FEB 8 2013

510(k) Summary – Uni-Gold™ Cryptosporidium

510(k) Number Assigned:	K121565
Introduction:	Trinity Biotech hereby submits this 510(k) summary for the Uni-Gold™ Cryptosporidium Rapid Lateral Flow Test Kit in accordance with the requirements of 21 CFR 807.92(C).
Submitter's Identification: Name & Address:	MarDx Diagnostics, A Trinity Biotech Company, 5919 Farnsworth Ct. Carlsbad, CA. 92008, USA.
Contact:	Contact Person: Bonnie DeJoy, Corporate VP of RA (Official Correspondent) Email: Bonnie.DeJoy@TrinityUSA.Com Phone: 716-483-3851 Extension 1030 Fax: 716-488-1990
Date Summary Prepared:	February 4, 2013
Device Trade Name:	Uni-Gold™ Cryptosporidium
Classification Name:	*Entamoeba histolytica* serological reagents. Cryptosporidium SPP 866.3220 Code MHJ
Classification Product Code:	MHJ
Intended Use:	Trinity Biotech Uni-Gold™ Cryptosporidium is a single use rapid immunoassay for the qualitative detection of *Cryptosporidium parvum (C. parvum)* antigens in human stool specimens. This test is intended for use with patients with gastrointestinal symptoms as an aid in the diagnosis of suspected *Cryptosporidium* gastrointestinal infections. As with other *Cryptosporidium* tests, results should be considered in conjunction with the clinical evaluation and medical history. For *In-Vitro* Diagnostic use.

Predicate Device

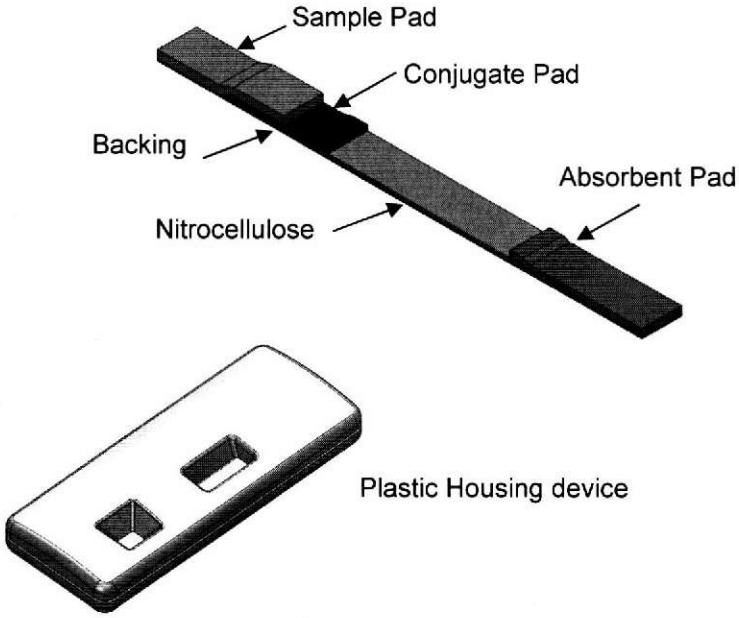
Remel Xpect® Cryptosporidium (510K #: K031965)

Device Description

The Trinity Biotech Uni-Gold™ Cryptosporidium Test was designed as a single use, rapid, lateral flow immunoassay to detect the presence of *Cryptosporidium parvum* antigen in unpreserved (fresh & frozen), preserved, and media containing human stool specimens.

The Trinity Biotech Uni-Gold™ Cryptosporidium test strip (5mm x 60mm) combines a nitrocellulose membrane with designated fiber pads (conjugate, sample and absorbant). The test strip is then placed into a plastic housing and is sealed constituting the Test Device. (Picture A)

Picture A- Cryptosporidium Test Strip - 5 mm x 60 mm



The Cryptosporidium nitrocellulose membrane test strip (above) consists of:

A) Mouse anti-*Cryptosporidium parvum* is coated onto the test line region of the test strip.

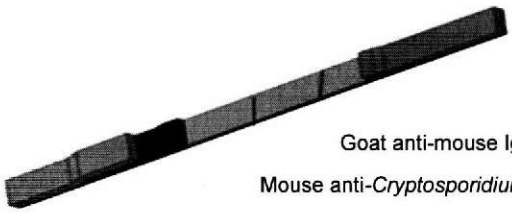
B) Goat anti-mouse IgG is coated onto the control line region of the test strip.

C) Mouse anti-*Cryptosporidium parvum* antibodies and Mouse IgG antibodies are conjugated to red latex particles and dried onto inert glass fiber (Conjugate pad), which is inserted into the test strip below the nitrocellulose zone.

When Cryptosporidium antigens are present in the sample they combine with the antibody/red latex. As this complex migrates it binds to the antibodies in the test region forming a visible pink/red band. Excess conjugate forms a second

pink/red band in the control region of the device. The control line should always appear as a visible pink/red band in the control region of the device. The internal control line is to ensure and indicate that the test device is functioning correctly. This forms the basis for the double antibody sandwich assay. (Picture B)

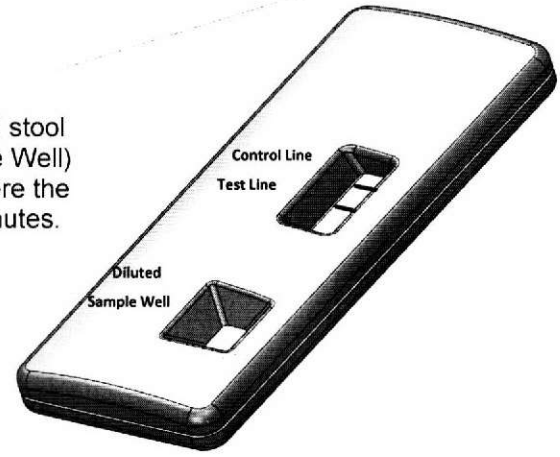
Picture B- Cryptosporidium Test Device



Goat anti-mouse IgG - Control Line

Mouse anti-*Cryptosporidium parvum* - Test Line

The housing contains a window where the diluted stool sample is added (Sample Well) and a window above where the results are read in 15 minutes.



The test concept:

Mouse anti-*Cryptosporidium parvum* is coated onto the test line region of the nitrocellulose zone of the test strip. Goat anti-Mouse IgG is coated onto the control line region. Mouse anti-*Cryptosporidium parvum* and Mouse IgG antibodies are conjugated to red latex particles and dried onto inert glass fiber. This is inserted into the test strip below the nitrocellulose zone.

A buffered solution is added to a dilution tube followed by the addition of the stool specimen (2 drops) via a disposable pipette. This mixture is then dispensed in total into the sample well of the lateral flow cartridge device with a dropper pipette and migrates through a pad containing red microspheres that have been coated with a antibody specific for the Cryptosporidium antigen. If the antigen is present, an immune complex forms. The migration continues along the membrane, which contains a striped down anti Cryptosporidium capture antibody. If Cryptosporidium antigen is present, the immune complex reacts with the anti- Cryptosporidium antibody at the test line on the membrane. Thus Cryptosporidium antigens present in the sample combine with the antibody/red

latex. As this complex migrates it binds to the antibodies in the test region forming a visible pink/red band.

Excess conjugate forms a second pink/red band in the control region of the device. The control line should always appear as a visible pink/red band in the control region of the device to indicate that the test device is functioning correctly.

Comparison with Predicate Device:

The predicate device and the Uni-Gold™ Cryptosporidium use similar lateral flow technology and concepts. The following table provides a comparative summary for both device design features. Any differences in technology do not raise additional concerns regarding safety and effectiveness. Safety and effectiveness are demonstrated to be substantially equivalent.

Aspect or Feature		
Comparison Table		
	Remel-K031965 Xpect® Cryptosporidium	**Trinity Biotech Uni-Gold™ Cryptosporidium**
Intended Use	Detection of Cryptosporidium specific antigen in fecal specimens.	Detection of Cryptosporidium antigens in stool (fecal) specimens.
Technology	Qualitative immune chromatographic assay	Qualitative immune chromatographic assay
Capture antibodies on membrane	Rabbit anti-Cryptosporidium, goat anti-mouse IgG	Mouse anti-*Cryptosporidium parvum*, goat anti-mouse IgG
Material: Membrane	Mylar-backed Nitrocellulose	Nitrocellulose
Conjugate antibodies	Monoclonal anti-cryptosporidium	Mouse anti-*Cryptosporidium parvum*, mouse IgG
Material: Conjugate	Anti-mouse and anti-Cryptosporidium colored microparticles diluted in buffer	Anti-Cryptosporidium and Mouse IgG colored latex dried onto conjugate pad
Specimen Types	Human Stool preserved in 10% formalin, SAF,or Cary Blair	Human Stool: fresh/frozen or preserved in 10% formalin, SAF or Cary Blair, or C&S Transport Medium
Sample volume	100 µl	2 drops- approximately 40-60 µl

Precision / Reproducibility

An Intra-run precision/reproducibility study was performed at 3 sites including one internal site. This study consisted of 12 blind proficiency panel members, varying in reactivity: (4) Low Positive, (4) High Positive and (4) Negative samples. This panel was tested for a period of 5 days. Each site generated 2 runs per day, by two individual technicians totaling 20 replicates per site per panel member, i.e.60 replicates total for each panel member in entire 3 site study. 100% reproducibility was observed for all sites, for all days using the blind panel sample set, therefore 100% of the samples tested for Cryptosporidium produced the expected result.

Percent Correlation

The Trinity Biotech Uni-Gold™ Cryptosporidium (1206620) along with Uni-Gold™ Cryptosporidium Control kit (1206621) was evaluated at 3 external laboratories. A total of 299 retrospective samples were tested side by side on the test device and a commercially available lateral flow test at three external sites in the following stool matrix types: unpreserved frozen (37), Cary Blair (4), SAF (159), and formalin (99). The percent agreement of Uni-Gold™ Cryptosporidium versus the comparator device was as follows:

Site 1	Cryptosporidium	Comparator Device		% Agr
		+	-	
Uni-Gold™	+	24	1	100% Pos Agr
	-	0	52	98.1% Neg Agr

Site 2	Cryptosporidium	Comparator Device		% Agr
		+	-	
Uni-Gold™	+	56	1	100% Pos Agr
	-	0	55	100% Neg Agr

Site 3	Cryptosporidium	Comparator Device		% Agr
		+	-	
Uni-Gold™	+	27	51*	96.4% Pos Agr
	-	1**	32	38.6% Neg Agr

*At Site 3, out of 51 samples that tested positive on Uni-Gold™ Cryptosporidium and negative on the comparator device, 30 samples were positive by Modified Kinyoun Stain light microscopy and three samples were positive for *Cryptosporidium* by DFA microscopy in agreement with the Uni-Gold™ Cryptosporidium result.

**The one sample that tested negative on Uni-Gold™ Cryptosporidium and positive on the comparator device was negative by Modified Kinyoun Stain microscopy in agreement with the Uni-Gold™ Cryptosporidium result.

Cross Reactivity	No cross reactivity was observed using samples containing the following organisms: *Adenovirus serotypes 3, 5, 7, 40, 41, Aeromonas hydrophila, Ascaris lumbricoides, Bacteroides fragilis, Bacillus cereus, Bacillus subtilis, Blastocystis hominis, Campylobacter coli, Campylobacter fetus, Campylobacter jejuni, Candida albicans, Chilomastix mesnili, Clostridium difficile, Clostridium biffermentans, Coronavirus OC43, Coxsackievirus, Cyclspora cayetanensis, Cytomegalovirus (CMV), Dientamoeba fragilis, Diphyllobothrium latum, Echovirus 20, Endolimax nana, Entamoeba coli, Entamoeba hartmanni, Entamoeba histolytica, Enterobius vermincularis, Enterococcus faecalis, Escherichia coli, Escherichia coli 0157H7, Giardia lamblia, Hookworm, Hymenolepis nana, Iodamoeba butschlii, Isospora sp., Klebsiella pneumoniae, Microsporidia, Salmonella typhimurium, Shigella dysenteriae, Shigella flexneri, Shigella sonnei, Staphylococcus aureua, Staphylococcus aureus (Cowan's), Staphylococcus epidermidis, Strongyloides stercoralis, Taenia sp., Trichurius trichiura, Vibrio parahaemolyticus, and Yersinia enterocolitica.* Cross Reactivity has not been established for *E. dispar.*
Interfering Substance	The analytical specificity of the test was determined in stool samples containing potentially interfering substances at clinically relevant concentrations. Compounds were respectively spiked into positive and negative samples at medically relevant dosages (treatment). All treatments, including the unspiked (neat) positive and unspiked (neat) negative samples were tested in duplicate with Uni-Gold™ Cryptosporidium. The following compounds were tested: Human blood (20% v/v), Mucin (3.5% w/v), Stool fat (Triglycerides 0.14mg/ml or Stearic Acid 20% v/v), Pepto-Bismol (Bismuth) (20% v/v), Imodium A-D (Loperamide HCl) (20% v/v), Kaopectate (Attapugite) (20% v/v), Vancomycin (0.6mg/ml), K-Y jelly (0.289mg/ml), Vasoline (0.22mg/ml), Condom lubricant (1.716mg/ml), Maalox (magnesium hydroxide, calcium carbonate) (20% v/v), Tagamet (Cimetidine) ($2.0x10^{-2}$ mg/ml), Pepsid (Famotidine) ($6.0x10^{-4}$ mg/ml), Zantac (Ranitidine) ($6.0x10^{-3}$ mg/ml), Prilosec (Omeprazole) ($6.0x10^{-3}$ mg/ml), Nitrazoxanide ($6.96x10^{-3}$ mg/ml), Atovaquone (0.031mg/ml), Azithromycin ($1.2x10^{-2}$ mg/ml), Metronidazole (0.12mg/ml), Paromomycin (0.42mg/ml), Trimethoprim-sulfamethoxazole (TRM 0.04mg/ml & Sulf 0.4mg/ml). No test interference was observed by any of the compounds at the concentrations tested.
Sensitivity / Specificity	The Trinity Biotech Uni-Gold™ Cryptosporidium (1206620) along with Uni-Gold™ Cryptosporidium Control kit (1206621) was evaluated at 4 external laboratories. The sensitivity and specificity of the test was compared against DFA microscopy with retrospective samples at sites 1 and 2 as shown in the following table.

Cryptosporidium			DFA Microscopy	
			+	-
Site 1	Uni-Gold™	+	28	0
		-	0	103
Site 2	Uni-Gold™	+	49	0
		-	0	54
Total	Uni-Gold™	+	77	0
		-	0	157

Sensitivity: 100% (77/77) 95% CI 94 - 100%
Specificity: 100% (157/157) 95% CI 97 - 100%

The positive samples were tested in the following stool matrix types: formalin (47), SAF (11), unpreserved frozen (14), Cary Blair (2), and C&S (3). The negative samples were tested in the following stool matrix types: formalin (71), SAF (49), unpreserved frozen (23), Cary Blair (2), C&S (12).

Additional retrospective studies

Performance of the test was compared to non-fluorescent microscopy (staining) at two external laboratories. At site 2, 47 retrospective samples were evaluated and demonstrated a Positive Percent Agreement (PPA) of 100% (26/26) and a Negative Percent Agreement (NPA) of 100% (21/21) versus Modified Acid-Fast Stain. At site 3, 281 retrospective SAF samples were evaluated and demonstrated a PPA of 92% (55/60) and a NPA of 90% (198/221) versus Modified Kinyoun Stain. Of the 23 negative samples (by Modified Kinyoun Stain) that tested positive on the Uni-Gold™ Cryptosporidium test, three of these samples subsequently tested positive for *Cryptosporidium* by DFA microscopy in agreement with the Uni-Gold™ Cryptosporidium result.

Prospective Study

The following table shows a summary of test performance compared against DFA microscopy with prospective samples at site 4.

			Cryptosporidium DFA	
Site 4	Cryptosporidium		+	-
	Uni-Gold™	+	0	0
		-	0	378

Specificity: 100% (378/378) 95% CI 99 – 100%

Due to infection prevalence, no positive samples were encountered during this prospective study. Samples were tested in the following sample matrix types: unpreserved fresh (153), unpreserved frozen (45), formalin (45), SAF (45), C&S (45), and Cary Blair (45).

	Expected Values The performance of the Uni-Gold™ Cryptosporidium Test Kit was evaluated at four external laboratories. The 940 (prospective and retrospective) samples were collected from Hospitals throughout the US and Canada and consisted of both male and female patients of all ages from pediatric to adult. The retrospective study included 163 positive samples and 399 negative samples confirmed by microscopy. The prospective study included 378 samples which were subsequently confirmed negative by microscopy. There were no differences observed in clinical performance between males or females, or between pediatric or adult populations.
Substantial Equivalence conclusion	The information submitted in this premarket notification is complete and supports a substantial equivalence decision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

FEB 8 2013

Trinity Biotech
C/O Bonnie DeJoy
5919 Farnsworth Ct.
Carlsbad, CA 92008

Re: K121565
Trade Name: Uni-Gold™ Cryptosporidium
Regulation Number: 21 CFR 866.3220
Regulation Name: *Entamoeba histolytica* serological reagents
Regulatory Class: Class II
Product Code: MHJ
Dated: January 11, 2013
Received: January 14, 2013

Dear Ms. DeJoy:

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.

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 Part 801); 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 regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K121565

Device Name: ***Uni-Gold™ Cryptosporidium***

Indications for Use:

Trinity Biotech Uni-Gold™ Cryptosporidium is a single use rapid immunoassay for the qualitative detection of *Cryptosporidium parvum (C. parvum)* antigens in human stool specimens. This test is intended for use with patients with gastrointestinal symptoms as an aid in the diagnosis of suspected *Cryptosporidium* gastrointestinal infections. As with other *Cryptosporidium* tests, results should be considered in conjunction with the clinical evaluation and medical history. For *In-Vitro* Diagnostic use.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Vitro Diagnostic Devices (OIVD)

CDR Roque Jaen, PhD

Division Sign -Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(K) K121565