

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A)  
For  
Brand Name Description

Acquisition Plan Action ID: VA244-17-AP-6032/646-18-1-080-0014

- 1. Contracting Activity:** Department of Veterans Affairs, VISN 04, VA Pittsburgh Healthcare System (VAPHS), Pittsburgh, PA, SAO East, Network Contracting Office 4 (NCO4), Clinical Support Services (Med 2).
- 2. Nature and/or Description of the Action Being Processed:** The VAPHS' Pathology & laboratory Medicine Service (P&LM) is requesting award of a firm fixed price purchase order. A competitive request for quote (RFQ) is to be issued with a brand name only description for Alere North America, LLC test kits as described in item 3 below. Quotes in response to the RFQ must be in accordance with the brand name description below to include part number. This procurement is in accordance with FAR 13.5 Simplified Procedures for Certain Commercial Items and specifically FAR 13.501 Special Documentation Requirements, where acquisitions conducted under Simplified Acquisition Procedures are exempt from the requirements of FAR Part 6, but still require a justification using the format of FAR 6.303-2.
- 3. Description of Supplies/Services Required to Meet the Agency's Needs:** Said purchase order contract will provide proprietary Alere test kits for testing of patient specimens for the presence of harmful organisms and parasites such as Legionella and Pneumococcus. Total estimated value is **\$84,846.80**. Applicable NAICS and PSC codes are 325413- In-Vitro Diagnostic Substance Manufacturing, and 6550-In-Vitro Diagnostic Substances, Reagents, Test Kits and Sets. Anticipated phased deliver period is 11/08/2017 through 09/30/2018. Specific brand name description test kits to be ordered, along with estimated quantities, unit, and total prices are listed in the table below:

CLIN	Description	UoM	Unit Price	PART #	QTY	TOTAL PRICE
0001	Legionella Binaxnow Antigen Kit	KT	\$ 523.00	852-000	100	\$ 52,300.00
0002	Panel Triage Parasite Kit	KT	\$ 480.00	96100	40	\$ 19,200.00
0003	S. Pneumococcus Urinary Antigen Kit	KT	\$ 333.67	710000	40	\$ 13,346.80

- 4. Statutory Authority Permitting Other than Full and Open Competition:** Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per FAR 6.302-1; *also*, the authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented for restricting competition on this procurement via FAR 13.106-1(b)(2).

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):** The required test kits support the continued utilization of Alere testing protocols already in place within the VAPHS P&LM. VAPHS P&LM has used these testing protocols since at least 2014. The Alere test kits have been properly vetted and validated for use in detecting the prior referenced harmful organisms and parasites. Each responsible medical technologist within the microbiology section is trained and verified to be competent for use of the Alere test kits. Additionally the P&LM service has approved procedures in place for utilizing these kits. Failure to procure the Alere test kits would require extensive work by the P&LM service to validate new test kits, establish new procedures, and train and validate competency for each medical technologist. At this time, it is not in the P&LM's effective operational interest to undertake such a re-validation effort.
6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** A combined synopsis/solicitation will be posted to FBO.gov for a reasonable period of time to allow for submission of competitive quotes. Furthermore, the Contracting Officer named below will forward a copy of the combined synopsis/solicitation to those vendors listed in item 10 below whom have expressed an interest in this acquisition.
7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:** Prices under the contemplated purchase order are anticipated to be fair and reasonable based on the following rationale:
- Prices are expected to be equal to or less than prices paid under previous procurements of these same Alere test kits by NCO4 and VISN4.
  - Furthermore prices are anticipated to be equal to or less than Alere's current open market price list prices applicable to these test kits.
  - This Contracting Officer further anticipates that prices can be determined to be fair and reasonable based upon adequate price competition.
8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** VAPHS P&LM most recently ordered the required test kits from Alere under open market purchase order VA244-17-F-0325 in the amount of \$84,846.80. These test kits have been ordered yearly on an open market basis since approximately 2014. This Contracting Officer also surveyed GSA Advantage and found the required Alere test kits are also supplied by Fisher Healthcare under their FSS contract V797P-5992X. On 10/03/2017, this Contracting Officer approached Government Scientific Source, Inc, a verified Veteran Owned Small Business (VOSB), about whether they offered the required kits under their FSS contract. Government Scientific Source sales personnel response that the required test kits are not available under their FSS, but they can provide them on an open market basis; they then provided an informational quote. The VA's Vendor Information Pages (VIP) was reviewed by the Contracting Officer on 11/02/2017 via search under NAICS code 325413 with keywords, "Test Kits". This search returned 14 results. These 14 results were reviewed to see if any vendors marketed and sold the required Alere test kits; it was subsequently found that none did.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** Based upon procurement history and market research, there are three known sources of supply for the required test kits: Alere North America, LLC, Government Scientific Source, Inc, and Fisher Healthcare. Alere manufactures and sells the kits on the open market. Government Scientific offers the kits on the

open market. Fisher Healthcare offers the test kits on a post award basis under their FSS contract. In this Contracting Officer's judgement, the prices offered by Fisher Healthcare under their FSS contract are not competitive with the prices obtainable in the open market. An unrestricted, open market, brand name only description procurement is the most efficient means of competing and fulfilling the Government's minimum need.

10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Alere North America, LLC, Government Scientific Source, Inc, and Fisher Healthcare.

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:** VAPHS P&LM will stay abreast of the latest FDA approved organism and parasite testing methodologies and products and conduct a competitive best value procurement in the near future with the assistance of NCO4. This procurement will utilize a thorough salient characteristics specification and allow competing brands and testing methods to be offered in response to the solicitation.

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.

JASON C.  
TEDROW 214979

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Jason Tedrow  
Quality Management, Quality Improvement Technologist  
VA Pittsburgh Healthcare System

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Date

13. **Approvals in accordance with the VHAPM Part 806.3 OFOC SOP:**

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

Matthew D  
Parlett 360547

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Matthew D. Parlett  
Contracting Officer  
NCO4, Clinical Support Services (Med 2)

11/03/2017  
\_\_\_\_\_  
Date

b. **One Level Above the Contracting Officer (Required):** I certify the justification meets requirements for other than full and open competition.

for Nancy L. Porter  
Branch Chief  
NCO4, Clinical Support Services (Med 2)

11/3/2017  
\_\_\_\_\_  
Date