Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	02D2144657	06/23/2023
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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of patient test results and an interview with the laboratory director, the laboratory failed to follow the manufacturer's instructions for reporting prostate specific antigens (PSA) using the Tosoh AIA-900 analyzer and AIA PSA test kits. Findings include: 1. The manufacturer's instruction for reporting PSA state "It is mandatory that results reported by the laboratory to the physician include the identity of the assay used." 2. A review of patient test reports for PSA revealed the reports lacked the identity of the assay used. 3. An interview conducted on June 23, 2023 at approximately 12:00 PM, the laboratory director confirmed the test reports were missing the required statement. 4. The laboratory reports performing approximately 1230 PSA tests annually.