

For Immediate Release:
December 18, 2003

First FDA Cleared Laboratory Test for Anthrax

Tetracore, Inc. announced today, December 18, 2003, that it has received 510(K) clearance from the Food and Drug Administration (FDA) for RedLineAlert™, an antibody-based test kit for use as an aid in the clinical laboratory identification of Bacillus anthracis colonies from culture plates. B. anthracis is the causative agent of anthrax. The test is a lateral flow immunoassay containing a monoclonal antibody which is specific for the presence of a cell surface protein found in Bacillus anthracis vegetative cells. The test can be used on colonies as early as 12 hours old. Attended time takes as little as 10 minutes and the test can be fully completed within 20 minutes. In data submitted to the FDA on 145 Bacillus anthracis isolates, the RedLine Alert percent correct was 98.6%; these isolates originated from 28 countries world-wide. This compared favorably to another well recognized confirmatory test called gamma phage lysis, which can require an additional day of culture to perform, whose percent correct was 97.2%. In addition, the RedLine Alert™ Test had an accuracy of 100% in correctly differentiating B. anthracis from forty-nine other non-hemolytic Bacillus. Dr. Beverly L. Mangold of Tetracore commented, "We are excited to be able to provide a significant new clinical and public health tool to aid in protecting against bio-terrorism threats."

Tetracore wishes to thank the following organizations for their help in evaluation of this test: Brigham Young University, Department of Microbiology (Dr. Richard Robison); U.S. Army Medical Research Institute of Infectious Diseases (Dr. John Ezzell); Wadsworth Center, New York State Department of Health (Dr. Nick Cirino); Los Alamos National Laboratory (Dr. Paul Jackson), Florida Department of Health Bureau of Laboratories - Miami (Dr. Segaran P. Pillai), St. Michael's Hospital Toronto, Canada (Dr. H. Roslyn Devlin), North Shore - Long Island Jewish Health System Laboratories (Dr. Christine C. Ginocchio), and Driscoll Childrens Hospital Microbiology Department, Corpus Christi, Texas (Ms. Pam Zapalac).

The FDA press release regarding RedLine Alert™ can be found at <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00992.html>

About Tetracore, Inc.

Tetracore is a biotechnology R&D and product company whose mission is to create and develop highly innovative diagnostic reagents and assays for infectious diseases and bio-terrorism threat agents. Areas of company focus include clinical, veterinary, and domestic

preparedness testing.