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FDA CLEARS LAB CULTURE TEST FOR ANTHRAX

The Food and Drug Administration (FDA) today cleared a test kit for clinical laboratories to use with culture testing to help distinguish the organism that causes anthrax disease, Bacillus anthracis, from similar organisms.

The Redline Alert test, manufactured by Tetracore, Inc., of Gaithersburg, Md., is intended to be performed with other laboratory tests and procedures on a laboratory culture of bacterial cells from people who may have been infected with B. anthracis. The test helps determine whether or not a person has anthrax disease.

"Today's approval of a lab test for anthrax infection is another first step forward in our urgent mission to protect Americans from biological weapons," said Mark B. McClellan, M.D., Ph.D., Commissioner of Food and Drugs. "Working with industry, the academic community, and our

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fellow public health agencies, we are doing more than ever to bring better protections against terrorism to the public."

The Redline Alert is an additional tool that laboratories can use to more easily identify B. anthracis. The test is easy and simple to use. Once cells are growing in the lab cultures, it can be performed in about 15 minutes and does not require specially trained personnel or special instrumentation. Other identification tests now used by laboratories may require overnight testing or special equipment and specially trained personnel.

To perform the test, a portion of the cultured cells is added to a

cassette that contains immunological reagents. If a certain protein is present in the cultured cells, a light red or pink line appears in the cassette.

This protein is found in the B. anthracis organism and also in some other organisms. These other organisms, however, do not usually resemble B. anthracis in laboratory cultures.

If the Redline Alert test is positive, and other culture characteristics are consistent with this organism, it is likely that the person from whom the cultured cells

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were taken is infected with B. anthracis. Other testing is needed to definitively identify B. anthracis. A negative result with the new test cannot rule out anthrax because in rare cases certain B. anthracis organisms may not give a positive result.

FDA cleared the test for marketing based on studies performed by the manufacturer on 145 cultured B. anthracis organisms from around the world. The Redline Alert correctly gave a positive result with 143 of these samples.

Redline Alert is not intended for use by all laboratories, only those whose staff are trained and proficient with microbiological culture procedures and who use Biological Safety Level-2 practices.

The Centers for Disease Control and Prevention (CDC) recommends consulting with the state public health laboratory director whenever B. anthracis is suspected.

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