



NEWS RELEASE

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Anthrax Test, Developed by Army and CDC, Receives FDA Approval

A method for identifying *Bacillus anthracis*, the causative agent of anthrax, has been cleared for diagnostic use by the U.S. Food and Drug Administration (FDA). The test, known as the Gamma Phage Assay, was modified by scientists at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) to improve its performance and reliability when used with clinical specimens. The original form of the Gamma Phage Assay was first developed by the Centers for Disease Control and Prevention (CDC) in the mid-1950s.

The modified gamma phage method is the first diagnostic test to gain FDA approval for human use within the Laboratory Response Network (LRN). This network, established by the CDC, is charged with maintaining an integrated system of state and local public health, federal, military, and international laboratories that can respond to bioterrorism, chemical terrorism and other public health emergencies.

According to USAMRIID senior scientist John W. Ezzell, the Gamma Phage Assay is a classical bacteriological method that has been used at USAMRIID and other laboratories for years as part of an extensive array of methods used to identify *B. anthracis*. The gamma phage is a virus capable of entering bacterial cells and causing cell destruction, or lysis—and it is specific to *B. anthracis*.

“Because of that specificity, the gamma phage gives a highly readable result,” Ezzell explained. “Wherever the virus is added to the surface of a culture plate that has been inoculated with suspicious anthrax colony growth, you can see clear zones where the *B. anthracis* cells have been destroyed—whereas other bacterial cells grow unaffected.”

Well before the anthrax attacks of 2001, scientists at USAMRIID and the CDC recognized the need for an FDA accepted method for identifying *B. anthracis* in clinical specimens. In 2002, FDA’s Division of Clinical Laboratory Devices agreed to recognize tests for *B. anthracis* as eligible for classification with a 510(k) premarket notification process—the designation given to devices and other non-biologics.

USAMRIID, with support from CDC, prepared and submitted a 510(k) Premarket Notification using both USAMRIID and CDC data on use of the gamma phage method. With FDA recognition of the assay as substantially equivalent to the classical assay used prior to 1976, it will be available for use for testing in designated civilian and military clinical laboratories.

“This is a big first step in helping to provide the LRN labs with FDA cleared assays,” said Judy Sheldon, a regulatory affairs microbiologist with the CDC’s Bioterrorism Preparedness and Response Program. “The work done at USAMRIID and here at CDC provided a solid scientific basis for FDA to evaluate the assay performance. This work has set a high bar for other tests to meet.”

USAMRIID scientists standardized and validated the test to make it more rugged, more reproducible across laboratories, and more resistant to user error. They developed a clearly defined method for production of gamma phage that proved to be highly stable, as reflected in the extended shelf life of the *B. anthracis*-specific virus. USAMRIID then provided sufficient gamma phage material to CDC for distribution within the LRN, so that each laboratory will have the same material to be used in the test. In addition, USAMRIID developed Standard Operating Procedures for the assay to ensure that each laboratory in the LRN will run the test the same way. This also increases confidence in the final result.

“This represents a very significant milestone for both of our organizations, in that all of the medical diagnostic products that we are developing must eventually follow a similar pathway for approval to allow clinical diagnosticians to use these tests to positively identify pathogens,” said Colonel George W. Korch, Jr., commander of USAMRIID. “Successes such as these demonstrate that we can translate our research efforts into products for our health care providers and clinical laboratory professionals.”

A study to document and validate the performance characteristics of the assay will be published in the September 2005 issue of the *Journal of Clinical Microbiology*. In the paper, authors Terry G. Abshire, J. Edward Brown, and John W. Ezzell of USAMRIID also describe how they standardized production of the phage and determined the stability of the assay.

USAMRIID, located at Fort Detrick, Maryland, is the lead medical research laboratory for the U.S. Biological Defense Research Program, and plays a key role in national defense and in infectious disease research. The Institute’s mission is to conduct basic and applied research on biological threats resulting in medical solutions (such as vaccines, drugs and diagnostics) to protect the warfighter. USAMRIID is a subordinate laboratory of the U.S. Army Medical Research and Materiel Command.

The CDC is one of the 13 major operating components of the Department of Health and Human Services (HHS), which is the principal agency in the United States government for protecting the health and safety of all Americans and for providing essential human services. Since it was founded in 1946, CDC has remained at the forefront of public health efforts to prevent and control infectious and chronic diseases, injuries, workplace hazards, disabilities, and environmental health threats.

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