

Attachment B: Request for Sole Source Memo Format

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval For Other Than Full and Open Competition

Contracting Activity: Department of Veterans Affairs, VISN 04, VA Pittsburgh Healthcare System, University Drive Division. 2237#646-12-3-233-0059

Nature and/or Description of the Action Being Processed: Brand Name Only Sole Source and Only One Responsible Source, Sole Source Award, to Sequenom.

Description of Supplies/Services Required to Meet the Agency's Needs:

MassArray Analyzer 4 System (Molecular Pathology Testing System)

Contract Amount - \$347,450.

Statutory Authority Permitting Other than Full and Open Competition: 41 USC 253 (c) (1), as implemented by FAR 6.302-1.

- (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1;
- () (2) Unusual and Compelling Urgency per FAR 6.302-2;
- () (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per FAR 6.302-3;
- () (4) International Agreement per FAR 6.302-4
- () (5) Authorized or Required by Statute FAR 6.302-5;
- () (6) National Security per FAR 6.302-6;
- () (7) Public Interest per FAR 6.302-7;

Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):

It is essential to the VA Pittsburgh Healthcare System that it purchase the Sequenom MassArray Analyzer 4 System, since it contains the following features that no other company makes in a similar System:

Sequenom MassArray Analyzer Unique Characteristics

The Sequenom MassArray® System is a Matrix Assisted Laser Desorption/Ionization Time-of-Flight (MALDI-TOF) Mass Spectroscopy instrument, for precise determinations in clinical laboratory patient testing. The Sequenom technology is a complete platform with Maldi-TOF Mass Spec, a Nanodispenser, and software which can perform the following applications on the same instrument:

Genotyping analyses includes:

Low level somatic mutation detection

Multiplexed Single Nucleotide Polymorphisms (SNP) genotyping economically
Methylation analyses using a MassCLEAVE chemistry for quantitative results
Quantitative Gene Expression
Allele specific expression
Copy Number Variation
Comparative sequence analysis of microbial, viral and other haploid organism genomes
May include Nosocomial infections

Unique performance characteristics and features of the Sequenom MALDI-TOF technology and MassArray Analyzer:

Unique performance characteristics for data acquisition by MALDI-TOF:

Data acquisition and system control for all MassArray MALDI-TOF-based platforms is via proprietary software developed by Sequenom. The computer workstation dedicated to these tasks was developed with software modules such that all data obtained through the MALDI-TOF is controlled through this workstation software. Once data is obtained from each sample the electronic signal is processed and analyzed using each individual software application. (i.e. genotyping, quantitative gene expression, methylation analysis, etc.). Ultimately, this method of data processing and acquisition is unique for Sequenom. Other vendors of MALDI-TOF do not have these capabilities for nucleic acid analysis or only supply small portions of this solution which makes these systems not suitable to perform or operate MassArray applications. Solutions marketed by other vendors are often slower and less specific than that delivered by Sequenom requiring greater user intervention and technique (manual sample analysis) resulting in more time and inconsistencies. The MassArray therefore provides a fully integrated turn-key system platform for application areas such as:

SNP & Mutation Genotyping
Allele Frequency Quantitation and CNV analysis
Quantitative Gene Expression Analysis
Quantitative DNA Methylation Analysis
• Comparative Sequence Analysis for Microbial and Viral Typing
• Somatic Mutation Profiling

Another consideration that makes the instrument both a high throughput multi-application platform is the Sequenom-designed MALDI-TOF sample loading chip (SpectroCHIP) that removes all sample handling ambiguity and data irreproducibility that can occur during sample processing. The instrument is designed to process two chips during any one run and has built-in intelligence to read the bar codes from the chips, and to calibrate itself before each chip is processed.

Unique features based on Instrumentation – for MassArray Analyzer 4 System

- (1) Ability to analyze up to 768 separate reactions in a single unattended run with no robotic feeder required
- (2) Ability to regularly analyze > 27,500 genotypes in a single unattended run (36-plex iPLEX Gold assay x 768 reactions) or process 768 samples in a single unattended run.

- (3) Ability to analyze and call genotypes in 5-10 seconds per sample.
- (4) Ability to call sample genotypes in real time so the system can identify results and call efficiency during the collection process.
- (5) Ability to fully automate the process of MALDI sample alignment and data collection through the use of proprietary vision recognition systems and motor drive controllers. System automatically locates SpectroCHIP launching pads, automatically calibrates oligo standards and locates and collects each reactions full data.
- (6) The full system provides the ability to process all biochemistry steps, liquid handling and sample transfer in a semi-automated way (excluding PCR setup).
- (7) Ability to process and analyze 3,840 multiplexed reactions in a 10-hour shift.
- (8) Ability to pre-load assay data parameters into MALDI capture device so that genotype data collection process is automated and optimized, yielding higher accuracy and call rate efficiency.

MassArray Nanodispenser - Unique performance characteristic of instrumentation for array dispensing

The MassArray Nanodispenser is a benchtop dispensing instrument employing advanced robotics for the rapid transfer of nanoliter volumes of analyte sample from micro-titer plates onto Sequenom SpectroCHIP arrays. Its standard configuration holds up to two 96- and 384-well microtiter plates.

The transfer is performed by an array of slotted pins that aspirate fluid via capillary action and dispense by contacting the pin array with the SpectroCHIP. Between each liquid transfer, the pin array is washed in an ultrasonic bath and dried to ensure no cross contamination between samples. The instrument automatically tracks samples by reading barcodes on the micro-titer plates and SpectroCHIPS. An onboard vision system is used to perform a volume check after each dispense and to automatically calibrate the instrument robotics. A touch screen monitor provides the user interface to the machine. The instrument operates completely autonomous and requires no external equipment other than AC power. An external air conditioning port is available for temperature and humidity control of the machine's internal work area.

MassArray Nanodispenser - Unique features based on instrumentation

- (1) Description: The MassArray Nanodispenser is a high precision, built in PC controlled, X, Y and Z stage motor controlled fluid dispensing system. This system utilizes miniature slotted pins to dispense analyte spots onto Sequenom's SpectroCHIPS
- (2) System Configuration is such that the machine has built in computer, Touch Screen monitor, and Water & Vacuum Control Unit, Water Tank.
- (3) Ability to spot a single 384 SpectroCHIP within ten (10) minutes (Rinse three (3.5) seconds, Ultra: four (5) seconds).
- (4) Instrument has vision system capability for auto alignment of pin to chip; and auto reject misplaced chips
- (5) Ability to accept 384 MTP and 384 SpectroCHIPS
- (6) Ability to store 2 MTPs, 1 Scout plates
Barcode reading of MTPs, Scoutplate and SpectroChip

Windows XP-PRO Operating System.
(7) Has pre-loaded "Nanodispenser – RS-1000" software.

In addition, it is essential that the VA Pittsburgh Healthcare System purchase the Sequenom MassArray Analyzer 4 System from Sequenom, since they are the sole exclusive seller of this System.

Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:

N/A. There is only one available source. A Notice of Intent to Sole Source, along with this Sole Source Justification Memorandum, will be posted to Fedbizopps for 5 days. In addition in accordance with FAR Part 12.603, and FAR 5.207 and FAR 5.203 (a) (1), a combined Synopsis/Solicitation will be posted to Fedbizopps for 5 days.

Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:

The price quoted by Sequenom for the System being purchased, of \$240,000, is the same as what Sequenom charged another entity in the open market for the same system, excluding Software Options and Shipping Charges. The price initially quoted by Sequenom for the three Software Options of \$39,500 each, was the same as they charged another entity for one of these Software Options. In addition, Sequenom lowered their originally quoted price for three Software Options by 10% for each Option. Based on this research, and additional discounting, the price is considered fair and reasonable. (See original and revised Quotes and copies of paid invoices, under Index S23 in the Solicitation Action Briefcase portion of the eCMS Contract File Briefcase).

Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:

Market research was conducted to determine if the items were commercial items, and since the items have been sold in the Commercial Marketplace by Sequenom, the items are considered commercial items. Confirmations were received from Sequenom that they are the sole seller of this equipment and that they do not sell this system off any Federal Supply Schedule Contract. A Query Search was conducted in the GSA E-Library and in GSA Advantage using the words "Sequenom" and "MassArray Analyzer" and there were no results. The Notice of Intent to Sole Source and combined Synopsis/Solicitation will also serve as further Market Research, to rule out whether there are any other companies that provide a system with the needed features.

Any Other Facts Supporting the Use of Other than Full and Open Competition:

None

Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

None

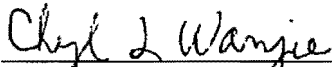
A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required:

NA – Sole Source

Requirements Certification:

I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and 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.

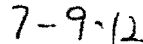
(This signature is the requestor's supervisor, fund control point official, chief of service, someone with responsibility and accountability)



Name: Cheryl L. Wangle

Title: Business Manager

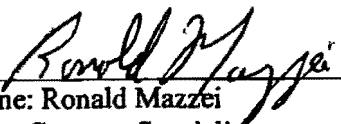
Department: Clinical Support



Date

Approvals in accordance with FAR 6.304:

Contracting Officer's Certification: (required) I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.



Name: Ronald Mazzei
Title: Contract Specialist
Facility: H.J. Heinz




Date

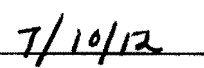
VISN/PCA QA: I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Name Date
Title
Facility

NCM/PCM: I certify the justification meets requirements for other than full and open competition.



Name Date
Network Contract Manager
VISN/PCA



Date

SAO: I certify the justification meets requirements for other than full and open competition.

Name Date
Director

Service Area Office, East

VHA HCA Review and Approval: I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and recommend approval (over \$50 million), approve (up to \$ 50 million) for other than full and open competition.

Norbert Doyle
Chief Procurement and Logistics Officer
VHA Head of Contracting Activity (HCA)

Date

VA Deputy Senior Procurement Executive Approval (over \$10 not exceeding \$50 million): I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

Iris B. Cooper Date
Deputy Senior Procurement Executive (DSPE)
Office of Acquisition and Logistics
Department of Veterans Affairs

VHA Senior Procurement Executive Approval (over \$50 million): I have reviewed the foregoing justification and find it to be complete and accurate to the best of my knowledge and belief and approve for other than full and open competition.

Jan R. Frye Date
Deputy Assistant Secretary for Acquisition and Logistics
Senior Procurement Executive (SPE)
Department of Veterans Affairs