

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2089476	(X3) Date Survey Completed 06/27/2024
Name of Provider or Supplier Birmingham Internal Medicine Associates Llc	Street Address, City, State 2834 Moody Parkway, Moody, AL	
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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the Quality Assurance Manager, the laboratory failed to retain the PT review page documentation for one of four events reviewed in 2022. The findings include: 1. A review of the API PT records revealed no documentation of a review from the Laboratory Director for the Hematology 3rd Event in 2022. 2. During an interview on 6/27/24, at 11:13 AM, the Quality Assurance Manager confirmed the above findings.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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: (1) Water quality. (2) Temperature. (3) Humidity. (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 environmental records and an interview with the Quality Assurance Manager, the Laboratory failed to ensure the room temperature for the</p>

Quidel Triage analyzer was within the manufacturer's acceptable limits. The room temperature was noted out of acceptable ranges for 135 days from 2022 to 2024. The findings include: 1. A review of the environmental records revealed the room temperature was out of the manufacturer's acceptable parameters (20-24 degrees Celsius) for a total of 135 days as follows: A) July, October, November and December 2022; 14 days; B) January through September, November and December 2023; 96 days C) January through April 2024; 25 days 2. During an interview on 6/27/24, at 1:30 PM, the Quality Assurance Manager confirmed the above findings. ----- Based on a review of the environmental records and an interview with the Quality Assurance Manager, the Laboratory failed to ensure the room temperature for the Quidel Triage analyzer was within the manufacturer's acceptable limits. The room temperature was noted out of acceptable ranges for 135 days from the date of the last survey, 6/15 /2022, to the date of the current survey, 6/27/2024. The findings include: 1. A review of the environmental records revealed the room temperature was out of the manufacturer's acceptable parameters (20-24 degrees Celsius) for a total of 135 days as follows: A) July, October, November and December 2022; 14 days; B) January through September, November and December 2023; 96 days C) January through April 2024; 25 days 2. During an interview on 6/27/24, at 1:30 PM, the Quality Assurance Manager confirmed the above findings.

D5437

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:
Based on a review of the Hematology calibration records and an interview with the Quality Assurance Manager, the Laboratory failed to perform calibrations on the Sysmex XP-300 Hematology analyzer every six months. This was noted for two of four possible calibrations in 2022 through 2023. The findings include: 1. A review of the Hematology calibration records revealed the Sysmex XP-300 was calibrated 4/6 /22 and then almost nine months later on 1/29/2023. There was no evidence of documentation to review for the second half of 2022. 2. During an interview on 6/27 /24, at 12:15 PM, the Quality Assurance Manager confirmed the calibration due in October 2022 was not performed due to lapse in contract.

D6047

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(i)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

This STANDARD is not met as evidenced by:
Based on a review of the Personnel records, a review of the Laboratory Personnel Report (CMS-209), and an interview with the Quality Assurance Coordinator, the Technical Consultant failed to conduct direct observation of routine patient specimens while assessing competency. This was noted for two out of two Testing Personnel. The findings include: 1. A review of the Personnel records revealed timely competency assessments for Testing Personnel #1 and Testing Personnel #2. All reviewed competency assessments documented the Phlebotomist Supervisor as the observer. The Phlebotomist Supervisor is not listed on the CMS-209 and does not meet the qualifications of Technical Consultant. 2. A review of the CMS-209 revealed the Laboratory Director to be the Technical Consultant. 3. During an interview on 6/27/2024 at 10:37 AM, The Quality Assurance Coordinator confirmed the above findings.