Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0317977	03/18/2021
Name of Provider or Supplier	**Street Address, City, State**	
Mississippi Urology Clinic Pllc	501 Marshall Street Suite 301, Jackson, MS	

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
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 review of the laboratory's procedure manual, the Individualized Quality Control Plan (IQCP) established for identification of urinary tract infection (UTI) pathogens performed on the Applied Biosystems QuantStudio 3 amplification instrument, and interview with the general supervisor on March 18, 2021 at 3:30 p.m., the procedure manual does not include a procedure for acceptability and rejection of specimens submitted for pathogen identification by polymerase chain reaction (PCR) testing on the QuantStudio 3 amplification instrument or a procedure for decontamination of the instrument. Findings include: 1. Review of the IQCP for PCR

	testing with the QuantStudio 3 amplification instrument revealed the Risk Assessment states a possible source of error could be that "Instrument has been contaminated by nucleic acids or foreign bodies." The instructions on how to reduce error state, "Training personnel on decontamination procedure." Review of the laboratory's procedure manual revealed no written decontamination procedure. The lack of this procedure was confirmed in an interview with the general supervisor on March 18, 2021 at 3:30 p.m. 2. Review of the IQCP for PCR testing with the QuantStudio 3 amplification instrument revealed the Quality Control Plan states "Verify Specimen Acceptability - Acceptance Criteria. Refer to specimen rejection policy in respective testing SOP and record specimens in specimen rejection log." Review of the laboratory's procedure manual revealed no written procedure for specimen acceptability and rejection for PCR testing. The lack of a procedure for specimen acceptability and rejection was confirmed in an interview with the general supervisor on March 18, 2021 at 3:30 p.m.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the quality control records for urinary tract infection (UTI) pathogen identification with polymerase chain reaction (PCR) testing performed with the Applied Biosystems QuantStudio 3 amplification instrument, the Individual Quality Control Plan (IQCP), and lack of documentation of review by the laboratory director, the laboratory director failed to approve, sign, and date the IQCP before the procedure was put in use for patient testing quality control on 8/13/20. Findings include: Review of quality control records (QC) for UTI pathogen identification performed with the QuantStudio 3 amplification instrument from 8/13/20 through 12 /28/20 revealed weekly QC is performed according to the IQCP. Review of the IQCP established for the PCR testing with the QuantStudio 3 amplification instrument revealed no documentation that the laboratory director had approved, signed, and dated the IQCP before the procedure was put in use for patient testing quality control on 8/13/20.