

DEPARTMENT OF VETERANS AFFAIRS

Justification and Approval (J&A)

For

Other Than Full and Open Competition (>\$150K)

1. **Contracting Activity:** The Contracting Activity for this requirement is the Department of Veterans Affairs (VA), Veterans Health Administration, Network Contract Office (NCO) 2, VA Western New York Healthcare System (VAWNYHCS) – Batavia Site, 222 Richmond Avenue, Building 3 Room 103, Batavia, NY 14020. This purchase is for the Samuel S. Stratton VA Medical Center, 113 Holland Avenue, Albany, NY 12208-3410.
2. **Nature and/or Description of the Action Being Processed:** This procurement is for Free Kappa and Free Lambda Light Chain reagents as well as applicable ancillary consumable items for the SPA Plus analyzer from The Binding Site Inc. of San Diego, California. This will be a new, firm-fixed price indefinite delivery, indefinite quantity (IDIQ) contract with a base year and four (4) option years. All options will be priced at the time of award.

These items will be procured under FAR 13.5. This procurement is for reagents and consumables for the SPA Plus analyzer in accordance with FAR 13.5 Test Program for Certain Commercial Items. Under this authority (specifically FAR 13.501 Special Documentation Requirements), 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 items to be included in this contract are Free Kappa Light Chain and Free Lambda Light Chain reagent kits as well as all calibrators, quality controls, diluents, wash solutions, sample cups, cuvettes, and analyzer maintenance items for use in analysis of Free Kappa and Free Lambda Light Chains on the SPA Plus analyzer. This requirement will be procured with a base year and four (4) option years. The overall length of the contract inclusive of options will be no greater than five (5) years.

This contract will allow for delivery orders to be placed under the following periods of performance:

Base Year – October 1, 2015 – September 30, 2016
Option Year 1 – October 1, 2016 – September 30, 2017
Option Year 2 – October 1, 2017 – September 30, 2018
Option Year 3 – October 1, 2018 – September 30, 2019
Option Year 4 – October 1, 2019 – September 30, 2020

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;

This procurement will be completed under FAR 13.5 – Commercial Item Test Program. The authority for applying the FAR 13.5 Commercial Test Program is Section 4202 of the Clinger-Cohen Act of 1996.

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 Binding Site has the only FDA approved Free Kappa and Free Lambda Light Chain assays available. The reagents and consumables are proprietary and are not available from other vendors. These reagents and consumables are commercial items available in both the public and the private sectors. Ultimately, this procurement will be completed under FAR 13.5 – Commercial Item Test Program. The authority for applying the FAR 13.5 Commercial Test Program is Section 4202 of the Clinger-Cohen Act of 1996. It should be noted that FAR 13.501(a)(1) states that "acquisitions conducted under simplified acquisition procedures are exempt from the requirements in Part 6".

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:** A GSA Advantage search for Serum Protein Analyzer yielded results for the SPA Plus analyzer from The Binding Site, the BN Prospec and the BN II analyzers from Siemens. I contacted Peggy Gruner from Siemens and verified that neither the BN Prospec nor the BN II are capable of performing Free Kappa and Free Lambda Light Chain Assays. These tests are critical in the diagnosis of certain cancers. Therefore, the SPA Plus analyzer with these corresponding reagents/consumables is the only analyzer and reagent combination that will meet the minimum needs of the facility. The Binding Site is the sole distributor of the SPA Plus analyzer, reagents and consumables. The SPA Plus equipment is on Federal Supply Schedule (FSS) 66 and has been purchased from The Binding Site through contract GS-07F-0258W for the purpose of performing Free Kappa and Free Lambda Light Chain Testing under task order VA528-15-F-1244. This task order was awarded on May 28, 2015.

Further, The Binding Site has the only FDA approved Free Kappa and Free Lambda Light Chain assays available. The proprietary reagents and consumables required to operate the SPA Plus analyzer are not available on FSS contract. A search of GSA Advantage for Free Light Chain gave results for Quest Diagnostics for Laboratory Testing Services. However, Quest Diagnostics utilizes The Binding Site reagents and consumables to provide testing services. Quest Diagnostics does not provide reagents and consumables to third party buyers and is not an authorized distributor of the reagents and consumables. Further, these send out tests are more expensive than bringing the test in house and have a significant turnaround time, which delays diagnosis/treatment.

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

These are commercial items for which the Binding Site charges a standard catalog price. See "P02 - Market Research - Invoices from Vendor - VA Invoices 080415" for the full list. It should be noted that the Binding Site occasionally offers quantity discounts. The Contracting Officer will ask for these and any other discounts during the solicitation. Further, the Contracting Officer will request verification that the VA price is no greater than the private sector price.

Ultimately, the Contracting Officer will utilize the estimate pricing data above and the historically pricing data below to evaluate the pricing provided in response to the solicitation. If the price falls within a reasonable differential, the price will be deemed fair and reasonable and the Contracting Officer will award a contract to the vendor. The Contracting Officer has no reason to believe that the vendor's quote will contain pricing outside of these ranges. See Market Research Report and files for more information on pricing.

8. **Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:** The Binding Site is the only vendor with FDA approved reagents for Free Kappa and Free Lambda Light Chain testing. The Stratton VAMC recently purchased a SPA Plus Analyzer for completing Free Kappa and Free Lambda Light Chain testing. In order to utilize this analyzer, the laboratory requires reagents that are capable of providing results on it. These reagents and consumables are only available through the manufacturer of the SPA Plus analyzer, The Binding Site. These reagents and consumables are commercial items and are available for use by other medical laboratories and hospital facilities in both the private sector and the public sector.

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Searches on FPDS-NG revealed that federal agencies have purchased these reagents in the recent past. Specifically, several VA and Army facilities have made such purchases. I reached out to several of the Contracting Officers listed for these recent purchases and requested pricing information. As a result, the following pricing information was obtained:

VA Brockton, MA

Product	Est. Yearly Quantity	Price
LK016.S (Free Kappa for SPA Plus)		
LK018.S (Free Lambda for SPA Plus)		
SN080.S SPAPLUS Diluent (1200 tests)		
SP2209 Acid Wash Solution (500 ml)		
SP2208 Alkaline Wash Solution (500 ml)		
TBS043 SPAPLUS Hitachi Sample Cups (1000/box)		
23-07-0055 SPAPLUS Cuvettes (60/box)		
SP2057 SPA Plus Halogen Bulb		
IK050.S Weekly Wash Protocol & Bottles (empty)		

VA Tampa, FL

Product	Est. Yearly Quantity	Price
LK016.S (Free Kappa for SPA Plus)		
LK018.S (Free Lambda for SPA Plus)		

VA Temple, TX

Product	Order Quantity	Price
LK016.S (Free Kappa for SPA Plus)		
LK018.S (Free Lambda for SPA Plus)		
SN080.S SPAPLUS Diluent (1200 tests)		
SP2209 Acid Wash Solution (500 ml)		
SP2208 Alkaline Wash Solution (500 ml)		
TBS043 SPAPLUS Hitachi Sample Cups (1000/box)		
SP2057 SPA Plus Halogen Bulb		
IK050.S Weekly Wash Protocol & Bottles (empty)		

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VA Manhattan, NY

Product	Order Quantity	Price
LK016.S (Free Kappa for SPA Plus)		
LK018.S (Free Lambda for SPA Plus)		
SN080.S SPAPLUS Diluent (1200 tests)		
SP2209 Acid Wash Solution (500 ml)		
SP2208 Alkaline Wash Solution (500 ml)		
23-07-0055 SPAPLUS Cuvettes (60/box)		
IK050.S Weekly Wash Protocol & Bottles (empty)		

Ft Sam Houston, TX – Free Lambda and Kappa for SPA Plus
 VA San Francisco, CA – Free Lambda and Kappa for SPA Plus

Please see the Market Research Report and files for more details.

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:** The Binding Site is the only source that is capable of providing the reagents and consumables required. This company has expressed an interest in providing these items.
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:**
 Currently, The Binding Site is not interested in adding these reagents and consumables to their Federal Supply Schedule contract. Further, it does not appear that this company is interested in using small business distributors. The Contracting Officer will suggest the use of small business distributors in the future to the contract representative at The Binding Site. If The Binding Site decides to create this type of distributor agreement in the future, the VA will likely be able to procure these items competitively amongst the distributors. However, it currently appears that this company is not interested in pursuing such agreements. Further, it should be noted that future advances in this scientific field of laboratory testing might generate other methods of providing these test results. Should such a discovery occur, the VA may have the opportunity to procure these test items competitively. At this time, there are no known, pending FDA approvals for similar testing assays. Since these tests take years to develop and to garner FDA approval, the VA plans to procure these reagents and consumables under a base year plus four (4) option year IDIQ contract. The VA reserves the right to decide not to exercise any/all options. Should another test meeting the same standards become available during that time, the VA may decide not to exercise an option and instead compete this requirement.

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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.

_____ Date _____

Samuel S. Stratton VAMC, Albany, NY

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.

_____ Date _____

Contracting Officer, NCO 2

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

_____ Date _____

NCO 2 Division Chief, NCO 2