Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0067746	11/03/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pioneer Valley Urology, Pc	100 Wason Ave, Suite 120, Springfield, MA	

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
D0000	A CLIA recertification survey was conducted for the Pioneer Valley Urology, P.C. laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
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 procedure review and interview the laboratory failed to have a procedure manual which included the following: a) A review of the laboratory procedure manual for the Precision Microbio polymerase chain reaction (PCR) methodology for the identification of bacterial organisms failed to include a pre-analytical section which

	outlined the labeling of patient samples as well as preparing the worksheets for the analytical portion of the assay. In addition, the laboratory scans results into the final report from a result spreadsheet and there was no post- analytical procedure outlining this process. b) The general supervisor interviewed on 11/3/21 at 11:20 PM confirmed that specific pre- and post-analytical processes were missing from the procedure manual. The laboratory performs approximately 1200 bacterial identifications utilizing the PCR system annually. .
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on procedural review and interview, the laboratory failed to define a function check protocol for all laboratory equipment as evidenced by the following: a) A review of the laboratory's procedure manual on 11/3/21 revealed no written protocol for verifying the accuracy of the pipettes used in Bacteriology by performing calibration checks. b) The general supervisor confirmed in an interview on 11/3/21 at 12:15 PM that a function check protocol was not available for checking the pipette calibrations. c) The laboratory performs 1200 bacteriology tests annually.