Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	02D1031794	12/06/2022
Name of Provider or Supplier	**Street Address, City, State**	
Alaska Regional Hospital Poc Testing	2801 Debarr Road, 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 surveyor review of policies and interview with technical consultant #1 (TC #1) the laboratory did not have a policy for critical result notification and documentation including the date, time, results, and to whom the critical test results were reported. Findings include: 1. A request was made to review the policy for critical result notification and documentation and the laboratory was unable to provide a policy or procedure. 2. An interview conducted on December 6, 2022 at approximately 3:30 PM with TC #1, confirmed the laboratory did not have a policy or procedure for critical value notification and documentation. 3. The total estimated

	annual test volume from the laboratory's CMS-116 is 20,608 chemistry tests and 3,190 hematology tests.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review and interview with the technical consultant 1 (TC #1), the laboratory failed to perform calibration verifications at least once every 6 months for pH, pCO2, pO2, glucose, sodium, potassium, ionized calcium, hemoglobin and hematocrit using the Abbott i-STAT CG8+ cartridges and pH, pCO2, pO2, glucose, sodium, potassium, ionized calcium, chloride, lactate, creatinine, blood urea nitrogen (BUN), hemoglobin, and hematocrit using Siemens EPOC 757 analyzers for 2021 and 2022. Findings include: 1. A request was made to review calibration verification documentation for the Abbott i-STAT CG8+ cartridges and the Siemens EPOC 757 analyzers and the laboratory was unable to provide documentation that it had been performed at least once every 6 months in 2021 and 2022. 2. An interview conducted on December 6, 2022 at approximately 3:30 PM with TC #1, confirmed the laboratory did not perform calibration verifications at least once every 6 months for this time frame. 3. The laboratory estimated an annual test volume of 12,600 tests performed on these analyzers.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the

	methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of quality control records and an interview with technical consultant #1 (TC #1), the laboratory failed to use statistical parameters to evaluate control results to detect shifts or trends over time in control values for the Abbott i-STAT and Siemens EPOC analyzers. Findings include: 1. The quality control records from 2022 for the i-STAT and EPOC analyzers did not include a statistical or graphical review of the control data. 2. An interview conducted on December 6, 2022 at approximately 3:30 PM with TC #1, confirmed the laboratory did not monitor the controls for shifts or trends. 3. The laboratory estimated an annual test volume of 12,600 tests performed on these analyzers.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on record review and interview with the technical consultant 1 (TC #1), the laboratory failed to perform method comparisons on pH, pCO2, pO2, glucose, sodium, potassium, ionized calcium, chloride, lactate, creatinine, blood urea nitrogen (BUN), hemoglobin, and hematocrit twice annually using the Abbott i-STAT CG8+ cartridges, the Siemens EPOC 757 and the Radiometer ABL 90 analyzers in 2021 and 2022. Findings include: 1. A request was made to review method comparison documentation for analytes run on the Abbott i-STAT CG8+ cartridges, the Siemens EPOC 757 analyzers, and the Radiometer ABL 90 analyzers; the laboratory was unable to provide documentation that it had been performed twice annually in 2021 and 2022. 2. An interview conducted on December 6, 2022 at approximately 3:30 PM with TC #1, confirmed the laboratory did not perform method comparisons twice annually in this time frame. 3. The total estimated annual test volume from the laboratory's CMS-116 is 20,608 chemistry tests and 3,190 hematology tests.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview with technical consultant #1 (TC #1), the laboratory director did not ensure existing policies and procedures are complete and current by reviewing, approving, and signing them prior to the survey on 12/6/2022. Findings include: 1. The surveyor requested documentation showing the current laboratory director had reviewed and approved laboratory policies and procedures, and the laboratory was unable to provide such documentation. 2. An interview conducted on December 6, 2022 at approximately 3: 30 PM with TC #1, confirmed the laboratory director had not reviewed or approved the policies or procedures from the date of hire on 4/4/2022 up to the survey on 12/6 /2022. 3. The total estimated annual test volume from the laboratory's CMS-116 is 20,608 chemistry tests and 3,190 hematology tests.