporidium infection is more common in patients with AIDS, and the prevalence of Cryptosporidium is higher in institutionalized populations than in the general population. The prevalence of Cryptosporidium is higher in institutionalized populations than in the general population.

13 PERFORMANCE CHARACTERISTICS

Clinical studies were conducted to evaluate the performance of the ProSpecT Cryptosporidium Cryptosporidium Assay with specimens obtained from large reference and laboratory hospitals which performed routine testing. A total of 214 specimens were tested, 81 were positive for Cryptosporidium by both kit (AP) and 17% by standard microscopic examination. Only one specimen was positive by standard microscopic examination. Only one specimen was positive by standard microscopic examination.
The ProSpecT Cryptosporidium Microplate Assay detects specific antigen (CSA) and 78 were negative. The results with the ProSpecT Cryptosporidium Microplate Assay are presented below:

<table>
<thead>
<tr>
<th>Acid Fast</th>
<th>Resolved</th>
</tr>
</thead>
<tbody>
<tr>
<td>ProSpecT</td>
<td>130</td>
</tr>
<tr>
<td>Cryptosporidium</td>
<td>78</td>
</tr>
</tbody>
</table>

Sensitivity 130/134 = 97% (92.5 - 99.2%) Specificity 78/78 = 100% (95.5 - 100%)

Numbers in parenthesis are 95% confidence intervals.

ANALYTICAL SENSITIVITY

The ProSpecT Cryptosporidium Microplate Assay detects approximately 20 nanograms/ml of CSA.

REPRODUCIBILITY

The inter assay and run-to-run coefficient of variation (CV) of the ProSpecT Cryptosporidium Microplate Assay was evaluated by selecting 10 positive specimens with varying optical density readings. Each sample was tested in 10 wells per day for five days. The mean inter assay CV was 10.0%.

CROSS-REACTIVITY

The ProSpecT Cryptosporidium Microplate Assay has been tested with stool specimens found to be O&P positive for a number of faecal parasites. No cross-reactivity was observed with any of the infectious agents listed below:

- Ascaris lumbricoides (1)
- Blastocystis hominis
- Chilomastix mesnili (1)
- Cystoisospora belli (2)
- Dientamoeba fragilis
- Dientamoeba histolytica
- Entamoeba histolytica
- Entamoeba hartmanni
- G. lamblia
- Giardia lamblia
- Iodamoeba butschlii
- Iodamoeba buetschlii (2)
- Isospora belli (2)
- Isospora pseudokrakowiakii (2)
- Isospora viveronii (2)
- Proteus mirabilis
- Strongyloides stercoralis
- Taenia solium
- Trichuris trichiura
- Trichuris trichiura
- Trichuris trichiura
- Trichuris trichiura

The numbers in parentheses indicate the number of specimens tested.

14 BIBLIOGRAPHY