

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0972314	(X3) Date Survey Completed 05/08/2025
Name of Provider or Supplier Atlantic Oncology Associates, Llc	Street Address, City, State 54 West Jimmie Leeds Road, Galloway Township, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Office Manager (OM), the laboratory failed to ensure that all Testing Personnel (TP) who performed Hematology tests participated in the AAB Medical Laboratory Evaluation (AAB MLE) Non Chemistry PT events in the calendar year 2024. The findings include: 1. A review of all three AAB MLE PT events in 2024 revealed that one out of four TP that were employed during 2024, performed PT for all three events in 2024. The TP that performed all three events is no longer employed and therefore not on the CMS-209. 2. The OM confirmed on 5/8/25 at 11:00 am that PT events were not rotated between TP in 2024. 3. Note: this deficiency was also cited during the 3/19 /24 survey.</p>
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(b)(7) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor review of the Proficiency Testing (PT) records and AAB Medical Laboratory Evaluation (AAB MLE) attestation statement sheets and</p>

interview with the Office Manager (OM), the laboratory failed to ensure the signed attestation statements were maintained from 3/19/24 to 5/8/25. The findings include: 1. Attestation sheets were not signed by the testing personnel (TP) and the Laboratory Director (LD) for all of the AAB MLE Non-Chemistry, Hematology surveys for all three events in 2024 and the first event of 2025. 2. The OM confirmed on 5/8/25 at 11:15 am that the attestation statements for 2024 and the first event of 2025 were not signed by the TP and LD. 3. Note: this deficiency was also cited during the 3/19/24 survey.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
Based on surveyor review of the "Procedure for Handling Abnormal Results" (PHAR), patient work records (WR) and test reports (TR) and interview with the Office Manager (OM), the laboratory failed to follow the procedure to verify abnormal automated differential results from 3/19/24 to 5/8/25. The findings include: 1. The PHAR states "Abnormal electronic differential results, ie those with incomplete results, region flags and/or abnormal distribution should be verified." 2. Five out of five flagged differential results reviewed had no verification performed and/or documented: a. ID 9680, 6/11/24, R flags and Messages b. ID 1029, 6/11/24, R flags and Messages c. ID 830, 9/18/24, Message d. ID 13363, 9/18/24, R flags and Messages e. ID 13156, 11/20/24, R flags and Messages 3. The OM confirmed on 5/8/25 at 1:00 pm that the laboratory failed to follow the PHAR. 4. Note: this deficiency was also cited during the 3/19/24 survey.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

(e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

This STANDARD is not met as evidenced by:
Based on surveyor review of Laboratory Personnel (LP) files and interview with the Office Manager (OM), the Laboratory Director (LD) failed to ensure that the laboratory had all education records from 3/19/24 to 5/8/25. The findings include: 1. There was no associate's degree in the personnel records for Testing Personnel #1 (TP #1) provided on the CMS-209 form. 2. The OM confirmed on 5/8/25 at 10:30 am, the LD failed to ensure the LP files had all education records.