

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2053686	(X3) Date Survey Completed 05/16/2024
Name of Provider or Supplier Apheresis Associates Of Nova	Street Address, City, State 3289 Woodburn Road - Suite 220, Annandale, VA	
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
D0000	An announced CLIA validation survey was conducted at Apheresis Associates of NOVA on May 16, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiency cited is as follows:
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, temperature records, and interviews, the laboratory failed to follow their established environmental monitoring policy for the daily monitoring of refrigerator temperatures for seventy-six (76) of eight-five (85) days from September 2023 until December 2023. The findings include: 1. Review of the laboratory's policies and procedures revealed a policy, "Facility, Equipment Maintenance and Monitoring SOP # APH-050" with the statement, "Each time a temperature is taken for environmental monitoring, the current temperature is recorded in the first space, followed by the high and low temperatures displayed for the period since last clearing the high low reading function. After recording this data, the clear button must be pressed. The high low reading will display the same as the current temperature display to indicate reset." 2. Review of the laboratory's "Refrigerator #1 Temperature Probe Record" from September 2023 until December 2023 revealed a high low temperature reading of "2.0-8.0" recorded in the "Range" column for 76 of 85 days. On May 16, 2024, at approximately 10:30 AM, the surveyor inquired with the Risk Assessment/Quality Assurance (RA/QA) Officer concerning the refrigerator high low temperature</p>

consistently recorded as "2.0-8.0". The RA/QA Officer stated the staff forgot to clear the "high low" temperature each day and recorded the "acceptable range of "2.0-8.0" instead. 3. In an exit interview with the RA/QA Officer on May 16, 2024 at approximately 12:00 PM, the findings were confirmed.