K081064

JAN 14 2009

Section 5

510(k) Summary

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This 510(k) summary is submitted in accordance with 21 CFR §807.92.

Owner:	IVD Research, Inc. 5909 Sea Lion Place, Suite D Carlsbad, CA 92010 USA Telephone: 760-929-7744; Fax 760-431-7759 Contact: Dave Lambillotte, President
Prepared:	April 12, 2008
Trade name:	IVD Research, Inc. *Giardia* Fecal Antigen Detection Lateral Flow Kit
Common name:	Giardia Fecal Antigen Detection Lateral Flow Kit
Classification name:	*Entamoeba histolytica* serological reagents (21 CFR §866.3220; Product Code: MHI)
Predicate device:	Xpect™ Giardia Lateral Flow Assay, K031942

Device description:
The IVD Research, Inc. *Giardia* Fecal Antigen Detection Lateral Flow Kit is an immunochromatographic assay for the detection of *Giardia lamblia* antigen in human fecal samples. The test uses sample wicking to capture *Giardia* antigen on a discrete test line containing antibodies specific for *Giardia* antigen. A specimen is added to a dilution tube and mixed with a buffer solution. The mixture is dispensed into the sample well of the device which resolubilizes the *Giardia* specific mouse monoclonal antibody that has been conjugated to colored microparticles. This solution wicks along a membrane containing capture antibodies bound to the membrane at the Test and Control lines. The *Giardia* immune complex, if present, reacts with anti-*Giardia* antibody at the Test line. Unbound conjugate not captured at the test line is captured at the Control line containing anti-mouse antibody. If *Giardia* antigens are present in the fecal sample, two pink-to-purple bands (one at the Sample line and one at the Control line) will appear in the test window. If no *Giardia* antigen is present, or if the level of antigen is below the detection limit of the assay, only one pink-to-purple band at the Control line will appear in the test window. For the test to be valid, a pink-to-purple band must always appear at the Control line position of the device test window regardless of whether the sample is positive or negative. This Control line indicates that the test is working properly.

Intended use:
The IVD Research, Inc. *Giardia* Fecal Antigen Detection Lateral Flow Kit is a qualitative immunoassay for the detection of *Giardia* antigens in preserved and unpreserved human fecal specimens. This test is indicated as an aid in the clinical laboratory diagnosis of suspected *Giardia* infections.

Comparison with the predicate device:
The technological characteristics of the IVD Research Inc. *Giardia* Fecal Antigen Detection Lateral Flow Kit are compared with the Xpect™ Giardia Lateral Flow Assay (K031942) in the table below. This comparison demonstrates the substantial equivalence of this device to the predicate device. The devices are similar in intended use, assay technology and materials used to construct the test strip, and both devices use the same *Giardia* specific monoclonal antibodies for the conjugate. Both devices have similar clinical performance. Differences between the two devices in the sample size and materials used in the membrane are minimal.

Item	IVD Research, Inc. Giardia Fecal Antigen Detection Lateral Flow Kit (Device)	Xpect™ Giardia Lateral Flow Assay (K031942) (Predicate)
	Similarities	
Intended Use	Detection of *Giardia* antigens in fecal specimens.	Detection of *Giardia* antigens in fecal specimens.
Technology	Qualitative immunochromatographic assay.	Qualitative immunochromatographic assay.
Capture antibodies or molecules	Rabbit anti-Giardia and goat anti-mouse IgG.	Rabbit anti-Giardia and goat anti-mouse IgG.
Material: Membrane	Mylar-backed nitrocellulose.	Mylar-backed nitrocellulose.
	Differences	
Antibodies: Conjugate	Monoclonal anti-Giardia.	Monoclonal anti-Giardia and normal mouse IgG.
Material: Conjugate	Colloidal gold labeled monoclonal antibody to *Giardia*.	Anti-Giardia and mouse IgG colored polystyrene particles diluted in buffer.
Specimen Type	Human stool preserved in 10% formalin or SAF.	Human stool preserved in 10% formalin, SAF or Cary Blair.
Sample Volume	50 uL	100 uL

Reproducibility:
Reproducibility testing was performed at three sites (one internal; two external) using a masked panel of ten samples of varying reactivity tested over three days along with positive and negative contols. All samples tested for *Giardia* produced the expected result, as summarized in the table below.

	No. Positive samples tested	No. Negative samples tested	Total results Number Expected	Total results Number Obtained	Percent Reproducibility Obtained
Number of tests (sites x test occasions)					
9	6		54	54	**100**
9		4	36	36	**100**

Analytical Sensitivity:
Analytical sensitivity was determined by diluting cultured *Giardia lamblia* (WB strain) in negative human stool and testing across an antigen concentration range of 2.5 ng/mL to 80 ng/mL. Test results determined the limit of detection for the device to be 20 ng/ml.

Analytical Specificity/cross-reactivity/interfering substances:
No cross-reactivity was observed using samples containing the following organisms: *Entamoeba hartmanni, Endolimax nana, Entamoeba histolytica/dispar, Entamoeba coli, Blastocystis hominis, Dientamoeba fragilis, Chilomastix mesnili, Cyclospora cayetanensis, Strongyloides stercoralis, Cryptosporidium, Ascaris lumbricoides, Enterobius vermicularis, Diphyllobothrium* species, *Hymenolepis nana, Clonorchis sinensis, Enteromonas hominis, Trichuris trichiura, Iodamoeba buetschlii, Schistosoma mansoni,* rotavirus, *Taenia* eggs, *Fasciola* eggs, *Isospora belli,* adenovirus, rotavirus and twenty-two (22) bacterial species (*Salmonella typhimurium, Proteus vulgaris, E. coli 43887, Campylobacter coli, Salmonella enteritidis, Campylobacter fetus, Staphylococcus aureus, Pseudomonas aeruginosa, Klebsiella pneumoniae, Serratia liquefaciens, Enterobacter cloacae, Citrobacter braakii, Shigella flexneri, Shigella sonneii, Shigella dysenteria, E. hermanii, Campylobacter jejuni, Salmonella hadar, Salmonella infantis, Yersinia enterocolitica, Enterococcus fecalis, Helicobacter cinaedi).* Additionally, six common microorganisms (*Campylobacter coli, E. coli, Salmonella enteritidis, Shigella flexneri, Campylobacter jejuni, Yersinia enetrocolitica)* spiked into preserved positive and negative fecal specimens did not affect the test result.

Human feces samples positive and negative for Giardia antigen were spiked with blood, mucin, or Imodium® prior to testing with the Giardia Fecal Antigen Detection Lateral Flow Kit. Testing indicated that none of these substances interfered with the test.

Specimen stability:
Assay performance in preserved specimen types claimed in the labeling was verified during assay development using specimens from an internal QC bank as follows: fifteen positive samples preserved in either 10% formalin or sodium acetate-acetic acid-formalin

(SAF) with a maximum age of 7 years; twenty-three 10% formalin/SAF negative samples (maximum age 18 months); three fresh-frozen, un-preserved samples (2 positive; 1 negative) approximately 10 years old which had undergone numerous freeze/thaw cycles; and eleven fresh negative samples that had undergone three freeze/thaw cycles. All samples gave the expected result when tested according to the assay procedure.

Unpreserved Fecal Specimens
Assay performance in unpreserved specimens was verified using a total of 42 unpreserved samples fecal samples that were positive or negative for antigens of *Giardia lamblia* as determined by a non-lateral flow methodology (*Giardia lamblia* Antigen Detection Microwell ELISA, IVD Research, Inc.). Fifteen of these samples tested positive in the ELISA test and 27 tested negative in the ELISA. All 15 of the positive samples and 20 of the negative samples were part of IVD Research's frozen sample bank and are stored at -15°C or lower.

The results summarized below demonstrate that the IVD Research *Giardia* Fecal Antigen Detection Lateral Flow Kit produces acceptable test results when samples are unpreserved.

	ELISA +	ELISA -
LF +	15	0
LF -	0	27

Sensitivity: 100% 95% CI = 78.2% to 100%
Specificity: 100% 95% CI = 87.2% to 100%

Specimen collection/preparation/stability:
Fresh, unpreserved stool samples should be stored at 2°C - 8°C and tested within 24 hours of collection. Samples that cannot be tested within this time should be frozen at -15°C to -25°C until use.

Stool specimens preserved in 10% formalin or SAF may be kept at room temperature (15°C - 25°C) and tested within 18 months of collection.

Do not freeze preserved specimens.

Do not concentrate stool specimens. The assay will not give accurate results on a concentrated sample.

Clinical performance:
The performance of the Giardia Fecal Antigen Detection Lateral Flow Kit was determined in retrospective studies using well-characterized, archived samples. Performance relative to patients' clinical status has not been established.

1. Sensitivity and Specificity Compared to Microscopy or Direct Immunofluorescence Assay
Clinical performance was evaluated using a total of 210 human fecal specimens collected in 10% formalin or SAF and submitted to an independent laboratory for testing with the *Giardia* Fecal Antigen Detection Lateral Flow Kit. The following results were obtained.

	Ref +	Ref -
LF +	106	4
LF -	3	97

Sensitivity: 97.2% (106/109) 95% CI = 92.2% to 99.4%
Specificity: 96% (97/101) 95% CI = 90.2% to 98.9%

Four "negative" specimens gave a false positive result when tested with the Giardia LF test. These samples were re-tested using a direct immunofluorescence assay and shown to be positive.

2. Percent Agreement vs. Predicate Device
The Percent Agreement of the IVD Research, Inc. Giardia Fecal Antigen Detection Lateral Flow Kit versus the predicate device was as follows:

	Remel Xpect®	Remel Xpect®
LF +	48	0
LF -	1	61

Positive Agreement 98% (48/49)
Negative Agreement 100% (61/61)

The results of the bench and clinical performance testing demonstrate that the IVD Research Inc., *Giardia* Fecal Antigen Detection Lateral Flow Kit is substantially equivalent in performance to the predicate device and to microscopic examination for the detection of *Giardia* in human fecal specimens.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

IVD Research, Inc.
c/o Mr. Michael Wienholt
Regulatory Consulting, LLC
5470 E. Edwin Road
Tucson, AZ 85739

JAN 14 2009

Re: k081064
Trade/Device Name: Giardia Fecal Antigen Detection Lateral Flow Kit
Regulation Number: 21 CFR 866.3220
Regulation Name: Entamoeba histolytica serological reagents.
Regulatory Class: Class II
Product Code: MHI
Dated: December 30, 2008
Received: December 31, 2008

Dear Mr. Wienholt:

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 such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
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Enclosure

Indications for Use Statement

510(k) Number (if known): K081064

Device Name: *Giardia* Fecal Antigen Detection Lateral Flow Kit

Indications for Use:

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Prescription Use ✓ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Andrew Steve

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

510(k) K081064