

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D0914292	<b>(X3) Date Survey Completed</b> 03/10/2025
<b>Name of Provider or Supplier</b> Cardiology Associates Of Altoona Llp	<b>Street Address, City, State</b> 1321 11th Avenue, Altoona, PA	
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>D5413</b>	<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 review of laboratory temperature records, lack of documentation and interview with the Laboratory Manager, the laboratory failed to monitor and document temperatures to ensure proper storage of reagents and test system operating conditions were met for instrumentation used to perform hematology testing for 400 of 728 days from 03/13/2023 to 03/10/2025. Findings include: 1. On the day of survey, 03/10/2025, review of the laboratory's temperature logs revealed the laboratory failed to monitor and document the following temperatures for 400 of 728 days from 03/13/2023 to 03/10/2025: - refrigerator temperature (laboratory's acceptable range 35 to 46 degrees Fahrenheit) to ensure proper storage of reagents. - room temperature (laboratory's acceptable range 64 to 86 degrees Fahrenheit) to ensure test system operating conditions were met for 1 of 1 i-Stat blood analyzer used to measure Activated clotting time. 2. The hours of laboratory testing are Monday-Friday 07:30 am to 05:00 pm (CMS 116). The laboratory could not provide documentation of temperatures taken on days the laboratory was closed. 3. The Laboratory Manager confirmed the above findings on 03/10/25 at 2:10 pm.</p>
<b>D6032</b>	LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(14)

(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview with the Laboratory Manager, the Laboratory Director (LD) failed to specify in writing the responsibilities and duties of 4 of 4 individual laboratory positions involved in the preanalytic, analytic, and postanalytic phases of moderate complexity testing in hematology from 03/13/2023 to date of survey. Findings include: 1. On the day of survey, 03/10/2025, the laboratory failed to provide documentation of the job responsibilities written by the LD for the following laboratory positions involved in the preanalytic, analytic, and postanalytic phases of moderate complexity testing in hematology (Activated clotting time) from 03/13/2023 to 03/10/2025: - Laboratory Director (LD) - Clinical Consultant (CC) - Technical Consultant (TC) - Testing Personnel (TP) 2. The Laboratory Manager confirmed the above findings on 03/10/2025 at 2:10 pm.