Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 02D2092701	**(X3) Date Survey Completed** 08/28/2025
Name of Provider or Supplier Medical Network Of Alaska	**Street Address, City, State** 3765 E Blue Lupine Drive, 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**
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based a review of temperature/humidity records, manufacturer instructions, and an interview with the Technical Consultant (TC), the laboratory failed to define criteria for room temperature and humidity consistent with the manufacturer's operating instructions for the Sysmex pocH-100i from January 2024 through July 2025. The findings include: 1. A review of temperature/humidity logs for May, June, and October 2024 and July 2025 showed the acceptable room temperature range for Sysmex pocH-1001 operation of 31-95 F, and the remaining months revealed an acceptable range of 61-95 F, misssing were logs for November, December 2024 and January and February 2025. 2. Review of temperature/humidity logs listed the acceptable humidity range as 20-80%, missing were logs for November, December 2024 and January and February 2025. 3. A review of the Sysmex pocH-100i manufacturer operating instructions showed that acceptable temperature range is 59-86 F and humidity range is 30-85%. 4. An on-site interview with the TC 8/28/25 at 12:00 PM confirmed that ranges on the temperature log were inconsistent and did not match the manufacturer operating ranges. 5. The laboratory reports performing 1100 Complete Blood Counts (CBCs) on the Sysmex pocH-100i annually.

D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on surveyor observation, record review, and interview with the Technical Consultant (TC), the laboratory failed to perform and document function checks to ensure three (3) of three (3) thermometers (refrigerator, freezer, and room temperature) where reagents and patient specimens are stored for the Complete Blood Count (CBC) on the Sysmex pocH-100i. Findings include: 1. Observation on 8/28/25 at 11:00 AM showed the refrigerator and freezer thermometers had a sticker that says 'QC passed 06' but no date of certification, in-use date, or expiration date. 2. Observation on 8/28/25 at 11:00 AM showed the room temperature thermometer had no date of certification, in-use date, or expiration date. 3. A request was made to review the documentation for verification of temperature checks or the process in place to verify the accuracy of thermometer readings, and none could be provided. 4. An on-site interview with TC 8/28/25 at 12:00 PM confirmed thermometer function checks were not documented. 5. The laboratory reports performing 1100 Complete Blood Counts (CBCs) on the Sysmex pocH-100i annually.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of temperature records and an interview with the Technical Consultant (TC), the laboratory failed to document corrective actions when the refrigerator temperature where Sysmex pocH-100i reagents are stored, was outside the manufacturer's acceptable range for 42 of 418 days in 2024 and 2025. Findings include: 1. A review of temperature logs showed refrigerator temperatures were out of range for 42 out of 418 days with no documentation of corrective actions. November and December 2024 and January and February 2025 logsheets were missing. 2. An on-site interview with TC 8/28/25 at 12:00 PM confirmed that corrective actions were not documented. 3.The laboratory reports performing 1100 Complete Blood Counts (CBCs) on the Sysmex pocH-100i annually.