Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D2044516	09/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Gwu Mfa At Sibley Urology	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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director and the analyst did not sign and date the attestation statement for the first proficiency test event of 2019 to attest that the proficiency test samples, for prostate specific antigen analysis, were tested in the same manner as patient specimens. Findings: 1. The labs proficiency test provider submits five samples (samples with unknown concentrations of PSA) to the lab for PSA testing, twice a year. The lab performs the testing and submits the results to the proficiency test provider for evaluation. The provider scores the labs performance for accuracy and sends its evaluation to the lab; 2. The lab proficiency test records for the first event of 2019 did not include an attestation statement signed by the lab director and analyst; and 3. This was confirmed during interview with staff on the day of survey.
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 record review and interview, the laboratory (lab) written procedures did not include reference ranges for prostate specific antigen (PSA) testing and step-by-step instructions for performing the PSA test. Findings: 1. Patient test reports included patient reference (normal) ranges by patient age, but these reference ranges were not included in the labs written procedure; 2. The written procedure did not include step-by-step instruction for performing a PSA test on a patient specimen; and 3. This was confirmed with staff during interview on the day of survey.
D6020	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 program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory (lab) director did not ensure that quality control procedures were maintained by the lab. Findings: 1. The lab performs PSA testing on patient specimens, the written procedure instructs testing staff to transcribe quality control results (results from level 1 and level 2 quality control reagents) from the analyzer printouts to a "Quality Control Chart"; 2. In January 2018 eight sets (level 1 and level 2) out of twenty quality control results (January 5, 12, 17, 18, 19, 24, 25 and 29, 2018) were not transcribed onto the "Quality Control Chart" for that month; 3. In February 2018 six sets (level 1 and level 2) out of nineteen quality control results (February 1, 2, 5, 8, 9 and 13, 2018) were not transcribed onto the "Quality Control Chart" for that month; 4. The transcription error was not identified in the monthly quality assurance reviews for January and February of 2018; and 5. This was confirmed during interview with staff on the day of survey.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory (lab) director did not ensure that the labs quality assessment program (for prostate specific antigen testing) was maintained to show quality assurance activities conducted in the lab. Findings: 1. The laboratory prepares a monthly "Quality Assurance Assessment" (quality assurance report or report) to ensure quality assurance reviews are documented and problems are corrected; 2. The monthly quality assurance report lists lab related activities to measure the quality of the lab, and the lab completes the report by responding to each activity by writing yes, no or not applicable in response to each activity statement; 3. On the May 2019 dated report dated May 30, 2019 and the January 2019 report dated February 2, 2019, the lab responded with an "N" for no to the statement "The FastPack IP System is operating optimally", there was no indication on the corrective action log, that the system was not optimal as reported on the monthly Quality Assessment"; 4. On the May 2019 report dated May 30, 2019 and the January 2019 report dated February 2, 2019, the lab responded with an "N" for no to the statement "Food and Drink are not kept in the laboratory refrigerator where FastPack ... [reagents] are stored", there was no indication on the corrective action log that the food or drink problem was resolved; 5. On the May 2019 report dated May 30, 2019 and the January 2019 report dated February 2, 2019, the lab responded with an "N" for no to the statement "No complaints or communication problems occurred this month", there was no indication on the corrective action log, that the problem(s) were corrected; 6. On the May 2019 report dated May 30, 2019 and the January 2019 report dated February 2, 2019, the lab responded with an "N" for no to the statement "The above information has been reviewed to determine whether errors occurred this month could have been prevented by changing policies...", there was no indication on the corrective action log, that the "no" responses reported on the "Quality Assessment" report were investigated and resolved. There are instructions on the "Quality Assurance Assessment" report to investigate, correct and document any "no" responses made on the quality assurance assessment; 7. On the May 2019 report dated May 30, 2019 and the January 2019 report dated February 2, 2019, the lab responded with an "N for no to "Any newly instituted policies and procedures have been reviewed for effectiveness", there was no explanation as to why the lab did not review new procedures for effectiveness; and 8; This finding was confirmed on interview with staff on the day of survey.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory (lab) director acting as the technical consultant (for prostate specific antigen testing) did not perform the competency evaluations for testing personnel, but delegated the duties to staff who was not credentialed by the director to act as technical consultant. Findings: 1. The lab

	written procedure (for prostate specific antigen) shows that the lab director responsibility and duties include technical responsibility duties; 2. The evaluator who performed the reviews did not have adequate documentation in their file (college transcripts) to credential for technical consultant; 2. The lab director acting as technical consultant did not sign as "evaluator" on 2018 competency check records evaluating competency of testing personnel; 3. Testing Person # 1 did not have a competency check record for 2018, the record was requested by the surveyor on the day of survey and the lab did not provide the document; and 4. This was confirmed with staff during interview on the day of survey.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory (lab) director acting as technical consultant did not ensure that testing persons were rotated to perform proficiency testing to demonstrate competency. Findings: 1. The labs proficiency test provider submits five samples (samples with unknown concentrations of prostate specific antigen - PSA) to the lab for testing, twice a year. Each submission is an event. The lab performs the testing and submits the results to the proficiency test provider for evaluation. The provider scores the labs performance for accuracy and sends its evaluation to the lab; 2. Testing person # 1 performed proficiency testing for three consecutive events that included the first and second event of 2018 and the first event of 2019; and 3. This was confirmed during interview with staff on the day of survey.