Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D2144657	(X3) Date Survey Completed 12/08/2025
Name of Provider or Supplier Fairbanks Urology	**Street Address, City, State** 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
D0000	The Fairbanks Urology laboratory was found to be in compliance with 42 CFR Part 493, Requirements for Laboratories as a result of a focused complaint survey on 12/08/2025. No deficiencies related to the focused complaint survey were found however; a full recertification survey was performed and the following deficiencies were found.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of the manufacturer's package inserts, patient test reports, and an interview with the laboratory supervisor (LS), the laboratory failed to follow the manufacturer's instructions for reporting the Total Prostate Specific Antigen (PSA) using the Tosoh since April 2025. The findings include: 1. The Tosoh ST AIA-PACK PA package insert for PSA states: 'It is mandatory that results reported by the laboratory to the physician include the identity of the assay used.' 2. A review of eight (8) patient reports on 12/8/25 at 2:20 PM revealed: a. Two (2) of two (2) patient test results (account numbers 13915 and 45873) that were reported after testing resumed did not include the identity of the Tosoh PA assay for PSA. b. Six (6) of six (6) patient test results (account numbers 15389 and 36413) that were reported prior to testing being temporarily halted revealed the patient test results did include the identity of the Tosoh PA assay for PSA. 3. The LS confirmed these findings in an

	interview at 2:20 PM on 12/8/2025. 4. The laboratory reports performing 1500 PSA tests annually.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) (b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; This STANDARD is not met as evidenced by: Based on review of competency assessments and a phone interview with the technical consultant (TC), the technical consultant failed to complete direct observations of patient testing for three (3) of three (3) competency assessments. The findings include: 1. Review of Tosoh AIA-900, DxH 520, and urinalysis competency assessments and supporting documentation for testing personnel one (TP1) revealed the procedure of direct observation was completed by performing a record review of results, controls, and calibrators. 2. A phone interview with TC on 12/8/25 at 3:00 PM confirmed that TC was not on-site to perform competency assessment. 3. The laboratory reports performing 20320 tests annually.
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv) (b)(8)(iv) Direct observation of performance of instrument maintenance and function checks; This STANDARD is not met as evidenced by: Based on review of competency assessments and a phone interview with the technical consultant (TC), the technical consultant failed to complete direct observations of instrument maintenance for three (3) of three (3) competency assessments. The findings include: 1. Review of Tosoh AIA-900, DxH 520, and urinalysis competency assessments and supporting documentation for testing personnel one (TP1) revealed the procedure of direct observation was completed by performing a record review of maintenance logs. 2. A phone interview with TC on 12/8/25 at 3:00 PM confirmed that TC was not on-site to perform competency assessment. 3. The laboratory reports performing 20320 tests annually.