

2237 Transaction # 578-12-3-904-0035

LIMITED SOURCES JUSTIFICATION

ORDERS >\$3,000

FAR PART 8.405-6(g)

2237 Transaction # or Vista Equipment Transaction #: 578-12-3-904-0035

This acquisition is conducted under the authority of the Multiple Award Schedule Program. The material or service listed in part 3 below is sole source, therefore, consideration of the number of contractors required by FAR Subpart 8.4-Federal Supply Schedules, is precluded for the reasons indicated below.

Restricted to the following source:

Manufacturer/Contractor: Tokyo Boeki/The Binding Site Inc.

Manufacturer/Contractor POC & phone number: The Binding Site Inc./Doug Anderson (800)633-4484

Mfgr/Contractor Address: 5889 Oberlin Dr Ste 101, San Diego, CA 92121-3759

Dealer/Rep address/phone number: Jennifer Vanderkooi/(630)277-6918

☒ The requested material or service represents the minimum requirements of the Government.

(1) AGENCY AND CONTRACTING ACTIVITY:

Department of Veterans Affairs

VISN 12

VISN:

Great Lakes Acquisition Center

115 S. 84th St., Ste 100

Milwaukee WI, 53214-1476

(2) NATURE AND/OR DESCRIPTION OF ACTION BEING APPROVED:

Limited Source Justification to purchase Serum Protein analyzer System and associated Serum Free Light Chain Assay consumables. This procurement will proceed on a limited source basis with The Binding Site Inc. for a Base period and four option years.

(3) (a) A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:

The Hines VA Hospital, Hines IL has a need for a Serum Protein Analyzer and associated consumables. The equipment and testing methodology must perform various analytical tests including Serum Free Light Chain

Assays and meet the performance characteristics for accuracy and precision as defined by the 1988 Clinical Laboratory Improvement Act (CLIA) and the Clinical and Laboratory Standards Institute (CLSI).

(b) ESTIMATED DOLLAR VALUE: \$256,150.00

(c) REQUIRED DELIVERY DATE: October 1, 2012

(4) IDENTIFICATION OF THE JUSTIFICATION RATIONALE (SEE FAR 8.405-6), AND IF APPLICABLE, A DEMONSTRATION OF THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS TO PROVIDE THE REQUIRED SUPPLY OR SERVICE.

☒ Specific characteristics of the material or service that limit the availability to a sole source (unique feature, function of the item, etc.).

The Binding Site Inc. is the only vendor that offers a Serum Protein Analyzer system with FDA approved consumables for Serum Free Light Chain assays. The consumables are proprietary and are only compatible with equipment offered by The Binding Site Inc.

(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.404(d) TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION.

Previously, to meet the needs of the facility, all testing was sent to (Quest Diagnostics) a commercial reference laboratory for processing, at an approximate cost of \$86,500.00 annually. This procurement would result in an approximate costs savings of \$35,270.00 per year.

(6) DESCRIBE THE MARKET RESEARCH CONDUCTED AMONG SCHEDULE HOLDERS AND THE RESULTS OR A STATEMENT OF THE REASON MARKET RESEARCH WAS NOT INCLUDED:

The Contracting Officer conducted market research and documented the following:

Equipment: A GSA Advantage search utilizing the keywords "Serum Protein Analyzer" resulted in no matches. Using the keywords "Serum Protein Analyser" indicated one product (SPA Plus) that will meet the minimum needs of the facility. The SPA Plus is on FSS Schedule 66 and is offered by The Binding Site through contract GS-07F-0258. The Binding Site is the sole distributor of the SPA Plus.

Consumables: The proprietary consumables to operate the above equipment are not available on FSS contract. A Google search revealed The Binding Site is the only FDA approved Free Light Chain assay available.

The only Free Light Chain results located on GSA Advantage were of Quest Diagnostics under FSS Schedule 621 II Medical Laboratory Testing and Analysis Services. Additionally, the consumables utilized by Quest are from The Binding Site.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION: None

(8) A STATEMENT OF THE ACTIONS, IF ANY, THE AGENCY MAY TAKE TO REMOVE OR OVERCOME ANY BARRIERS THAT LED TO THE RESTRICTED CONSIDERATION BEFORE ANY SUBSEQUENT ACQUISITION FOR THE SUPPLIES OR SERVICES IS MADE: None, equipment and consumables are offered only by The Binding Site Inc.

(9) REQUIREMENTS CERTIFICATION:

by FAR Subpart 8.4. (This signature is the requestor's supervisor, fund control point official, chief of service or someone with responsibility and accountability.)

Karen Brown
SIGNATURE

August 28, 2012
DATE

Karen Brown
NAME

Business Manager, Pathology & Lab Medicine Service Line
TITLE SERVICE LINE/SECTION

Hines VA Hospital (578/113)
FACILITY

(10) APPROVALS IN ACCORDANCE WITH FAR 8.405-6(h):

a. CONTRACTING OFFICER'S CERTIFICATION (required): I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

[Signature]
CONTRACTING OFFICER'S SIGNATURE

8/28/2012
DATE

DARLY MAHAFFY Contracting Officer
NAME AND TITLE

GLAC NCO 12
FACILITY

c. NCM/or Designee : I certify the justification meets requirements for restricting consideration of Federal Supply Schedule contractors to fewer than the number of required by FAR Subpart 8.4.

Christina Hansen
NAME

8/28/2012
DATE

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VISN 12 NCM