

Detection of infection

Q fever is an emerging infectious disease among US soldiers serving in Iraq and elsewhere. **Idaho Technology** chief corporate development officer Todd Ritter explains how the Q Fever Kit, which runs on the company's joint biological agent identification and diagnostic system, is different to other laboratory tests for detecting the bacteria.

Can you give us some background of Idaho Technology's history in DNA analysis?

Todd Ritter: Idaho Technology is a privately held biotechnology company. We pioneered the field of rapid DNA amplification with the development of our first instrument in 1990. The invention of air thermal cycling revolutionised DNA analysis by reducing amplification time from three hours to 30 minutes. Further improvements led to the development of real-time DNA analysis, in which DNA detection occurs as the molecular reaction progresses. This technology was licensed to Roche Diagnostics, and used in its popular LightCycler platform in the diagnostic market. Now, Idaho Technology has developed RAPID, the first ruggedised DNA analysis instrument capable of being used by soldiers in the field.

What experience does Idaho Technology have of working with the military?

We have developed and fielded a number of systems for the US Department of Defense. Among them are the joint biological agent identification and diagnostic system (JBAIDS) – which has become the biothreat identification and diagnostics standard for the US military – the field-hardened and battery-powered RAZOR, and a suite of complementary sample preparation and reagent products.

Over the past ten years, Idaho Technology has delivered thousands of testing platforms, and millions of reagents and prep kits for biothreat identification and diagnostics. We are always working to improve the technology, and give soldiers additional capabilities that are easy to use, reliable and – most importantly – mission capable.

Why did you create the JBAIDS?

The JBAIDS was developed in response to a US Department of Defense request for a diagnostic platform to improve the speed and accuracy of the detection and identification of biological warfare agents. Prior to JBAIDS, it took between two and four days in a lab to accurately identify biological agents. The JBAIDS has improved that time to 40 minutes in the field, and has 95% accuracy.

What are the benefits of deploying the JBAIDS? Does it enhance force protection?

The JBAIDS provides rapid identification of threat agents so that soldiers in the field can react appropriately – whether that means determining the proper personal protective equipment needed or evacuating an area.



Idaho Technology's products allow soldiers to be tested immediately in the field, eliminating the need to wait for lab results.

In recent years, the system's capability has been expanded to include soldier diagnostics, as several JBAIDS assays have received US Food and Drug Administration (FDA) clearance. Currently, there are seven FDA-cleared JBAIDS assay kits, with variants for influenza A and influenza B recently receiving the necessary clearance. Today, JBAIDS is used not only to detect biothreat agent detection, but also to diagnose more common diseases.

How has the JBAIDS programme allowed you to expand your military products and services?

It has allowed Idaho Technology to have a mutually beneficial relationship with the US Military, aided in the development of military products and services, and helped to enhance the US military's biological identification capability.

An example of such a collaboration is the development and successful fielding of Idaho Technology's RAZOR EX biothreat detection system, which uses the same DNA analysis principles as JBAIDS, but shrinks the form factor to a hand-carry instrument that can be powered by a lithium-ion battery in the field.

Other operational improvements and features increase RAZOR EX's ease-of-use; the product has been simplified to the point that non-scientific personnel can reliably perform DNA analysis without sacrificing accuracy. In fact, RAZOR EX has been adopted by civilian agencies – including civil defence forces, first responders and private security personnel – and deployed after white-powder threats.

Q fever is an emerging infectious disease among US soldiers. How is the disease contracted, and what are the dangers if it is not treated?

According to the US Centers for Disease Control and Prevention, human infection usually occurs by inhalation of the bacteria *Coxiella burnetii* from air that contains barnyard dust contaminated by dried placental material, birth fluids or waste from infected animals. Transmission can also occur through tick bites and the ingestion of unpasteurised milk or dairy products.

Although most people that contract acute Q fever recover, there is the possibility of secondary infections such as pneumonia. The disease can also manifest in a chronic form, which has a higher mortality rate. Early diagnosis and treatment with antibiotics reduces the illness's course.

The FDA recently cleared Idaho Technology's polymerase chain reaction (PCR) test for early-stage Q fever diagnosis. How does the test work?

DNA is extracted from a patient's whole-blood sample using Idaho Technology's Platinum Path Kit and then run on the JBAIDS. The test detects a region of DNA specific to *Coxiella burnetii*. It is a qualitative test that alerts the clinician to the presence or absence of the disease-causing agent.

Other laboratory tests exist to detect the bacteria. How is your test different?

Diagnostic tests based on the detection of antibodies can be used, but are not practical as they will frequently appear negative in the first seven to ten days of illness, which is the critical period for beginning a course of antibody treatment. In most cases, doctors decide to treat Q fever based on clinical suspicion, and send samples to the lab for analysis using a PCR-based test. However, PCR is most sensitive in the first week of the illness and decreases in sensitivity as appropriate antibiotics are administered. The JBAIDS Q fever assay allows soldiers to be immediately tested using PCR rather than waiting for results to be returned from the lab.

How do you see the market developing?

It is changing to encompass multi-use instruments such as FilmArray. With shrinking budgets, militaries can no longer afford to deploy rarely used equipment. They want instruments that they can use on a day-to-day basis to diagnose common diseases that affect soldiers' health, as well as have the capability of identifying a bioterrorism agent if one is ever deployed. ■

Further information

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