JUL 10 2003

K 031059

510(k) Summary of Safety and Effectiveness
for
IVD Research Inc.'s Cryptosporidium Human Fecal Antigen Detection Microwell ELISA Kit

Submitter: IVD Research Inc.
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Tel: 760-929-7744 Contact: Dave Lambillotte, President
Prepared: 12 May 2003

Common name: Cryptosporidium Human Fecal Antigen Detection Microwell ELISA Kit

Proprietary name: IVD Research's Cryptosporidium Human Fecal Antigen Detection Microwell ELISA Kit

Classification name: Entamoeba histolytica serological reagents

Predicate Device: LMD Laboratories' Cryptosporidium Antigen Detection ELISA, 510(k) K955345

DESCRIPTION AND PRINCIPLE:

This microwell enzyme-linked immunoabsorbant assay (ELISA) detection kit (Cryptosporidium ELISA Kit) is an in vitro diagnostic (IVD) immunoassay for the detection of antigen to Cryptosporidium species in human feces using peroxidase as the indicator enzyme. The assay may be read visually or with an ELISA reader. Concentrated fecal samples cannot be used with this immunoassay. Rather, this IVD Cryptosporidium ELISA Kit is intended to be used with human stools that are fresh, frozen or preserved in 10% formalin, SAF or Medical Chemical Corporation's (MCC's) Universal fixative in a clinical laboratory use setting.

This **ELISA** 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: MHJ.**
This ELISA is an *in vitro* immunoassay for the qualitative determination of *Cryptosporidium* species antigen in feces. The ELISA uses a rabbit anti-*Cryptosporidium* antibody to capture the antigen from the stool supernatant. A second goat anti-*Cryptosporidium* antibody is then added which sandwiches the captured antigen. This reaction is visualized by the addition of an anti-second antibody conjugated to peroxidase and the chromogen tetramethylbenzidine (TMB). The resulting blue color development indicates the presence of *Cryptosporidium* species antigens being bound by the anti-*Cryptosporidium* antibodies.

SUBSTANTIAL EQUIVALENCE COMPARISON

A similar ELISA kit was developed and manufactured by LMD Laboratories (San Diego, CA). The FDA cleared this assay under 510(k) K955345 in 7 June 1996. This current kit uses the same methodology (ELISA) and similar reagents as that cleared predicate assay.

Following is the data that shows this firm's ELISA provides substantial equivalence to the gold standard for parasitology (O&P microscopy) as well as the predicate device. The 95% Confidence Interval (CI) was determined using a Confidence Interval Analysis Microcomputer Program published by the British Medical Journal.
All specimens are human samples supplied by clinical laboratories or in-house collections.

May 12, 2003

Study #1 (Outside Lab)

A total of 174 formalin, SAF, fresh/frozen and Universal Fixative preserved stools were tested against the ELISA test The results were interpreted visually.
The following results were obtained.

	Micro + (O&P)	Micro – (O&P)
IVD ELISA +	24	4
IVD ELISA -	0	146

Sensitivity: 100% (24/24) 95% CI = 86% to 100%
Specificity: 97% (146/150) 95% CI = 93% to 99%

No cross-reactions were seen with the following organisms:
Entamoeba hartmanni, Endolimax nana, Entamoeba histolytica/dispar, Entamoeba coli, Blastocystis hominis, Dientamoeba fragilis, Chilomastix mesnili, Giardia lamblia, Cyclospora cayetanensis oocysts, *Strongyloides stercoralis, Ascaris lumbricoides, Enterobius vermicularis* (pinworm), *Diphyllobothrium* species, *Hymenolepis nana, Clonorchis sinensis, Enteromonas hominis, Trichuris trichiura, Iodamoeba buetschlii,* Hookworm (*Necator americanus), Schistosoma mansoni, Taenia* eggs, *Fasciola* eggs, *Isospora belli, Entamoeba polecki*, adenovirus, rotavirus, *E. coli, Campylobacter, Salmonella, Shigella, Yersinia* and 29 other bacterial species (list available on request).

Study #2 (Manufacturer Performed)

A total of 44 fresh or fresh/frozen stools examined by O&P microscopy and/or another commercial ELISA were tested against this IVD ELISA. The following results were obtained.

	ELISA	ELISA
IVD ELISA +	14	0
IVD ELISA -	0	30

Positive Agreement = 100% (14/14)
Negative Agreement = 100% (30/30)

The breakdown for the samples in the studies is as follows:

Media	Cryptosporidium +	Other Parasites
Fresh/Frozen	14	0
10% Formalin	24	25
SAF	1	83
MCC	2*	31

*These two samples were seeded samples.

Analytical Sensitivity

This assay can detect approximately 50 nanograms of soluble protein per ml of *Cryptosporidium* species antigen or 10 oocysts per well. At these detection levels, an OD range of 0.15 to 0.30 can be expected.

CONCLUSION

IVD Research's Cryptosporidium Human Fecal Antigen Detection Microwell ELISA 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 and O&P microscopy.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 10 2003

IVD Research, Inc.
c/o Alfredo J. Quattrone, Ph.D., D.A.B.T.
California Department of Health
Food & Drug Branch
P.O. Box 942732 (MS-357)
Sacramento, CA 94234

Re: k031059
Trade/Device Name: Cryptosporidium Human Fecal Antigen Detection Microwell ELISA Kit
Regulation Number: 21 CFR 866.3220
Regulation Name: Entamoeba histolytica serological reagents
Regulatory Class: Class II
Product Code: MHJ
Dated: March 27, 2003
Received: March 28, 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). 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/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: Pending this Submission K031059

Device Name: Cryptosporidium Human Fecal Antigen Detection Microwell ELISA Kit

Indications for Use: This microwell enzyme linked immunoabsorbant assay (ELISA) detection kit is an in vitro diagnostic (IVD) immunoassay for the detection of Cryptosporidium antigen in human feces using peroxidase as the enzyme. The assay may be read visually or with an ELISA reader. This IVD assay is intended to be used with stools that are fresh, frozen or preserved in 10% formalin, SAF or Medical Chemical Corporation's (MCC) Universal fixative. Concentrated samples cannot be used with this IVD.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031059