12/21/99 K994101

SUMMARY OF SAFETY AND EFFECTIVENESS (*E. histolytica II*)

1. Name of Manufacturer

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

2. Establishment Registration

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

3. Trade Name

E. histolytica II

4. Common Name

E. histolytica ELISA

5. Class of Device

This device is classified in Class II.

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 *E. histolytica II* can be used to detect adhesin (also referred to as galactose-inhibitable lectin) produced by strains of *E. histolytica*. It does not cross-react with the adhesin from *E. dispar* (formerly known as nonpathogenic *E. histolytica*). The test can be used to detect the adhesin in fecal specimens from persons suspected of having amebiasis. The kit, which includes ready-to-use reagents, contains microtiter wells coated with polyclonal antibody, positive control reagent, monoclonal-antibody conjugate, diluent, one component substrate, wash solution, and stop solution. The microtiter wells coated with polyclonal antibody "capture" the adhesin and the monoclonal antibody-conjugate serves as the "detecting" antibody. The polyclonal antibody used to coat the wells is prepared from hyperimmune antiserum developed in goats. The monoclonal antibody used to prepare the conjugate is prepared from mouse ascites fluid.

SUMMARY OF SAFETY AND EFFECTIVENESS (*E. histolytica II*) (cont'd)

The *E. histolytica II* is to be used in an ELISA format and is substantially equivalent to culturing and zymodeme analysis that are used in some clinical laboratories as diagnostic aids. It also is more sensitive than our *E. histolytica* TEST (K955895), which has been cleared previously for *in vitro* diagnostic use. Culturing is used to obtain the isolate and zymodeme analysis is used to examine the enzyme profile of the isolate. Zymodeme analysis must be used to determine if the isolated *Entamoeba* strain is pathogenic. The major disadvantages are that culturing and zymodeme are time-consuming and labor-intensive. Only a few clinical laboratories around the world are capable of performing this type of analysis. The *E. histolytica II* offers a major advantage to clinical laboratories because it is rapid, easy-to-perform, and it is more sensitive than our *E. histolytica* TEST, which was the first test to offer clinical labs a simpler and easier alternative format than zymodeme analysis for the specific detection of pathogenic *E. histolytica*. Like the *E. histolytica* TEST, the *E. histolytica II* is highly specific for pathogenic *Entamoeba*

The *E. histolytica II* is different from TechLab's *Entamoeba* TEST and the Alexon ProSpecT *Entamoeba histolytica* Test. These two tests detect both *E. histolytica* (formerly referred to as pathogenic *E. histolytica*) and *E. dispar* (formerly referred to as nonpathogenic *E. histolytica*). They do not distinguish between *E. histolytica* and *E. dispar*. The *E. histolytica II* is very similar to TechLab's *E. histolytica* TEST. Both are highly specific for the adhesin of *E. histolytica* and neither cross-reacts with the adhesin of *E. dispar*. Both have the same procedure and utilize an ELISA format. The difference between the *E. histolytica II* and the *E. histolytica* TEST is that the *E. histolytica II* offers increased sensitivity. Although all of these tests serve as diagnostic aids for amebiasis, the *E. histolytica II* is specific for pathogenic strains and offers higher sensitivity.

The *E. histolytica II* was used to analyze stool specimens in areas where amebiasis is endemic, and the results were compared with zymodeme analysis of *Entamoeba* isolates cultured from these specimens and with the *E. histolytica* TEST. It is important to remember that culture, without the aid of zymodeme analysis, does not distinguish between *E. histolytica* and *E. dispar*. Zymodeme analysis, which is available only in a select number of clinical laboratories around the world, is the only method that distinguishes these species. For the purpose of our studies, zymodeme analysis represents the "gold standard". The results of our clinical evaluations show that the *E. histolytica II* exhibits a correlation of >97% when compared with zymodeme analysis, and that it is more sensitive than the *E. histolytica* Test for detecting *E. histolytica* trophozoites and adhesin. Our findings demonstrate that the test is useful for the detection of pathogenic *E. histolytica* in stool specimens.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 21 1999

David M. Lyerly, Ph.D.
Vice President
TechLab, Inc.
VPI Research Park
1861 Pratt Drive, Suite 1030
Blacksburg, Virginia 24060-6364

Re: K994101
Trade Name: *E. histolytica II*
Regulatory Class: II
Product Code: KHW
Dated: November 22, 1999
Received: December 6, 1999

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 Gutman

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

K 994101

510(k) Number (if known): K994101

Device Name: *E. histolytica II*

Indications For Use:

The *E. histolytica II* is an enzyme immunoassay for the rapid detection of the adhesin of *E. histolytica* in human fecal specimens. It is indicated for use with fecal specimens from patients with diarrhea or dysentery to determine the presence of *E. histolytica* gastrointestinal infection. The test can be used for fecal specimens submitted for routine clinical testing from adults or children. Conventional microscopy is not a prerequisite for use of the test. 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 Dutcher

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K994101

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)

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