SUMMARY OF SAFETY AND EFFECTIVENESS

1. Name of Manufacturer

K955852

AUG - 5 1996

TechLab, Inc.
Corporate Research Center
1861 Pratt Drive
Blacksburg, VA 24060

2. Establishment Registration

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

3. Trade Name

Crypto-Cel IF Test

4. Common Name

Cryptosporidium Immunofluorescent Test

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 TechLab *Crypto*-Cel IF Test can be used to detect *Cryptosporidium* oocysts in fecal specimens from persons suspected of having intestinal disease due to this pathogen. The kit, which includes ready-to-use reagents, contains an antibody reagent consisting of FITC-labeled anti-*Cryptosporidium* monoclonal antibody. This antibody functions as the detecting antibodies. The monoclonal antibody is prepared from mouse ascites fluid.

The *Crypto*-Cel IF Test is to be used in an immunofluorescent assay and is substantially equivalent to an approved immunofluorescent test that can be used for the detection of *Cryptosporidium* and *Giardia* in stool specimens. These tests serve as diagnostic aids for cryptosporidiosis by detecting the organism or its antigens.

The TechLab *Crypto*-Cel IF Test was compared in two studies with the Merifluor *Cryptosporidium/Giardia* Direct Immunofluorescent Detection Procedure (Meridian Diagnostics, Inc., Cincinnati, OH) for the detection of *Cryptosporidium* in fecal specimens. In addition, the TechLab test was compared with the *Crypto/Giardia*-Cel IF Test, for which we have submitted a 510(k) application. The results of our clinical evaluations show that the TechLab *Crypto*-Cel IF Test exhibits a correlation of 100% when compared with these tests. These results show that the TechLab *Crypto*-Cel IF Test is useful for the detection of these pathogens in fecal specimens.