

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D2201556	(X3) Date Survey Completed 04/25/2023
Name of Provider or Supplier Medical Network Of Alaska	Street Address, City, State 501 1st Street, Prudhoe Bay, 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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of documentation and an interview with the Technical Consultant (TC), the laboratory failed to verify the accuracy, precision, reportable range, and reference range for the Sysmex Poch-100i Hematology analyzer prior to reporting patient Complete Blood Count (CBC) test results beginning August 2022. Findings include: 1. A request was made to review verification records for the Sysmex Poch-100i and documentation could not be provided. 2. An interview with the Technical Consultant on 4/25/23 at 10:00 AM, confirmed the laboratory did not have documentation or evidence of accuracy, precision, reportable range, or reference range verification. 3. The laboratory reports performing seventy (70) CBCs annually.</p>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number</p>

and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of patient results, quality control (QC) logs, and an interview with the Technical Consultant (TC), the laboratory failed to perform QC each day patients were tested for seventeen (17) of the twenty-four (24) patients who had a Complete Blood Count (CBC) from August 2022 through April 2023. Findings include: 1. A review of the patient results and quality control logs indicated the laboratory performed CBC patient testing on 17 days in August 2022 through April 2023 and did not perform QC. 2. During an interview at approximately 10:00 AM on 10/24/2023, the technical consultant confirmed the laboratory did not perform CBC QC each day of patient testing. 3. The laboratory reports performing seventy (70) CBCs annually.