

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0125771	(X3) Date Survey Completed 09/02/2026
Name of Provider or Supplier Rwjuh Blood Services	Street Address, City, State Clinical Academic Bldg Attn Kathryn Owens, New Brunswick, NJ	
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 on-site validation survey was completed on September 02, 2026 with the following standard level deficiencies cited.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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. This STANDARD is not met as evidenced by: Based on direct observation, review of the laboratory's written policies, temperature /humidity records, manufacturer's instructions, and interview with the Quality Assurance (QA) director, the laboratory failed to monitor and document humidity in the laboratory room where the Biomerieux BacT/Alert 3D system was in use for 2 of 2 years (2025 and 2026). Findings Included: 1) During a laboratory tour on 9/2/2026 at 11:37 AM, one Biomerieux BacT/Alert 3D testing system (Serial Number 311CL2129) was observed in use in the testing room. 2) Review of the laboratory's written policy titled 'RWJ Barnabas Health Thermometer and Temperature Annual Calibration' stated the following on page 3 of 5: "3.0 Daily Temperature of Storage Areas with Min/Max Thermometer 3.1 For designated storage areas within the RJWBLDS daily temperature and humidity readings will be taken using the MIN /MAX Thermometers ... 3.2.2 Actual Humidity will be recorded where Optia and Trima kits are stored and CTP collections take place. Notify supervisor if Humidity is

out of range." 3) Review of the laboratory's temperature/humidity records for 2025 and 2026 revealed no humidity monitoring and documentation in the testing room where the Biomerieux BacT/Alert 3D testing system was in use. 4) Review of the manufacturer's instructions titled 'BacT/Alert 3D User Manual' revealed the following on page 3 of 9: "Controller Module Environmental Requirements Operating Humidity Range - 10 to 90% relative humidity, non-condensing." 5) In an interview on 9/2/2026 at 11:38 AM, the QA director of the laboratory confirmed the testing room did not have humidity monitored and documented.