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Summary of 510(k) Safety and Effectiveness information.
Trade / Proprietary Name: TREND *Cryptosporidium* Direct Detection
Test System, Cat.# EA49-

DESCRIPTION and INTENDED USE of the DEVICE:

The intended use of the device is for the qualitative determination of *Cryptosporidium* antigen in feces. The ELISA test kit is indicated for use with fecal specimens from patient's with diarrhea to aid in the detection of *Cryptosporidium* gastrointestinal infection.

Traditional detection of parasitic organisms has been conventional microscopic examination of fecal material. During the last few years, ELISA technology for the identification of specific parasites has become more common and cost effective for many laboratories.

Cryptosporidium parvum is a coccidian parasite recognized as a human and animal pathogen. Symptoms of a parasitemia caused by this organism include diarrhea, nausea, low grade fever, abdominal cramps, and anorexia. The organism is a common cause of self-limiting diarrhea in immunocompetent persons and may cause a chronic, severe, and life-threatening diarrhea in immunocompromised patients, particularly those with HIV. Transmission modes include person-to-person or animal-to-person contact with fecal material and contact with contaminated food or water supplies.

SCIENTIFIC PRINCIPLES:

The device is an antigen capture enzyme linked immunosorbent assay (ELISA) for use with stools/ fecal material. The antigen capture takes place in microplate wells. During the first incubation, *Cryptosporidium* antigens present in the stool supernatant are captured by antibodies attached to the test wells. The second incubation adds an additional anti-*Cryptosporidium* antibody that "sandwiches" the antigen. The next incubation identifies the antibody/ antigen complex and amplifies the signal by the addition of an anti-immunoglobulin antibody conjugated to horse radish peroxidase (HRP). After washings that remove unbound enzyme, a substrate is added which develops a blue color in the presence of the enzyme complex. The stop solution ends the reaction and turns the blue color to yellow. The results may be read spectrophotometrically with a microplate reader or visually.

TECHNOLOGY:

The ELISA technology of the device, as defined in the Scientific Principles section above, is utilized in a number of in vitro diagnostic test kits currently used in diagnostic laboratories. ELISA kits specific for the detection of other parasitic organisms (for example, *Giardia lamblia*) are also being used.

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PERFORMANCE TESTING:

Clinical Laboratory Bench Studies were performed in-house and at two off-site locations, a parasitology reference laboratory with a high incidence of immunocompromised patients and a university research center, to validate SUBSTANTIAL EQUIVALENCE of the device.

Fecal samples known to be positive or negative for *Cryptosporidium parvum* by conventional microscopy with modified acid fast (MAF) staining were tested. Sensitivity / Specificity values were calculated and compared with the Sensitivity/ Specificity values for the referenced predicate device. Substantial equivalency was validated by the testing.

Reference Data for Predicate Kit:**Study #1:**

Sensitivity: 97%
 Specificity: 100%
 Microscopy + = 134
 Microscopy - = 78
 Study Base: 212

Study #2: (Resolved)

Sensitivity: 97%
 Specificity: 98%
 Microscopy + = 35
 Microscopy - = 343
 Study Base: 378

**TREND *Cryptosporidium*
Performance Data:****Study A:**

Sensitivity: 96.2%
 Specificity: 97.1%
 Microscopy + = 26
 Microscopy - = 70
 Study Base: 96

Study B:

Sensitivity: 97%
 Specificity: 100 %
 Microscopy + = 68
 Microscopy - = 29
 Study Base: 97

Additional Testing:

Further bench studies validated performance equivalency in the following parameters:

- Parallel studies were performed using referenced specimen preparations and "types".
- Testing of known parasite positive fecal specimens was performed to validate specificity/ freedom from cross reactivity. No cross reactivity was seen with any of the parasitic samples tested. Following is a list of the tested parasitic organisms:

<i>Ascaris lumbricoides</i>	<i>Blastocystis hominis</i>	<i>Chilomastix mesnili</i>	<i>Clonorchis sinensis</i>
<i>Cyclospora spp.</i>	<i>Dientamoeba fragilis</i>	<i>Diphyllobothrium latum</i>	<i>Eimeria spp.</i>
<i>Entamoeba coli</i>	<i>Entamoeba hartmanni</i>	<i>Entamoeba histolytica</i>	<i>Entamoeba polecki</i>
<i>Endolimax nana</i>	<i>Fasciola hepatica</i>	<i>Giardia lamblia</i>	<i>Hymenolepis diminuta</i>
<i>Hymenolepis nana</i>	<i>Iodamoeba butschlii</i>	<i>Isoospora belli</i>	<i>Microsporidia spp.</i>
<i>Paragonimus wester.</i>	<i>Strongyloides sterc.</i>	<i>Taenia spp.</i>	<i>Trichuris trichuria</i>
<i>Trichomonis hominis</i>	Hookworm		

No cross reactivity was seen with any of the following fecal source microorganisms:

Pathogenic Enteric Bacteria:

- Campylobacter jejuni*
- Escherichia coli*
- Salmonella typhimurium*
- Shigella flexneri*

Fungi:

- Candida albicans*
- Cryptococcus neoformans*

Virus:

- Rotavirus

- Testing to determine Analytical Sensitivity of the Test System was performed. The sensitivity was determined to be approximately 4.6 ng/ml. of *Cryptosporidium* antigen.
- Testing for Precision and Reproducibility was performed at three off-site locations.

SUBSTANTIALLY EQUIVALENCY CONCLUSIONS:

The above provided information validates that the TREND device is substantially equivalent to the referenced predicate kit.

- The Intended Use of the kit is the same.
- Scientific Principle / Technology is the same.
- Performance Data, as presented, validates that the performance (Sensitivity / Specificity) is equivalent.
- Analytical Sensitivity of the device is equivalent.

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