Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0694743	09/26/2022
Name of Provider or Supplier	**Street Address, City, State**	
Joseph M Johnson	1675 N 200 W Ste 9c, Provo, UT	

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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of Proficiency Testing (PT) records and interview with Testing Personal (TP), the laboratory failed to document review of all unsatisfactory scores and the corrective action taken for 1 of 7 PT surveys reviewed. Findings include: 1. A review of PT records at approximately 12:00 AM on 9/26/22 revealed that the laboraotry had obtained a score of 0 for PT Survey Routine Microbiology Combination (RMC-B) 2021 from the College of American Pathologists. 2. A review of PT records at approximately 12:00 AM on 9/26/22 revealed that the laboratory had failed to document the review of, and corrective action for PT Survey RMC-B 2021 from the College of American Pathologists. 3. An interview with TP1 at approximately 12:05 AM on 9/26/22 confirmed that the laboratory had failed to document a review of all unsatisfactory scores and the corrective actions taken for 1 of 7 PT Surveys reviewed..
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 upon a record review of the Standard Operating Procedures (SOPs) and interview with the laboratory director (LD), the laboratory failed to include requirements for labeling of specimens and urine culture media plates in the laboratory's Urinalysis Procedure. Findings include: 1. A review of the laboratory's SOPs at approximately 12:26pm on 9/26/22 revealed that the Urinalysis Procedure failed to include requirements for labeling of specimens and urine culture media plates. 2. In an interview with the LD at approximately 12:30pm on 9/26/22, it was confirmed that the laboratory's Urinalysis Procedure failed to include requirements for labeling of specimens and urine culture media plates. 3. The laboratory performs approximately 1499 combined urine dipstick and culture tests annually.