

JUSTIFICATION
FOR OTHER THAN FULL AND OPEN COMPETITION

1. Contracting Activity: Department of Veterans Affairs
Office of Acquisition Operations
Strategic Acquisition Center
10300 Spotsylvania Avenue, Suite 400
Fredericksburg, VA 22408

2. Nature and/or Description of Action Being Processed: The proposed action is to award a single award indefinite-delivery, indefinite-quantity contract to the College of American Pathologists (CAP), 325 Waukegan Road, Northfield, IL, as the only responsible source for proficiency testing (PT) services for Veteran's Health Administration (VHA) Clinical Laboratories.

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

The Veterans Health Administration (VHA) requires the renewal of services to support laboratory accreditation requirements per Clinical Laboratory Improvement Amendments of 1988 (CLIA) and VHA Handbook 1106.01. According to accreditation standards, any Department of Veterans Affairs (VA) laboratory that performs patient testing must perform PT on all regulated analytes and any unregulated analytes when PT material is available.

The VA Pathology and Laboratory Medicine Service (P&LMS) requires a contractor that is a CLIA certified provider, as attested by Centers for Medicaid and Medicare Service (CMS), to provide PT material and performance evaluation services for approximately 980 clinical laboratory testing sites. This includes patient testing in the following specialties/subspecialties:

- Specialties – Chemistry, Diagnostic Immunology, Hematology, Immunohematology, Microbiology, and Cytology
- Subspecialties - Bacteriology, Blood Gas, Endocrinology, General Immunology, Immunoglobulins, Mycobacteriology, Mycology, Parasitology, Routine (Chemistry), Syphilis Serology, Toxicology, and Virology

This proposed action will allow each VHA clinical laboratory to continue to operate in a CLIA approved PT program. If PT services are interrupted, both the laboratory and the medical center's accreditation status is jeopardized.

The laboratory must perform PT on every instrument that is utilized for patient testing. The PT process is a complex process of related and interdependent testing activities. It includes pre-survey activities (e.g., application), testing the specimens and submitting results, and post survey activities (e.g., review and investigate performance findings). It

involves two – five challenges for each analyte strategically spread over a one-year period.

The period of performance will be for a base period of nine months and four one-year options. The total estimated value of the proposed action is \$

4. Statutory Authority:

The statutory authority permitting other than full and open competition is 41 U.S.C. 3304(a)(1) as implemented by the Federal Acquisition Regulation (FAR) 6.302-1 entitled, "Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements."

5. Rationale for Authority:

VA hospital accreditation (VHA Handbook 1100.16) requires the servicing laboratory to be accredited. The laboratory accreditation process requires continuous participation in a PT program. If PT services are interrupted, both the laboratory and the medical center's accreditation status are jeopardized. This is a sole source justification; no other service providers were able to provide PT program services for VHA laboratory testing sites (servicing laboratories). CAP is currently the only contractor on CMS's list of approved PT providers that provides PT material for all CLIA specialties/subspecialties required by VHA. This services provider is the only one capable of providing all of these specialties/subspecialties that include: Microbiology, Bacteriology, Mycobacteria, Mycology, Parasitology, Virology, Diagnostic Immunology, Syphilis, General Immunology, Immunoglobulins, Chemistry (routine), Blood Gases, Endocrinology, Toxicology, Hematology, Immunohematology, Histocompatibility and Cytology.

6. Description of Efforts Made to Ensure that Offers are Solicited from as Many Potential Sources as is Practicable:

Market research was conducted, details of which are in section 8 of this document. This effort did not yield any additional sources that can meet the Government's requirements. There is no competition anticipated for this acquisition. Additionally, the proposed action will be synopsisized on the Federal Business Opportunities in accordance with FAR 5.201 and 6.302-1(d)(2) and the justification will be made publically available. Any proposals that are received shall be considered.

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

The contracting officer hereby determines that the anticipated price to the Government for this contract action will be fair and reasonable in accordance with FAR 15.404-1. Proposal analysis techniques more specifically based on comparison with published price list and comparison with independent government estimate.

8. Market Research:

Market research was conducted by the VA's technical experts from Acquisition Rapid Response Service and the Contracting Officer's Representative from August thru December of 2014. Based on the information provided, the Market Research Team determined that only the CAP can perform the services for this action as they are currently the only CMS approved PT service provider that provides samples and services for all aforementioned specialties/subspecialties required by VHA under this requirement.

The following actions were used to conduct market research:

- Obtained CMS list of approved PT providers from CMS website:
<http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/downloads/ptlist.pdf>
- Charted CLIA approved PT providers against the specialty/subspecialties for which they are CLIA approved to perform

Specialty/Subspecialty	Accutest	AAFP-PT	AAB	API	CTS	CAP	ExCEL	MLE	COM of PA	PR-PTS	WSIH	MD	ASCP	NY
Microbiology														+
Bacteriology	+	+	+	+	0	+	+	+	0	+	+	0	0	+
Mycobacteria	+	+	+	+	0	+	0	0	0	0	+	0	0	+
Mycology	+	+	0	+	0	+	0	0	0	0	+	0	0	+
Parasitology	+	+	+	+	0	+	0	0	0	+	+	0	0	+
Virology	+	+	+	+	0	+	+	+	0	0	+	0	0	+
Diagnostic Immunology														+
Syphilis	+	+	+	+	0	+	+	+	0	+	+	0	0	+
General Immuno	+	+	+	+	0	+	+	+	0	+	+	0	0	+
Immunoglobulins	+	+	+	+	0	+	+	+	0	+	+	0	0	+
Chemistry														+
Routine	+	+	+	+	+	+	+	+	0	+	+	0	0	+
Blood Gases	+	+	+	+	+	+	+	+	0	+	+	0	0	+
Endocrinology	+	+	+	+	0	+	+	+	0	+	+	0	0	+
Toxicology	+	+	+	+	0	+	+	+	+	+	+	0	0	+
Hematology	+	+	+	+	+	+	+	+	0	+	+	0	0	+
Immunohematology	+	+	+	+	0	+	+	+	0	+	+	0	0	+
Cytology	0	0	0	0	0	+	0	0	0	0	0	+	+	0

There are 14 CMS approved PT providers:

- Accutest,
- American Academy of Family Physicians – Proficiency Testing (AAFP-PT),
- American Association of Bioanalysts (AAB),
- American Proficiency Institute (API),
- California Thoracic Society (CTS),

- External Comparative Evaluation for Laboratories (EXCEL),
- Medical Laboratory Evaluation (MLE),
- Commonwealth of Pennsylvania (COM of PA),
- Puerto Rico Proficiency Testing Service (PR-PTS),
- Wisconsin State Laboratory of Hygiene (WSLH),
- Maryland Department of Health and Mental Hygiene (MD)
- New York State Department of Health (NY),
- American Society for Clinical Pathology (ASCP),
- College of American Pathologists (CAP).

Puerto Rico Proficiency Testing Service and Wisconsin State Laboratory of Hygiene were not viable sources as they do not provide PT for Cytology.

Maryland Department of Health and Mental Hygiene is not a viable source, because it does not provide PT for any other specialty/subspecialty except Cytology.

New York State Department of Health is not a viable source, because it does not provide PT for cytology.

American Society for Clinical Pathology is not a viable source, because it is only approved to provide PT for cytology; it does not provide PT for any other specialty/subspecialties.

CMS was contacted to see if ASCP or any other CMS approved PT provider was approved to subcontract for cytology PT. CMS stated not at this time. Further, CMS stated that no approved and documented CMS PT providers intend to establish subcontracting relationships for PT services on their annual PT re-approval request.

- Sources Sought Notice was published on FedBizOpps on December 18, 2014 with responses due on December 26, 2014. One vendor responded, American Proficiency Institute (API). API was not considered viable because they were not able to provide cytology.

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:

A Sources Sought Notice was published on FedBizOpps on December 18, 2014, with responses due on December 26, 2014. One firm responded, API. Based on API's response, it was determined that they were able to provide all specialties with the

exception of Cytology. Therefore, it was determined that there was only one responsible source since all specialties are required to fulfill the requirement.

11. Actions Taken to Remove or Overcome Barriers to Competition Before any Subsequent Acquisitions for Services:

The Government will continue to conduct market research to ascertain if there are changes in the market place that would enable future actions to be competed.

12. Technical and Requirements Certification:

I certify that the supporting data under my cognizance, which are included in this justification, are accurate and complete to the best of my knowledge and belief.

Signature _____

Date _____

Office of Pathology and Laboratory Services

13. Contracting Officer Certification: I certify that this justification is accurate and complete to the best of my knowledge and belief.

Signature _____

Date 25 February 2015

Contracting Officer

14. Legal Sufficiency Certification: I have reviewed this justification and find it legally sufficient as to formalities and compliance with requirements set forth in FAR 6.303-2.


Name _____ Date: _____

Legal Counsel Signature: _____

In my role as Contracting Activity Competition Advocate, based on the foregoing justification, I hereby approve the acquisition of proficiency testing services in the amount of \$ _____ on an other than full and open competition basis pursuant to the statutory authority cited in 41 U.S.C. 3304(a)(1) as implemented by the Federal Acquisition Regulation (FAR) 6.302-1, "Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements", subject to availability of funds and provided that the property and services herein described have otherwise been authorized for acquisition.

Date: 3/9/15

Signature: _____


Phyllis Bower
Head of the Contracting Activity
Office of Acquisition Operations