

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D1079047	(X3) Date Survey Completed 04/15/2025
Name of Provider or Supplier Aspirus Rhinelander Clinic Laboratory	Street Address, City, State 1630 N Chippewa Dr, Rhinelander, 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
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 surveyor observation of freezer storage, review of temperature records, and interview with the Laboratory Director, the laboratory did not define an acceptable temperature range for one of two item types stored in the freezer that was consistent with the manufacturer's acceptable range. The laboratory defined acceptable temperature range for the freezer did not ensure storage of the Validate Calibration Verification Test Sets within the manufacturer's acceptable temperature range. Findings include: 1. Observation of a laboratory freezer (#3) on April 15, 2025, at 1:45 PM showed the freezer contained Validate Calibration Verification Test Sets and Bio-Rad control material. The box of Validate Calibration Verification Test Sets showed the manufacturer required storage at negative 10 to negative 25 degrees Celsius (C). The Bio-Rad control cartons showed the manufacturer required storage at negative 20 to negative 70 C. Further observation showed the freezer was monitored with a SensoScientific remote temperature monitor. 2. Review of online SensoScientific temperature records for freezer #3 showed the laboratory defined the acceptable temperature range as less than negative 20 C. The current freezer temperature was negative 34.4 C. Review of temperature data points from the last month showed the freezer temperature was consistently below negative 25 C. 3.</p>

Interview with the Laboratory Director on April 15, 2025, at 1:45 PM confirmed the laboratory's defined acceptable range for freezer #3 was not consistent with the manufacturer's acceptable range for the Validate Calibration Verification Test Sets.

D5441

CONTROL PROCEDURES

CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

This STANDARD is not met as evidenced by:

Based on surveyor review of one of one Individualized Quality Control Plan (IQCP) and quality control records, and interviews with the Laboratory Director and a Testing Person (Staff A), the IQCP for the i-STAT troponin assay did not establish the frequency of external control testing to ensure control testing monitored the cartridge lot number in use for patient troponin testing in order to detect system failures. Findings include: 1. Review of the IQCP for troponin testing with the i-STAT analyzer showed the laboratory will, "verify the integrity of cartridges included in every shipment, upon receipt, by analyzing two levels of external controls. We also run two levels of external controls monthly." 2. Review of i-STAT troponin quality control records from April 1, 2024, through April 1, 2025, showed the following: Cartridge lot: QC testing dates (month/day/year) 524009A: 4/1/24, 5/1/24, 7/1/24 524093: 6/1/24, 8/2/24, 9/1/24 524187A: 10/1/24, 11/1/24, 12/2/24, 1/1/25 524287: 1/19/25, 2/1/25, 2/17/25, 4/1/25 524649A: 3/2/25 3. Interview with Testing Personnel, Staff A, on April 15, 2025, at 11:55 AM confirmed personnel used cartridge Lot 524009A for patient troponin testing from April 2024 through July 2024 and confirmed personnel did not test external controls with lot 524009A in June 2024. Further interview confirmed personnel used cartridge lot 524287 for patient troponin testing from January 2025 through April 2025 and confirmed personnel did not test external controls with lot 524287 in March 2025. 4. Interview with the Laboratory Director on April 15, 2025, at 12:10 PM confirmed testing personnel did not test the cartridge lot in use for patient troponin testing with external controls in June 2024 and March 2025 to ensure errors due to test system failure would be detected.