PROJECT DESCRIPTION/STATEMENT OF OBJECTIVES (SOO)

2.1 OBJECTIVE Title – Assay Expansion for Chemical Diagnostic System

2.1.1 OBJECTIVE OF THE PROJECT:

Warfighters often deploy to austere environments under potential chemical and biological warfare agents. In this scenario, rapid and timely diagnosis facilitates appropriate medical countermeasures and broader force health protection measures. The Medical Diagnostics Branch (RD-CBMD), a component of the Defense Threat Reduction Agency (DTRA), and the Joint Science and Technology Office (JSTO), is developing novel capabilities to protect the Joint Force against chemical and biological threats.

One system currently in advanced development is the ChemDx device, a portable hand-held point of care diagnostic device that can rapidly (less than 1 min) provide quantitative and qualitative detection of acetylcholinesterase (AChE) activity in blood samples, which is indicative of exposure to cholinesterase inhibiting substances, such as nerve agents or organophosphate pesticides. This potentiometer-based sensor, adapted from a traditional glucose monitor and test strips, measures acetylcholinesterase activity using a blood sample from a finger prick or from a whole blood sample. There is a need for additional portable and rapid technologies against chemical agents including, but not limited to, opioids, pharmaceutical based agents (PBAs), and toxins. RD-CBMD has interest in expanding the ChemDx platform capabilities to diagnose the exposure to these agents and develop a single integrated device against chemical agents, as developing multiple diagnostic devices for each individual agent encumbers warfighters in field-forward settings.

ChemDx Platform Reference:
https://mrdc.health.mil/index.cfm/media/articles/2021/USAMRICD_develops_chemDx_field_diagnostic_system_to_detect_chemical_exposure#:~:text=The%20ChemDx%20Test%20System%20is%20designed%20to%20inform,and%20lowering%20the%20burden%20on%20the%20medical%20response

2.1.2 STATEMENT OF OBJECTIVES (SOO):

I. Project Objective:

The main goal of this project is to iteratively expand the ChemDx platform to diagnose exposure to additional chemical agents including but not limited to opioids, pharmaceutical based agents (PBAs), toxins (e.g. but not limited to marine toxins, palytoxin, saxitoxin), vesicants and toxic industrial chemicals. Solutions to biological agent exposure will be considered as well although considered lower priority.

II. Performance Objectives:

A. **Project Objectives:** Diagnostics assays or sensors that leverage electrochemical-based sensors that focus on host biomarkers, agent-based analytes (e.g. intact agent, metabolites, protein adducts), and binding activity (e.g. immunoassays, agent-target interaction). Technical approaches may include adaptation of established detection assays or novel sensors compatible with integration on the ChemDx system. Sample types shall be minimally invasive (e.g. saliva, sweat, capillary blood). Novel approaches to diagnostic assay development methods not included above are also encouraged and welcomed to respond. The government is not interested in developing a new electrochemical diagnostics device but rather expand the assays amendable for integration on the ChemDx system. The offeror shall work with the ChemDx device manufacturer (Conductive Technologies, Inc.; https://conductivetech.com/) to accomplish integration of the developed test strips onto the portable electrochemical device platform. Within each submission, Offerors shall address the below items to meet the requirement for this SOO:

1. Description of the scientific basis for the proposed technology including sensor target, sensor chemistry, sensing method, sample matrices, and potential challenges.
2. Current Technology Readiness Level (TRL) and feasibility to reach TRL 4 or higher at the end of the Period of Performance. Provide data and documentation as justification of the current TRL (Appendix A)
3. Technical approach for sensor development and feasibility for adaption to ChemDx platform.
4. Description of sensor characteristics; approach to electrochemical signal, ability to port sensor on a test trip format and description of storage conditions (e.g. temperature stability), time to read-out.
5. Ability to multiplex targets on one sensor.
6. Include preliminary data and/or literature supporting the proposed sensor technology.
7. Intellectual Property associated with the assay and platform.
8. Delivery of functioning prototype (TRL 4) to move into analytical testing within 24 months after award. Ability to transition prototype to integration of verification with ChemDx system in a laboratory environment.

B. **Regulatory Objectives**: Prepare a detailed regulatory strategy document including draft intended use statement, analytical and clinical study plans and specimen requirements. Provide Target Product Profile. The desired test strip/assay prototype (including sample prep) is intended as a prescription home use and 510K with CLIA waiver FDA approved device.

C. **Project Management Objectives: The project agreement holder shall:**

a. Coordinate a project kickoff meeting within 15 days of award. Project kickoff may be an in-person meeting at the contractor facility.
b. Schedule and coordinate monthly, or other agreed upon interval, project

update meetings with the Government via teleconference if meeting in person impractical

c. Provide deliverables as outlined under 2.1.4.1

D. **Logistics Objectives:** The main goal of this effort is to develop a field-forward portable test against chemical agents. The assay prototype shall be stored at room temperature (no cold chain) with an operating temperature between 4-50℃-

III. Performance Requirements

The desired assay test strip shall:

1. utilize minimally invasive clinical samples (e.g. finger prick, saliva, urine, ocular fluids),
2. be portable, ruggedized, and perform in a wide range of temperature conditions,
3. be compatible with the ChemDx detection platform.

2.1.3 PERIOD AND PLACE OF PERFORMANCE:

The anticipated Period of Performance for this effort is estimated to be about 24 months from date of award for initial prototype delivery. It is anticipated that this effort will continue past the initial period of performance to allow for iterative development of follow-on or additional assay targets. If prototype delivery is successful, it is envisioned to continue with advance development of the assay(s) and device to include analytical studies and clinical trials. Specific dates and schedule to be negotiated. It is anticipated that the primary place of performance will be the Agreement Holders' facilities, however this aspect can be negotiated as part of each Offerors' submission.

2.1.4 DELIVERABLES:

2.1.4.1 DATA DELIVERABLE(S):

The contractor shall deliver all report submissions to the Agreement Officer's Representative (AOR) in the applicable format. Data Deliverables are listed below.

I. Meeting/Teleconference Agendas and Minutes: The awardee shall provide an agenda and all supporting documentation at least three days prior to each scheduled meeting. The agenda shall include action items from the previous meetings as well as new topics to discuss. Provide meeting minutes within 3 calendar days after all meetings / teleconferences conducted. Frequency is anticipated to once a month. However, this may vary depending on critical issues.

II. Monthly Financial Status and Progress Report: The contractor shall include an expenditure forecast for each reporting period, include both the monthly planned accrual and cumulative total expenditures and a spend plan and monthly estimates for the remaining effort.

The schedule update shall include the explanation for any changes on the schedule and drivers for the change, as applicable.

A. The progress report should also address any concerns the awardee might have that would impact performance, schedule, or cost planned for the effort. The awardee shall use a risk matrix format, to include risk mitigation strategies.

B. Submission shall be fifteen calendar days after the end of each month of performance. The Government will have five business days to respond to the report with any comments, and the awardee will have an additional five calendar days to revise the deliverable or respond to those comments.

III. Integrated Master Schedule (IMS): The Awardee shall provide an Integrated Master Schedule (IMS) depicting all agreement activities linked to the work breakdown structure (WBS) level, as applicable. The IMS shall contain all critical and high-risk elements, tasks/activities. All tasks/ activities in the IMS shall be logically linked together showing predecessor/successor relationships and activities of major subcontractors and suppliers.

Initial IMS shall be submitted within 30 days after award and, at a minimum, updated quarterly.

IV. Final Report: A Final Report shall be submitted at the end of the contract, regardless of whether any or all of the contract options are exercised. This report takes the place of the last annual report due. (A Financial Report is still required.) The report shall narrate a complete summary of the contract performance and associated results obtained. The report shall document any outstanding problems and their potential solution, as well as any problems solved during the course of the contract, along with the solution to the solved problems. The report shall address whether the Technology Readiness Level (TRL) has been advanced, and if so, provide details as to its advancement.

V. Patents-Reporting of Subject Inventions: The awardee shall furnish to the AOR, the following reports for those prototype projects fully funded by the Government:

A. Interim reports every twelve months from the date of the award, listing subject inventions during that period, and stating that all subject inventions have been disclosed, or that there are no such inventions.

B. Upon request, the awardee shall furnish to the Government the filing date, serial number and title, a copy of the patent application with number, and issue data for any subject invention for which the awardee has retained title.

Note: Technical data deliverables described herein shall be delivered to the Government with a minimum of Government Purpose Rights.

2.1.4.2 PROTOTYPE DELIVERABLE(S):

The prototype resulting from the Government project will be a diagnostic assay for integration onto the ChemDx system that:

1) utilizes minimally invasive clinical samples (e.g. finger prick, saliva, urine, ocular fluids),
2) detects opioids, pharmaceutical based agents (PBAs), toxins (e.g. but not limited to marine toxins, palytoxin, saxitoxin), or toxic industrial chemicals exposure,
3) provides either a binary yes/no answer, sample concentration, or personal health risk assessment within five minutes, compatible with the ChemDx system
4) requires no cold chain,
5) requires no intermediary sample preparation steps between sample acquisition and test strip analysis (objective), -in order to be approved as prescription home use or 510k with CLIA waiver.

The desired end deliverable of this project are sufficient prototype assays ready for evaluation including 3 modified ChemDx systems for validation in laboratory environment, to the Government, at a location or locations to be agreed upon with the awardee in the final year of performance. The awardee shall also provide training materials and training for a representative group or groups of users, as determined by the Government.

2.1.5 SPECIAL REQUIREMENTS:

2.1.5.1 Export Control: Export Controls shall be in accordance with the Base Agreement.

2.1.5.2 Security and Classified Data: This prototype project is UNCLASSIFIED. All deliverables and work performed under this agreement will be UNCLASSIFIED. However, at the determination of the government, this effort may generate Controlled Technical Information that is categorized as CONTROLLED UNCLASSIFIED INFORMATION (CUI). To protect against unauthorized release, all technical reports, engineering drawings, product specifications, data sets, studies and analyses delivered under this effort shall be labeled with the applicable distribution statement, as determined by the AOR. The awardee shall maintain a facility security clearance and personnel with the ability to handle CUI and export-controlled material. All personnel assigned to this project shall be U.S. Citizens or permanent U.S. residents.

2.1.5.3 Acceptance of Deliverables: The Government will provide acceptance of all data deliverables within fifteen days of delivery. The Government will provide acceptance of all prototype deliverables within thirty days of delivery.

Go/No-Go decision points will be inserted into the review schedule at six-month intervals and be based upon the completion of project milestones and Government acceptance of deliverables.

2.1.5.4 Travel: A maximum of three travelers, as determined by the awardee, shall travel to the following meetings at Government expense:

a) The DTRA / RD-CB-JSTO Science & Technology Conference for 2026, at a location to be

announced.

b) Training events for personnel tasked with prototype validation (facilities to be determined).
c) Travel to any sub-contractor(s), as deemed necessary by the awardee, in coordination with the Government.

2.1.6 GOVERNMENT FURNISHED PROPERTY: None.

2.1.7 FUNDING CONFIDENCE LEVEL:

CL-1 Highly Confident funds will be available.

This effort is anticipated for award: Q3FY25

2.1.8 FOLLOW-ON PRODUCTION: This prototype project will be awarded after a competitive solicitation, evaluation and award process. As such, in accordance with 10 U.S.C. 4022 and upon a determination that the prototype project for this transaction has been successfully completed, or at the accomplishment of particularly favorable or unexpected results that would justify transitioning to production, any competitively awarded prototype OTA as a result of this RPP may result in the award of a follow-on production contract or transaction without the use of competitive procedures. Follow-on quantities/requirements are unknown at this time.

APPENDIX A:

TTA_Workbook_for_Vendors.xlsx