

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2095211	(X3) Date Survey Completed 06/23/2025
Name of Provider or Supplier Oakleaf Clinics Menomonie	Street Address, City, State 2919 Stout Road, Menomonie, WI	
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
D6010	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(2)</p> <p>(e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of temperature logs, interview with the Laboratory Director, and evidence provided in the laboratory's plan of correction received in response to the survey completed on May 14, 2025 (Event 4FL5 11), the laboratory director did not ensure the environmental conditions of the laboratory were appropriate for the testing performed on the Sysmex hematology analyzer when humidity readings were below the manufacturer defined acceptable range of 20 - 85% for 65 of 90 days from January through March 2025. Findings include: 1. Review of temperature logs from January through March 2025 showed the acceptable room humidity level was 20 - 85%. Further review showed testing personnel recorded the humidity as 19%, which is below the acceptable range, on 65 of 90 days. Month / total recorded days / days with unacceptable humidity January / 31 / 31 February / 28 / 23 March / 31 / 11 2. Interview with the Laboratory Director on May 14, 2025, at 11:45 AM confirmed the laboratory defined range for humidity was determined using the manufacturer's specification for operation for the Sysmex XP300 hematology analyzer. 3. The evidence received on June 5, 2025, for the plan of correction signed by the laboratory director on June 5, 2025, did not show the laboratory director had performed an internal study with accompanying data to establish a range (suitable for their laboratory) that showed the instrument can operate outside of specified environmental requirements, or that the laboratory explored the use of other means to ensure the laboratory operated within the manufacturer's environmental specifications.</p>