

Statement of Work
For
Pathology and Laboratory Medicine Service Proficiency Testing (PT) Program

A. Background

As required by VHA Handbook 1106.01,

1. All Department of Veterans Affairs (VA)'s Pathology and Laboratory Medicine Service laboratories and all Ancillary Testing Sites that perform testing on patients must subscribe to an external proficiency testing program that meets Clinical Laboratory Improvement Act 1988 and amendments (CLIA) 1988 requirements to:
 - a) ensure reliability of patient testing in the laboratory, and
 - b) meet accreditation requirements
2. All laboratories must successfully participate in a Centers for Medicare and Medicaid Services (CMS)- Clinical Laboratory Improvement Amendments (CLIA) approved PT program.
3. External Proficiency Testing (PT) Program: As an enhancement to the internal Quality Control Program, to ensure reliability of patient testing in the laboratory, and to maintain accreditation requirements, each Pathology and Laboratory Medicine Service and all Ancillary Testing Sites must subscribe to external PT programs that meet CLIA'88 requirements for all analytes for which PT is available, including waived testing, Provider Performed Microscopy (PPM), and unregulated analytes.
4. Laboratories that perform clinical diagnostic tests on human specimens and fail to meet the PT requirements as described in 42 CFR 493, Subpart H, or who have demonstrated deficiencies which pose a direct threat to patients may be instructed to terminate those processes.

CMS has determined the analyte-specific evaluation criteria and target values used to grade proficiency testing results for regulated analyte. CLIA approved proficiency testing providers may specify grading criteria for other-than-regulated analytes.

CLIA categorization is determined after the FDA has cleared or approved a marketing submission. The FDA determines the test's complexity by reviewing the package insert test instructions, and using a criteria "[scorecard](#)" to categorize a test as moderate or high complexity.

B. Scope

The overall purpose of this requirement is to obtain a contractor to provide a CLIA '88 approved proficiency testing program so that all VHA medical laboratories and ancillary testing sites that perform patient testing are in compliance with VHA Handbook 1106.01 proficiency testing requirements.

Currently there are approximately 1061 VHA patient testing sites. A current listing of VA facilities can be found on Attachment 1 to the solicitation. The sites are located in the contiguous 48 states as well as Alaska, Hawaii, Philippines, American Samoa, Guam and Puerto Rico.

VHA medical laboratories and ancillary testing sites perform patient testing in the following CLIA 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

Proficiency testing shall be performed at each medical laboratory or ancillary testing site that performs patient testing in accordance with calendar of events or shipping table provided by the contractor. Each site must perform proficiency testing on every instrument (including backups) for the primary test method, for each test (assay) performed on-site.

The proficiency testing program must be CLIA approved for all aforementioned CLIA specialties/subspecialties. The proficiency testing program must offer PT for all Non-Waived testing for which PT is required.

Pertinent proficiency testing information will be internally managed VA National Enforcement Office database.

C. Period of Performance

The contract period of performance shall be January 1st, 2020 – January 02, 2024 which includes a 1year base and 4 option years that may be unilaterally exercised at the Government's discretion. Place of performance is each VHA medical laboratory.

D. Type of Contract

The Government intends to award a Firm Fixed Price, Requirement contract as a result of this solicitation.

E. Tasks

Task 1: Implement a Proficiency Testing program

1. The contractor's program must be a CLIA approved proficiency testing program. The proficiency testing program must:
2. Be administered as specified in package submitted for CLIA proficiency testing program approval.
3. Provide, at minimum, PT specimens for all CLIA specialties/subspecialties for which patient testing is performed in VHA clinical laboratories which include: Microbiology, Bacteriology, Mycobacteria, Mycology, Parasitology, Virology, Diagnostic Immunology, Syphilis, General Immunology, Immunoglobulins, Chemistry (routine), Blood Gases, Endocrinology, Toxicology, Hematology, Immunohematology, Histocompatibility, and Cytology. Furthermore, offer PT specimens for all Non-Waived testing for which PT is required by CMS.
4. Include a mechanism for the contractor to notify the government if proficiency testing updates become available and promptly notify each proficiency testing laboratory and COR, in writing (mailed or electronic), of such updates.
5. Include a contractor established event calendar and/or shipping table that identifies the date each proficiency testing deliverable is scheduled to be shipped to the testing laboratory
6. Have a method that allows each individual laboratory to transmit proficiency testing results electronically (i.e., secured website, secure direct interface capability, facsimile, etc.).
7. Meet, or be more restrictive than, evaluation criteria (allowable limits and target values) determined by CMS for each regulated analyte. For other-than-regulated analytes, the grading criteria may be determined by the contractor.
8. Include formal evaluation of results for each test. Formal evaluations reports must include:
 - a) A mechanism for each laboratory to compare its proficiency testing performance and/or results against peer laboratories using the same instrument/reagent system (when available)
 - b) A summary of the individual laboratory's historic performance over the past three proficiency testing events for each regulated analytes
 - c) Overall performance summary report for each regulated analyte that indicates whether current performance is satisfactory, at risk pending future performance, or unsatisfactory.
 - d) A summary of peer participant results
 - e) As applicable for each analyte: analyte tested, test methodology, reported results, graded score, peer statistics (such as mean standard deviation) and contractor determined intended result
 - f) The reason any proficiency testing result was not scored/graded
9. The contractor must provide the proficiency testing laboratory's POC, the respective Regional Medical Technologist, and the laboratory's accrediting organization:
 - a) Documentation of proficiency testing formal evaluations

- b) Written notification when proficiency testing results are not received by contractor
 - c) Written notification when analyte performance is scored as unacceptable
 - d) Written notification when analyte overall performance is assessed as unsatisfactory
10. Provide a plan for replacement of defective or damaged deliverable (proficiency testing material/supplies)
 11. Provide a glossary of terms if technical terminology is used. Otherwise, information must be phrased in audience appropriate language
 12. Have an electronic method (i.e., website, fax, email) for receipt of VA furnished correspondence (i.e., proficiency testing results, VA facility demographics) that is required for the proficiency testing program. Contract prices should include any costs associated with electronic data transmission.

Task 2: Deliverables: Mailed, Written Correspondence, Microsoft Access based files

1. All Mailed deliverables, which includes proficiency testing material/supplies shall be shipped Freight on Board (FOB) Destination (paid by contractor).
 - a) Proficiency Testing specimens/materials shall be delivered to the individual VHA laboratory determined by patient testing performed at each individual laboratory. The package should be shipped according to shipping table provided by contractor.
2. Written correspondence may be shipped FOB Destination (paid by contractor) or delivered electronically (PDF, Word, Excel, or other mutual agreement between COR and Contractor) to respective VHA clinical laboratory POC and/or VA Regional Technologist (as provided by individual laboratories post award). Electronic format must mirror contents of paper format.
 - a) Proficiency Testing updates shall be provided to all VHA clinical laboratory POCs, VA Regional Technologists, and the COR within 10 working days of change.
 - b) Proficiency Testing Manuals, Proficiency Testing Catalogs, and Proficiency Testing event calendars and/or shipping tables shall be made available to all VHA clinical laboratory POCs, VA Regional Technologists and the COR within 10 working days of award for base and each option year
 - c) Formal evaluation reports and other proficiency testing notifications shall be made available to the respective VHA clinical laboratory POC, the respective VA Regional Technologist, and the laboratory's accrediting organization within 30 calendar days of evaluation.
3. Database compatible format files (i.e., XML, Excel, HTML) shall be submitted to the COR electronically.
 - a) Proficiency testing ordering, shipping, pricing information (to include updates/changes), and cut-off dates shall be provided to COR or NEO Liaison within 10 working days of availability

- b) Summary/Confirmation of all order changes and a running balance report shall be provided weekly, in weekly increments (or 30 calendar days for initial annual order).
- c) Consolidated or summarized data report for overall proficiency testing performance shall be provided weekly, in weekly increments
 - i) The contractor shall provide PT survey performance data in both a paper report format as well as Extensible Mark-up Language (XML) format available through a secured FTP server connection for import into the National Enforcement Office Database.
 - ii) The contractor must notify the COR or PLMS central office Liaison of any changes to analyte test name or test code within 10 days.
 - iii) If a change is made to the analyte test name or code an electronic spreadsheet must be provided to include the data elements such as fulfillment group, product test code, analyte name to PLMS central office within 10 working days.
 - iv) All non-regulated analytes including educational challenges must have statistical data supplied directly on the PT evaluation summary must be included in database compatible format files as outlined in a) above.
- 4. The contractor shall submit documentation (formal evaluations and other proficiency testing notifications) to the laboratory's accrediting organization using any compatible format/method routinely accepted by the accrediting organization.
- 5. The contractor shall submit documentation to CMS for all regulated analytes (formal evaluations and other proficiency testing notifications).

F. Authorized Office

Delivery Order will be awarded by the Contracting Officer and managed by the designated appointment Contracting Officer's Representative (COR) from The National Enforcement Office for each facility. The COR and Contractor will be reconciling an actual (running) balance weekly of each facility's internal orders.

G. Government Furnished Items

Contract prices should include any costs associated with electronic data transmission.

- 1. Each VHA clinical laboratory will provide proficiency testing results to the contractor via electronic method(s) determined by contractor
- 2. Each VHA clinical laboratory will provide its respective POC and other demographics using forms provided by contractor
- 3. National Enforcement Office or COR will provide regional Medical Technologist information to contractor post award.
- 4. National Enforcement Office or COR will provide initial (annual) proficiency testing order (manually and/or electronically), by due date determined by contractor, using forms provided by contractor.
- 5. National Enforcement Office or COR will provide all order changes to contractor on a weekly basis, electronically.

H. Changes to the Statement of Work:

Any changes to this SOW shall be authorized and approved only through written correspondence from the Contracting Officer.

I. Travel

Travel is not anticipated for this effort.

J. Contractor Experience Requirements

The contractor must be on CMS list of CLIA-approved proficiency testing providers for the following specialty/subspecialties: Microbiology, Bacteriology, Mycobacteriology, Mycology, Parasitology, Virology, Diagnostic Immunology, Syphilis, General Immunology, Immunoglobulins, Chemistry (routine), Blood Gases, Endocrinology, Toxicology, Hematology, Immunohematology, Histocompatibility, and Cytology. The contractor must have offerings for all non-waived testing for which PT is required.

K. VA INFORMATION AND INFORMATION SYSTEM SECURITY/PRIVACY LANGUAGE FOR INCLUSION INTO CONTRACTS, AS APPROPRIATE

1. GENERAL

Contractors, contractor personnel, subcontractors, and subcontractor personnel shall be subject to the same Federal laws, regulations, standards, and VA Directives and Handbooks as VA and VA personnel regarding information and information system security.

2. ACCESS TO VA INFORMATION AND VA INFORMATION SYSTEMS

a. A contractor/subcontractor shall request logical (technical) or physical access to VA information and VA information systems for their employees, subcontractors, and affiliates only to the extent necessary to perform the services specified in the contract, agreement, or task order.

b. All contractors, subcontractors, and third-party servicers and associates working with VA information are subject to the same investigative requirements as those of VA appointees or employees who have access to the same types of information. The level and process of background security investigations for contractors must be in accordance with VA Directive and Handbook 0710, *Personnel Suitability and Security Program*. The Office for Operations, Security, and Preparedness is responsible for these policies and procedures.

c. Contract personnel who require access to national security programs must have a valid security clearance. National Industrial Security Program (NISP) was established by Executive Order 12829 to ensure that cleared U.S. defense industry contract personnel safeguard the classified information in their possession while performing work on contracts, programs, bids, or research and development efforts. The Department of Veterans Affairs does not have a Memorandum of Agreement with Defense Security Service (DSS). Verification of a Security Clearance must be processed through the Special Security Officer located in the Planning and National Security Service within the Office of Operations, Security, and Preparedness.

d. Custom software development and outsourced operations must be located in the U.S. to the maximum extent practical. If such services are proposed to be performed abroad and are not disallowed by other VA policy or mandates, the contractor/subcontractor must

state where all non-U.S. services are provided and detail a security plan, deemed to be acceptable by VA, specifically to address mitigation of the resulting problems of communication, control, data protection, and so forth. Location within the U.S. may be an evaluation factor.

e. The contractor or subcontractor must notify the Contracting Officer immediately when an employee working on a VA system or with access to VA information is reassigned or leaves the contractor or subcontractor's employ. The Contracting Officer must also be notified immediately by the contractor or subcontractor prior to an unfriendly termination.

3. VA INFORMATION CUSTODIAL LANGUAGE

a. Information made available to the contractor or subcontractor by VA for the performance or administration of this contract or information developed by the contractor/subcontractor in performance or administration of the contract shall be used only for those purposes and shall not be used in any other way without the prior written agreement of the VA. This clause expressly limits the contractor/subcontractor's rights to use data as described in Rights in Data

- General, FAR 52.227-14(d) (1).

b. VA information should not be co-mingled, if possible, with any other data on the contractors/subcontractor's information systems or media storage systems in order to ensure VA requirements related to data protection and media sanitization can be met. If co-mingling must be allowed to meet the requirements of the business need, the contractor must ensure that VA's information is returned to the VA or destroyed in accordance with VA's sanitization requirements. VA reserves the right to conduct on site inspections of contractor and subcontractor IT resources to ensure data security controls, separation of data and job duties, and destruction/media sanitization procedures are in compliance with VA directive requirements.

c. Prior to termination or completion of this contract, contractor/subcontractor must not destroy information received from VA, or gathered/created by the contractor in the course of performing this contract without prior written approval by the VA. Any data destruction done on behalf of VA by a contractor/subcontractor must be done in accordance with National Archives and Records Administration (NARA) requirements as outlined in VA Directive 6300, *Records and Information Management* and its Handbook 6300.1 *Records Management Procedures*, applicable VA Records Control Schedules, and VA Handbook 6500.1, *Electronic Media Sanitization*. Self-certification by the contractor that the data destruction requirements above have been met must be sent to the VA Contracting Officer within 30 days of termination of the contract.

d. The contractor/subcontractor must receive, gather, store, back up, maintain, use, disclose and dispose of VA information only in compliance with the terms of the contract and applicable Federal and VA information confidentiality and security laws, regulations and policies. If Federal or VA information confidentiality and security laws, regulations and policies become applicable to the VA information or information systems after execution of the contract, or if NIST issues or updates applicable FIPS or Special Publications (SP) after execution of this contract, the parties agree to negotiate in good faith to implement the information confidentiality and security laws, regulations and policies in this contract.

e. The contractor/subcontractor shall not make copies of VA information except as

authorized and necessary to perform the terms of the agreement or to preserve electronic information stored on contractor/subcontractor electronic storage media for restoration in case any electronic equipment or data used by the contractor/subcontractor needs to be restored to an operating state. If copies are made for restoration purposes, after the restoration is complete, the copies must be appropriately destroyed.