Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0067567	09/30/2021
Name of Provider or Supplier	**Street Address, City, State**	
Urology Group Of Western New England Pc	3640 Main Street Suite 103, 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 Urology Group of Western New England, PC 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 manually transcribes results into the final report from a result spreadsheet and there was no post- analytical procedure outlining this process. b) The technical supervisor interviewed on 9/30/21 at 12:24 PM confirmed that pre- and post-analytical processes were missing from the procedure manual. The laboratory performs approximately 3,525 bacterial identifications utilizing the PCR system annually. .
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on observation and interview, the laboratory director failed to ensure that the environmental conditions provided a safe environment in which employees were protected from biological hazards as evidenced by the following: a) On the day of the survey at 11:15 AM in the presence of the Technical Supervisor it was observed that a small fan, located on top of the refrigerator in the room utilized for urinalysis as well as the planting of urine cultures for colony counts, was observed venting air into the laboratory area with the potential of dispersing infectious agents into the air. b) The Technical Supervisor interviewed on 9/30/21 at 10:15 AM confirmed that the fan had been placed in the laboratory area without his knowledge. A medical assistant present in the room at the time also stated that the room was too warm stated that the temperature of the laboratory had been too warm so the fan had been placed in there to cool it down.