

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0942535	(X3) Date Survey Completed 11/21/2025
Name of Provider or Supplier Chester County Rheumatology Pc	Street Address, City, State 795 E Marshall Street Ste 101, West Chester, 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 records, lack of documentation, and interview with the Billing Manager, the laboratory failed to monitor and document room temperature and humidity for 518 of 724 days to ensure reliable test system operation and test result reporting for instrumentation used to perform microscopic slide examinations of synovial fluid crystals from 11/28/2023 to the date of survey. Findings include: 1. The operating conditions listed in the instruction manual for the Nikon Eclipse 50i microscope stated: "temperature: 0 C to 40C, humidity: 85% RH max." 2. On the date of the survey, 11/21/2025 at 10:23 am, the laboratory could not provide documentation for monitoring room temperature and humidity to ensure operating conditions were met for 1 of 1 Nikon Eclipse 50i microscope (s/n 112824) used to perform microscopic slide examinations of synovial fluid crystals for 518 of 724 days from 11/28/2023 to 11/21/2025. 3. Review of the laboratory's test logs revealed the laboratory performed 45 synovial fluid crystal microscopic slide examinations from 11/28/2023 to 11/21/2025. 4. The Billing Manager confirmed the findings above on 11/21/2025 at 11:00 am.</p>