

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0665264	(X3) Date Survey Completed 11/04/2025
Name of Provider or Supplier A2c1 Aurora Health Center - Edgerton	Street Address, City, State 6901 W Edgerton Ave, Milwaukee, 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
D6005	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c)</p> <p>(c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with a technical consultant (Staff A), the laboratory director did not meet the requirement of conducting and documenting an onsite visit at least once every six months, with at least four months between onsite visits, for one of two required visits in 2025. Findings include: 1. Review of laboratory records revealed that the laboratory director conducted and documented an onsite visit using the "Medical Director Onsite Visit Documentation" form on December 11, 2024, and on October 16, 2025. 2. During an interview on November 4, 2025, at 2:35 PM, Staff A stated the laboratory director missed the scheduled visit in May 2025, and confirmed that the laboratory director did not meet the requirement of conducting and documenting an onsite visit in the first six months of 2025.</p>
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>

This STANDARD is not met as evidenced by:

Based on surveyor review of documented humidity readings in the laboratory and interview with a technical consultant (Staff A), the laboratory director did not ensure the laboratory could meet its established humidity range in January and February 2025, two of two winter months reviewed. Findings include: 1. Review of the "Temperature Recording Log" indicated the laboratory's humidity range was 30% to 85%. Review of the "Temperature Recording Log" records from January and February 2025 showed the laboratory documented daily humidity readings. Testing personnel documented readings that were less than 30% every day in January and February 2025. 3. Interview with Staff A on November 4, 2025, at 3:45 PM confirmed the laboratory's humidity range was 30% to 85%, that the daily humidity readings were less than 30% during the two months reviewed, and that the laboratory director did not ensure the laboratory could meet its humidity range in January and February 2025.