

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A)
For
Other Than Full and Open Competition (>SAT)

Acquisition Plan Action ID: VA248-18-AP-3430

1. **Contracting Activity:** Department of Veterans Affairs, VISN 08, Orlando VA Healthcare System
675-19-1-2223-0018

Department of Veterans Affairs
Orlando VA Healthcare System
Network Contracting Activity 8 (NCO 8)
13800 Veterans Way
Orlando, FL 32827

Requesting Activity:

Department of Veterans Affairs
Orlando VA Healthcare System
Pathology & Laboratory
13800 Veterans Way
Orlando, FL 32827

2. **Nature and/or Description of the Action Being Processed:** This is a new firm fixed IDIQ Base Plus Four Year price contract for reagents and consumables for the continued operation of the Dako Omnis automated immunohistochemical (IHC) staining system. The old contract #VA248-17-P-3484 expires on 09/30/2018.

FAR13.5 Simplified Procedures for Certain Commercial Items:

This procurement is for Dako reagents and consumables 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:** The Orlando VA Healthcare System Anatomic Pathology Laboratory located at 13800 Veterans Way, Orlando FL 32827 is currently using the Dako Omnis IHC stainer since October 2017. The Pathology Laboratory requires the continued use of the staining system which is already validated and in use in the Pathology Lab. This is a requirement for a Base year with four option years Cost per Test (CPT) agreement. The estimated cost of this procurement is \$570,542.75. Estimated delivery date is 10/01/2018.

The IHC staining system that performs the staining of human tissue to target specific proteins and In Situ Hybridization (ISH) using probes to localize specific nucleic acid sequences. The system allows for growth of test options to include all antibodies and probes currently available from Dako and future releases of antibodies and probes as they are developed.

The CPT price will include the existing equipment currently located at 13800 Veterans Way Orlando FL 32827, all ancillaries, detection kits, quality controls, slides, disposables, consumables, antibodies, reagents, supplies, technical manual, service manual, hardware and software, preventative and repair maintenance agreement, and operator training in the operation and performance of preventive maintenance.

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

- (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;

FAR13.5 Simplified Procedures for Certain Commercial Items:

The authority for applying the Simplified Procedures for Commercial Items of FAR 13.5 is 41 U.S.C. 1901 and is implemented by 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):

This is a Brand Name justification. Agilent Technologies, Inc. is the sole provider of the Dako Pathology products, which are considered In Vitro Diagnostic (IVD) Medical Devices and require specialized training for labeling and distribution. Agilent does not distribute IVD Medical Devices through any resellers to ensure proper handling of these products. The Dako instrument is FDA-approved and requires specially trained Agilent personnel to repair the instrument. The detection system utilized in the Dako Omnis is only available from Agilent Technologies and no other detection system can be used with the Dako Omnis. The consumables for this equipment are manufactured exclusively for the Dako Omnis and can only be purchased through Agilent.

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

In an effort to obtain competition, market research was conducted through GSA Advantage, FBO, FPDS, NAC and the Internet. Agilent works with some SDVOSB/VOSB and other small business partners for distribution of other products, however, not for Dako Pathology products.

7. Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:

Anticipated costs are considered fair and reasonable compared to the same price the Orlando VA Healthcare System paid on previous contract VA248-17-P-3484 9/29/2017-9/28/2018. The price was previously determined to be fair and reasonable therefore, in accordance with FAR 13.106-3(a)(2)(ii) is deemed fair and reasonable.

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 6 above, market research, in accordance with FAR Part 10, was conducted by advising industry of the pending acquisition and soliciting inquiries from interested parties.

There are no authorized Service Disabled Veteran-Owned Businesses or Veteran-Owned Businesses (SDVOSB/VOSB) or Small Businesses of any kind for the Dako Pathology and Companion Diagnostics product lines. Additional Market Research was conducted on the internet, GSA, FBO, FPDS, and the NAC. An approved 2268 is on file for previous award to Agilent Technologies, Inc. for this requirement from 09/29/2017-9/28/2018.

9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** In accordance with FAR 6.302-1(b)(2) and FAR 6.303-2(b)(9)(i), Agilent owns all proprietary interest in the products/ services being purchased. Dako Pathology products are considered Vitro Diagnostic Medical Devices which requires specialized training for labeling and distribution. The Dako Omnis equipment is already validated, operational and currently in use by the Orlando VA Healthcare System Pathology Laboratory. Only Agilent Technologies can supply the consumables required to operate the Dako Omnis instrument, which is proprietary to Agilent Technologies.
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:**
Agilent Technologies, Inc.
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 Government will continue to research the market place for potential new sources that can provide a the products that the Orlando VA Healthcare's Pathology Laboratory requires. Market research will be conducted through GSA Advantage, FBO, FPDS, NAC and the Internet. If brand specific conditions are not required, competitive procedures will be utilized.
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.



Esther Murphy
Pathology & Laboratory Manager
Orlando VA Healthcare System

8/8/2018
Date

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

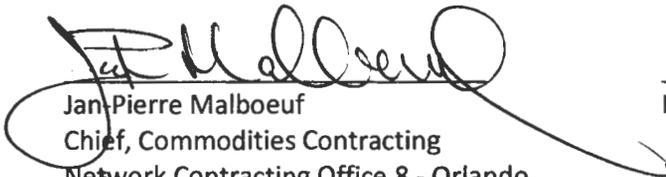
- a. **Contracting Officer or Designee's Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.



Pedro J. Catinchi
Contracting Officer
Network Contracting Office 8 - Orlando

8/10/2018
Date

- b. **One Level Above the Contracting Officer (Required over SAT but not exceeding \$700K):** I certify the justification meets requirements for other than full and open competition.



Jan Pierre Malboeuf
Chief, Commodities Contracting
Network Contracting Office 8 - Orlando

8/10/2018
Date