

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0391644	<b>(X3) Date Survey Completed</b>  06/19/2025
<b>Name of Provider or Supplier</b>  A2c1 Aurora Health Center - Mayfair North	<b>Street Address, City, State</b>  3289 N Mayfair Road, Wauwatosa, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D6010</b>	<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 laboratory records and evidence provided in the laboratory's plan of correction received in response to the survey completed on May 20, 2025 (Event U7NN), the laboratory director did not ensure the environmental conditions of the laboratory were appropriate for the operation of the Sysmex XN-550 hematology analyzer or Sysmex CA-600 Series coagulation analyzer during four of four months, January through April 2025. Findings include: 1. Review of the laboratory 'Room Temperature and Humidity Monitoring' records from January through April 2025 showed the laboratory documented relative humidity readings once each day. The records showed the acceptable humidity range was 20 - 80%. The humidity records for the four months showed: Month / Number of recordings / Number of recordings less than 20%: January / 31 / 29 February / 28 / 19 March / 31 / 9 April / 30 / 2 2. The laboratory provided two letters as evidence for their plan of correction. a. The first letter, from Sysmex, dated May 21, 2025, identified a 20 - 85% humidity range for operation of the analyzer. The letter stated the specifications provided are the ranges the company determined they can ensure reliable performance of the analyzer and stated, "the final decision to operate the analyzer outside the established ranges stated in our IFU/Operator's Manual would have to be made by you, the end user laboratory. Your own validation may be used to demonstrate the analyzer's capability of generating consistent and reliable results within your laboratory's environment." b. The second letter, from Siemens Healthineers, dated January 2020, referenced the Sysmex CA-600 series coagulation analyzers and stated, "It is up to the user to decide whether to operate our analyzer outside the environmental conditions stated in its documentation. The user should validate the</p>

analyzer's performance if operating outside these environment conditions, as required by local regulatory agency guidelines." 3. The evidence received on June 5, 2025, for the plan of correction signed by the laboratory director on June 3, 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.