

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2136530	(X3) Date Survey Completed 09/04/2024
Name of Provider or Supplier Amg Dba Atlantic Hematology/	Street Address, City, State 100 Madison Ave, Morristown, NJ	
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
D2123	<p>HEMATOLOGY CFR(s): 493.851(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Manager (LM), the laboratory failed to participate in the College of American Pathologists (CAP) PT for the 1st event of 2023 for Hematology tests. The findings include: 1. The laboratory failed to participate in the 1st event of 2023 for Hematology Auto Differentials. 2. The LM confirmed on 9/4/24 at 11:00 am that the laboratory did not participate in the 1st CAP event of 2023.</p>
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the laboratories NJ State License, Proficiency Testing</p>

(PT) and interview with the Laboratory Manager (LM), the laboratory failed to be in compliance with New Jersey Administrative code N.J.A.C. 8:44-2.5(b)3. for calendar years 2023 and 2024. The finding includes: 1. N.J.A.C. 8:44-2.5(b)3. states Laboratories shall: iii. Maintain records of all proficiency testing results in surveys in which they participate and make such records, including results, interpretations and cumulative performance data routinely available to the Department of Health and Senior Services. 2. The PT records for all PT events in 2023 and 2024 state the reports were only copied to Centers for Medicare and Medicaid Services (CMS) and not the Department of Health and Senior Services. 3. The LM confirmed on 9/4/24 at 11:30 am the laboratory failed to make PT for Hematology performance data routinely available to the Department of Health and Senior Services.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Manager (LM), the Laboratory Director (LD) failed to ensure that PT samples were tested for Hematology Auto Differentials for the 1st event of 2023 from the College of American Pathologists (CAP). The findings include: 1. The laboratory failed to participate in the 1st event of 2023 for Hematology test from CAP. 2. The LM confirmed on 9/4/24 at 10:45 am that the LD failed to ensure PT samples for the 1st event of 2023 for Hematology Auto Differentials were tested.