Sole Source Justification and Approval
Under FAR 13.501

1. Contracting Activity: The contracting activity responsible for this action is the US Army Medical Research Acquisition Activity (USAMRAA), on behalf of the US Army Research institute of Environmental Medicine (USARIEM).

2. Description of Action: This will be a new sole source single award Indefinite Delivery Indefinite Quantity (IDIQ) contract for metabolomics analysis services. Funding will be provided at the task order level using Army Research Development Test & Evaluation, Defense Health Agency or other sources. The ordering period for the IDIQ will be for five years.

3. Description of Supplies/Services: The Government requires an IDIQ contract with Metabolon, Inc. to provide metabolomics analysis services of urine, blood, fecal, saliva and tissue samples. This will be a Firm Fixed Price IDIQ contract. The total estimated value for five years is [redacted] The results of this work will provide data needed to fulfill requirements of approved and planned research protocols.

4. Authority Cited: 41 United States Code 1901 as implemented in Federal Acquisition Regulation 13.501(a)(1)(ii), sole source under the authority of the simplified procedures for certain commercial items.

5. Reason for Authority Cited: USARIEM requires metabolomics analysis services to support their research study protocols. Metabolomics analyses measure small molecules, known as metabolites, which are present in biological samples (e.g., blood, urine, tissue, etc.). Metabolomics analyses can be done using both targeted and untargeted approaches. Targeted approaches measure a pre-defined suite of metabolites. Untargeted approaches measure hundreds to thousands of metabolites in a single small volume sample. The major challenge with untargeted approaches is identifying the measured metabolites. Identification requires maintaining an extensive library of metabolites and the analytical information associated with those metabolites (i.e., to match results from the analytical instrument with the metabolite identification) Identification is a time and cost-intensive process for laboratories that do not maintain extensive metabolite libraries, and without proper identification, investigators are often left with meaningless data.

Controlled by: Defense Health Agency (DHA)
Controlled by: USAMRAA
CUI Category(ies): Source Selection
Limited Dissemination Control: FED Only
POC: [redacted]

Thus, extensive libraries that enable identification of hundreds to thousands of metabolites are critical for extracting meaningful information using small volume samples. USARIEM needs to continue to have a large volume of measured metabolites integrated into interpretable maps of biological pathways in order to extract meaningful information from their analysis. Metabolon can provide this service.

The most critical aspects of these metabolomics analysis services are the:

- ✓ Ability to conduct both untargeted and targeted metabolite analysis.
- ✓ Access to an extensive library of over 4,000 known metabolites and ability to accurately identify more than 1,000 metabolites in a small volume sample
- ✓ Expertise in utilizing ultra-high performance liquid chromatography/tandem high resolution/accurate mass spectrometry for identifying metabolites in biological samples across multiple chemical classes
- ✓ Expertise in bioinformatics and pathway analysis of metabolomics data
- ✓ Laboratory systems that are governed by a set of Standard Operating Procedures that have been reviewed, updated, and include quality control steps
- ✓ Has a documented history of contributing to peer-reviewed publications using metabolomics analyses in order to prove and validate current and ongoing protocols.

Metabolon, Inc. is the only Company that can meet all of these requirements.

While other companies, such as MetaSci and MedChem, have only metabolite libraries of 1,200 and 990; respectively, Metabolon, Inc. has over 4,000 metabolites in their library which aids USARIEM in identifying thousands of samples during testing and analysis. Not only does Metabolon maintain an extensive library of over 4,000 known metabolites, but they are also able to accurately identify over 1,000 metabolites per research sample. The large database and identification capability that Metabolon offers is something that no other company is capable of providing.

Lastly, there are vast inconsistencies in the performance of the assays between one laboratory and another laboratory. These unknown inconsistencies make it critical that samples from current and ongoing research studies utilize the same methodology in the same laboratory to allow direct comparisons between studies. Without this continuity, the scientific integrity and validity of comparing results across studies will be compromised, and studies would need to be scraped and repeated in order to obtain accurate and dependable results across all studies. Scraping and repeating current tests would incur a significant sunk cost to the Government in the amount [redacted] to [redacted] test; thereby costing the Government over [redacted] per study to repeat these tests in a different laboratory. Furthermore, metabolites may or may not be able to be identified for each research study sample at USARIEM. This inability to identify samples

would make the current information and data meaningless and would disrupt ongoing research studies at USARIEM.

Therefore, only Metabolon's extensive metabolite library and ability to interpret maps of biological pathways to extract meaningful information can meet these requirements to provide metabolomics analysis support services.

6. Efforts to Obtain Competition: A Notice of Intent (NOI) was posted to the governmentwide point of entry (GPE) on 18 November 2024 in accordance with FAR Subpart 13.5, *Simplified Procedures for Certain Commercial Products and Commercial Services*. Two responses were received: Quality Choice and Bridging Pieces. From their capability statement, it was difficult to determine if Bridging Pieces had expertise in identifying known compounds (i.e., targeted metabolomics), or conducting quantification of short-chain fatty and bile acids. These are services that encompass this effort. Therefore, Bridging Pieces was deemed to not have enough information to make a determination of acceptability as a result of the NOI. In addition, the Capabilities Statement provided by Quality Choice appeared that this company may be able to meet most of the Requirements/Specifications. However, there was no documentation provided or available on their website to support these claims. Therefore, Quality Choice was deemed to not have enough information to make a determination of acceptability as a result of the NOI.

A Request For Information (RFI) was then drafted with additional information that better specified the requirement, and was posted to the GPE on 17 December 2024 in order to see if there were any companies that could perform this effort. Two responses were again received by the same two companies. Even though these companies were able to provide additional information, they were still unable to meet the capabilities that the Customer required for this effort. The Capabilities Statement provided by Bridging Pieces did not address or relate to capabilities specified for this effort. It is for this reason, that Bridging Pieces was found to be unacceptable in accordance with the terms of the RFI. Quality Choice provided a possible teaming arrangement with Panome Biotechnology. However, their exact arrangement was unclear, which raised significant concerns regarding capabilities to meet requirements. Further, Panome Biotechnology itself appeared to be a new company and their website did not provide enough information to verify capability to perform this effort. The lack of publicly available information coupled with the absence of evidence for any peer reviewed publications precludes evaluating past performance or the evaluation of capabilities specific to this effort. It is for this reason, that Quality Choice was found to be unacceptable in accordance with the terms of the RFI.

7. Actions to Increase Competition: This is a follow-on requirement; however, the previous contract was competed as full and open. The revised NOI will be posted for for a period of 15 days with all responses being considered. However, as the first NOI and the RFI yielded no viable sources, it is anticipated that there will be no sources capable

of performing this work. Metabolon is therefore the only company that can provide these metabolomic analysis services as they have the extensive metabolite library and the ability to interpret maps of biological pathways to extract meaningful information for the USARIEM. For ongoing and future requirements, the marketplace will continue to be monitored to determine if this requirement could be competed in the future.

8. Market Research: Using internet searches, literature review and discussions with colleagues several sources were identified (Metabolon, Inc., MS-Omics ApS, Biocrates Life Sciences AG, Prometheus Metabolomics, Stemina Biomarker Discovery, David H. Murdock Research Institute). Of those entities, only Metabolon was found to able to provide services that fully meet the requirements of the Performance Work Statement. Additionally, three of the companies, MS-Omics, Prometheus and Biocrates, are international companies. It is not clear if working with those companies would be feasible due to international shipping restrictions on biological samples. However, neither of the companies identified expressed interest during the NOI.

9. Interested Sources: The notices required by FAR 5.201 shall be published, and that any bids or proposals received shall be considered. As stated in Section 6 above, both Bridging Pieces and Quality Choice expressed interest in this requirement however, they were found to be unacceptable.

10. Other Facts: N/A

a. *Procurement history.*

(1) Contract numbers and dates of all awarded contracts for these same requirements. IDIQ contract W81XWH20D0059 (1 May 2020-30 April 2025

(2) The competitive status of these actions. Competitive; only one proposal was received from Metabolon, Inc.

(3) Authority previously cited if less than full and open competition was used. Not applicable.

(4) If a justification was prepared to support the procurement made before this one, a summary of the contents of paragraph 7 of the justification for that procurement and an explanation of the results. Not applicable. The previous award was made under full and open competition.

(5) If any prior contract for this requirement was accomplished using full and open competition, include a detailed explanation of the changed circumstances causing this action to now limit the sources. Not applicable.

(6) An explanation of any unusual patterns that may be revealed by the history, e.g., several consecutive, urgent buys. Not applicable.

(7) If a justification was prepared to support the procurement made before this one, briefly describe the circumstances justifying the procurement and whether there have been any significant changes. Not applicable.

b. Other facts. Not Applicable.

11. Technical Certification:

I certify that the supporting data under my cognizance, which are included in the justification are accurate and complete to the best of my knowledge and belief.

[redacted]

12. Requirements Certification:

I certify that the supporting data under my cognizance, which are included in the justification are accurate and complete to the best of my knowledge and belief.

[redacted]

13. Fair and Reasonable Cost Determination:
I hereby determine that the anticipated cost to the Government for this contract action will be fair and reasonable.

This determination will be made using the following:
☒ Price analysis
☐ Cost analysis
☐ IGE
☐ Audit:
☐ Other:

Certified cost or pricing data is not required per FAR 15.403-1(b)(3).

[redacted]
Contracting Officer

14. Contracting Officer Certification:
I certify that this justification is accurate and complete to the best of my knowledge and belief.

[redacted]
Contracting Officer

Reviews

I have reviewed this justification and find it adequate to support other than full and open competition.

Concurrence

[redacted]
Branch Chief, CB10
USAMRAA

[redacted]
Chief, Contracts Group 2, Chief of the Contracting Office
USAMRAA

[redacted]
Legal
USAMRDC

Approval

Based on the foregoing justification, I hereby approve the procurement of metabolomics analysis services on an other than full and open competition basis pursuant to the authority of 41 U.S.C. 1901 as implemented by FAR 13.501, subject to availability of funds, and provided that the services and property herein described have otherwise been authorized for acquisition.

[redacted]
Command Advocate for Competition