

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A) For Other Than Full and Open Competition (>\$150K)

Acquisition Plan Action ID: VA248-17-AP-2072

- Contracting Activity:** Department of Veterans Affairs, VISN 08, Orlando VA Medical Center (VAMC) Purchase Request 675-17-2-2223-0038
- Nature and/or Description of the Action Being Processed:** This is a Brand Name Justification for the purchase of reagents and consumables to operate the Leica Biosystems Bond III Immunohistochemistry (IHC) instrument. This procurement is for a new Fixed Priced Estimated Quantity contract 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.
- Description of Supplies/Services Required to Meet the Agency's Needs:** The Orlando VAMC Pathology and Laboratory Medicine Service require the immediate purchase of reagent test kits and supplies to operate the Leica Bond Instruments. The estimated cost to the government is [REDACTED] for base year and four option years. The estimated base period of performance is date of award – September 30, 2017. Please see List of test kits below.

Item	Part Number	Description
1	AR9222	Dewax Solution (AR9222)
2	AR9352	Primary Antibody Diluent
3	AR9551	Enzyme Pretreatment Kit
4	AR9590	Wash Solution 10X Concentrate
5	AR9640	Epitope Retrieval 2
6	AR9961	Epitope Retrieval 1
7	CS9100	Aspirating Probe Cleaning System
8	CS9100	Aspirating Probe Cleaning Kit
9	DS9390	Polymer Refine Red Detection
10	DS9477	Chromplex 1 Duel Detection
11	DS9800	Polymer Refine Detection (DAB)
12	OP309700	Open Containers-30 ml
13	OP79193	Open Containers-7ml
14	S21.1971.110	Mixing Stations
15	S21.2001	Universal Covertiles
16	S21.4564	Slide Label and Print Ribbon
17	IHC5994-A	H. pylori
18	PA0046	Cylin D1
19	PA0515	Chromagranin a

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):

Leica Biosystems is the manufacturer of Bond III IHC instrument along with the supplies and reagents required for operation of the unit, some of which are unique to Leica Biosystems. The unit was acquired through competitive procedures for the OVAMC Pathology and Laboratory Service on February 27, 2013 to produce diagnostic IHC slides. The Bond III is a fully automated IHC and In Situ Hybridization (ISH) staining device that provides continuous processing and simultaneous detection at superior speeds while reducing hazardous waste. The system was validated using Leica reagents and tests must be performed with same reagents and consumables. In addition, the reagents are packaged for use with the Bond III system. Leica Biosystems has provided written authorization to Government Scientific Sources (GSS) to distribute these items (documentation is on file).

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

Sources sought notice VA248-17-N-0312 was posted on FBO January 10, 2017. Responses were received from Leica Biosystems and Government Scientific Sources (GSS) indicating that they can provide the requested items. In addition, Leica Biosystems has provided written authorization to GSS to provide the items. A sources sought notice was also posted on GSA eBuy, but there were no positive responses received (documentation is on file). Furthermore, no other vendor/manufacture has indicated that their product(s) are compatible with the Leica Bond instrument in response to either of the sources sought notices issued.

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) (ii) the anticipated price is considered fair and reasonable, based on comparison of the proposed price with prices found reasonable on previous Orlando VAMC purchases and VISN 19 BPA VA259-14-A-0176. In addition, the proposed prices are on average 30% lower than those paid under BPA VA259-14-A-0176, which was awarded on 10-01-2014.

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 advising industry of the pending acquisition and soliciting inquiries from interested parties. Through market research it was confirmed that at this time only Leica Biosystems and Government Scientific Sources can provide the reagents and consumables.
9. **Any Other Facts Supporting the Use of Other than Full and Open Competition:** None
10. **Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:** Leica Biosystems (manufacturer) and Government Scientific Sources a certified Service Disabled Veteran Owned Business (SDVOSB).
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 continuously evaluates market availability of comparable products and services, and will consider other sources if it appears the reagents and consumable become available, and can satisfy the minimum needs of the Government.
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.

03-23/2017

Laboratory Manager, OPC/CBOC

Date