SUMMARY OF SAFETY AND EFFECTIVENESS

K955895

1. Name of Manufacturer

TechLab, Inc.
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1861 Pratt Drive
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2. Establishment Registration

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

3. Trade Name

E. histolytica Test

4. Common Name

E. histolytica ELISA

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 *E. histolytica* Test 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, two component substrate, wash solution, and intensifier. 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 rabbits. The monoclonal antibody used to prepare the conjugate is prepared from mouse ascites fluid.

The *E. histolytica* Test 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. 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* Test offers a major advantage to clinical laboratories because it is rapid, easy-to-perform, and it is the first test to offer clinical labs a simpler and easier alternative format for the specific detection of pathogenic *E. histolytica*.

The *E. histolytica* Test is different from two other ELISAs currently on the market in the U.S. These other ELISAs, TechLab's *Entamoeba* Test and the Alexon ProSpecT *Entamoeba histolytica* Test, 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* Test is specific for the adhesin of *E. histolytica* and it does not cross-react with the adhesin of *E. dispar*. Although all of these tests serve as diagnostic aids for amebiasis, the *E. histolytica* Test offers the advantage of being specific for pathogenic strains.

The *E. histolytica* Test 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. It is important to remember, however, 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* Test exhibits a correlation of >93% when compared with zymodeme analysis, and demonstrate that the test is useful for the detection of pathogenic *E. histolytica* in stool specimens.