

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2124641	<b>(X3) Date Survey Completed</b>  07/16/2025
<b>Name of Provider or Supplier</b>  Birmingham Internal Medicine Associates Llc	<b>Street Address, City, State</b>  480 Walker Drive, Springville, AL	
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 a review of the refrigerator and freezer temperature records, the Sysmex Eightchek 3WP Quality Control (QC) package insert, the Quidel Triage BNP (Brain natriuretic peptide) quick reference document, and an interview with the Technical Consultant, the Laboratory failed to ensure QC material and patient specimens were stored within the manufacturer's acceptable limits. Refrigerator #1 temperatures were outside acceptable ranges for 99 days and Refrigerator #2 temperatures were out 23 days all from 23 months reviewed in 2023 through 2025. Freezer #1 temperatures were outside acceptable ranges for 370 days and freezer #2 temperatures were out for 399 days all from 23 months reviewed in 2023 through 2025. The findings include: 1. A review of the temperature records revealed refrigerators #1 and #2 in which the Sysmex Eightchek 3WP Controls were stored were outside the manufacturer's acceptable limits for the following days: a) Refrigerator #1: i) 2023: 12 ii) 2024: 87 b) Refrigerator #2: i) 2023: 5 ii) 2024: 13 iii) 2025: 5 2. A review of the Sysmex Eightchek 3WP Control package insert revealed, "temperature limitation at 2-8 degrees Celsius." 3. A review of the freezer #1 and #2 temperature records revealed how many days each year freezer temperatures were outside acceptable limits: 1) Freezer #1: i) 2023: 103 ii) 2024: 206 iii) 2025: 61 2) Freezer #2: i) 2023: 103 ii)</p>

2024: 231 iii) 2025: 65 4. A review of the Quidel Triage BNP quick reference guide revealed, "store plasma at -20 degrees Celsius until tested." 5. During an interview on 7/16/2025, at 10:15 AM, the Technical Consultant confirmed the above findings.