SAND2009-4546P

**THE 2009 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 — Regional Partnership Award

☐ Representative of the Year Award — STEM Mentorship Award

☐ Notable Technology Development Award — **X Excellence in Technology Transfer**

**DESCRIPTIVE TITLE OF NOMINATED TECHNOLOGY DEVELOPMENT**

**Rapid, Automated, Point-of-Contact System (RapiDx)**

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## BASIS FOR THE NOMINATION

### Criteria Part A–Background and Technology Transfer Process

**A1. Description of Technology and Transfer (30 points)**

In critical situations, time is of the essence when it comes to saving lives. RapiDx is a point-of-care (POC) clinical diagnostics system that detects indicators of disease and exposure to toxins. Based on lab-on-a-chip technology, RapiDx is highly sensitive and rapidly measures disease and toxin biomarkers from human biological samples including blood, saliva, and urine. RapiDx addresses a variety of critical needs for technologies that can be used at the point of care or point of incident: it provides rapid results; it is non-invasive (e.g., it does not require a blood draw); it is automated and easy to use; it will be available for a low cost; and it uses disposable cartridges and reagents that have a long shelf life with stability under various ambient conditions including space.

Lives are saved by timely measurements of protein signatures (biomarkers) linked to injury, disease, or infection. It is widely acknowledged that measuring biomarker signatures as early as possible—often before symptoms even appear—is critical for early diagnosis and effective treatment of patients. Early detection, before too much damage occurs, avoids the more costly and invasive treatments and improves patient outcomes for quality of life and longevity. No other device is currently suitable for addressing national security issues, such as screening of potential victims in a bioterrorism event or for rapid assessment of troops in a battle zone. If a crowd is exposed to dangerous biotoxins, the exposed population can be rapidly triaged with RapiDx for timely treatment—critical in such an event—while conserving valuable health resources and saving lives.

Sandia's hand-portable RapiDx instrument is designed to meet the needs for effective pre-symptomatic screening. We designed the system to measure large panels of biomarkers rapidly and simultaneously with a single drop of saliva or blood so that physicians will be able to act without other signs or symptoms. RapiDx is intended for the most demanding applications: bioterrorism where potentially thousands of exposed people would need instant on-the-spot diagnosis, and pre-symptomatic monitoring of astronaut health in space. Current diagnostic methods lack the sensitivity necessary to detect key low-abundance protein biomarkers present in bodily fluids, and they are too expensive to be used for a large-panel biomarker screen. The RapiDx large-panel biomarker

screening platform represents the new paradigm in diagnostics where the focus lies on pre-emptive, or very early-stage detection of disease, rather than reactionary, post-symptomatic approaches.

This technology is being transferred to several organizations for a variety of applications. Our first industrial partner is AM Biotechnologies, a small business awarded a Small Business Innovation Research (SBIR) award from NASA. Sandia is working with AM Biotechnologies to customize a RapiDx system to detect osteoporosis (bone demineralization), as well as other conditions, that may impact astronauts as a result of space flight.

RapiDx is also being transferred to other Federal Agencies including the National Biodefense Analysis and Countermeasures Center (NBACC) for forensics analysis of samples to detect biothreats, and to the Armed Forces Radiobiology Research Institute (AFRII) for rapid diagnostics of radiation exposure incidents. Sandia is collaborating with both of these institutions to further develop a customized RapiDx system for the relevant applications before engaging commercialization partners. Finally, Sandia is providing ongoing specialized advice and customized microfluidic systems to support the development of new diagnostic technologies and platforms for the Western Regional Center of Excellence for Biodefense and Emerging Infectious Diseases Research (WRCE).

**A2. Initiation of Technology Transfer Partnership (5 points)**

In October 2008, Sandia publicly announced the opportunity to collaborate with partners on RapiDx, and the availability of licenses to RapiDx technology. Prior to that time, companies knew about RapiDx through publications and press releases.
The collaboration with AM Biotechnologies came about as a result of the NASA SBIR solicitation. AM Biotechnologies proposed that a new diagnostics device could be developed to meet NASA's needs by combining Sandia's RapiDx system with AM Biotechnologies proprietary thioaptamers. AM Biotechnology's role on this project is to develop thioaptamers that address NASA's objectives. Sandia's role is to develop the device and implement thioaptamer-based assays that will run on the RapiDx system. AM Biotechnologies will license Sandia's intellectual property and commercialize the device upon successful demonstration of the device. The partnerships with the University of Texas Medical Branch (UTMB) and other federal agencies came about as a result of Sandia's initiative. Sandia's objective in seeking these partnerships was to complement our own capabilities.

**A3. Technology Transfer Processes and Innovations Used (5 points)**

The technology transfer with AM Biotechnologies is being funded by NASA because the application is being developed to respond to a need that NASA has in the space program. The contractual mechanism used for this agreement is a "Work for Others–Non Federal Entity (WFO-NFE)." Upon successful demonstration of the technology, AM Biotechnologies plans to license Sandia Intellectual Property needed to commercialize the device.

**A4. Time Frame Challenges (5 points)**

AM Biotechnologies submitted the SBIR proposal to NASA in August, 2008. The NASA award was announced in October 2008. AM Biotechnologies received funding from NASA in January 2009. Sandia began work under the WFO-NFE in April 2009.

**A5. Patents (5 points)**

At present, there are seven patents pending for the RapiDx system. In addition, RapiDx uses a variety of valves, manifolds, connectors, and an optical detector that were not specifically designed for RapiDx. These parts are covered by an additional eight issued patents and three patents pending. Many of these parts are already commercially available for purchase.

***Patents Pending***

A.K. Singh, A.E. Herr, D.J. Throckmorton, "METHOD AND APPARATUS FOR GEL ELECTROPHORETIC IMMUNOASSAY", U.S. Patent Application No. 11/137,745, Filed May 24, 2005.

A.V. Hatch, A.K. Singh, A.E. Herr, D.J. Throckmorton, "PRECONCENTRATION AND SEPARATION OF ANALYTES IN MICROCHANNELS" U.S. Patent Application No. 11/536,753, Filed September 29, 2006.

A.K. Singh, A.E. Herr, D.J. Throckmorton, “DIAGNOSTIC IMMUNOASSAY SYSTEM”, U.S. Patent Application No. 11/540,803, Filed September 29, 2006.

A.V. Hatch, A.K. Singh “METHOD FOR VOLTAGE-GATED PROTEIN FRACTIONATION”, US Patent Application No. 11/779,407, Filed July 18, 2007.

A.V. Hatch, G.J. Sommer, A.E. Herr, A.K. Singh, “METHODS FOR PROVIDING AND USING SOLUTION GRADIENTS IN MICROCHANNELS”. US Patent Application No. 12/182,755, Filed July 30, 2008.

A.V. Hatch, G.J. Sommer, Y. Wang, A.K. Singh, “DEVICES, SYSTEMS AND METHODS FOR MICROSCALE ISOELECTRIC FRACTIONATION”, US Patent Application No. 12/243,817, Filed October 1, 2008.

A.V. Hatch, G.J. Sommer, Y. Wang, A.K. Singh, “SANDWICH-METHOD POLYMERIZED MICROFLUIDIC DEVICES”, US Patent Application No. 12/321,881, Filed January 26, 2009.

## Criteria Part B –Results

**B1. New Relationships Formed as the Result of the Transfer (5 points)**

As a result of the collaboration with AM Biotechnologies, Sandia is interacting with NASA. Additional relationships are expected to arise when partners are engaged to commercialize products resulting from the collaborations with NBACC, AFRII and the WRCE.

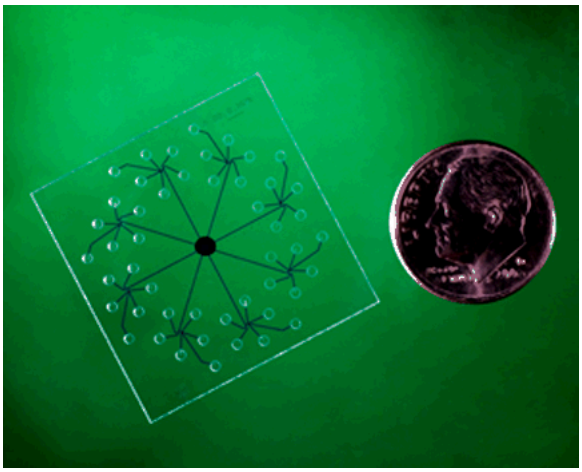
**B2. Outcome of the Technology Transfer Effort (45 points)**

The technology transfer effort has already been successful in demonstrating the ability to use aptamers provided by AM Biotechnologies on Sandia’s RapiDx system. Therefore, it is anticipated that the RapiDx system can be used to monitor astronaut health during and after space flight, and that it can be further developed for related applications. AM Biotechnologies will be able to license Sandia intellectual property and sell their thioaptamers for use with the system.

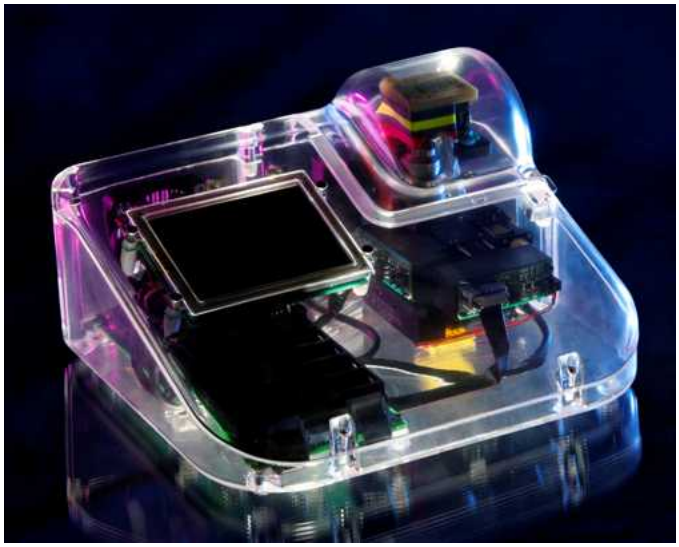
The early success with the AM Bio system provides increased confidence in our ability to customize successfully the system for other life saving applications. For example, we are currently awaiting news from another small business, P2D Corporation, on the award of an SBIR from the National Institute of Health (NIH). P2D is interested in developing RapiDx to diagnose traumatic brain injury (TBI). Commercialization of RapiDx for TBI would result in the fastest possible diagnosis of the deadly condition and potentially save lives. The collaboration with UTMB will soon result in rapid low-cost forensic analysis of bio-threats such as botulinum, and the collaboration with AFRII could lead to a system to mitigate disastrous radiation or bioterrorism scenarios so that victims can be rapidly and effectively treated, potentially saving millions in treatment costs and lives. Numerous other medical diagnostic applications will be targeted in the future.

RapiDx’s success in the US will ultimately open the door to new markets in developing countries where diseases go untreated because of poor access to medical diagnosis facilities. When diseases such as bacterial or viral infections are spotted early in these countries, treatment can begin promptly and ultimately lead to successful outcomes. Early detection and treatment will result in saving lives worldwide and lessen the suffering of many. RapiDx, indeed, can play a pivotal role.

**Sandia National Laboratories' RapiDx**



RapiDx processes and detects protein signatures by conducting each sample -processing and -analysis step within a microfluidic chip.



Sandia's RapiDx can analyze drops of blood or saliva in a doctor's office, enabling low-cost, rapid diagnoses during an office visit.

*Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company, for the United States Department of Energy's National Nuclear Security Administration under Contract DE-AC04-94AL85000.*