

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0870786	(X3) Date Survey Completed 06/26/2025
Name of Provider or Supplier Jay B Herman Md Lab	Street Address, City, State 532 South Aiken Avenue Suite 210, Pittsburgh, PA	
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>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory temperature records, lack of documentation and interview with the Laboratory Director (LD), the laboratory failed to monitor and document room temperature and humidity to ensure proper test system operating conditions were met for 1 of 1 Qualigen FastPack IP System used to perform routine chemistry testing from 07/13/2023 to 06/26/2025. Findings include: 1. On the day of survey, 06/26/2025 at 9:10 am, the laboratory failed to provide documentation for monitoring room temperature and humidity to ensure operating conditions were met for 1 of 1 Qualigen FastPack IP System (acceptable room temperature range: 15 to 32 degrees Celsius, humidity range: 10% to 90%) used to perform routine chemistry testing from 07/13/2023 to 06/26/2025. 2. The laboratory performed 491 routine chemistry tests in 2024 (CMS-116 estimated annual volume). 3. The LD confirmed the above findings on 06/26/25 at 9:46 am.</p>