Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 09D2044516	**(X3) Date Survey Completed** 06/01/2021
Name of Provider or Supplier Gwu Mfa At Sibley Urology	**Street Address, City, State** 5215 Loughboro Road, Nw Suite 210, Washington, DC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	**Summary Statement of Deficiencies**
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of chemistry proficiency testing (PT) records for performing PSA and interview with the testing person, the laboratory director failed to attest that PT was performed in the same manner as patient testing. Findings: 1. The LD failed to review, sign, and date the required attestations provided by the PT agency. 2. The LD failed to sign and date fourteen chemistry testing event attestations. 3. The TP stated that the LD has not been in the laboratory since spring of the year 2020 and that she tries to get documents signed at another office where the LD is located. 4. The TP confirmed that the LD failed to review, sign, and date the required attestation provided by the PT agency.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test

	procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the testing person, the laboratory did not have written step by step instructions for performing PSA testing. Findings: Repeat Deficiency 1. The written procedure manual did not include step by step instructions for performing PSA testing that included the preanalytic, analytic and postanalytic phases of patient testing. 2. The TP stated that they have the procedures and it may be at another office waiting for the director's signature. 3. The written procedure manual did not include the PSA unit of measurement nor the reportable range that is needed to calculate and report patient results. 4. The TP stated that the PSA unit of measurement and reportable range was included with the written PSA procedure that was at another office waiting for the director's signature. 5. The TP confirmed that the written procedure manual did not include step by step instructions for performing PSA testing that included the preanalytic, analytic and postanalytic phases of patient testing.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for

	verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the TP, the laboratory did not perform calibration verification procedures. Findings: 1. The laboratory performs PSA testing. 2. The laboratory did not perform calibration verification procedures for PSA testing during the years 2021 and 2020. 3. The TP stated that calibration verification (CV) procedures are performed every six months and she could not remember the last time CV procedures were performed for PSA testing. 4. The TP confirmed that CV procedures were not performed during the years 2021 and 2020.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient final reports and interview with the testing person, the laboratory did not include the unit of measurement nor the reference range of PSA results on the final report. Findings: 1. Review of three patient final reports performed during April 2021 did not include the unit of measurement nor the reference range needed for interpretation of the PSA value on the report. 2. Review of patient final reports from March 2021 on the 12th, 19th, and 26th did not include the unit of measurement nor the reference range needed for interpretation of the PSA value on the report. 3. Review of patient final reports from February 2021 on the 26th and 19th did not include the unit of measurement nor the reference range needed for interpretation of the PSA value on the report. 4. Review of patient final reports from August 2020 on the 28th, 21st, 14th did not include the unit of measurement nor the reference range needed for interpretation of the PSA value on the report. 5. Review of patient final reports from July 2020 on the 31st, 30th, 24th, 10th did not include the unit of measurement nor the reference range needed for interpretation of the PSA value on the report. 6. The laboratory did not hand write the unit of measurement nor the reference range needed for interpretation of the PSA value on the reports. 7. The TP stated the reason for not having the unit of measurement and the reference range of PSA results on the final report was an LIS problem that needed to be fixed by the software company. 8. The TP confirmed that the unit of measurement nor the reference range of PSA results were included on the patient final report.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.

	1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of chemistry testing documents and interview with the testing person, the laboratory director failed to attest that PT was performed in the same manner as patient testing (Refer to D2015); failed to have step by step written instructions for performing PSA testing (Refer to D5403); failed to perform calibration verification procedures (Refer to D5439); and failed to include the unit of measurement and the reference range of PSA results on the patient final report (Refer to D5805). The laboratory director failed to ensure that laboratory testing was performed in an accurate and reliable manner and failed to maintaine the laboratory's criteria of acceptability.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the TP, the laboratory director failed to ensure that calibration verification procedures were performed to ensure accurate and reliable patient PSA testing. Findings: Refer to D5439 The laboratory failed to perform calibration verification procedures for PSA testing during the years 2021 and 2020.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of chemistry proficiency testing (PT) records for performing PSA samples and interview with the testing person, the laboratory director failed to attest that PT was performed in the same manner as patient testing. Findings: Refer to D2015 The LD failed to review, sign, and date the required attestations provided by the PT agency.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the testing person, the laboratory director (LD) failed to review and sign chemistry performance evaluations. Finding: 1. The laboratory performs prostatic specific antigen (PSA) testing. 2. The LD failed to review and sign the 2021 and 2020 PT 1st event core chemistry PSA testing performance evalutions. 3. The TP stated that the LD has not been in the laboratory since spring of the year 2020 and that she tries to get documents signed at another office where the LD is located. 4. The TP confirmed that the LD failed to review and sign the 2021 and 2020 PT 1st event core chemistry PSA testing perfromance evaluations.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of quality assessment (QA) procedures and interview with the testing person, the laboratory director failed to ensure that monthly QA procedures were performed which included a QA review of chemistry quality controls (QC) and printed patient final reports. Findings: 1. The laboratory performs Prostatic Specific Antigen (PSA) testing. 2. The LD failed to complete the monthly QA report for February, March, and April 2021 that included the preanalytic laboratory assessment, the analytic assessment of QC, and the postanalytic assessment of patient final reports that did not include the unit of measurement nor the reference range needed for interpretation of the PSA value on the report. 3. The LD failed to review and sign the monthly QA report for July and August 2020 that included the preanalytic laboratory assessment, the analytic assessment of QC, and the postanalytic assessment of patient final reports that did not include the unit of measurement nor the reference range needed for interpretation of the PSA value on the report. 4. The LD failed to complete the monthly QA report for June 2020 that included the preanalytic laboratory assessment, the analytic assessment of QC, and the postanalytic assessment of patient final reports. 5. The LD failed to review and sign the monthly QA report for February and March 2020 that included the preanalytic laboratory assessment, the analytic assessment of QC, and the postanalytic assessment of patient final reports. 6. The TP stated that the LD has not been in the laboratory since spring of the year 2020 and that

	she tries to get documents signed at another office where the LD is located. 7. The TP confirmed that the LD failed to ensure that monthly QA procedures were performed which included a QA review of chemistry quality controls (QC) and printed patient final reports.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on review of quality assessment (QA) procedures and interview with the testing person, the laboratory director failed to ensure that monthly QA procedures were performed which included a QA review and documentation of remedial action procedures when performing PSA chemistry testing. Findings: 1. The LD failed to perform remedial action procedures during the months of February, March, and April 2021 when patient final reports did not include the unit of measurement nor the reference range needed for interpretation of the PSA value on the report. 2. The LD failed to perform remedial action procedures during the months of July and August 2020 when patient final reports did not include the unit of measurement nor the reference range needed for interpretation of the PSA value on the report. 3. The LD failed to review and sign the remedial action log during the month of December 2020. 4. The TP confirmed that the LD failed to ensure that monthly QA procedures were performed which included a QA review and documentation of remedial action procedures when performing PSA chemistry testing.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the testing person, the laboratory director failed to provide written duties and responsibilities for each person involved with chemistry laboratory testing. Findings: 1. The laboratory performs PSA testing. 2. The LD failed to include the written duties and

	responsibilities for the technical consultant and the testing person in the written procedure manual. 3. The TP confirmed that written duties and responsibilities for the technical consultant and the testing person were not included in the written procedure manual.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the written procedure manual, competency records, and interview with the testing person, the laboratory director acting as the technical consultant (TC) failed to perform competency procedures for all laboratory personnel. Findings: 1. The TC failed to perform annual competency procedures for all testing persons performing PSA testing. 2. Two of the four testing persons did not have annual competency procedures performed for the year 2020. 3. The TP confirmed that annual competency procedures were not performed for all laboratory personnel performing PSA testing.