

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D0671921	(X3) Date Survey Completed 12/17/2025
Name of Provider or Supplier Kuparuk Medical Clinic	Street Address, City, State Koc Spine Road, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of documentation and an interview with Testing Person 1 (TP1), the laboratory failed to monitor and document the room temperature and humidity in the room where hematology testing using the Sysmex Poch-100i CBC analyzer was performed. Findings include: 1. A request was made to review the room temperature and humidity in the laboratory, and documentation could not be provided. 2. An on-site interview with the TP1 on 12/17/2025 at 14:00 PM confirmed that room temperature and humidity levels were not documented. 3.The laboratory reports performing approximately 1,800 hematology tests annually.</p>