

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2186646	(X3) Date Survey Completed 09/10/2024
Name of Provider or Supplier New Jersey Cancer And Blood Specialists	Street Address, City, State 201 Route 17 N, Rutherford, 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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (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 surveyor review of the Users Manual (UM) for the Olympus BX45, BX41 microscope and the Leica DM2500 LED Opitcal Microscope, the lack of temperature and humidity logs and interview with the General Supervisor (GS) the laboratory failed to monitor and document room temperature and humidity where the Professional Component (PC) for Histopathology and Cytology tests were performed from 7/6/22 to 9/10/24. The findings include: 1. The UM for the Leica DM2500 LED optical microscope defined the operating environment ambient temperature and humidity as 15 to 35C and a maximum humidity of 80% 2. The UM for the Olympus BX45 and BX41 microscopes defined the operating environment ambient temperature and humidity as 5 to 40C and a maximum humidity of 80% 3. There was no record of temperature or humidity in the two rooms where the PC was being performed. 4. The GS confirmed on 9/10/24 at 10:35 am the laboratory failed to monitor and document room temperature and humidity where the PC was being performed.</p>