Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D0208500	11/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
Foxhall Urology	3301 New Mexico Avenue Nw #311, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on observation and interview with the technical consultant, the laboratory (lab) director did not perform competency assessments of the technical consultant for carrying out duties required of a technical consultant. Findings: 1. The laboratory did not have a written responsibility and duty statement for the technical consultant to determine duties assigned to her; 2. Competency assessment records for the technical consultant were requested at the time of survey, but the lab was unable to produce them; and 3. During interview in the afternoon, on the day of survey, the technical consultant confirmed that the lab did not have competency evaluations for duties performed.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on observation and interview with the technical consultant, the laboratory (lab) did not have proficiency test procedures to check the accuracy of the [-2] proPSA

	antigen (P2 PSA/ isoform of free PSA). Findings: 1. The P2 PSA antigen is a measured analyte that is used for calculating the health index of the patient; and 2. The laboratory did not perform and did not have written procedures to check the accuracy of the P2 PSA antigen test at least two times each year (such as split sampling or other means); and 3. This was confirmed during interview with the technical consultant in the afternoon of the day of survey.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observation and interview with laboratory staff, the laboratory (lab) did not have a written standard operation procedure manual (SOPM) for performing chemistry testing in the laboratory. Findings: 1. The SOPM for chemistry testing was requested on the day of survey, lab staff were unable to locate the SOPM and when interviewed in the afternoon on the day of survey, staff stated that the SOPM could not be located; 2. The laboratory did not have an SOPM that was reviewed, and approved in writing by the lab director; and 3. The lab did not have written procedures for ordering lab tests, patient identification, specimen collection and labeling of samples to assure positive identification, specimen rejection procedures, labeling and storage of specimens held for testing, step by step testing procedures, quality control procedures, preventive maintenance procedures, data management and reporting of test results, proficiency testing procedures, reportable ranges for each analyte, normal patient reference ranges for each analyte, identification of testing person, quality assurance, corrective action, are not all inclusive and represent a few examples of procedures that were lacking in the laboratory.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory (lab) staff, the chemistry lab did not have written procedures to ensure that records identifying testing reagents were maintained for at least two years as required by CLIA, these records include reagent manufacturer name, lot numbers of reagents and expiration dates of reagents including quality control reagents to be maintained for at least two years to ensure they are not used past expiration. Findings: 1. During interview with lab staff in the afternoon of the day of survey, it was reported that the reagent information is stored in the analyzers hard computer drive, but there was no description on how to maintain the data so that it is not overwritten due to changes in reagent lots, and there was no description of how long the reagent information is stored within the hard drive.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and interview with the technical consultant, the laboratory (lab) did not perform preventive maintenance on the chemistry analyzer as indicated on the preventive maintenance log. Findings: 1. The preventive maintenance log directs the lab to perform weekly cleaning procedures, but the lab was performing these duties on a monthly basis and there was no reference provided to show that the manufacturer allows for less frequent cleaning maintenance; 2. During all of 2018 and 2019 weekly maintenance was performed on a monthly basis; and 3. This finding was confirmed with the technical consultant during interview on the afternoon of the day of survey.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and interview with the technical consultant, the laboratory (lab) did not have a written corrective action report for a testosterone proficiency testing failure that was reported to the lab. Findings: 1. The lab enrolls in a proficiency testing program with a provider, three times a year, the proficiency test provider sends the lab unknowns to test in the same manner as patient samples. The lab submits the test results to the proficiency test provider to evaluate, and the provider scores the labs performance and reports the results to the lab; 2. On the third event of 2018, the lab received a failing score (50%) for testosterone. The lab did not perform and document a corrective action review to determine if there could have been a problem with the testing at the time of testing, and if needed provide a corrective action plan to ensure that the problems were corrected; and 3. This finding was confirmed , during interview, with the technical consultant, in the morning, on the day of survey.
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 record review and interview with staff, the chemistry laboratory did not document corrective action for one of twenty problems identified during review of quality control results and corrective action records performed by the surveyor. Findings: 1. The laboratory reported corrective actions on a log and on June 27 and 20, 2019 the P2PSA lot 8325901 was expired, this was flagged as expired on the quality control test report; 2. The lab did not perform and document corrective action for this problem to determine cause and ensure it does not recur; and 3. This finding was confirmed during interview with the technical consultant on the afternoon on the day of survey.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on observation, the laboratory director did not have policies to maintain credentials for lab staff to ensure they met CLIA requirements. Findings: 1. Testing person #1 did not have a copy of their degree or certifications on file and available for review; and 2. At the time of the survey, the technical consultant had to retrieve her degree and certification to provide to the lab for surveyor review.
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 observation, the laboratory director did not have written duties and responsibility statements for each staff member and position. The surveyor reviewed through lab records but did not observe responsibility and duty statements.