Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D1050103	03/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Metropolitan Urologic Services	438 Elmont Road, Elmont, NY	

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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a surveyor's review of laboratory's temperature documentation and interview with the office manager and the testing person, the laboratory failed to follow the manufacturer's temperature requirement for the laboratory testing. FINDINGS: 1. On March 26, 2018 at approximately 11:30 AM the office manager and the testing person confirmed surveyor's findings that the laboratory failed to monitor and document the refrigerator temperature as required by the manufacturer's criteria for proper storage of the patients' specimens, the reagents and quality control materials from 3/19/18 through the survey date. 2. The laboratory's temperature policy and the manufacturer's criteria for proper storage of the reagents and quality control materials require that the refrigerator temperature to be 2-8 degree Celsius or 35-45 degree Fahrenheit on each day of testing. The refrigerator temperature was out of range for 40 days from September 2016 through February 2018. 3. Approximately 40 patient samples were tested and reported during the above time frames.
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 a surveyor's review of the Qualigen operator's manual, calibration records and an interview with the office manager and the testing person, the laboratory failed to perform the required calibration verification at least once every six months in calendar years 2016 and 2017 and through survey date. FINDINGS: 1. The office manager and testing person confirmed on March 26, 2018 at approximately 11:30 AM, that the laboratory failed to follow the Qualigen Fast Pack System requirements and perform calibration verification every six months for the test analytes PSA using a three point calibrator from 9/8/16 through survey date. The calibration verification was last performed on 3/7/16. 2. Approximately 200 patient samples were tested and reported from 9/8/16 through survey date.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a surveyor review of Quality Control (QC) records and interview with the office manager and the testing person, the laboratory failed to retain the QC assay sheets for the Qualigen Fast Pack System for PSA testing from September 2016

	through the survey date. FINDINGS: 1. On March 26, 2018 at approximately 11:30 AM, the office manager and the testing person confirmed the surveyor's review of QC records finding that the laboratory failed to retain the QC assay sheets for the Qualigen Fast Pack System PSA test performed. 2. Without the established QC limits, the surveyor could not determine if the quality control results were within the acceptable ranges for the PSA testing. 3. Approximately 200 patients' specimens were tested and reported for PSA during this time period.
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 surveyor's findings and interview with the office manager and the testing person, the laboratory director failed to provide overall management of the laboratory. Finding: The laboratory director failed to ensure that the laboratory maintained the laboratory's QC program for chemistry; refer to D6020.
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 a surveyor's review of QC records and confirmed in an interview with the office manager and the testing person at the time of this survey, the laboratory director failed to ensure that the QC program for chemistry testing was maintained to assure the quality of laboratory services. Refer to: D5413, D5439, D5469