Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2155829	(X3) Date Survey Completed 08/01/2023
Name of Provider or Supplier Vanguard Medical, Pa	**Street Address, City, State** 16 Pocono Road, Suite 310, Denville, 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	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (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. This STANDARD is not met as evidenced by: Based on the lack of Temperature Logs (TL), review of the Operators Manual (OM) for the Olympus CX22 microscope and interview with the Office Supervisor (OS), the laboratory failed to monitor and document room temperature and humidity range where the Professional component (PC) for Histopathology tests are performed from 1 /19/22 to the date of the survey. The finding include: 1. The OM defined the operating environment ambient temperature for the aforementioned equipment 5 to 40C (41 to 104 F). 2. The OM defined the operating environment maximum relative humidity for the aforementioned equipment 80% for temperatures up to 31C (88F). 3. There was no TL in the office where PC was being performed. 4. The OS confirmed on 8/1/23 at 1:35 pm the laboratory failed to monitor and document room temperature and humidity.