DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 10, 2017

TECHLAB, INC.
DONNA LINK
DIRECTOR REGULATORY AND COMPLIANCE
2001 KRAFT DRIVE
BLACKSBURG VA 24060-6358

Re: K171078
Trade/Device Name: Tri-combo Parasite Screen
Regulation Number: 21 CFR 866.3220
Regulation Name: Entamoeba histolyticaserological reagents
Regulatory Class: II
Product Code: MHJ, MHI and KHW
Dated: April 10, 2017
Received: April 11, 2017

Dear Ms. Link:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ribhi Shawar -S For

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
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and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171078

Device Name

TRI-COMBO PARASITE SCREEN

Indications for Use *(Describe)*

The TECHLAB® TRI-COMBO PARASITE SCREEN test is an enzyme immunoassay for the simultaneous qualitative detection of Giardia spp., Cryptosporidium spp. and/or E. histolytica antigen in human fecal specimens. The test is indicated as an aid in the diagnosis of gastrointestinal infection when giardiasis, cryptosporidiosis and amebiasis is suspected. The test does not differentiate between the three parasites and follow-up testing is required for all positive results to confirm the specific diagnosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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***TRI-COMBO PARASITE SCREEN* 510(k) SUMMARY**

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

Applicant/Contact Information:

Date Prepared:	July 10, 2017
Name:	TECHLAB, Inc.
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Contact Person:	Donna T. Link
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1.1 Manufacturing Facility Address

TECHLAB, Inc.
20 Corporate Drive
Radford, VA 24141 USA

1.2 Product and Trade Name of the Device

TRI-COMBO PARASITE SCREEN

1.3 Common Name or Classification Name

Giardia spp., *Cryptosporidium* spp., and *E. histolytica* detection test

1.4 Classification and Regulation

Class II
21 CFR 866.3220; *Entamoeba histolytica* serological reagents

1.5 Product Code

MHJ – *Cryptosporidium* spp.

1.6 Panel

83 Microbiology

Intended Use

The TECHLAB® *TRI-COMBO PARASITE SCREEN* test is an enzyme immunoassay for the simultaneous qualitative detection of *Giardia* spp., *Cryptosporidium* spp. and/or *E. histolytica* antigen in human fecal specimens. The test is indicated as an aid in the diagnosis of gastrointestinal infection when giardiasis, cryptosporidiosis and amebiasis is suspected. The test does not differentiate between the three parasites and follow-up testing is required for all positive results to confirm the specific diagnosis.

Explanation

The most common method used to detect giardiasis, cryptosporidiosis and amebiasis has been diagnosis by ova and parasite (O&P) light microscopy. However, accuracy of O&P results depends upon the skill of the technician and also relies on the presence of intact cysts in the feces, which may not be present in all samples. In addition, it is only rarely possible to distinguish between the pathogenic and non-pathogenic species of *Entamoeba* using microscopy. The success rate of fecal examination by microscopy varies between 50 and 70%, and multiple specimens are usually necessary to establish a diagnosis. When infection is present but parasites are not detected by microscopy, sampling and testing of duodenal fluid may detect trophozoites, but this method is invasive and expensive. Detection of the organism and antigens by ELISA provides an alternative method of diagnosis and is sensitive and specific. The *TRI-COMBO PARASITE SCREEN* ELISA procedure is straightforward to perform and exhibits increased sensitivity compared to microscopic examination. Large numbers of specimens can be tested rapidly and objectively, and the procedure is less labor-intensive than most microscopy methods.

Device Description

The *TRI-COMBO PARASITE SCREEN* test is an enzyme immunoassay for the simultaneous qualitative detection of *Giardia* spp., *Cryptosporidium* spp. and/or *E. histolytica* antigen in human fecal specimens. The test uses monoclonal and polyclonal antibodies to cell-surface antigens of *Giardia*, *Cryptosporidium* and *E. histolytica*. The microassay plate in the kit contains immobilized monoclonal antibodies against the antigens, and the *Conjugate* consists of polyclonal antibodies against the antigens. In the assay, an aliquot of a diluted fecal specimen is transferred to a microassay well. The immobilized monoclonal antibodies bind the *Giardia*, *Cryptosporidium* and/or *E. histolytica* antigens if they are present. Upon addition, *Conjugate* then binds to the antigen/ antibody complex. Any unbound materials are removed during the washing steps. Following the addition of *Substrate*, a color is detected due to the enzyme-antibody-antigen complexes that formed in the presence of antigens and conjugate.

Materials Provided

- ***Conjugate* (7 mL)** – Antibodies against antigens of *Giardia* spp*., Cryptosporidium* spp*.,* and *E. histolytica* in a buffered protein solution containing 0.05% ProClin® 300
- ***Diluent* (50 mL)** – Buffered protein solution containing 0.02% thimerosal. The *Diluent* is also to be used as the negative control solution
- ***Stop Solution* (7 mL)** – 0.6 N sulfuric acid. Caution: Avoid contact with skin; flush with water immediately if contact occurs
- ***Giardia Positive Control* (3.5 mL)** – *Giardia* antigen in a buffered protein solution with 0.02% thimerosal
- ***Cryptosporidium Positive Control* (3.5 mL)** – *Cryptosporidium* antigen in a buffered protein solution with 0.02% thimerosal
- ***E. histolytica Positive Control* (3.5 mL)** – *E. histolytica* antigen in a buffered protein solution with 0.02% thimerosal

- ***Substrate*** (**14 mL)** – solution containing tetramethylbenzidine and peroxide
- ***Wash Buffer Concentrate* (50 mL) –** 20X concentrate containing phosphate buffered saline, detergent, and 0.2% thimerosal
- ***Microassay Plate*** – 12 strips, each consisting of 8 wells coated with antibodies to *Giardia* spp*., Cryptosporidium* spp*.,* and *E. histolytica* antigen (stored with desiccant)
- ***Disposable plastic transfer pipettes*** – Quantity 100
- ***Plastic adhesive sheets*** – Quantity 2 Sheets
- ***Wash Solution Label*** – Quantity 1

Predicate Device Information

The predicate device (*GIARDIA/CRYPTOSPORIDIUM CHEK*®) and the *TRI-COMBO PARASITE SCREEN* test use the same EIA (enzyme immunoassay) technology and are substantially equivalent in principle. The following tables show a comparison of both devices' similarities and differences.

Similarities

Item	Device (K171028)	Predicate (K051929)
Intended Use	The TECHLAB® *TRI-COMBO PARASITE SCREEN* test is an enzyme immunoassay for the simultaneous qualitative detection of *Giardia* spp., *Cryptosporidium* spp. and/or *E. histolytica* antigen in human fecal specimens. The test is indicated as an aid in the diagnosis of gastrointestinal infection when giardiasis, cryptosporidiosis and amebiasis is suspected. The test does not differentiate between the three parasites and follow-up testing is required for all positive results to confirm the specific diagnosis.	The *GIARDIA/ CRYPTOSPORIDIUM CHEK* test is an enzyme immunoassay for the qualitative detection of *Giardia* cyst and *Cryptosporidium* oocyst antigen in human fecal specimens. It is indicated for use as an aid in the diagnosis of patients with diarrhea suspected of *Giardia* and/or *Cryptosporidium* gastrointestinal infections
Technology	Enzyme Linked Immunoassay (ELISA)	Same
Antibody Format	Monoclonal capture Ab Polyclonal secondary Ab	Same
Type of Test	Qualitative	Same
Format/Tests	Microassay Well Plate (96 tests)	Same
Controls	Positive and negative control are included in the kit	Same
Interpretation	Spectrophotometrically and visually	Same

Differences

Item	Device	Predicate
Analyte Detected	*Giardia* spp., *Cryptosporidium* spp., and *E. histolytica* specific antigens	*Giardia* spp., and *Cryptosporidium* spp., specific antigens
Acceptable Specimen Type	Fecal specimens in Cary-Blair and C&S Transport Media	Specimens in preservation media of 10% buffered formalin or Sodium Acetate Formalin (SAF)

Summary of Performance Data

Prospective Study

The performance of the *TRI-COMBO PARASITE SCREEN* test was evaluated at 3 independent sites. The three sites yield a total of 14 microscopy positive samples (13 *Giardia* and one *E. histolytica*). The remaining 740 samples were negative. Of the 740 negative samples, four were *E. histolytica* positive by molecular comparison only but were negative by the *TRI-COMBO PARASITE SCREEN* test, negative by microscopy, and negative by FDA cleared antigen test for *E. histolytica*. Table 1 summarizes the performance observed, which is primarily a study to evaluate specificity due to the low number of positive specimens (see retrospective study for evaluation of sensitivity). Prospective testing was also read visually and performance was not significantly different from spectrophotometric readings.

Table 1. Summary of prospective clinical performance comparing the *TRI-COMBO PARASITE SCREEN* test to microscopy for *Giardia*, *Cryptosporidium* and *E. histolytica*

***TRI-COMBO PARASITE SCREEN* (N = 754)**	**Microscopy**	
	Positive	**Negative**
Positive	**13**	**14***
Negative	**1**	**726**
		95% Confidence Limits
Sensitivity	92.9%	68.5% - 98.7%
Specificity	98.1%	96.9% - 98.9%

Specimens Positive for *Giardia* by microscopy/ Specimens Detected by the *TRI-COMBO PARASITE SCREEN*	12/13
Specimens Positive for *E. histolytica* by microscopy/ Specimens Detected by the *TRI-COMBO PARASITE SCREEN*	1/1

*The fourteen *TRI-COMBO PARASITE SCREEN* positives that were microscopy negative were confirmed to be positive for *Giardia* with an alternate FDA cleared antigen test or by PCR with sequencing.

Retrospective Study

Testing consisted of 96 archived specimens previously collected and frozen from one clinical site. The Frozen samples are included in the bank based on being characterized as microscopy and PCR positive. The specimens were collected from an *E. histolytica* endemic area and contained specimens also positives for *Giardia* and *Cryptosporidium.* Table 2 summarizes the performance observed. Retrospective testing was also read visually and performance was not different from spectrophotometric readings.

Table 2. Summary of retrospective clinical performance comparing the *TRI-COMBO PARASITE SCREEN* test to Microscopy and PCR

***TRI-COMBO PARASITE SCREEN* (N = 96)**	**Microscopy and PCR**	
	Positive	**Negative**
Positive	**85**	**0**
Negative	**5**	**6**

		95% Confidence Limits
Sensitivity	94.4%	87.7% - 97.9%
Specificity	100%	61.0% - 100%
Specimens Positive for *Giardia*/ Specimens Detected by the *TRI-COMBO PARASITE SCREEN*		41/41
Specimens Positive for *Cryptosporidium*/ Specimens Detected by the *TRI-COMBO PARASITE SCREEN*		27/30
Specimens Positive for *E. histolytica*/ Specimens Detected by the *TRI-COMBO PARASITE SCREEN*		28/30
Note: Eight specimens were dual positive for *Giardia* and *E. histolytica* by the Microscopy and PCR and tested positive in the *TRI-COMBO PARASITE SCREEN* test. Three specimens were dual positive for *Giardia* and *Cryptosporidium* by Microscopy and PCR and tested positive in the *TRI-COMBO PARASITE SCREEN* test.		

The prospective study results were analyzed by considering composite results from multiple tests that consisted of light microscopy, molecular testing consisting of a commercial FDA cleared device and PCR with sequencing for the identification of *Giardia* spp., *Cryptosporidium* spp., in addition to identification and subspeciation of *E. histolytica.* This testing was mainly done because identification of *E. histolytica* organisms cannot be determined solely by microscopy because it is morphologically indistinguishable from the non-pathogenic *E. dispar*. Use of an alternate molecular testing is needed to confirm *Entamoeba* speciation. The molecular testing algorithm used provides a comparator method that is highly sensitive at the detection of *Giardia* spp., *Cryptosporidium* spp. and *E. histolytica*. The performance is summarized in table 3 and is presented as positive percent agreement and negative percent agreement.

Table 3. Summary of prospective clinical performance comparing the *TRI-COMBO PARASITE SCREEN* test to microscopy and molecular testing

***TRI-COMBO PARASITE SCREEN* (N = 754)**	**Microscopy and Molecular testing**	
	Positive	**Negative**
Positive	**18**	**9***
Negative	**11****	**716**
		95% Confidence Limits
Positive Percent Agreement	62.1%	44.0% - 77.3%
Negative Percent Agreement	98.8%	97.7% - 99.4%

Specimens Positive for *Giardia*/ Specimens Detected by the *TRI-COMBO PARASITE SCREEN*	17/24
Specimens Positive for *E. histolytica*/ Specimens Detected by the *TRI-COMBO PARASITE SCREEN*	1/5
Specimens Positive for *Cryptosporidium*/ Specimens Detected by the *TRI-COMBO PARASITE SCREEN*	0/0

* These nine specimens were tested with an alternate FDA cleared antigen test resulting in 9/9 *Giardia* determined to be antigen positive.

**These eleven specimens were tested with an alternate FDA cleared antigen test resulting in 6/7 *Giardia* and 4/4 *E. histolytica* were determined to be antigen negative.

Reproducibility

The reproducibility of the *TRI-COMBO PARASITE SCREEN* test was determined using 20 human fecal specimens coded to prevent their identification during testing. Testing was performed at 2 independent laboratories and on-site at TECHLAB, Inc. The samples were tested twice a day over a 5-day period by multiple technicians at each site using 2 different kit lots. Positive and negative controls were run with each panel of the masked samples. The results from each laboratory were submitted to TECHLAB, Inc. and compared with in-house results. The results were consistent among the different locations and exhibited a correlation of 99.9%. The samples produced the expected results 99.9% of the time.

Analytical Sensitivity

Limit of Detection (LoD) – cutoff points for *Giardia* cysts, *Cryptosporidium* oocysts and *E. histolytica* pathogenic zymodemes in fecal specimens for the *TRI-COMBO PARASITE SCREEN* test. Determined following CLSI document EP17-A2.
CLSI. *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline - Second Edition.* CLSI document EP17-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2012.

The analytical sensitivity of the test was determined by using purified *Giardia* cysts, *Cryptosporidium* oocysts, and *E. histolytica* pathogenic zymodemes in a sample matrix. The concentration of *Giardia* cysts, *Cryptosporidium* oocysts, and *E. histolytica* pathogenic zymodemes in fecal matrix of which specimens were positive by the *TRI-COMBO PARASITE SCREEN* test 95% of the time was the assay limit-of-detection (LoD). Test results determined the LoD for the assay to be 8450 cysts/mL of feces for *Giardia* (equivalent to 169 cysts detected per test), 47,962 oocysts/mL of feces for *Cryptosporidium* (equivalent to 959 oocysts detected per test), and 1,676 PZs/mL (equivalent to 34 PZs detected per test). For fecal matrix/Cary Blair, the LoD for the assay was determined to be 34,155 cysts/mL of feces for *Giardia* (equivalent to 427 cysts detected per test), 99,456 oocysts/mL of feces for *Cryptosporidium* (equivalent to 1243 oocysts detected per test), and 4655 PZs/mL (equivalent to 58 PZs detected per test). For fecal matrix/C&S, the LoD for the assay was determined to be 37,095 cysts/mL of feces for *Giardia* (equivalent to 464 cysts detected per test), 122,299 oocysts/mL of feces for *Cryptosporidium* (equivalent to 1529 oocysts detected per test), and 3948 PZs/mL (equivalent to 49 PZs detected per test).

Because the *TRI-COMBO PARASITE SCREEN* test detects soluble antigen in fecal specimens in addition to cysts, oocysts, and trophozoites, this LOD study represents an estimate of analytical sensitivity.

Analytical Specificity (Cross Reactivity)

The *TRI-COMBO PARASITE SCREEN* test was evaluated for cross-reactivity with the bacterial and viral strains listed below. None of the strains were shown to interfere with the performance of the *TRI-COMBO PARASITE SCREEN* test.

Aeromonas hydrophila	*Bacillus cereus*	*Bacillus subtilis*
Bacteroides fragilis	*Campylobacter coli*	*Campylobacter fetus*
Campylobacter jejuni	*Candida albicans*	*Clostridium bifermentans*
Clostridium difficile	*Enterococcus faecalis*	*Escherichia coli*
Escherichia coli 0157:H7	*Escherichia coli EIEC*	*Escherichia coli EPEC*
Escherichia coli ETEC	*Klebsiella pneumonia*	*Salmonella typhimurium*
Shigella dysenteriae	*Shigella flexneri*	*Shigella sonnei*
Staphylococcus aureus	*Staphylococcus aureus (Cowan's)*	*Staphylococcus epidermidis*
Vibrio parahaemolyticus	*Yersinia enterocolitica*	

Calicivirus	Cytomegalovirus	Echovirus 11, 18, 33
Human Adenovirus 1, 2, 3, 5, 40, 41	Human Coronavirus	Human Coxsackievirus B2, B3, B4, B5
Human Echovirus 9	Human Enterovirus 68, 69, 70, 71	
Human parechovirus 1 [Echovirus 22]		Human Rotavirus

Additionally, the *TRI-COMBO PARASITE SCREEN* test was run on fecal specimens documented to be positive for other parasites by microscopy. The number in parentheses is the quantity of each organism found in the clinical specimens. No cross-reactivity was seen with the following organisms.

Ascaris lumbricoides and with eggs (22)	*Entamoeba coli* (16)	*Trichuris trichiura* eggs (12)
Blastocystis hominis (11)	*Entamoeba moshkovskii* (3)	
Entamoeba bangladeshi (3)	*Iodamoeba bütschlii* (10)	

Cross reactivity with Norovirus is unknown because it was not tested in analytical studies. However, Norovirus GI/GII was identified in 34 clinical specimens and Enterotoxigenic *E. Coli* - ETEC LT/ST was identified in 107 clinical specimens, using an FDA cleared multiplex NAAT assay during clinical testing and no cross reactivity was found using the *TRI-COMBO PARASITE SCREEN* in those samples.

Strain Specific Study

Due to the similarity in morphology between pathogenic and non-pathogenic *Entamoeba* species, 3 specimens identified by PCR as positive for non-pathogenic *Entamoeba moshkovskii* and 3 positive for non-pathogenic *Entamoeba bangladeshi* were evaluated using the *TRI-COMBO PARASITE SCREEN* test. These 6 specimens tested negative in the *TRI-COMBO PARASITE SCREEN* test.

Interfering Substances (U.S. Formulation)

The following substances had no effect on positive or negative *TRI-COMBO PARASITE SCREEN* test results analyzed at the concentrations indicated:
Barium sulfate (5% w/v), Benzalkonium Chloride (1% w/v), Ciprofloxacin (0.25% w/v), Ethanol (1% w/v), Hog gastric mucin (3.5% w/v), Human blood (40% v/v), Hydrocortisone (1% w/v), Imodium® (5% v/v), Kaopectate® (5% v/v), Leukocytes (0.05% w/v), Maalox® Advanced (5% v/v), Mesalazine (10% w/v), Metronidazole (0.25% w/v), Mineral Oil (10% w/v), Mylanta® (4.2 mg/mL), Naproxen Sodium (5% w/v), Nonoxynol-9 (1% w/v), Nystatin (1% w/v), Palmitic Acid/Fecal Fat (40% w/v), Pepto-Bismol® (5% v/v), Phenylephrine (1% w/v), Polyethylene glycol 3350 (10% w/v), Prilosec OTC® (5 µg/mL), Sennosides (1% w/v), Simethicone (10% w/v), Stearic Acid/Fecal Fat (40% w/v), Tagamet® (5 µg/mL), TUMS (50 µg/mL), Human Urine (5% v/v), and Vancomycin (0.25% w/v).

Precision – Intra-assay

For the determination of intra-assay performance, 24 fecal samples were analyzed by the *TRI-COMBO PARASITE SCREEN* test. The samples included 2 negative, 2 high negative, 2 low positive, and 2 moderate positive samples for each analyte. Each specimen was assayed a total of five times using two different kit lots. Positive specimens consistently tested positive and negative specimens consistently tested negative. High negative samples tested within 95% agreement of each other for all three analytes.

Precision – Inter-assay

For the determination of inter-assay performance, 24 fecal samples were analyzed by the *TRI-COMBO PARASITE SCREEN* test. The samples included 2 negative, 2 high negative, 2 low positive, and 2 moderate positive samples for each analyte. The samples were tested twice a day by multiple

technicians over a 12-day period using 2 different kit lots. All positive samples remained positive and all negative samples remained negative.

Fresh Versus Frozen Samples

The effect of long term frozen specimen storage on antigen stability was evaluated. For the analysis, a total of 39 fecal samples were tested with the *TRI-COMBO PARASITE SCREEN* test. The samples consisted of negative fecal samples, high negative fecal samples, low positive fecal samples, moderate positive fecal samples, and high positive fecal samples. Samples were prepared by spiking a negative fecal pool with *Giardia* cysts, *Cryptosporidium* oocysts, or *E. histolytica* pathogenic zymodemes at respective concentrations and stored at ≤ -10°C. These samples were tested at 0, 1, 4 and 8 weeks. No conversion of positive-to-negative or negative-to-positive was observed in any of the samples at the specified time points.

Prozone

To ensure that a high concentration of analyte does not interfere with a positive reaction in *TRI-COMBO PARASITE SCREEN* test, high samples were prepared by spiking a negative fecal pool with *Giardia* cysts, *Cryptosporidium* oocysts, or *E. histolytica* pathogenic zymodemes, and then tested. A total of 5 different dilutions of each, up to and including the clinically observed high concentration, were prepared and tested in triplicate. The results demonstrated that there was no overall prozone affect, that elevated levels of analyte did not affect the detection of each organism.

Conclusion

The conclusions drawn from the nonclinical and clinical tests demonstrate that the *TRI-COMBO PARASITE SCREEN* test is safe and effective for the detection of *Giardia* spp., *Cryptosporidium* spp., and *E. histolytica* in human fecal specimens. The information submitted in this premarket notification is complete and supports a substantial equivalence decision.