Attachment 3
RFQ #VA101-12-Q-0058
Performance Work Statement

A. GENERAL INFORMATION

1. **Title of Project:** Blind Performance Test Program for VA Drug-Free Workplace Program

2. **Scope of Work:** The Department of Veterans Affairs (VA) requires a contract to furnish a quality control program in the VA Drug-Free Workplace Program as stated in VA Handbook 5383, Part II – Urine Drug Testing: Collection and Transportation of Urine Specimens, Appendix F – VA Blind Performance Test Procedures.

The submission of blind performance test samples is an important element in ensuring the reliability and accuracy of drug testing results. This requirement is in accordance with Mandatory Guidelines for Federal Workplace Drug Testing Programs published by the US Department of Health and Human Services (DHHS).

VA will test for marijuana, cocaine, opiates, amphetamines, and phencyclidine (PCP) as part of the Department's pre-employment and random drug testing program. When conducting reasonable suspicion, injury, illness, unsafe, or unhealthful practice testing, VA may test for any drug identified in Schedule I or II of the Controlled Substances Act (21 USC 812).

3. **Background:** A program designed to implement Executive Order 12564; Drug-Free Federal Workplace has been established in the Department of Veterans Affairs (VA). Testing for illegal drugs for applicants and employees is part of VA's comprehensive drug prevention program to achieve the goal of a drug-free workplace with due consideration for the rights of the employee and the government. VA Directive 5383 and VA Handbook 5383 provides departmental policy for the program, certified by the Department of Health and Human Services (DHHS) on April 27, 1988 in accordance with Public Law 100-71, and provide instructions for implementing those provisions relating to the drug testing of employees and applicants for VA employment. The VA Plan includes the following types of drug testing: (a) applicant testing; (b) monthly random testing of sensitive employees in testing designated positions; (c) reasonable suspicion testing; (d) injury, illness, unsafe, or unhealthful practice testing and (e) voluntary testing; (f) testing as part of or as a follow-up to counseling or rehabilitation.

4. **Performance Period:** The period of performance is for a base year from date of award, with 4 option years. Any work at a government site shall not take place on Federal holidays or weekends unless directed by the Contracting Officer (CO).

5. **Type of Contract:** Firm-Fixed-Price (FFP) contract.

6. **Place of Performance:** The work shall be performed at selected VA facilities participating in the VA Drug-Free Workplace Program.

B. KICK-OFF MEETING

The contractor shall not commence performance on the tasks in this Performance Work Statement (PWS) until the CO has conducted a kick off meeting or has advised the contractor that a kick off meeting is waived.

C. GENERAL REQUIREMENTS

1. For every task, the contractor shall identify in writing all necessary subtasks (if any), associated costs by task, together with associated submilestone dates. The contractor's subtask structure shall be reflected in the technical proposal or detailed project management plan (PMP).

2. All written deliverables will be phrased in layperson language. Statistical and other technical terminology will not be used without providing a glossary of terms.

D. SPECIFIC REQUIREMENTS AND TASKS

Description of Tasks and Associated Deliverables: The contractor shall provide the specific deliverables described below within the performance period stated in Section A.4 of this PWS.

1. Prepare blind quality control materials to include negatives and positives selected from the drugs marijuana, cocaine, opiates, amphetamines phencyclidine, and adulterated and substituted samples as required in DHHS, Substance Abuse and Mental Health Services Administration, Mandatory Guidelines for Federal Workplace Drug Testing Programs; Notices (Federal Register, Vol. 73, No. 228/Tuesday, November 25, 2008). Other tests required in for the blind quality control sample include: creatinine, specific gravity, and pH test.

2. At least 60-70 mL of blind sample material will be provided to the designated VA laboratory collector.

3. The composition and drug concentration of the positive samples should be in compliance with the general guidelines for blind QC samples in the DHHS, Substance Abuse and Mental Health Services Administration, Mandatory Guidelines for Federal Workplace Drug Testing Programs; Notice. The samples should be certified for content by immunoassays and gas chromatography/mass spectrometry (GC/MS) by at least two DHHS certified laboratories.

Cutoff Concentrations for Drug Tests

Initial Test Analyte	Initial test cutoff concentration

Marijuana metabolites	50 ng/mL
Cocaine metabolites	150 ng/mL
Opiate metabolites – Codeine/Morphine	2000 ng/mL
6-Acetylmorphine	10 ng/mL
Phencyclidine	25 ng/mL
Amphetamines/methamphetamine	500 ng/mL
Methylenedioxymethamphetamine	500 ng/mL
Confirmatory test analyte	**Confirmatory test cutoff concentration**
Delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA)	15 ng/mL
Benzoylecgonine	100 ng/mL
Codeine	2000 ng/mL
Morphine	2000 ng/mL
6-Acetylmorphine	10 ng/mL
Phencyclidine	25 ng/mL
Amphetamine	250 ng/mL
Methamphetamine	250 ng/mL
Methylenedioxymethamphetamine (MDMA)	250 ng/mL
Methylenedioxyamphetamine (MDA)	250 ng/mL
Methylenedioxyethylamphetamine (MDEA)	250 ng/mL

4. Ship 9-10 samples (7 negatives; 1-2 positives, and 1 adulterated or substituted sample) to each of four VA collection sites per month, for a total of 38 samples monthly in the following numbers:

Site #1: 7 negatives
1 positive
1 adulterated or substituted

Site #2: 7 negatives
1 positive
1 adulterated or substituted

Site #3: 7 negatives
2 positives
1 adulterated or substituted

Site #4: 7 negatives
2 positives
1 adulterated or substituted

Of the blind samples tested, 75 percent must be negative, 15 percent must be positive for one or more drugs, and 10 percent must be either adulterated or substituted The blind sample that is positive must be validated by the supplier as to its content using appropriate initial and confirmatory tests. For a blind sample that is drug positive, the concentration of the drug it

contains should be between 1.5 and 2.0 times the initial drug test cutoff concentration and must be spiked or contain one or more of the drugs or metabolites listed in the above Cutoff Concentrations for Drug Tests table. A blind that is negative (certified to contain no drug) must be negative using appropriate initial and confirmatory tests. A blind sample that is adulterated must have the characteristics to clearly show that an adulterated sample at the time it is validated by the contractor using tests such as pH, specific gravity, and creatinine. A blind sample that is substituted must have the characteristics to clearly show that it is a substituted sample at the time it is validated by the contractor.

5. A control document will be prepared for each set of samples sent. A separate control document will be enclosed for positive, negative, and adulterated or substituted samples. Fictitious names and Social Security numbers are to be provided and will appear on the control document. The control form will allow the sample batch number, fictitious name and social security number, drug concentration, collection site access number, and lab results to be recorded. The control form should record the blind sample providers name, mailing address, responsible person, blind sample expiration date, and person preparing the sample.

6. Select four sites every month on a random basis from a list of sites to be provided by VA Central Office, Pathology & Laboratory Medicine Services (P&LMS). The contractor must code each site with a five-character code specific to the site's location to be used for reporting results.

7. Provide detailed instructions with the samples to each site on handling, repackaging, and shipping to the VA primary testing laboratory in Minneapolis, Minnesota taking every precaution to prevent the Minneapolis laboratory from knowing the specimens are blind quality control specimens. Sample must be submitted by the collector using the same Federal Custody and Control Form (CCF) as is used for donor samples. The contractor provides the required information to ensure that the Federal CCF can be properly completed as well as providing fictitious initials on the specimen label/seal. The collector must indicate that the specimen is a blind sample on the Medical Review Officer (MRO) copy where a donor would normally provide a signature.

8. Provide a fictitious unique donor name and social security number for each specimen, which are to be used by the VA Medical Centers to fill out the chain of custody and control form before submitting to the VA testing laboratory in Minneapolis.

9. The contractor will be responsible for monitoring the results of the laboratory testing of the blind QC samples.

10. Provide instructions for the VA Medical Review Officer (MRO) to forward the contractor the laboratory results on the blind QC specimens. The contractor will evaluate and forward a monthly composite report to the VA Central Office, P&LMS and Director, VA Comprehensive Drug Free Work Place Program. If the VA testing laboratory reports a result for a blind sample that is inconsistent with the expected result, the MRO must contact the contractor supplying the blind sample and attempt to determine if there was a mistake made when preparing the blind sample. The MRO must contact the collector and determine if the collector made an

error when preparing the blind sample for transfer to the laboratory. If there is no obvious reason for the inconsistent result, the MRO must notify the Director, VA Comprehensive Drug Free Work Place Program. On behalf of the Secretary of Veterans Affairs, the Director, VA Comprehensive Drug Free Work Place Program shall investigate the blind sample findings and the contractor will cooperate in the investigation.

11. Provide a protocol for receiving, evaluating and reporting the test results to VA Central Office, P&LMS at Department of Veterans Affairs, Patient Care Services, National Enforcement Office, 1722 Eye Street, NW GL-7, Washington, DC, 20420 and the Director, VA Comprehensive Drug Free Work Place Program, One Veterans Drive (V68), Minneapolis, MN 55417.

12. Submit a report to VA Central Office, P&LMS, Patient Care Services, National Enforcement Office and Director, VA Comprehensive Drug Free Work Place Program on a quarterly basis outlining which sites received specimens and whether or not reports have been received.

13. Provide complete security for VA information, reports and specimens in a manner consistent with DHHS, Substance Abuse and Mental Health Services Administration, Mandatory Guidelines for Federal Workplace Drug Testing Programs; Notices.

14. Invoice the VA Financial Services Center (FSC) in Austin, Texas on a monthly basis (for 38 specimens) when specimens are shipped. This includes cost of specimens and cost of shipping. In addition to submitting the invoice to FSC as directed, provide a copy of the invoice to VA Central Office, P&LMS.

E. SCHEDULE FOR DELIVERABLES

The contractor shall provide the specific requirements and tasks described above.

F. CHANGES TO PERFORMANCE WORK STATEMENT

Any changes to this PWS shall be authorized and approved only through written correspondence from the CO. A copy of each change will be kept in a project folder along with all other products of the project. Costs incurred by the contractor through the actions of parties other than the CO shall be borne by the contractor.

G. REPORTING REQUIREMENTS

1. Based on the laboratory results from the blind QC samples submitted by the VA Medical Review Officer (MRO), the Contractor shall submit a report to VA Central Office, P&LMS and Director, VHA Comprehensive Drug Free Work Place Program on a monthly basis

that includes the Blind QC Specimen Order Log and the Certificates of Analysis for each blind specimen submitted.

2. The Contractor shall submit a Composite Report to VA Central Office, P&LMS and Director, VHA Comprehensive Drug Free Work Place Program on a quarterly basis outlining which sites received specimens and which sites reported results.

H. GOVERNMENT RESPONSIBILITIES

VA Central Office, P&LMS, will provide the Contractor with a list of all participating VA Medical Centers in the Drug-Free Workplace Program.

I. CONTRACTOR QUALIFICATION REQUIREMENTS

Qualified contractors must be registered with the Food and Drug Administration and should be certified by DHHS for performing workplace drug testing. The contractor should be registered by the Drug Enforcement Agency as a manufacturer and analytical laboratory. The contractor should be certified by the College of American Pathologists.

J. CONFIDENTIALITY AND NONDISCLOSURE

It is agreed that:

1. Press releases, marketing material or any other printed or electronic documentation related to this project, shall not be publicized without the written approval of the CO.

2. The CO will be the sole authorized official to release verbally or in writing, any data, the draft deliverables, the final deliverables, or any other written or printed materials pertaining to this task order. No information shall be released by the contractor. Any request for information relating to this task order presented to the contractor shall be submitted to the CO for response.

K. QUALITY ASSURANCE SURVEILLANCE PLAN FOR BLIND PERFORMANCE TEST PROGRAM

This Quality Assurance Surveillance Plan (QASP) has been developed to evaluate contractor services while implementing this PWS. It is designed to provide an effective surveillance method of monitoring contractor performance for each listed Performance Objective. The QASP provides a systematic method to evaluate the services the contractor is required to furnish.

This QASP is based on the premise that the Government desires to receive and maintain a blind sample quality control (performance test) program for the VA Drug Free Workplace Program.

The contract is to provide blind samples for the VA drug testing laboratory that are drug positive, drug negative, and either adulterated or substituted as the best means of achieving that objective. The contractor, not the Government, is responsible for management and quality control actions to meet the terms of the contract. The role of the Government is quality assurance to ensure contract standards are achieved.

In this contract, the quality assurance surveillance program is the primary instrument for product quality. The contractor is required to develop a comprehensive program of inspections and monitoring actions. The first major step to ensuring a "self-correcting" contract is to ensure that the quality control program approved at the beginning of the contract provides the measures needed to lead the contractor to success.
Once the surveillance program is approved, careful application of the process and standards presented in the remainder of this document will ensure a robust quality assurance program.

Performance Objective	Performance Standard	PWS Para	Performance Threshold	Method of Surveillance
Blind Quality Control – Positive Sample	A positive blind sample needs to have the concentration of the drug it contains to be between 1.5 and 2.0 times the initial drug test cutoff concentration and must be spiked or contain one or more of the drugs or metabolites listed in the Cutoff Concentrations for Drug Tests table of the PWS.	D.4.	98%.	Record review
Blind Sample Shipping	Nine to ten blind samples are shipped to four VA donor specimen collection facilities each month per PWS.	D.4.	98%.	Record review
Blind Sample Identifier	Fictitious unique donor name and social security number for each sample is provided for donor specimen collection site.	D.8.	98%	Record review
Adulterated or Substituted Blind Sample	At least 10% of blind samples are adulterated or substituted.	D.4.	98%	Record review
Blind Sample Control Document	A separate sample control document will be enclosed for each shipment of positive, negative, and adulterated or substituted sample.	D.5.	98%	Record review

SURVEILLANCE: The Contracting Officer's Representative (COR) will review and monitor the contractor's performance and identify quality control issues for correction.
Contracting Officer's Representative (COR) - The COR is responsible for technical administration of the contract and shall assure proper Government surveillance of the contractor's performance. The COR shall keep a quality assurance file. The COR is not empowered to make any contractual commitments or to authorize any contractual changes on the Government's behalf.

Assigned COR: **To be provided at time of award.**

STANDARD: 100% of all blind quality control samples are without complaint from VA collection centers and the Medical Review Officer based on sample drug concentration, drug negative and adulterated/substituted samples and fictitious labeling. For example, if there are 36 blind sample submissions each month, the COR should have or receive zero complaints based on quality of the blind samples and control documents. For the purpose of these X services, preparation of drug positive, drug negative, and adulterated/substituted samples; quality control sample log/documents; sample expiration date; fictitious identification; Blind Quality Control Specimen Order Log; Blind Quality Control Specimens Composite Report; condition of blind sample delivered at VA collection site; volume of blind sample received; monitor the VA laboratory drug testing results for a 100% correlation with the contractor reference test results. There should never be more than two complaints per month from the VA collection site or Medical Review Officer. The COR shall notify the Contracting Officer for appropriate action in accordance with FAR 52.212.4, Contract Terms and Conditions-Commercial Items (May 1997) or the appropriate Inspection of Services clause, if any of the above service areas exceed five complaints.

SURVEILLANCE: The Government COR will evaluate the services required by each month to ensure compliance.

STANDARD: The Contractor shall perform all work required by the task or delivery order in a satisfactory manner in accordance with the appropriate Performance Work Statement (PWS). The COR shall not consider the task or delivery order complete until all deficiencies have been corrected.

PROCEDURES: The Government COR will inspect all work tasks required by the task or delivery order to ensure contractor compliance with the appropriate paragraphs D.1., D.2., D.3., D.4., D.5., D.6., D.7., D.8., D.9., D.10., D.11., D.12., D.13., D.14., G.1., and G.2 Of the PWS each time the quality control service is performed. The COR will record results of inspection, noting the date and time of inspection. If inspection indicates unacceptable performance, the COR will notify the Drug Free Workplace Program Manager of the deficiencies for correction. The Contractor shall be given two days after notification to correct the unacceptable performance.