Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	02D0674496	06/29/2022
Name of Provider or Supplier	**Street Address, City, State**	
Alaska State Public Health Laboratory	5455 Dr Martin Luther King Jr Ave, Anchorage, 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
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 a review of Chemistry policies, patient reports, a lack of documentation and an interview with the Chemistry technical supervisor (TS#2) it was determined that the laboratory failed to follow its own policy for documenting notification of results when lethal levels of alcohols are present in clinical samples. Additionally, the policy does not state how reports on serial samples for the same patient should be documented. Findings: 1. A request was made to review documentation of results notification when lethal levels of toxic alcohols were present in clinical samples and documentation could not be provided. 2. An interview conducted on June 29, 2022 at

	approximately 2:40 PM with TS#2, confirmed that the laboratory did not have written documentation or any evidence of oral reporting. 3. The procedural manual did not address the process for reporting oral or written results on patients with multiple laboratory encounters to ensure that the name, date, time and identification of specimen is conveyed to the authorized person or how it is documented. 4. The laboratory reports performing approximately 2,026 patient samples in Chemistry annually.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a surveyor's review of the patient test reports and an interview with the technical supervisor (TS#5), the laboratory failed to include pertinent reference intervals, normal or expected values on the final test reports. Findings: 1. A review of final test reports for the following tests revealed that no normal or expected values were available on the final test reports for: a. RPR b. Chlamydia trachomatis c. Neisseria gonorrhoeae d. Trichomonas vaginalis 2. An interview conducted on June 29, 2022 at approximately 11:30 AM with TS #5, confirmed that the final reports for all analytes do not include reference intervals, normal or expected values. 3. The laboratory reports performing approximately 164,275 patient samples in Bacteriology and 6470 samples in Syphilis Serology annually.