THE 2014 FLC MID-CONTINENT REGION ANNUAL AWARDS

Nomination Form

Please note the specific criteria for the nominated award.

I nominate the following individual, technology, or organization for the following award (please √):

- ❑ Regional Laboratory Award
- ❑ Representative of the Year Award
- ❑ Notable Technology Development Award
- ❑ Notable State & Local Government Collaboration
- ❑ Regional Partnership Award
- ❑ STEM Mentorship Award
- x **Excellence in Technology Transfer**

Nomination submitted by: Jackie Kerby Moore, Manager, Technology and Economic Development Department
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Nominees' Names: Thayne Edwards, Senior Member of Technical Staff, Jason Harper, Senior Member of Technical Staff, Melissa Finley, Principal Member of Technical Staff, David Wick, Licensing Executive, Yasmin Dennig, Senior CRADA Agreements Specialist, Sandia National Laboratories; Markku Koskelo, Chief Scientist, Martha Talbott, Director of Contracts, Aquila; Luay Shawwa, NIMA Ventures.

Affiliations: Sandia National Laboratories and as noted above.

Laboratory Director/CEO or Point of Contact: Linda von Boetticher T#/email: (505) 844-9462, lvonboe@sandia.gov

BaDx (Bacillus anthracis Diagnostic) Cartridge - also known as Anthrax Detection Cartridge
Basis for Nomination—Excellence in Technology Transfer
Overview

The consequences of not testing animals suspected of having anthrax are life-and-death. Farmers, particularly those in developing countries where testing is not easily accessible, are at risk if they are exposed to an infected animal. Current diagnostic tests, at about $30, still require expensive laboratory equipment for sample analysis and possibly long-distance transport of live bacteria, but a new anthrax detection cartridge developed by Sandia National Laboratories, the BaDx (*Bacillus anthracis* Diagnostic) Cartridge, is making testing much less costly, about $8, eliminates the long-distance transport, and is suitable for environments with very limited resources.

Farmers and those eating sick animals aren't the only people at risk. Laboratory staff members risk exposure to the dangerous spores in the course of culturing and testing them. Anthrax also poses a significant threat to U.S. national security as demonstrated by the 2001 terrorist attacks targeting the U.S. Postal Service and Hart Senate Office Building in Washington, D.C.

A Laboratory Directed Research and Development (LDRD) project at Sandia to develop an anthrax detection device for low-resource environments resulted in the BaDx, a self-contained detector which is efficient, safer, and more secure than current test methods. The device has recently been licensed to Aquila, a small business that specializes in the design and manufacture of technologies and services for nuclear security and international safeguards. Orders for the device have been placed and long-term goals include adapting the device to test for other types of dangerous bacteria such as *E. coli, Staphylococcus*, and *Streptococcus*.

Figure 1. The BaDx Cartridge

Description of Technology Transferred

The BaDx is a self-contained credit-card sized anthrax detection cartridge which is safe, cost-effective, and easy to use. It helps people improve the safety, security, and efficiency of testing for *bacillus anthracis*, the bacteria that causes anthrax, through its simplicity and features such as self-contained decontamination.

The BaDx requires no battery or electric power to operate, no cold-chain storage, and it can detect very small numbers of *B. anthracis* spores. That makes it especially useful in parts of the world where anthrax is prevalent, but refrigeration and lab facilities are lacking. To run a test, a sample is placed into the amplification chamber (patent pending), which contains selective growth media. The device then uses a lateral flow assay (LFA), similar to a common pregnancy test, to detect the *B. anthracis*. Magnetically operated valves (patent pending) allow the sample to advance from stage to stage to complete the testing process. A colored line will appear on the device, if the test is positive. The last stage of the process is the included self-disinfection step.

The team expects to use the basic device design to develop tests for other types of infectious, dangerous bacteria simply by changing the selective growth media and LFA strip.

The recipient of the technology transfer is Aquila, a woman-owned small business based in Albuquerque, NM. The transfer took place in December 2013 with the signing of a license for the two patents regarding the technology of the *anthracis* detector, and was furthered in March, 2014 when a related CRADA was approved.

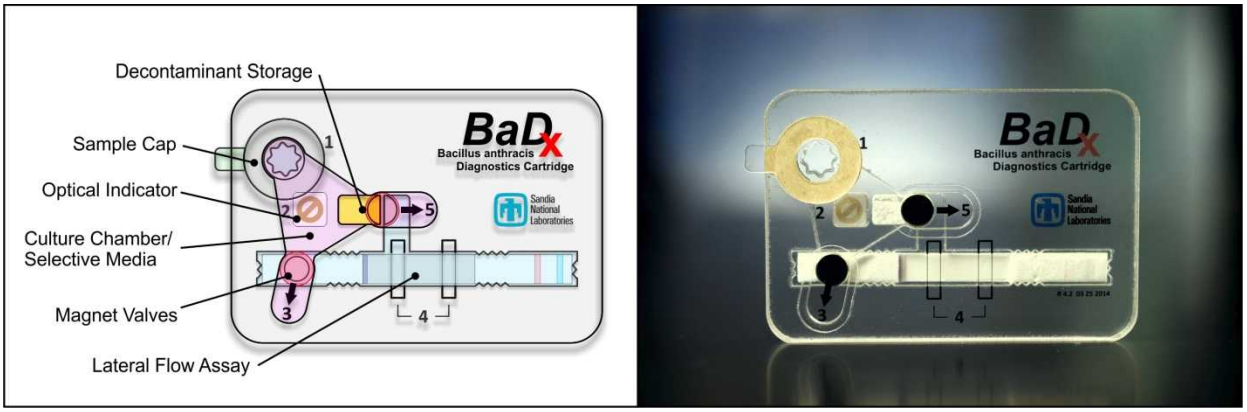

Figure 2. Left: Schematic of cartridge showing major components. Right: Photo of the fabricated cartridge with dimensions of 0.25 in. x 1.875 in. x 2.75 in.

The Technology Transfer Story

Thayne Edwards of Sandia was introduced to Luay Shawwa of NIMA Ventures while discussing research and commercialization of biosensor technology. When Edwards heard that one of NIMA's goals was to commercialize research related to homeland security, he shared information about the *anthracis* biosensor, which had recently been protected by patent filings. Shawwa had worked with Aquila for years on various projects and became the significant driving force for this project. Shawwa introduced Edwards to Markku Koskelo, chief scientist at Aquila, a non-disclosure agreement (NDA) was signed between NIMA, Aquila, and Sandia. Edwards introduced Jason Harper of Sandia to the team which began discussions about the detector technology and its future.

The goal of Aquila was to secure a non-exclusive license for the anthrax detection cartridge device and to sign an umbrella CRADA in order to work with Sandia on all the additional variants of the basic concept, as well as for the development and industrialization of other related and unrelated ideas, some of which became obvious already during the early discussions.

The goal of Sandia was to commercialize a technology which could be of use to people around the world, particularly in developing countries. It will benefit the livestock industry as well as prevent human mortality while reducing security risks associated with anthrax.

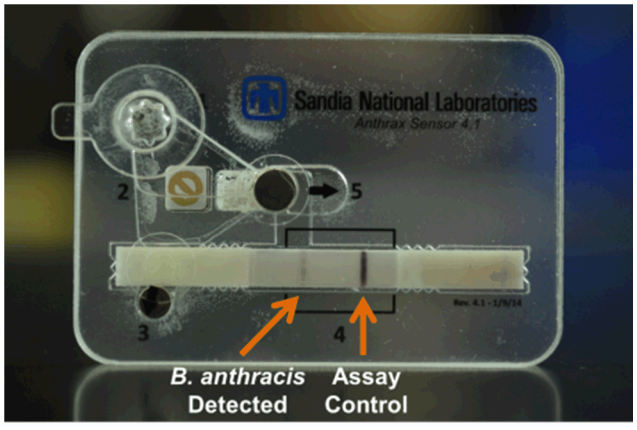

Figure 3. The cartridge in operation with a control sample in the culture chamber which has been introduced onto the LFA through the valve. The LFA indicates a positive response.

An NDA, filing for regular patents to upgrade provisional patents, a license for the anthrax detection cartridge technology, and an umbrella CRADA were utilized to transfer the technology.

Parties included Shawwa of NIMA Ventures as a business partner for Aquila, Koskelo, as the technology transfer expert and scientific advisor and Martha Talbott as the contract expert at Aquila along with the Aquila management team. David Wick, a Sandia licensing executive, and Yasmin Dennig, a Sandia CRADA expert joined the discussions. With Sandia management approval, the license and the CRADA moved along quickly due to all parties' hard work, excellent communication, and motivation. Two months after agreeing to proceed, the license was acquired, and by March 2014, the CRADA was finalized. This was made possible in part by having Wick work with Aquila to establish the terms of the license while Dennig worked simultaneously to detail the CRADA.

The expectations of Sandia and Aquila were exceeded. The process went very quickly. It only took five months from the initial meeting of Edwards, Shawwa, and Koskelo in late July, 2013 to the signing of the license in December, and then a few more months for the CRADA. While Aquila has licensed other Sandia technologies and dealt with other national laboratories, they are particularly enthusiastic about the BaDx project. They feel that the technical support and collaboration with Sandia researchers, as well as the smooth and rapid licensing process, have been excellent. The Umbrella CRADA should also result in more collaboration with Sandia on other joint projects.

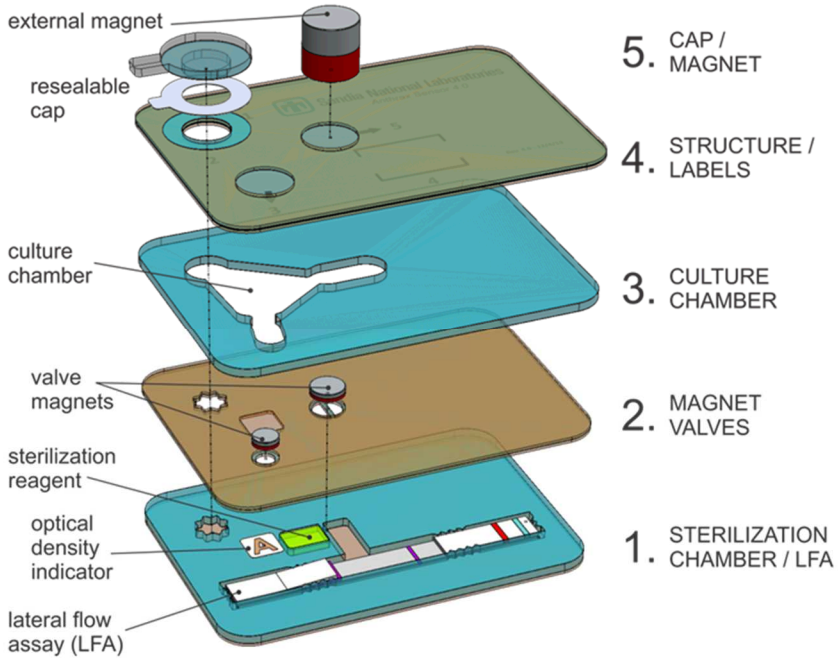

Figure 4. This schematic is an exploded view of the various cartridge modules and indicates the primary components of each module..

Outcomes of the Technology Transfer

The technology has potential for government customers and nongovernmental organizations, as well as commercial markets across the globe. As part of the CRADA, Sandia has placed an order for these devices from Aquila. Another unnamed customer has also placed an order for fieldable units. The NIMA/Sandia/Aquila NDAs and subsequent umbrella CRADA has encouraged a vision of a continued pipeline of development, technology transfer, and identification of potential additional collaboration. Also, an NDA was put in place between Sandia and Landauer to talk about crossover technologies. And finally, another company with differing but complementary technology has reached out to both Aquila and Sandia due to their interest in joining the technology commercialization adventure.

As Sandia is not a manufacturing company, this technology transfer was necessary to provide BaDx as a reliable tool for reducing biological threats to national security. Melissa Finley's research in Sandia's International Biological Threat Reduction Program inspired the detector. Finley works with veterinary labs in less-developed countries, helping them improve safety, security, and efficiency at diagnosing infectious diseases.

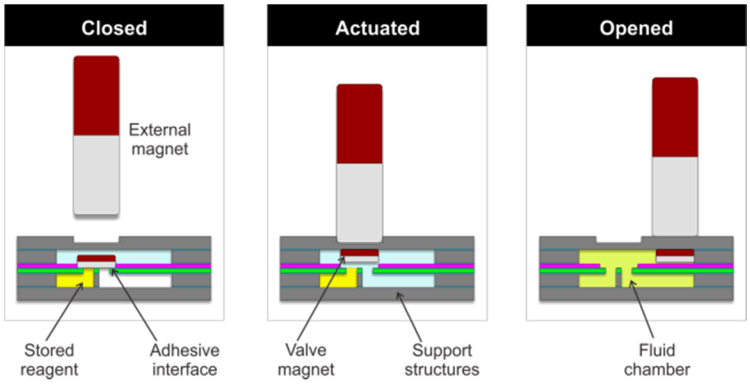

Figure 5. Operation of valve for cartridge decontamination. Left: valve is closed. Middle: an external magnet brought in close proximity unseats the valve magnet. Right: the magnet is moved away, allowing the reagents to mix.

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