

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D2007735	(X3) Date Survey Completed 09/03/2026
Name of Provider or Supplier Medical Network Of Alaska	Street Address, City, State 3066 E Meridian Park Loop, Wasilla, 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) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 procedure review, interview with testing personnel (TP1), and interview with the Lab Director (LD), the laboratory failed to include all the applicable requirements in two (2) of seven (7) procedures since August 2024. The findings include: 1. Review of the procedure Wet Prep / KOH (Wet Mount) revealed no information for the reportable range, limitations and interfering substances, reference intervals, or entering results in the patient record. 2. Review of the procedure Reichert Unistat Bilirubinometer revealed no information for the reportable range, reference

	intervals, or entering results in the patient record. 3. In an interview on 9/3/2026 at 12:45 PM, TP1 described the process for manually documenting qualitative and semiquantitative results for KOH on a worksheet and then in the laboratory information system which is not in the procedure. 4. An interview with the LD on 9/3/26 at 1:00 PM confirmed the findings. 5. The laboratory reports performing 279 Wet mount / KOH and neonatal bilirubin tests annually.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation and an interview with the Lab Director (LD), the laboratory failed to label fourteen (14) of fourteen (14) open BioRad quality control (QC) vials with the expiration date. The QC vials are used for performing quality control for tests performed on the Beckman Coulter AU480 and Beckman Coulter Access. The findings include: 1. During a laboratory tour on 9/3/2026 at 10:30 AM, the surveyor observed open QC vials in the refrigerator labeled with the open date but no expiration date. The open vials are used to perform quality control checks for thirty-seven (37) assays in the specialty of Chemistry. 2. An interview with the LD on 9/3/2026 at 10:30 AM confirmed that the open vials are not labeled with the expiration date because new QC vials are opened each week with the exception of one set (two vials), which are opened every other week. 3. The laboratory reports performing 230,255 chemistry tests annually.