

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D2132441	(X3) Date Survey Completed 04/18/2018
Name of Provider or Supplier Medical Network Of Alaska	Street Address, City, State 1100 E Dimond Blvd Suite 103, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: D5413 Based on record review and technical consultant interview, the laboratory was missing temperature and humidity logs, and did not follow the manufacturer's requirement for room humidity. 1. The laboratory opened on October 15, 2017. There were no temperature or humidity logs for October, November, and December 2017. 2. The lab is using the Sysmex Poch-100i for Complete Blood Counts (CBC) and stores the reagents at room temperature and in the refrigerator. 3. The operating instructions for the Poch-100i state the humidity range should be between 30 and 85%; the humidity logs from January to April 2018 indicate the room humidity was between 10-11%. 4. The laboratory performs approximately 300 CBCs annually.</p>