K024113

510(k) Summary of Safety and Effectiveness

for

MAR 0 5 2003

IVD Research, Inc.'s Cryptosporidium/Giardia Direct Fluorescent Antigen (DFA) Detection Kit

Submitter: IVD Research Inc.
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Carlsbad, CA 92008 USA
Tel: 760-929-7744 Contact: Dave Lambillotte, President

Prepared: 8 January 2003

Common name: Cryptosporidium/Giardia Direct Fluorescent Antigen Detection Kit

Proprietary name: IVD Research's Cryptosporidium/Giardia Direct Fluorescent Antigen Detection Kit

Classification name: Entamoeba histolytica serological reagents

Predicate Device: Meridian Diagnostic's Merifluor ™ Cryptosporidium/Giardia Direct Fluorescent Antigen Detection Kit, 510(k) K912408

DESCRIPTION AND PRINCIPLE:

This **IVD Research, Inc. Cryptosporidium/Giardia Direct Fluorescent Antigen Detection Kit (DFA Assay)** is intended for use as an in vitro diagnostic (IVD) fluorescent immunoassay for the qualitative determination of Cryptosporidium oocysts and Giardia cysts in stool feces. This assay may be used with stool samples that are preserved in 10% formalin, SAF, or Medical Chemical Corporation's (MCC's) Universal Fixative.

This **DFA Assay** corresponds to FDA Classification Name: **Entamoeba Histolytica Serological Reagent**, a class II (non-exempt) Device, within the **Microbiology Classification Panel,** having **FDA Reg. Citation Number: 21 CFR 866.3220, and FDA Product Codes: MHI and MHJ**, and, as such, utilizes the principle of direct immunofluorescence microscopy. The conjugate contains a mixture of FITC-labeled monoclonal antibodies (derived from hybridized mouse B-cells) directed against Cryptosporidium oocysts and Giardia cysts, which, if present, are affixed to a treated slide (provided). The slide with sample material is then rinsed with wash solution to remove unbound conjugate and debris, and air-dried. The prepared slide is then examined using a fluorescent microscope, looking for an apple-green color and the characteristic morphology of the Cryptosporidium oocysts and the Giardia cysts.

SUBSTANTIAL EQUIVALENCE COMPARISON

This **DFA Assay** *in vitro* diagnostic (IVD) kit utilizes a principle of direct immunofluorescence. Conjugate solution within this kit contains a mixture of FITC-labeled mouse-derived monoclonal antibodies antigenically directed against *Cryptosporidium* oocysts and *Giardia* Cysts, which, if present, are affixed to a provided slide. The slide is then rinsed to remove unbound conjugate

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and examined under a fluorescent microscope looking for an apple-green color and the characteristic morphology of the *Cryptosporidium* oocysts and the *Giardia* cysts.

The visual microscopic finding of glowing oocysts or cysts with the correct morphology indicates the positive presence of *Cryptosporidium* or *Giardia*. A similar DFA kit is manufactured by Meridian Diagnostics (Cincinnati, OH). The FDA cleared this assay under 510(k) K912408 in 24 July 1991. This current **DFA Assay** uses the same methodology as that cleared predicate assay.

The following is the data that shows this IVD **DFA Assay** provides substantial equivalence to the gold standard for parasitology (O&P microscopy) as well as the predicate device. The 95% Confidence Interval (CI) for this **DFA Assay** was determined using a Confidence Interval Analysis Microcomputer Program published by the British Medical Journal.

Unless otherwise indicated, all fecal samples are derived from humans.

The "form" of the fecal sample (i.e. formed, soft, liquid, etc.) is not significant to the diagnosis of parasitic infections. *Cryptosporidium* and *Giardia* can be present regardless of the sample form.

Study #1

A total of 170 unconcentrated stools (145 human stools and 25 bovine stools) examined by O&P microscopy were tested against this IVD DFA Assay.
The following results were obtained.

	Micro +	Micro -
DFA +	46	0
DFA -	0	124

For Giardia:
Sensitivity: 100% (46/46) 95% CI = 92% to 100%
Specificity: 100% (124/124) 95% CI = 97% to 100%

	Micro +	Micro -
DFA +	39	0
DFA -	0	131

For Cryptosporidium:
Sensitivity: 100% (39/39) 95% CI = 91% to 100%
Specificity: 100% (131/131) 95% CI = 97% to 100%

Study #2

A total of 53 unconcentrated stools examined by O&P microscopy were tested against this IVD DFA Assay. The following results were obtained.

	Micro +	Micro -
DFA +	16	0
DFA -	0	37

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For Giardia:
Sensitivity: 100% (16/16) 95% CI = 79% to 100%
Specificity: 100% (37/37) 95% CI = 90% to 100%

	Micro +	Micro -
DFA +	11	0
DFA -	0	42

For Cryptosporidium:
Sensitivity: 100% (11/11) 95% CI = 72% to 100%
Specificity: 100% (42/42) 95% CI = 92% to 100%

Study #3

A total of 74 formalin and SAF preserved stools were tested against this IVD DFA Assay. The following results were obtained.

	Micro +	Micro -
DFA +	26	0
DFA -	0	48

For Giardia:
Sensitivity: 100% (26/26) 95% CI = 87% to 100%
Specificity: 100% (48/48) 95% CI = 93% to 100%

	Micro +	Micro -
DFA +	18	0
DFA -	1	55

For Cryptosporidium:
Sensitivity: 95% (18/19) 95% CI = 74% to 100%
Specificity: 100% (55/55) 95% CI = 94% to 100%

Study #4

A total of 69 formalin and SAF preserved stools were tested in the predicate device and the IVD DFA Assay. There was 100% correlation between the two assays.

No cross-reactions were seen with this DFA Assay for the following organisms:
Entamoeba hartmanni, Endolimax nana, Entamoeba histolytica/dispar, Entamoeba coli, Blastocystis hominis, Dientamoeba fragilis, Chilomastix mesnili, Strongyloides stercoralis, Ascaris lumbricoides, Enterobius vermicularis, Diphyllobothrium species, *Hymenolepis nana, Enteromonas hominis, Trichuris trichiura, Iodamoeba buetschlii,* Hookworm, *Taenia* eggs,
White Blood Cells, *Cyclospora cayetanensis.*

ANALYTICAL SENSITIVITY

This DFA Assay is capable of detecting 1 oocyst or cyst per 10 ul of unconcentrated sample.

CONCLUSION

IVD Research's Cryptosporidium/Giardia Direct Fluorescent Antigen Detection Kit uses similar methodology to the predicate device. In testing of various fecal specimens, the assay also showed equivalent sensitivity and specificity to the predicate device.

Sincerely,

Dave Lambillotte

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

IVD Research, Inc.
c/o Alfredo J. Quattrone, Ph.D., D.A.B.T.
Third Party 510(k) Review Coordinator
Medical Device Safety Section
Food and Drug Branch, MS-357, DHS
Department of Health Services
601 North 7th Street, P.O. Box 942732, MS-357
Sacramento, CA 94234-7320

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Re: k024113
Trade/Device Name: Cryptosporidium/Giardia Human Fecal Direct Fluorescent Antigen (DFA) Detection Kit
Regulation Number: 21 CFR 866.3220
Regulation Name: Entamoeba Histolytica Serological Reagents
Regulatory Class: Class II
Product Code: MHI, MHJ
Dated: February 6, 2003
Received: February 7, 2003

Dear Dr. Quattrone:

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 (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K024113

Device Name: Cryptosporidium/Giardia Human Fecal Direct Fluorescent Antigen (DFA) Detection Kit

Indications for Use: This direct fluorescent antigen (DFA) detection kit is an in vitro diagnostic (IVD) immunoassay for the detection of Cryptosporidium oocysts and Giardia Cysts in human feces using fluorescent microscopic visualization. This IVD assay is intended to be used with stools preserved in 10% formalin, SAF or Medical Chemical Corporation's (MCC's) Universal fixative. Such samples may be concentrated or unconcentrated.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sally J Selepak for F. Poole

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 024113

Prescription Use ✓ OR Over-the Counter Use _____
(Per 21 CFR 801.109)