

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D0640332	(X3) Date Survey Completed 08/14/2025
Name of Provider or Supplier Anchorage Neighborhood Health Center	Street Address, City, State 4951 Business Park Blvd, 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>(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 review patient test reports, the manufacturer's package inserts, and an interview with the laboratory director, the laboratory failed to follow the manufacturer's instructions for reporting test methodology for Total Prostate Specific Antigen (PSA) using the Beckman Coulter Access 2 since implementation of the new laboratory information system (LIS) in May 2025. Findings include: 1. A review of results on patient #839842 revealed the report did not include the identity of the Beckman Coulter Access 2 Assay as required in the manufacturer's instructions. 2. A review of the package insert for the Beckman Coulter Access 2 PSA states: 'The results reported by the laboratory to the physician must include the identity of the PSA assay used.' 3. The technical consultant confirmed these findings in an interview at 2:30 PM on 8/14/2025. 4. The laboratory reports performing 1000 PSA tests annually."</p>