

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0139635	(X3) Date Survey Completed 06/23/2023
Name of Provider or Supplier Westchester Medical Group Pllc	Street Address, City, State 3030 Westchester Avenue, Purchase, NY	
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 lack of temperature and humidity documentation, review of the Cepheid GeneXpert Xpress operations manual, and an interview with testing personnel, the laboratory failed to monitor and document room temperature and humidity. FINDINGS: 1. Cepheid GeneXpert Xpress analyzer required temperature range of 15-30C (59-86F) and humidity range of 20-80%. 2. Cepheid GeneXpert Xpress testing cartridges required storage temperature range of 2-28C (35.6-82.4F). 3. Room temperature and relative humidity were not documented from calendar year 2022 through the survey date. 4. Findings were confirmed by interview with testing personnel on June 23, 2023, at approximately 12:15 P.M.</p>