

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D2163824	<b>(X3) Date Survey Completed</b>  11/18/2025
<b>Name of Provider or Supplier</b>  Ascension Medical Group-Fox Valley Wisconsin, Inc	<b>Street Address, City, State</b>  5045 W Grande Market Drive, Appleton, 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>D2006</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>(b)The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records generated for submission to the Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) program, patient records, and interview with the technical consultant (Staff A), the laboratory did not perform testing on PT samples for electrolyte tests in the same manner as it tests patient samples for one of two general chemistry events completed to date in 2025. Findings include: 1. Review of laboratory records generated for general chemistry PT event two of 2025, revealed the laboratory performed electrolyte (lytes) testing, including Sodium (Na) and Chloride (Cl) tests, on the PT samples on July 3, 2025, and repeated the tests on July 8, 2025 based on humidity and quality control (QC) concerns. Notes in the records for the runs on July 3, 2025, state, "Humidity issues today. Na and Cl QC is in, but not great. May pull sample and re-run lytes on a day with less humidity." Notes in the records for the runs on July 8, 2025, state, "Better humidity, better QC than 7-3-25." The laboratory reported the electrolyte results from July 8, 2025, to the WSLH PT program. 2. Review of laboratory patient records revealed 43 patient samples had electrolyte testing performed and resulted between July 3 and July 7, 2025. 3. Interview with Staff A on November 18, 2025, at</p>

12:45 PM confirmed the laboratory repeated PT sample testing for electrolytes after the laboratory humidity improved and submitted the repeated results to the PT program, but continued to perform and report electrolytes for patients during the same period of time, confirming the laboratory did not test PT samples in the same manner as it tests patient samples.

**D6005**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(c)

(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.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory records and interview with the technical consultant (Staff A), the laboratory director did not meet the requirement for conducting and documenting on-site visits to the laboratory once every six months, with at least four months between, for two of two required visits in 2025. Findings include: 1. Review of laboratory records revealed that as of November 18, 2025, there was no evidence the laboratory director conducted any on-site visits in 2025. 2. Interview with Staff A on November 18, 2025, at 1:30 PM confirmed that the laboratory director had not yet conducted the two required on-site visits in 2025.

**D6010**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(2)

(e)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and

This STANDARD is not met as evidenced by:

Based on surveyor review of documented humidity readings in the laboratory and interview with the technical consultant (Staff A), the laboratory director did not ensure the laboratory could meet its established humidity range for all working days of January, February, March, and April 2025, four of four months reviewed. Findings include: 1. Review of the "Room Temperature and Humidity Recording Chart" indicated the laboratory's acceptable humidity range was 40% to 80%. Review of the "Room Temperature and Humidity Recording Chart" records showed the laboratory documented daily humidity readings. Testing personnel documented readings that were less than 40% every working day of January through April 2025. 2. Interview with Staff A on November 18, 2025, at 3:10 PM confirmed the laboratory's humidity range was 40% to 80%, that the daily humidity readings were less than 40% during the four months reviewed, and that the laboratory director did not ensure the laboratory operated within its acceptable humidity range during January through April 2025.