Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D0208500	01/08/2018
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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policies and procedures manual and accuracy verification records and confirmation by interview with the laboratory's Technical Consultant (TC), the laboratory failed to develop an accuracy assessment mechanism for one (1) of the two (2) microscopic procedures the laboratory performs (qualitative semen analysis). The findings included: 1. There was no evidence that the laboratory has developed a mechanism for assessing the accuracy of the laboratory's procedure for performing qualitative semen analysis. 2. Interview with TC conducted on January 8, 2018 at approximately 2:30 PM confirmed the lack of accuracy verification procedure semen analysis.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policies and procedures manual and accuracy verification records and confirmation by interview with the laboratory's Technical

	Consultant (TC), the laboratory's quality assessment for the general laboratory system failed to identify the laboratory's failure to develop an accuracy verification mechanism for one (1) of the two (2) microscopic procedures the laboratory performs (qualitative semen analysis). Cross-reference D5217.
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 the review of the laboratory's policies and procedures manual and confirmation by interview with the laboratory's Technical Consultant (TC), the laboratory's procedure manual failed to include a step - by- step procedure for one (1) of the two (2) microscopic procedures the laboratory performs (qualitative semen analysis). The findings included: Review of the laboratory's procedure manual failed to provide evidence of a procedure for the qualitative analysis of semen. Interview with the laboratory's TC on January 8, 2017 at approximately 2:00 PM revealed that the laboratory analyzes semen specimens. However, the laboratory had not develop a step-by-step procedure.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, the review of the laboratory's policies and procedures manual, quality control log and confirmation by interview with the laboratory's Technical Consultant (TC), the laboratory failed to develop a quality control mechanism that monitors its procedure for performing urine sediment microscopic analysis. The

	findings included: 1. During inspection of the laboratory on January 8, 2018 at approximately 11:30 AM, positive and negative quality control materials that did not identify cells or substances that could be seen in normal and abnormal urine sediment were observed being in use as a daily control for urine microscopic examination. 2. According to the review of the manufacturer's insert for the control and the laboratory's policies and procedures, the two level urine microscopic controls that the laboratory uses measures number of cells per high power field and did not identify any type of cells. 3. Interview with TC conducted on January 8, 2018 at approximately 12:00 PM confirmed the lack of control that monitors the laboratory's procedure for performing urine sediment examination.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: A. Based on the review of the laboratory's policies and procedures manual and the laboratory's quality assurance documentation and confirmation by interview with the laboratory's Technical Consultant (TC), the laboratory's quality assessment for the analytical phase of testing failed to identify the laboratory's failure to develop a step - by- step procedure for one (1) of the two (2) microscopic procedures the laboratory performs (qualitative semen analysis). Cross reference D5403. B. Based on observation, the review of records (the laboratory's policies and procedures manual, quality control log and quality assurance documentation), and confirmation by interview with the laboratory's TC, the laboratory's quality assessment for the analytic phase of testing failed to identify the laboratory's failure to develop a quality control mechanism that monitors its procedure for performing urine sediment microscopic analysis. Cross reference D5447.
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: A. Based on the review of the laboratory's policies and procedures manual and the laboratory's quality assurance documentation and confirmation by interview with the laboratory's Technical Consultant (TC), the Laboratory Director (LD) failed to ensure that quality assessment for the analytical phase of testing identified the laboratory's failure to develop a step - by- step procedure for one (1) of the two (2) microscopic procedures the laboratory performs (qualitative semen analysis). Cross reference D5791-A. B. Based on observation, the review of records (the laboratory's policies

	and procedures manual, quality control log and quality assurance documentation), and confirmation by interview with the laboratory's TC, the LD failed to ensure that quality assessment for the analytic phase of testing identified the laboratory's failure to develop a quality control mechanism that monitors its procedure for performing urine sediment analysis. Cross reference D5791-B. C. Based on the review of the laboratory's policies and procedures manual and accuracy verification records and confirmation by interview with the laboratory's TC, the Laboratory Director failed to ensure that the quality assessment for the general laboratory system identified the laboratory's failure to develop an accuracy verification mechanism for one (1) of the two (2) microscopic procedures the laboratory performs (qualitative semen analysis). Cross-reference D5291.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on observation, the review of the laboratory's policies and procedures manual, quality control log and confirmation by interview with the laboratory's Technical Consultant (TC), the laboratory's TC failed to develop a quality control mechanism that monitors the laboratory's procedure for performing urine sediment microscopic analysis. Cross-reference D5447.