

K980354

MAY 18 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

1. Name of Manufacturer

TechLab, Inc.
1861 Pratt Drive, Ste. 1030
Corporate Research Center
Blacksburg, VA 24060-6364

2. Establishment Registration

Federal ID # 54-1527427
Initial Registration of Medical Device Establishment, #1122855

3. Trade Name

Cryptosporidium TEST

4. Common Name

Cryptosporidium enzyme immunoassay

5. Class of Device

This device is classified in Class I.

6. Performance Standards

No performance standards have been developed for this device under 514 of the Food, Drug, and Cosmetic Act.

7. Safety and Effectiveness

The *Cryptosporidium TEST* can be used to detect *Cryptosporidium parvum* oocyst antigen in fecal specimens from persons suspected of having cryptosporidiosis. The kit, which includes ready-to-use reagents, contains microtiter wells coated with monoclonal antibody, positive control reagent, detecting antibody (polyclonal antibody), conjugate (anti-rabbit IgG-peroxidase), substrates, wash solution, and stop solution. The microtiter wells coated with monoclonal antibody "capture" the antigen and the polyclonal antibody serves as the "detecting" antibody. The polyclonal antibody used as the detecting antibody is prepared from hyperimmune antiserum developed in rabbits. The monoclonal antibody used to coat microtiter wells is prepared from mouse ascites fluid.

The *Cryptosporidium TEST* is to be used in an enzyme immunoassay format and is substantially equivalent to microscopy (conventional staining methods) used in some clinical laboratories as diagnostic aids for cryptosporidiosis. In addition, the *Cryptosporidium TEST* is substantially equivalent to the Alexon ProSpecT *Cryptosporidium* Microplate Assay which has been approved for *in vitro* diagnostic use. These tests all serve as diagnostic aids for *Cryptosporidium*-associated disease by detecting the organism or its antigens.

The *Cryptosporidium TEST* was compared with the detection of the organism in fecal specimens by microscopy with conventional staining and immunofluorescence. In addition, the test was compared with the Alexon ProSpecT *Cryptosporidium* Microplate Assay for the detection of *Cryptosporidium* antigen in fecal specimens. The results of our clinical evaluations show that the *Cryptosporidium TEST* exhibits a correlation of >95% when compared with these other methods for detecting *Cryptosporidium* in fecal specimens. These results show that the *Cryptosporidium TEST* is useful for the detection of *Cryptosporidium* in fecal specimens.



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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

David M. Lyerly, Ph.D.
Vice President
TechLab, Inc.
1861 Pratt Drive, Suite 1030
Corporate Research Center
Blacksburg, VA 24060-6364

Re: K980354
Trade Name: Cryptosporidium Test
Regulatory Class: II
Product Code: MHJ
Dated: April 20, 1998
Received: April 24, 1998

Dear Dr. Lyerly:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

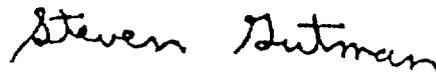
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>"

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K980354

Device Name: Cryptosporidium TEST

Indications For Use:

The *Cryptosporidium TEST* is an enzyme immunoassay for the qualitative detection of *Cryptosporidium* oocyst antigen in fecal specimens. It is indicated for use with fecal specimens from patients with diarrhea to determine the presence of *Cryptosporidium* gastrointestinal infection. This test can be used for fecal specimens submitted for routine clinical testing from adults or children. FOR *IN VITRO* DIAGNOSTIC USE.

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

_____ Concurrence of CDRH, Office of Device Evaluation (ODE) _____

Woody Dubois
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K980354

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)