

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval
For
Other Than Full and Open Competition

1. **Contracting Activity:** Department of Veterans Affairs, VHA, SAO EAST, NCO 7, Ralph H. Johnson VA Medical Center, 109 Bee Street, Charleston, SC 29401. VA2237: 534-16-1-025-0014.
2. **Nature and/or Description of the Action Being Processed:** Request for approval for a new, firm fixed price contract for Nanosphere Inc to provide a Reagent Rental Agreement and all service and maintenance support for new instrumentation for stool sample processing.
3. **Description of Supplies/Services Required to Meet the Agency's Needs:** The Ralph H. Johnson VA Medical Center currently performs all stool testing using media obtained from Remel Inc. A Reagent Rental Agreement provided by Nanosphere Inc would provide the Microbiology department with two Verigene processor SPs and one Verigene reader. Nanosphere Inc is the sole provider of these instruments, including rental, preventative maintenance, and services necessary to maintain the instrumentation. Nanosphere Inc does not outsource or endorse any 3rd part providers of service and support. Thus, Nanosphere Inc is the sole and exclusive provider of these instruments.

The estimated period of performance is twelve (12) months for the base period, plus four (4) twelve (12) month option periods. The total estimated value, including options, is \$232,500.00. A further breakout is identified below:

Description	Qty	Unit	Unit Cost	Total Cost
BASE: (1yr-POP TBD)				
0001 Reagent Rental Agreement for two (2) Verigene Processor SP(s) and one (1) Verigene Reader [REDACTED]	25	KT	[REDACTED]	[REDACTED]
[REDACTED]				
0002 Verigene Enteric Pathogen Test/cartridge, [REDACTED]	25	KT	[REDACTED]	[REDACTED]
[REDACTED]				
Option 1: (1yr-POP TBD)				
1001 Reagent Rental Agreement for two (2) Verigene Processor SP(s) and one (1) Verigene Reader [REDACTED]	25	KT	[REDACTED]	[REDACTED]
[REDACTED]				
1002 Verigene Enteric Pathogen Test/cartridge, [REDACTED]	25	KT	[REDACTED]	[REDACTED]
[REDACTED]				
Option 2: (1yr-POP TBD)				
2001 Reagent Rental Agreement for two (2) Verigene Processor SP(s) and one (1) Verigene Reader [REDACTED]	25	KT	[REDACTED]	[REDACTED]
[REDACTED]				

2002 Verigene Enteric Pathogen Test/cartridge, [REDACTED] [REDACTED]	25	KT	[REDACTED]	[REDACTED]
Option 3: (1yr-POP TBD)				
3001 Reagent Rental Agreement for two (2) Verigene Processor SP(s) and one (1) Verigene Reader [REDACTED] [REDACTED] [REDACTED]	25	KT	[REDACTED]	[REDACTED]
3002 Verigene Enteric Pathogen Test/cartridge, [REDACTED] [REDACTED]	25	KT	[REDACTED]	[REDACTED]
Option 4: (1yr-POP TBD)				
4001 Reagent Rental Agreement for two (2) Verigene Processor SP(s) and one (1) Verigene Reader [REDACTED] [REDACTED] [REDACTED]	25	KT	[REDACTED]	[REDACTED]
4002 Verigene Enteric Pathogen Test/cartridge, [REDACTED] [REDACTED]	25	KT	[REDACTED]	[REDACTED]

4. **Statutory Authority Permitting Other than Full and Open Competition:**

- (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;

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** In accordance with FAR 6.302-1, there is only one responsible source to provide the services to satisfy Agency requirements by being uniquely capable of providing the rental and preventative maintenance and service for the Verigene instrumentation. No other supplies or services will satisfy Agency requirements. Nanosphere Inc is the sole and exclusive manufacturer of the Verigene instrumentation. The instrumentation is currently in the laboratory and has been validated according to proprietary standards. The Verigene instrumentation is proprietary and contains proprietary software; therefore the requisite maintenance services require special and unique software which can only be provided by the sole and exclusive manufacturer, Nanosphere Inc. Because Nanosphere Inc is the sole and exclusive provider of these instruments, it is uniquely qualified to perform under this requirement. Nanosphere Inc does not outsource or endorse any 3rd party providers for reagents or service. Thus, Nanosphere Inc is the sole and exclusive provider of these instruments. Accordingly, Nanosphere Inc is the only entity capable of providing the supplies and services described in Section III above without the Veteran's Health Administration experiencing substantial duplication of cost that could

be expected to be recovered through competition and unacceptable delays in fulfilling its requirement.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** A FedBizOpps Sources Sought Notice was posted January 23, 2016 to January 29, 2016 seeking sources capable of providing the following: The Microbiology Section of the Ralph H. Johnson VAMC Pathology and Laboratory Department in Charleston, SC needs an updated methodology to perform automated and less labor intensive stool culture processing using real-time PCR assays (Moderate complexity testing) for testing of common enteric pathogens. The instrument must be easy to use, simple, and require less hands-on time than current culturing methodology. The instrument must be able to use unprepared clinical samples with little preparation time (approximately 10 minutes or less). No responses were received.

Market research was also conducted seeking sources from within the Department of Veterans Affairs. Other Medical Centers were consulted through email for the requirement and two companies (BioFire and Nanosphere Inc) were consulted for this requirement. Both vendors were invited to provide demonstrations and provide a detailed quote of their reagent rental agreements. BioFire was able to meet the needs of the department, but duplicated current testing already being utilized by the department. This would add cost to testing currently available, but would not allow for test reimbursement. Nanosphere Inc provided similar testing, but did not duplicate testing that is currently available to the department which made this vendor the only provider capable of providing the unique services that were required. No other vendors have the capabilities and expertise necessary to support this requirement.

7. **Determination by the Contracting Officer that the Anticipated Cost to the Government will be Fair and Reasonable:** In accordance with FAR 13.106-3(a)(2)(i),(iii),(vi) & (vii), the total estimated costs of these rentals, inclusive of all consumable and services is valued at \$232,500.00 over five years. The Contracting Officer has determined that the anticipated cost to the Government will be fair and reasonable based on Market Research and the proposed price being comparable to the Independent Government Estimate provided by RHJ VA MC Supervisory Medical Technologist and Technical Expert [REDACTED]. Additionally, Nanosphere Inc is offering a 9.8257% discount per test compared to their confidential pricing for commercial laboratories. This pricing includes shipping and Nanosphere Inc is providing the testing equipment on a rental basis of [REDACTED] per test so the government does not have to purchase the equipment.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** As described in Section VI above, market research, in accordance with FAR Part 10, was conducted by synopsis of the proposed acquisition, advising industry of the pending acquisition and soliciting inquiries from interested parties. A Vetbiz VIP search produced 39 potential vendors under NAICS 334516, Analytical Laboratory Instrument Manufacturing however no responses to the sources sought notice were received. Only one vendor is the sole and exclusive provider of these services – Nanosphere Inc. These unique services are not found on Federal Supply Schedule and must be purchased “open market”. The mandatory sources available on GSA and the NAC VA Federal Supply Schedules were reviewed in addition to examining the acquisition history and experience with the marketplace. Nanosphere Inc is the only entity offering the specific requirement. Market research has demonstrated that the only source capable of obtaining this proprietary, Verigene instrumentation and associated test and service is from the

manufacturer. The Verigene instruments contain technical data proprietary to Nanosphere Inc and are licensed, sold, and distributed exclusively by Nanosphere Inc. Nanosphere Inc does not outsource or endorse any 3rd party providers of service or support.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** Nanosphere Inc is offering a 9.8257% discount to the government compared to confidential pricing normally offered to commercial laboratories for the same test and providing the required testing equipment on a rental base which is unique only for the government. Commercial laboratories are required to purchase the equipment.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** See Section VI above.
11. **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:** The Ralph H. Johnson VA Medical Center will continue to conduct market research, including interacting with vendors at professional conferences, exhibitions, and trade shows, to identify alternative sources that could be considered for future acquisitions.
12. **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.

For:

[Redacted]
[Redacted]
[Redacted]
Assistant Laboratory Manager
Ralph H. Johnson VA Medical Center

03-10-2016

Date

13. **Approvals in accordance with the VHAPM, Volume 6, Chapter VI: OFOC SOP.**

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

[Redacted]
[Redacted]
[Redacted]
Contracting Officer
Ralph H. Johnson VA Medical Center

03-10-2016

Date

- b. **Director of Contracting /Designee (Required \$150K and above):** I certify the justification meets requirements for other than full and open competition.

[Redacted]
Deputy Director of Contracting, NCO 7

03-10-2016

Date