

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

**Acquisition Plan Action ID:** VA257-18-AP-5687

**1. Agency:** Department of Veterans Affairs (VA)

**Contracting Activity:** Network Contracting Office 17 (NCO-17)  
7201 W. Interstate 40, Ste. 100  
Amarillo, TX 79106-2612

**2. Nature and/or Description of the Action Being Processed:**

NCO-17 intends to enter into an open market sole source contract with The Binding Site for the acquisition of a cost-per-test (CPT) program. The proposed action will be considered a standing order; where the requested supplies, will be ordered on an as-needed basis throughout the period of the contract. The proposed action will be awarded as a new firm-fixed-price contract. The contract will consist of a base period of performance. Base period of performance: 10/13/2018 through 10/12/2019.

**FAR13.5 Simplified Procedures for Certain Commercial Items:**

This procurement is for commercial off the shelf equipment and supplies, which will be acquired in accordance with FAR Subpart 13.5, Simplified Procedures for Certain Commercial Items. The contract value, to include the costs of all option periods, is estimated over the SAT.

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

The Central Texas Veterans Health Care System (CTVHCS), Pathology & Laboratory Medicine Service, requires an automated chemistry analyzer capable of providing freelite kappa and freelite lambda analysis, which is used for the diagnosis of abnormal protein of patient specimens. The CTVHCS CPT requirement also includes all of the reagents, controls, consumable supplies and equipment maintenance services necessary to perform protein analysis of veteran patients.

Vendor, The Binding Site, offers their FDA approved Optilite protein analyzer with computer (Item number: IE700) through a CPT program. In the CPT program, The Binding Site provides use of the Optilite analyzer with computer, an uninterruptable power supply (UPS, Item number: 520-000-30) and a printer (Item number: 11200) for the costs of the reagents and consumable supplies.

Estimated annual reagents, controls and consumable supplies consist of the following:

Product Code	Description	Est. Annual Quantity
LK016.OPT.A	Freelite Kappa	33
LK018.OPT.A	Freelite Lambda	33
LK043.OPT.A	Beta Microglobulin	10

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NK045.OPT.A	Ceruloplasmin	21
LK151.OPT.A	Rheumatoid Factor	18
IK709	Optilite Diluent 1	5
IK710	Optilite Diluent 2	2
989220	Sample Cups, 0.5 ml	1
989221	Sample Cups, 2 ml	1
IK702	Cuvettes, Tencell	2
IK703	Wash Solution, 20 ml	3
IK704	Wash Solution, 100 ml	4

The estimated value of the proposed action, to include all options, is \$REDACTED

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

41 USC §3304(a)(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;

**FAR13.5 Simplified Procedures for Certain Commercial Items:**

The value of the acquisition is estimated to exceed the SAT. The authority for applying simplified procedures for the acquisition of commercial items exceeding the SAT is 41 USC 1901, as implemented by 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 kappa and lambda protein analyzers offered by The Binding Site are currently the only know FDA approved platforms for freelite testing in the US. Market research performed for this acquisition did not find any other FDA approved testing analyzers.

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

A special notice, notice of intent to award a sole source procurement, was posted to the Federal Business Opportunities (FBO) website for this requirement under 36C25718Q9776 on 7/23/2018. The notice provided a description of the requirement and stated that all responsible sources may submit a capability statement, proposal or quotation, which shall be considered by the agency, to

determine if a comparable source is available and more advantageous to the government. The special notice archived in FBO on 8/8/2018 with no responses to the notice.

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

The Contracting Officer has determined that the anticipated proposal costs to be fair and reasonable. The Contracting Officer can compare the proposed prices with the prices paid on previous orders found to be fair and reasonable.

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

The requesting activity market research performed on the College of American Pathologists (CAP) website identified three (3) potential analyzers that perform kappa and lambda analysis; the Optilite offered by The Binding Site, and two (2) others. A review of the specifications of the other two lab instruments revealed that they are not FDA approved.

A search of the mandatory sources of procurement for supplies, UNICOR and Ability One, revealed that they do not offer the requested supplies and services.

A search of GSA Advantage did not identify a procurement source. The GSA search did not find a vendor that provides a kappa and lambda testing analyzer, or reagents and supplies for the request.

A search of the VA NAC MedSurg catalog with keyword "lambda" revealed 20 matches. A review of the matches revealed that the items are identification of testing parameters for reference laboratory testing services, not for the purchase of reagents.

An overview of the VA Medical-Surgical Prime Vendors (MSVP) noted that vendor The Binding Site is not one of the four (4) MSVPs.

A search of the VA Office of Small and Disadvantaged Business Utilization's (OSDBU) Vendor Information Pages (VIP) did not find a vendor that offers the requested supplies and services. A search of VIP with keyword "lambda" produced one (1) match. A review of the matching vendors capability narrative revealed that the vendor provides IT services. The search picked up on the vendor's keyword "Lambdas".

A search with the Small Business Administration's (SBA) Dynamic Small Business Search (DSBS) did not find another small business that can provide the requested supplies and services. A search of the DSBS with keyword "lambda" produced one (1) match. A look at the matching vendor's website indicated he was primarily a veterinary business and does not appear to offer the sale or rental of analyzers.

As described in item six (6) above, there were no responses to a special notice that was posted on FBO for the requirement.

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

N/A

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

None

**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 Binding Site is the only known firm capable of providing the requested supplies and services. Market research will be conducted prior to the exercise of options and for new requirements to determine if there have been any changes in the marketplace.

**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.

Signature:

//SIGNED// \_\_\_\_\_ 9/5/2018  
REDACTED Date:  
Chief Technologist, Pathology & Laboratory Medicine Service  
Central Texas Veterans Health Care System

**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.

//SIGNED// \_\_\_\_\_ 9/5/2018  
REDACTED Date:  
Contracting Officer

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- 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.

<u>//SIGNED//</u>	<u>9/14/2018</u>
REDACTED	Date:
Branch Chief, Services III	
Network Contracting Office 17	