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Development of a Commercial Prototype of the Autonomous Pathogen Detection System Final Report CRADA No. TC-02077-04

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September 28, 2017

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Development of a Commercial Prototype of the Autonomous Pathogen Detection System

Final Report
CRADA No. TC-02077-04
Date Technical Work Ended: March 31, 2006

Date: May 10, 2006

Revision: 1

A. Parties

This project was a relationship between Lawrence Livermore National Laboratory (LLNL) and GE Ion Track, Inc.

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Lawrence Livermore National Laboratory
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B. Project Scope

This was a collaborative effort between The Regents of the University of California, Lawrence Livermore National Laboratory (LLNL), and GE Ion Track, Inc. (GEIT) to develop a commercial prototype of the Autonomous Pathogen Detection System (APDS), an instrument that monitors the air for all three biological threat agents (bacteria, viruses and toxins).

This was originally a one year CRADA project, with the cost of the work at LLNL being funded by the Department of Homeland Security's Office of National Laboratories. The original project consisted of five major tasks and deliverables. The CRADA was then amended, converting the CRADA from a programmatically funded CRADA to a funds-in CRADA, extending the project for an additional 14 months, and adding four new tasks and deliverable to the project.

The nine major tasks and deliverables were as follows:

1. Establish team (month 1) (LLNL/GEIT)
2. Develop product management (month 1 through month 4) (LLNL/GEIT)
 - 2.1. Document current prototype (month 1)
 - 2.2. Translate to GEIT system (month 1 through month 2)
 - 2.3. Commercial system requirements (month 2 through month 3)
 - 2.4. Commercial subsystem specifications (month 3 through month 4)
3. Develop commercial prototype (month 4 through month 9) (LLNL/GEIT)
 - 3.1. Redesign subsystems (month 4 through month 5)
 - 3.2. Fabricate test hardware (month 5 through month 7)
 - 3.3. Laboratory development (month 6 through month 9)
4. Fabricate integrated prototype (month 7 through month 11) (GEIT)
5. Test prototype (month 11 through month 12) (LLNL)

The following tasks were added under Amendment One:

6. Documentation update - LLNL will provide updated documentation regarding the APDS software and assays.
 - 6.1. Transfer information on instrument communication software and protocols (month 1) (LLNL)
 - 6.2. Provide access and support to enable GEIT to understand and implement algorithms for both Immunoassay and PCR (month 1) (LLNL)
 - 6.3. Drawings of recent design updates (current revisions) made to the APDS (month 1) (LLNL)
 - 6.4. Theory and process of the reagent preparation (month 1) (LLNL)
 - 6.5. List of current suppliers of antibodies and control antibodies being used in the system (month 1) (LLNL)
 - 6.6. Selection criteria used for procurement of primers and probes employed in the PCR process (month 1) (LLNL)
7. Additional testing of subsystem hardware - GEIT will fabricate next-generation subsystems for the commercial prototype and support tests of the subsystems. LLNL will design and support performance tests of the subsystems. The tests may be performed at LLNL and at GEIT.
 - 7.1. Design experiments (month 4 through month 7) (LLNL)
 - 7.2. Fabricate subsystems (month 4 through month 6) (GEIT)
 - 7.3. Support experiments (month 4 through month 7) (LLNL/GEIT)
 - 7.4. Analyze and document (month 7) (LLNL)
8. Biological testing and evaluation - GEIT will fabricate and deliver two integrated commercial prototypes for extended biological testing, including initial operational tests and aerosol chamber releases. LLNL will support these tests. Initial operational tests will be performed at LLNL and aerosol chamber tests will be performed at a government facility such as the U.S. Army Dugway Proving Ground. GEIT will also support the tests.
 - 8.1. Fabricate integrated prototypes (month 7 through month 8) (GEIT)
 - 8.2. Coordinate the set up of the biological testing (month 8) (LLNL)

- 8.3. Support biological testing (month 8 through month 10) (LLNL/ GEIT)
- 8.4. Analyze and document (month 11) (LLNL)
- 9. Field testing and evaluation - GEIT will fabricate four integrated commercial prototypes for extended field-testing. GEIT will select, with LLNL input, facilities that are potential applications of the APDS technology. LLNL and GEIT will support and document these tests.
 - 9.1. Fabricate integrated prototypes (month 11 through month 12) (GEIT)
 - 9.2. Coordinate the deployments for field-testing (month 12) (GEIT/ LLNL)
 - 9.3. Support field-testing (month 13 through month 14) (GEIT/ LLNL)
 - 9.4. Analyze and document (month 14) (GEIT/ LLNL)

Deliverables:

- 1. Deliverables for Task 1 (Establish the joint technology transfer team):
 - 1.1. LLNL will deliver to GEIT a list of names, expertise, and contact information for team members. (month 1)
 - 1.2. GEIT will deliver to LLNL a list of names, expertise, and contact information for team members. (month 1)
- 2. Deliverables for Task 2 (Develop product management):
 - 2.1. LLNL will deliver to GEIT documentation of the current prototype (system description, process flow diagram, bill of materials). (month 1)
 - 2.2. GEIT will deliver to LLNL the commercial system requirements and commercial subsystem specifications for review. (month 4)
- 3. Deliverables for Task 3 (Develop the commercial prototype):
 - 3.1. GEIT will deliver to LLNL the first iteration of subsystem redesigns for review. (month 5)
 - 3.2. GEIT will deliver to LLNL the last subsystem hardware for laboratory development and testing. (month 7)
 - 3.3. LLNL will deliver to GEIT development and testing results from the last subsystem. (month 9)
- 4. Deliverables for Task 4 (Fabricate the integrated prototype):
 - 4.1. LLNL will deliver to GEIT all subsystem hardware to be provided by LLNL. (month 10)
 - 4.2. GEIT will deliver to LLNL the integrated commercial prototype for testing. (month 11)
- 5. Deliverables for Task 5 (Test the integrated prototype):
 - 5.1. LLNL will deliver to GEIT the results of testing of the integrated commercial prototype. (month 12)
- 6. Deliverables for Task 6 (Documentation update):
 - 6.1. Transfer documentation pertaining to instrument communication software and protocols (month 1) (LLNL)
 - 6.2. Transfer and explain detection algorithms (month 1) (LLNL)

- 6.3. Provide software consultation/documentation as needed for product commercialization (month 4 through month 7) (LLNL)
- 6.4. Transfer drawings of recent design updates (current revisions) made to APDS (month 1) (LLNL)
- 6.5. Transfer information around theory and process of the reagents/assay fabrication (month 1) (LLNL)
- 6.6. Provide a list of current suppliers of antibodies and control antibodies being used in the system (month 1) (LLNL)
- 6.7. Details of the criteria used for procurement of primers and probes used in the DNA process (month 1) (LLNL)
- 6.8. Details of the QA/QC process used for Immunoassay and PCR reagents and their relation to the threshold settings on the instrument (month 1) (LLNL)
7. Deliverables for Task 7 (Additional testing of subsystem hardware):
 - 7.1. Subsystems for testing (month 4 and month 7) (GEIT)
 - 7.2. Bi-weekly status of experiments (month 4 through month 7) (LLNL)
 - 7.3. Report summarizing subsystem experiments (month 7) (LLNL)
8. Deliverables for Task 8 (Biological testing and evaluation):
 - 8.1. Two integrated prototypes (month 8) (GEIT)
 - 8.2. Bi-weekly status of biological testing (month 8 through month 9) (LLNL)
 - 8.3. Report summarizing biological testing (month 10) (LLNL)
9. Deliverables for Task 9 (Field-testing and evaluation):
 - 9.1. Four integrated prototypes (month 11) (GEIT)
 - 9.2. Facility selection (month 11) (GEIT)
 - 9.3. Site selection results (month 11) (LLNL)
 - 9.4. Participation in field-testing status meetings (month 13 through month 14) (LLNL)
 - 9.5. Report summarizing field-testing (month 14) (LLNL)
10. Final Report and Abstract due within 30 days of completion or termination of the project, as required under Article XI of the CRADA (LLNL/GEIT).

The CRADA was terminated before the expiration date. Tasks 1, 2, and 6 and Deliverables 1.1 through 3.1 and 6.1 through 6.8 were successfully completed. Other tasks and deliverables were delayed by GEIT prior to the termination of the CRADA.

C. Technical Accomplishments

The overall goal of this CRADA project was to transfer the APDS technology and technical "know-how" from LLNL to GEIT, which was to be completed under the separate license agreement. This involved evolving a laboratory-validated and field-tested research prototype at LLNL to a commercially feasible, fully functional prototype built by GEIT. The primary responsibility of LLNL was to aid GEIT in design, development, and prototyping of the commercial system.

In general, the transfer of documentation and specifications (tasks 1, 2, and 6) went as planned. GEIT was delayed in their prototyping (tasks 3 and 4) by company resource limitations. This, in turn, prevented the testing (tasks 5, 7, 8, 9) from occurring before the CRADA was terminated.

The main specific accomplishments were

- Detailed documentation of the drawings and bill of materials for the current APDS
- Transfer and training on control and communications software
- Development of requirements for the commercial system
- Transfer and explanation of the detection algorithms
- Design review of the commercial system
- Successful prototyping and laboratory testing of the aerosol collector subsystem

D. Expected Economic Impact

GE Ion Track has decided to not pursue this technology as a business area, so there is little expected economic impact. Some of the subject inventions may have commercial applications.

D.1 Specific Benefits

Benefits to DOE

The CRADA was terminated at GE Ion Track's request. This CRADA could have benefited DOE by evolving bioterrorism detection technology from the Laboratory's R&D and feasibility demonstrations to a commercial instrument. DOE could have benefited by fulfilling its mission to aid in the security of the USA in the form of a commercially available instrument. This CRADA project could have also benefited homeland security.

Benefits to Industry

The CRADA was terminated at GE Ion Track's request. GE Ion Track could have benefited from the R&D efforts of the Laboratory in biological detection. Industry and the US taxpayer could have benefited by having early detection of bioterrorism made available to the hosts of critical facilities and special events.

E. Partner Contribution

GE Ion Track developed a product management package for their commercial version of the APDS (to be called the BioGuard). Most of this work was kept internally at GE Ion Track, though LLNL provided comments on requirements and specifications and reviews of prototype designs.

Two joint subject inventions resulted from this project. See below.

F. Documents/Reference List

Protected CRADA Information is indicated with an asterisk (*)

Reports

"Reference Manual for the Autonomous Pathogen Detection System (APDS), Version 1.0", John M. Dzenitis et al., 29 March 2004

"APDS commercial prototype redesign notes for Aaron Mason", John M. Dzenitis, 17 August 2004

"Prototype notes", John M. Dzenitis, 6 December 2004

"APDS reagent notes", John M. Dzenitis, 14 February 2005

"Multiplex PCR for the APDS", John M. Dzenitis, 15 February 2005

"LLNL/GE CRADA Project Meeting", John M. Dzenitis, 11 October 2005

"Availability notes for GE", John M. Dzenitis, 28 October 2005

"LLNL GE APDS project update", John M. Dzenitis, 5 January 2006

"BioGuard Aerosol Collector Evaluation", Anthony J. Makarewicz, 4 May 2006

Copyright Activity

None

Subject Inventions

The following two joint subject inventions were developed in this project:

IL-11456, Patent Application anticipated

IL-11708, Patent Application anticipated

GE Ion Track decided to not pursue this technology and has not expressed an interest in licensing these inventions.

Background Intellectual Property

LLNL disclosed the following Background Intellectual Property for this project:

U.S. Patent No. 6,688,187 (LLNL Docket IL-11041) - *Aerosol Sampling System*; issued ;
Inventor: Donald A. Masquelier

IL-10778 – Patent Pending

IL-10964 – Patent Pending

IL-11052 – Patent Pending

GE Ion Track, Inc. licensed the above Background Intellectual Property under License Agreement No. TL01827-04, executed on August 27, 2004.

LLNL also transferred the software for control, communications, and remote viewing (APDS Control, APDS Command Console Viewer) to GE Ion Track to assist them in developing their own version of this software. GE Ion Track is aware that this is LLNL proprietary information covered by the Non Disclosure Agreement.

LLNL also detailed the APDS signal analysis algorithms (e.g., “APDS Data Analysis and Interpretation”) for GE Ion Track as part of the documentation update. GE Ion Track is aware that this is LLNL proprietary information covered by the Non Disclosure Agreement.

GE Ion Track, Inc. did not express an interest in licensing the following Background Intellectual Property:

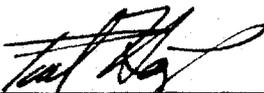
IL-11024 – Patent Pending

GE Ion Track did not disclose any Background Intellectual Property for this project.

G. Acknowledgement

Industrial Participant's signature of the final report indicates the following:

- 1) The Participant has reviewed the final report and concurs with the statements made therein.
- 2) The Participant agrees that any modifications or changes from the initial proposal were discussed and agreed to during the term of the project.
- 3) The Participant certifies that all reports either completed or in process are listed and all subject inventions and the associated intellectual property protection measures generated by his/her respective company and attributable to the project have been disclosed and included in Section E or are included on a list attached to this report.
- 4) The Participant certifies that if tangible personal property was exchanged during the agreement, all has either been returned to the initial custodian or transferred permanently.
- 5) The Participant certifies that proprietary information has been returned or destroyed by LLNL.



Paul Haigh, Product Manager
GE Ion Track, Inc.

07/14/06

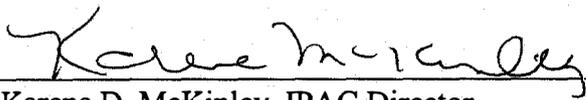
Date



John M. Dzenitis, LLNL Principal Investigator
Lawrence Livermore National Laboratory

7/31/06

Date



Karena D. McKinley, IPAC Director
Lawrence Livermore National Laboratory

8/3/06

Date

Attachment I – Final Abstract

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Final Abstract (Attachment I)
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C. Benefit to Industry

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D. Benefit to DOE/LLNL

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E. Project Dates

The planned project dates for this CRADAD were April 2, 2004 through November 16, 2006. The actual project dates were April 2, 2004 through March 31, 2006, due to early termination of the CRADA at the request of GE Ion Track, Inc.