

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2153972	(X3) Date Survey Completed 03/10/2026
Name of Provider or Supplier The Blood Connection	Street Address, City, State 2709 Blue Ridge Road, Raleigh, NC	
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	A validation survey was conducted March 10, 2026, with standard level deficiencies cited.
D2005	<p>ENROLLMENT CFR(s): 493.801(a)(4)</p> <p>(a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) 0155 report, laboratory proficiency testing (PT) records and confirmed in an interview with Vice President of Quality Systems, the laboratory failed to authorize the proficiency testing program to release required PT scores to the Centers for Medicare and Medicaid for 3 of 3 testing events in 2025. Findings: 1. Review of the CASPER 0155 report revealed proficiency testing scores for the regulated analytes ABORh, antibody detection, antibody identification, and compatibility testing were not provided to CMS for 2025. 2. Review of College of American Pathologists (CAP) proficiency testing events J-A, J-B, and J-C Transfusion Medicine 2025 revealed the laboratory performed and submitted PT for ABORh, antibody detection, antibody identification, and compatibility testing. Further review of the PT records revealed no CLIA certificate number associated with the events. 3. In an interview on March 10, 2026, at 11:15 am, the Vice President of Quality Systems confirmed the findings.</p>
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</p>

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:

I. Based on observation, review of manufacturer's instructions, laboratory environmental records, and confirmed in an interview with Vice President of Quality Systems, the laboratory failed to ensure manufacturer's specifications for 33 of 33 refrigerated reagents. Findings: 1. During a tour of the testing area on March 10, 2026, at 10:15 am, thirty-three vials of immunohematology reagents were observed stored in "Refrigerator 17". A random sampling of these vials included: a. Two vials of ALBAclone Anti-M; Lot number V285406; Expiration date 09/04/2027 b. Six vials of ALBAclone Anti-JKb; Lot number V278798; Expiration date 02/06/2027 c. Two vials of ALBAclone Anti-N; Lot number V275819; Expiration date 06/10/2027 2. On the label of each vial, the manufacturer specified a storage temperature of 2C-8C. 3. Review of the laboratory's environmental records for Refrigerator 17 revealed an acceptable temperature range of 1.50C - 5.50C. This acceptable range exceeded the manufacturer's specified lower limit of 2C. 4. In an interview on March 10, 2026, at 10:29 am, the Vice President of Quality Systems confirmed the findings. II. Based on observation, review of manufacturer's instructions, laboratory environmental records, and confirmed in an interview with the General Supervisor, the laboratory failed to ensure manufacturer's room temperature and relative humidity specifications for 68 of 68 days. Findings: 1. During a tour of the reference laboratory testing area on March 10, 2026, at 10:15 am, a Helmer Scientific Automatic Cell Washer (Serial Number 0000356) was observed in use by the laboratory. Also observed were 2 boxes of Ortho Anti-Human Globulin IgG gel cards (Lot number 011226001-01; Expiration date 10/22/2026; 100 gel cards per box). 2. The operator's manual (360386/D) for the Helmer Scientific Automatic Cell Washer stated " ...6.1 Operating Standards ...Ambient Temperature Range: 5C to 40C Relative Humidity ...80% for temperatures up to 31C ..." The manufacturer's instructions for Ortho Anti-Human Globulin IgG gel cards (J32848 Version 8.0) stated " ...Storage Requirements Store cards upright at 2C - 25C." 3. The laboratory was asked to provide environmental records of documented room temperature and relative humidity monitoring in the reference laboratory testing area from January to present date 2026. No documentation was provided. 4. In an interview on March 10, 2026, at 11:14 am, the General Supervisor confirmed the laboratory did not document room temperature or relative humidity in the testing area.