

LIMITED SOURCES JUSTIFICATION

1. Contracting Activity: Department of Veterans Affairs (VA)
Office of Acquisition Operations
Technology Acquisition Center
1701 Directors Blvd
Austin, TX 78744
2. Description of Action: The proposed action is for the award of a firm-fixed price (FFP) contract under the General Services Administration (GSA) Federal Supply Schedule (FSS) GS-35F-362CA (SKU#PRAEDICO025) from Bitscopic, Inc. for continued licensing and maintenance of PraediGene Bronze Edition (Annual License) software.
3. Description of the Supplies or Services: The VHA public health reference laboratory (PHRL) has been providing clinical laboratory testing for Veterans since 2014, and public health investigation laboratory services since 2009. PHRL is a laboratory division of the Public Health Surveillance and Research office (PHSR) located at the VA Palo Alto Health Care System and is a high-complexity CLIA-licensed laboratory that offers many validated assays for clinical care and public health investigations. PHRL participates in College of American Pathologists (CAP) proficiency testing and is accredited by CAP. PHRL also participates in proficiency testing through the CDC (e.g., influenza, dengue or norovirus testing) and is aligned with the CDC-sponsored Laboratory Response Network (LRN), composed of state, territory, and DoD laboratories that support the nation's public health efforts. PHRL serves as the VA's primary reference microbiology laboratory to test for, and aid in the diagnosis of unusual pathogens; confirm atypical laboratory test results; test epidemiologically significant specimens with potential public health implications; and test for infectious diseases of public health consequence that are too rare or unusual for other laboratories to maintain testing capacity. In March of 2016, PHRL became a member of the VA National Reference Laboratory Network (NRLN).

PHRL requires the renewal purchase of twelve months PraediGene Bronze Edition (Annual License) software. PraediGene is a laboratory workflow tool designed to allow users at three of the NRLN sites (West Haven, Iowa City, Palo Alto) to electronically enter and track various medical lab tests for VA systemwide customers. In addition to these core capabilities, PraediGene contains advanced computational biology features and interfaces with Electronic Health Record (EHR) systems. The DNA analysis features automatically predict and report important resistance mutations given the organism's genetic sequence. The period of performance for this effort will consist of 12 months. The total estimated value of the proposed action is [REDACTED]
4. Statutory Authority: This acquisition is conducted under the authority of the Multiple-Award Schedule Program. The specific authority providing for a limited source award is Federal Acquisition Regulation (FAR) Part 8.405-6(a)(1)(i)(B), "Only One source is capable of providing the Supplies or Services required at the level of quality required because the supplies or services are unique or highly specialized."

5. Rationale Supporting Use of Authority Cited Above: The proposed source for this action is Bitscopic, Inc. 585 Broadway Street, Redwood City, CA. PraediGene Bronze Edition is a proprietary system of Bitscopic, Inc. no other company would be permitted to work on adaptation of the PraediGene Bronze Edition for VA. The original purchase of the software was made after an exhaustive search of the industry.

VA technical experts determined that the PraediGene Bronze Edition (Bitscopic, Inc.) is the only system that meets the VA data and architecture requirements. These requirements included: (a) Establishing and maintaining the VA network connectivity needs; (b) Integrating & complying with SSL certs and VA Security standards; (c) Section 508 Compliance (system access to Federal Employees with disability); (d) Compatibility with VistA data interfaces, and (e) Compatible with the VA Site Tracking (VAST) system to support VA lab site-level reporting.

Moreover, data and architecture analysis confirmed the following functional properties: (a) automates laboratory workflow tasks used by PHRL, (b) enables electronic entry and tracking of all medical lab tests, (c) delivers full support of DNA sequencing analysis used by PHRL for HIV and HCV tests, (d) automatically predicts and reports resistance mutations given an organism's genetic sequence, (e) interfaces with the VA's EHR system (VistA) and can retrieve patient information directly from VistA and produce Vista-compatible test results, (f) delivers fully integrated DNA Quality Control checks and maintains all laboratory records to support CLIA and CAP licensing and audits, and (g) supports automated laboratory reports, financial reports, and management reports.

6. Efforts to Obtain Competition: Market research was conducted, details of which are in the market research section of this document. This effort did not yield any additional sources that can meet the Government's requirements. It was determined that Bitscopic, Inc. is the only provider of PraediGene Bronze Edition software and maintenance. No other sources have access to the software code necessary to perform technical support or upgrades. There is no competition anticipated for this acquisition. TAC-Austin will post the justification along with the Request For Quotation to e-Buy in accordance with FAR 8.405-6(b)(3)). In accordance with FAR 5.301 and 8.405-6(a)(2), this action will be synopsisized at award on the Federal Business Opportunities Page (FBO) and the justification will be made publicly available.

7. Actions to Increase Competition: The Government will continue to conduct market research to ascertain if there are changes in the market place that would enable future actions to be competed.

8. Market Research: VA technical experts have been conducting on-going market research since April 2015 through the present. There are other off-the-shelf several products on the market that can perform PART of the tasks provided by PraediGene [REDACTED], however, they are all incapable of performing the customized QC tasks required by PHRL (e.g. determining the

uniqueness of given sequences at a certain threshold), and are incapable of performing the specific analyses of HIV and HCV sequences for resistance mutations and report in a format compatible with VISTA and CPRS (without significant workarounds which are time-consuming and error-prone).

In addition, The Contract Specialist issued a Request for Information (RFI) with a draft Product description on May 16, 2018 to open market contractors through Federal Business Opportunities, National Aeronautics and Space Administration Solutions for Enterprise-Wide Procurement Governmentwide Acquisition Contract, and General Services Administration Federal Supply via the General Services Administration's e-Buy tool to ascertain the ability of any other source to provide an alternate product. The intent of the RFI was to ascertain if any other brand name products could meet VA's needs. The RFI included language to secure participation of small business, small disadvantaged business, service-disabled Veteran-owned small business (SDVOSB), Veteran-owned small business (VOSB), women-owned small business, and HubZone small business concerns. Responses to the RFI from all venues were due on May 23, 2018. No responses were received.

9. Other Facts: N/A

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

[REDACTED]

11. Determination of Best Value: I hereby determine that the proposed contract action will represent the best value to the Government consistent with FAR 8.404(d). GSA has already determined that the prices on the FSS contract are fair and reasonable. Further price analysis will be conducted and subsequent negotiations held as necessary. Additionally, price discounts will be sought.

[REDACTED]

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

[REDACTED] C-21-1 [REDACTED]
[REDACTED] [REDACTED]
[REDACTED] [REDACTED]