

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D2093926	<b>(X3) Date Survey Completed</b> 07/30/2025
<b>Name of Provider or Supplier</b> Atlantic Medical Oncology	<b>Street Address, City, State</b> 89 Sparta Avenue, Suite 207, Sparta, NJ	
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>D5211</b>	<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 surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to review and evaluate PT results obtained from the College of American Pathologists (CAP) for Hematology tests from 3/1/25 to 7/30/25. The findings include: 1. Code 26 (educational challenge) results for Immature Granulocytes (IG) % and IG Absolute for PT event FH9-B-25 were not reviewed or evaluated. 2. TP #1 as listed on the CMS 209 form confirmed on 7/30/25 at 11:10 am, the laboratory did not review and evaluate all PT results obtained from CAP.</p>
<b>D5215</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records, Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to verify the accuracy of all not graded results for PT events for Chemistry tests performed on the</p>

Piccolo Abaxis analyzer with the American Proficiency Institute (API) from 3/1/24 to 7/30/25. The findings include: 1. Review of PT records revealed the laboratory received Not Graded scores from API for Total Bilirubin for the 1st Chemistry event of 2024. 2. There was no documented evidence the laboratory evaluated all Not Graded scores received from the PT provider. 3. TP #1 as listed on the CMS 209 form confirmed on 7/30/25 at 11:20 am, the laboratory failed to verify the accuracy of all Not Graded PT scores from API.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Procedure Manual and interview with Testing Personnel(TP), the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from 1/16/24 to 7/30/25. The finding includes: 1. The laboratory failed to have a procedure to verify new lots of controls before they were put in use on the Piccolo Abaxis. 2. The laboratory did verify new lots of QC, but did not have a detailed procedure to follow. 3. TP #1 as listed on the CMS-209 form confirmed on 7/30/25 at 10:40 am that the laboratory failed to have a procedure to verify new lots of controls before they were put in use.