

Quality Assurance Surveillance Plan (QASP)

VISN 15 Laboratory Testing Services

The contractor will be evaluated in accordance with the following:

1. PURPOSE

This Quality Assurance Surveillance Plan (QASP) provides a systematic method to evaluate performance for the stated contract. This QASP explains the following:

- What will be monitored?
- How monitoring will take place.
- Who will conduct the monitoring?
- How monitoring efforts and results will be documented.

This QASP does not detail how the contractor accomplishes the work. Rather, the QASP is created with the premise that the contractor is responsible for management and quality control actions to meet the terms of the contract. It is the Government's responsibility to be objective, fair, and consistent in evaluating performance.

This QASP is a "living document" and the Government may review and revise it on a regular basis. The QASP shall not become a part of the resultant contract.

2. GOVERNMENT ROLES AND RESPONSIBILITIES

The following personnel shall oversee and coordinate surveillance activities.

a. Contracting Officer (CO) – The CO shall ensure performance of all necessary actions for effective contracting, ensure compliance with the contract terms, and shall safeguard the interests of the United States in the contractual relationship. The CO shall also assure that the contractor receives impartial, fair, and equitable treatment under this contract. The CO is ultimately responsible for the final determination of the adequacy of the contractor's performance.

Assigned CO: Ashely Bogart

Organization or Agency:

b. 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: Brenda Hinck

Organization or Agency: Kansas City VAMC

3. CONTRACTOR REPRESENTATIVES

The following employee(s) of the contractor serve as the contractor's program manager(s) for this contract.

Primary: _____

Alternate: _____

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4. PERFORMANCE STANDARDS

The contractor is responsible for performance of ALL terms and conditions of the contract. CORs will provide contract progress reports quarterly to the CO reflecting performance on this plan and all other aspects of the resultant contract. The performance standards outlined in this QASP shall be used to determine the level of contractor performance in the elements defined. Performance standards define desired services. The Government performs surveillance to determine the level of Contractor performance to these standards.

The Performance Requirements are listed below in Section 6. The Government shall use these standards to determine contractor performance and shall compare contractor performance to the standard and assign a rating. At the end of the performance period, these ratings will be used, in part, to establish the past performance of the contractor on the contract.

5. INCENTIVES/DEDUCTS

The Government shall use past performance as incentives. Incentives shall be based on ratings received on the performance standards.

6. METHODS OF QA SURVEILLANCE

Various methods exist to monitor performance. The COR shall use the surveillance methods listed below in the administration of this QASP.

a. PERIODIC INSPECTION. Inspections scheduled and reported quarterly per COR delegation or as needed.

- Measure 1 (Maintains Licensing and certifications) – Review by ordering activities will occur within 2 months of biennial anniversary dates of CAP and CLIA licensure. Sources can include documentation that is downloaded on vendors webpage, documentation from CLIA Laboratory Demographics website (http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Laboratory_Demographic_Information.html), confirmation on CAP.org website of CAP certification or verbal request from vendor for documentation.
- Measure 4 (Test Accuracy) – Review by ordering activities will occur when modified test results are entered into the VISTA computer system. Modified test results require that each ordering activity manually change results, resulting in generation of comments “Reported incorrectly as” . These comments can reviewed by running the Supervisor reports Option: changes in verified lab data.

b. VALIDATED USER/CUSTOMER COMPLAINTS.

- Measure 3 (Transportation of Samples)– Sites will notify vendor of any missed pickups. An incident report will be completed by each site for each occurrence. These will be reported to the facility COR and VISN COR.

c. Verification and/or documentation provided by Contractor.

- Measure 2 (Sample Processing) – Vendor will supply monthly a pre-analytical processing report for each ordering activity. This report will include any test that is received by an electronic method and no sample was received. Ordering activities will compare this to documented incident reports generated at each facility.

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- Measure 5 (Turnaround Time) – Vendor will randomly select 20 test per month and provide a turnaround time report for each VISN 15 ordering activity. This report should be provided within 10 calendar days to each ordering activity. Ordering activities, will compare the reported turnaround times to time the report was generated at the facility. The time from anticipated arrival at vendor location to report release can be compared to the published turnaround time provided by the vendor in their vendor catalog.

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SAMPLE PERFORMANCE MEASURES

Measures	PWS Reference	Performance Requirement	Standard	Acceptable Quality Level	Surveillance Method	Incentive	Disincentive/Deduct
1. Maintains Licensing and Accreditation.	2.1.	The Contractor shall comply with all applicable OSHA, Federal and State Law, The Joint Commission, and regulations as required for performing the type of services required.	<i>All CAP and CLIA licenses(100%) are current for facilities within the contractors testing system.</i>	100%. No deviations accepted.	Random inspections of licenses.	Consideration of Favorable contractor performance evaluation	Consideration of Unfavorable contractor performance evaluation. Removal from contract.
2. Transportation of Samples	5.3.1.	Contractor shall provide routine scheduled specimen pickup at times mutually agreed upon by the ordering activity	<i>All samples (100%) should be picked up for transport to the contractors site</i>	<3 missed courier pickups per Quarter	Notification by ordering activity to contractor of missed courier pickup	Consideration of Favorable contractor performance evaluation	Consideration of Unfavorable contractor performance evaluation
3. Sample Processing	5.3.2.	Contractor shall ensure integrity of samples during transport	<i>All samples (100%) shipped to the contractor should arrive at the contractor site and be assayed.</i>	< 3 lost specimens per Quarter	Review of incomplete test list with shipping manifest	Consideration of Favorable contractor performance evaluation	Consideration of Unfavorable contractor performance evaluation
4. Test Result Accuracy	5.3.3.	Contractor shall provide accurate testing	All samples (100%) should be reported accurately	<0.02% of all patient results received	Notification by contractor to ordering activity of modified test report	Consideration of Favorable contractor performance evaluation	Consideration of Unfavorable contractor performance evaluation
5. Turnaround Time	5.3.4.	Contractor shall provide routine results to the ordering activity in accordance with the testing specifications defined in the contractor's commercial specimen collection guide	<i>100% of results should be released with published turnaround</i>	<i>Less than 6 delays from published turnaround times per month</i>	Review of 20 random tests compared to published turnaround times provided by the vendor. Ordering activities will compare information to published TAT's and time provided on final report.	Consideration of Favorable contractor performance evaluation	Consideration of Unfavorable contractor performance evaluation

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7. RATINGS

Metrics and methods are designed to determine rating for a given standard and acceptable quality level. The following ratings shall be used:

EXCEPTIONAL:	<p>Performance meets contractual requirements and exceeds many to the Government’s benefit. The contractual performance of the element or sub-element being assessed was accomplished with few minor problems for which corrective actions taken by the contractor were highly effective.</p> <p>Note: To justify an Exceptional rating, you should identify <u>multiple</u> significant events in each category and state how it was a benefit to the GOVERNMENT. However a singular event could be of such magnitude that it alone constitutes an Exceptional rating. Also there should have been NO significant weaknesses identified.</p>
VERY GOOD:	<p>Performance meets contractual requirements and exceeds some to the Government’s benefit. The contractual performance of the element or sub-element being assessed was accomplished with some minor problems for which corrective actions taken by the contractor were effective.</p> <p>Note: To justify a Very Good rating, you should identify a significant event in each category and state how it was a benefit to the GOVERNMENT. Also there should have been NO significant weaknesses identified.</p>
SATISFACTORY:	<p>Performance meets contractual requirements. The contractual performance of the element or sub-element contains some minor problems for which corrective actions taken by the contractor appear or were satisfactory.</p> <p>Note: To justify a Satisfactory rating, there should have been only minor problems, or major problems the contractor recovered from without impact to the contract. Also there should have been NO significant weaknesses identified.</p>
MARGINAL:	<p>Performance does not meet some contractual requirements. The contractual performance of the element or sub-element being assessed reflects a serious problem for which the contractor has not yet identified corrective actions. The contractor’s proposed actions appear only marginally effective or were not fully implemented.</p> <p>Note: To justify Marginal performance, you should identify a significant event in each category that the contractor had trouble overcoming and state how it impacted the GOVERNMENT. A Marginal rating should be supported by referencing the management tool that notified the contractor of the contractual deficiency (e.g. Management, Quality, Safety or Environmental Deficiency Report or letter).</p>
UNSATISFACTORY:	<p>Performance does not meet most contractual requirements and recovery is not likely in a timely manner. The contractual performance of the element or sub-element being assessed contains serious problem(s) for which the contractor’s corrective actions appear or were ineffective.</p> <p>Note: To justify an Unsatisfactory rating, you should identify multiple significant events in each category that the contractor had trouble overcoming and state how it impacted the GOVERNMENT. However, a singular problem could be of such serious magnitude that it alone constitutes an unsatisfactory rating. An Unsatisfactory rating should be supported by referencing the management tools used to notify the contractor of the contractual deficiencies (e.g. Management, Quality, Safety or Environmental Deficiency Reports, or letters).</p>

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8. DOCUMENTING PERFORMANCE

a. The Government shall document positive and/or negative performance. Any report may become a part of the supporting documentation for any contractual action and preparing annual past performance using CONTRACTOR PERFORMANCE ASSESSMENT REPORT (CPAR).

b. If contractor performance does not meet the Acceptable Quality level, the CO shall inform the contractor. This will normally be in writing unless circumstances necessitate verbal communication. In any case the CO shall document the discussion and place it in the contract file. When the COR and the CO determines formal written communication is required, the COR shall prepare a Contract Discrepancy Report (CDR), and present it to CO. The CO will in turn review and will present to the contractor's program manager for corrective action.

The contractor shall acknowledge receipt of the CDR in writing. The CDR will specify if the contractor is required to prepare a corrective action plan to document how the contractor shall correct the unacceptable performance and avoid a recurrence. The CDR will also state how long after receipt the contractor has to present this corrective action plan to the CO. The Government shall review the contractor's corrective action plan to determine acceptability. The CO shall also assure that the contractor receives impartial, fair, and equitable treatment. The CO is ultimately responsible for the final determination of the adequacy of the contractor's performance and the acceptability of the Contractor's corrective action plan.

Any CDRs may become a part of the supporting documentation for any contractual action deemed necessary by the CO. See Sample CDR below.

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CONTRACT DISCREPANCY REPORT				
1. CONTRACT NUMBER		2. REPORT NUMBER FOR THIS DISCREPANCY		
3. TO: <i>(Contracting Officer)</i>		4. FROM: <i>(Name of COR)</i>		
5. DATES				
a. CDR PREPARED	b. RETURNED BY CONTRACTOR:	c. ACTION COMPLETE		
6. DISCREPANCY OR PROBLEM <i>(Describe in detail. Include reference to PWS Directive; attach continuation sheet if necessary.)</i>				
7. SIGNATURE OF COR				Date:
8. SIGNATURE OF CONTRACTING OFFICER				Date:
9a. TO <i>(Contracting Officer)</i>		9a. FROM <i>(Contractor)</i>		
10. CONTRACTOR RESPONSE AS TO CAUSE, CORRECTIVE ACTION AND ACTIONS TO PREVENT RECURRENCE. <i>(Cite applicable quality control program procedures or new procedures. Attach continuation sheet(s) if necessary.)</i>				
11. SIGNATURE OF CONTRACTOR REPRESENTATIVE				Date:
12. GOVERNMENT EVALUATION. <i>(Acceptance, partial acceptance, reflection. Attach continuation sheet(s) if necessary.)</i>				
13. GOVERNMENT ACTIONS <i>(Acceptance, partial acceptance, reflection. Attach continuation sheet(s) if necessary.)</i>				
14. CLOSE OUT				
	NAME	TITLE	SIGNATURE	DATE
CONTRACTOR NOTIFIED				
COR				
CONTRACTING OFFICER				

