

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0931536	(X3) Date Survey Completed 04/10/2025
Name of Provider or Supplier Pediatric And Neonatal Specialists	Street Address, City, State 6500 Preston Hwy, Louisville, KY	
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
D0000	A recertification survey was conducted on 04/10/2025. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
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 direct observation, review of the Sysmex XN-L Series manufacturer's instructions, laboratory environmental records, and confirmed in staff interview, the laboratory failed to ensure relative humidity was monitored daily for 3 of 3 months (04 /2024, 07/2024, 12/2024). Findings include: During a tour of the laboratory area on 04 /10/2025 at 11:10 AM, a Sysmex XN 300 (Serial Number 11800) was observed. Review of the Sysmex XN-L Series Installation Site Requirements (Document No. 1352-MKT, Rev. 3 October 2017) revealed a relative humidity requirement of 20 % to 85%. A random review of the laboratory's environmental records (April 2024, July 2024, December 2024) revealed the laboratory failed to monitor relative humidity in the laboratory area for the following dates: April 2024 - 12,15,16,17,18,19,30 July 2024 - 22,23,24,25,26,29,30 December 2024 - 2,3,4,5,6,7,8,9,10,11,12,13,16,17,18,19,20,23,24,26,27,30,31 In an interview on 04/10 /2025 at 12:45 PM in the conference room, Testing Personnel #1 and Testing</p>

Personnel #4 confirmed that the relative humidity was not monitored for the days in question. This confirmed the findings.