

LIMITED SOURCES JUSTIFICATION

1. Contracting Activity: Department of Veterans Affairs (VA)
Office of Procurement, Acquisition, and Logistics
Technology Acquisition Center
23 Christopher Way
Eatontown, NJ 07731
2. Description of Action: The proposed action is for the award of a firm-fixed price Delivery Order under the General Services Administration (GSA) Federal Supply Schedule (FSS) 70 Contract GS-35F-362CA with Bitscopic, Inc. for the purchase of PraediGene Precision Oncology Module software.
3. Description of the Supplies or Services: VA Veterans Health Association Public Health Reference Laboratory (PHRL) has a requirement for the purchase of the PraediGene Precision Oncology Module, inclusive of maintenance, to add to our existing PraediGene Suite of Tools. The PHRL has been providing clinical laboratory testing for Veterans since 2014, and public health investigation laboratory services since 2009. PHRL is located at the VA Palo Alto Health Care System and is a high-complexity, Clinical Laboratory Improvement Amendments (CLIA)-licensed laboratory offering 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 Centers for Disease Control and Prevention (CDC) (e.g., influenza, dengue or norovirus testing) and is aligned with the CDC-sponsored Laboratory Response Network (LRN) that supports 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. PHRL is well positioned through experience and existent infrastructure to expand and provide VHA with clinically validated sequencing assays for somatic (tumor) and germline (blood) samples for lung and prostate cancers from Veteran patients.

PHRL has several years of experience in receiving, testing, and storing clinical samples from over 80 VA medical centers. PHRL also worked with the VHA Office of Finance to establish a charge-back system, that allows PHRL to invoice sites efficiently for payment and cost transfer back to PHRL. PHRL purchased a license for the PraediGene (Bitscopic Inc.) laboratory software tool, which is a Commercial Off-the-Shelf (COTS) application that provides multiple features for efficient laboratory work flow. PraediGene provides for: enhanced electronic sample log-in utilizing VistA extraction technology to minimize manual data entry, thus reducing risk of human error; gene sequencing analysis and archiving of gene sequences; instantaneous creation of clinical report documentation of final laboratory test results back to providers through a variety of formats depending on the receiving site's needs; and autogenerated monthly billing statements for each VA site using PraediGene's Financial Tool.

In support of the VA's mission to provide cutting edge precision healthcare service in medicine to our nation's veterans, PHRL will be offering laboratory testing services for the Precision Oncology Genomics Program. Therefore, we need to expand are suite of tools to include the PraediGene Precision Oncology Module.

PraediGene is a laboratory workflow tool designed to allow users 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 Veterans Information Systems and Technology Architecture (VistA) Electronic Health Record (EHR) and Computerized Patient Record System (CPRS) systems. To ease reporting and transcription requirements, PraediGene is also able to generate "EHR friendly" input. Like all PraediGene Tools, the PraediGene Precision Oncology Module will support the complete range of functions required by the PHRL, which includes:

- Automated PHRL workflow tasks and enabling staff to electronically enter and track all medical lab tests, including Protected Health Information (PHI) and Personally Identifiable Information (PII)
- Full support of DNA sequencing analysis
- Integration to VA's VistA EHR and CPRS systems, retrieving patient information directly from VistA and produce Vista-compatible test results
- Fully integrated DNA Quality Control (QC) checks and maintains all laboratory records to support CLIA and CAP licensing and audits
- Automated laboratory reports, financial reports, and management reports

To add to these capabilities, the PraediGene Precision Oncology Module will allow PHRL to perform next generation sequencing and custom-tailored laboratory diagnoses.

The contractor shall provide support in accordance with its GSA Schedule contract for the PraediGene Precision Oncology Module, which includes publishing of bug/defect fixes via patches and updates/upgrades in function and technology to maintain the operability and usability of the software product. The contractor shall deliver all software maintenance no later than 30 days from receipt of order. The period of performance for the software maintenance shall be 12 months after contract award. The total estimated value of the proposed action is

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. Based on market research, as described in Section 8 of this justification, it was determined that only the PraediGene Precision Oncology Module will meet the Government's requirements. Only the PraediGene Precision Oncology Module can provide the following critical

requirements:

- a) Rules-based, configurable resistance sequence analysis
- b) PIV & Active Directory login integration
- c) Role Base Access Control
- d) Web-based installation, cloud-ready, modest hardware requirements
- e) Appliance options
- f) TRM approval / running in VA
- g) VistA R/W capability
- h) Cerner R/W capability
- i) Can run stand-alone (i.e. no EMR integration - precision oncology features only)
- j) HL7 support, integration with VistA HL7, etc.
- k) Financial components:
 - a. granular invoicing capabilities (site, VISN, user-definable accounting, etc)
 - b. generate "master invoices" per VA requirements
 - c. commercial lab cost comparison feature
- l) Quality Control checks on results
- m) Configurable workflow support (e.g. new test -> pending -> results available-> completed)
- n) Advanced analytics & querying capabilities w/ mapping support
- o) Print & download/export functionality
- p) Bulk import functionality
- q) Integration with clinical trials tools
- r) Lab performance measure reports (e.g. Turn-Around-Time)
- s) Barcode scan
- t) Integration with PraediGene
- u) 508 Compliance

These functions are critical to PHRL in order to guarantee thorough, efficacious specialized testing for veteran clinical care.

PraediGene and its entire suite of tools, are a proprietary software product; therefore, no other company has rights to access the proprietary code base necessary to maintain the PraediGene Precision Oncology Module for VA including software upgrades, updates, enhancements, and corrections. Access to this code is also needed to ensure all services provided are properly configured. Bitscopic, Inc. owns the proprietary intellectual rights to the PraediGene software.

If PraediGene Precision Oncology Module is not purchased, PHSR's ability to effectively perform genomic cancer testing would be seriously diminished. Test results for Reference Lab samples from VA physicians would be delayed or not processed. The potential cost savings of several millions of dollars in future years would disappear and, instead, costs for physician-ordered lab tests would increase. Moreover, manual processes would need to be used and the potential for errors would increase, thus affecting Veteran patient care. Further, non-searchable scanned laboratory data would not be seamlessly integrated with VistA.

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 the PraediGene Precision Oncology Module and associated maintenance. There is no competition anticipated for this acquisition. In accordance with FAR 5.301 and 8.405-6(a)(2) the award notice for this action will be synopsisized on the Federal Business Opportunities website and this justification will be made publicly available within 14 days of award.

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, as recently as April 2019. VA technical experts reviewed other similar software products such as GenomOncology (<https://www.genomoncology.com/>); Tempus (<https://www.tempus.com/>); Syapse (<https://www.syapse.com/>); IntelliSpace Precision Medicine (PHILIPS) (<https://www.usa.philips.com/healthcare/product/HC881088/intellispace-precision-medicine-oncology>), and determined that only PraediGene can meet all of the Government functional requirements as described in Section One of this memorandum. Specifically, the similar products are incapable as a single solution of performing the customized electronic tracking of specimens and their testing status, performing integrated Quality Control (QC) tasks (sequence uniqueness and control tracking) required by PHRL, performing the specific rules-based analyses sequences for resistance mutations, and generating reports in a format compatible with VistA and CPRS.

In addition, VA issued a Request for Information (RFI) with a draft Product Description on May 16, 2018 to open market contractors through Federal Business Opportunities, NASA SEWP V GWAC, and GSA FSS via the GSA's e-Buy tool to ascertain the ability of any other source to provide an alternate product. The intent of the three RFIs was to ascertain if any other brand name products could meet VA's needs. The three RFIs 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 Historically Underutilized Business Zones (HUBZone) small business concerns. Responses to the RFIs from all venues were due on May 23, 2018. No responses were received from the three RFIs.

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.

Date: _____

Director
Public Health Surveillance
and Research

Signature: _____

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 by comparing the quote with the Independent Government Cost Estimate. Additionally, price discounts will be sought.

Date: _____

Procuring Contracting Officer

Signature: _____

12. Procuring Contracting Officer Certification: I certify that this justification is accurate and complete to the best of my knowledge and belief. As this contract action does not exceed \$700,000, the certification below required by FAR 8.405-6(d)(1) serves as approval.

Date: _____

Procuring Contracting Officer

Signature: _____