Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	02D2144657	12/02/2021
Name of Provider or Supplier	**Street Address, City, State**	
Fairbanks Urology	1211 Cushman St, Fairbanks, AK	

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
D3007	FACILITIES CFR(s): 493.1101(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs. This STANDARD is not met as evidenced by: Based on surveyor observation, procedure and reference review, and interview with the Technical Supervisor, the laboratory failed to have an appropriate centrifuge for centrifuging urine samples from the time the urine sedimentation test was initiated on 10/14/2021. Findings include: 1. The laboratory has a single speed LabCorp Horizon Centrifuge, serial number 160613B1790, designed for centrifuging blood samples, last pm on 9/12/2020 determined the set speed of the centrifuge was 3290 rpm. 2. The laboratory's reference for processing urine sediment "A Handbook of Routine Urinalysis" by Sister Laurine Graff states on page 72 to centrifuge urine for 2000 rpm for 5 minutes. 3. The laboratory performs approximately 40 urine sediments per month. 4. The technical supervisor confirmed these findings on 12/2/21 at 2 pm.
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 interview with the Technical Supervisor, and review of the laboratory's 'Microscopic Urinalysis Examination" procedure effective 10/14/2021, the laboratory failed to include the centrifugation rate (revolutions per minute, RPM) in the procedure. Findings include: 1. In the laboratory's procedure entitled "Microscopic Urinalysis Examination", effective date 10/14/2021, there was no written acceptable RPM for centrifuging the urine. 2. The laboratory performs approximately 40 urine sediments per month. 3. The technical supervisor confirmed these findings on 12/2/21 at 2 pm.