

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0972314	(X3) Date Survey Completed 03/19/2024
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>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 PT events in the calendar year 2023. The finding includes: 1. A review of all PT events revealed that one out of two TP, TP #2 as provided on the survey CMS-209, performed PT for all three events in 2023. 2. The OM confirmed on 3/19/23 at 11:00 pm that PT events were not rotated between TP in 2023.</p>
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) 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 the lack of attestation statements and interview with the Office Manager (OM), the laboratory failed to ensure that attestation statements signed by the testing personnel (TP) and the Laboratory Director (LD) were provided for all of the AAB Medical Laboratory Evaluation Non-Chemistry, Hematology surveys in calendar year 2023 . The OM confirmed on 3/19/24 at 11:15 am that the attestation statements for the M1 and M2 events were not signed by the TP and LD.</p>
<p>D3037</p>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</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 Director failed to ensure that they reviewed and signed all AAB Medical Laboratory Evaluation graded results for the 2023 surveys. The OM confirmed on 3/19/24 at 11:30 am that the laboratory director did not review and sign the graded results for the Non-Chemistry, Hematology M1 and M2 2023 surveys.</p>
<p>D5221</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with Office Manager (OM), the laboratory failed to document the evaluation of all incorrect scores and corrective action taken for Non-Chemistry, Hematology events performed with AAM Medical Laboratory Evaluation for the M1 and M2 events of 2023. The findings include: 1. The following samples were graded as incorrect for the Non-Chemistry, Hematology M1 and M2 events of 2023. a) Vial 5 for Platelet, M1 event b) Vial 3 for Erythrocyte, M2 event 2. There was no documented evidence for evaluation or corrective action performed for the aforementioned PT events. 3. The OM confirmed on 3/19/24 at 11:45 am, the laboratory failed to evaluate and perform corrective action for the failed analytes for Non-Chemistry, Hematology PT events M1 and M2 in calendar year 2023.</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p>

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 12/19/19 to the date of the survey. 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 68670, 3/11/24, R flags and Messages b. ID 8-31-58, 3/11/24, R flags and Messages c. ID 66531, 12/19/23, R flag and Message d. ID 8515, 12/19/23, R flag and Message e. ID 11048, 12/19/23, R flag and Message 3. The OM confirmed on 3/19/24 at 1:15 pm that the laboratory failed to follow the PHAR.

D5403

PROCEDURE MANUAL
 CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
 Based on surveyor review of the Procedure Manual (PM) and interview with the Office Manager (OM), the laboratory failed to include all applicable procedres in the PM from 12/19/19 to the date of the survey. The findings include. 1. The laboratory failed to include Complete Blood Cell (CBC) flags in the "Procedure for Handling Abnormal Results." 2. The laboratory failed to provide established reportable ranges for the CBC and instructions on how to report patient results beyond those ranges in their PM. 3. The laboratory failed to provide their reference intervals (RI) and the source of those RI's in their PM. 4. The OM confirmed on 3/19/24 at 12:00 pm that the laboratory failed to provide the aforementioned procedures.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
 CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the

manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on surveyor review of Performance Specification (PS) records and interview with the Office Manager (OM), the laboratory failed to ensure that all PS records were adequate for the Complete Blood Cell (CBC) testing on the Beckman Coulter DxH 520 analyzer from 5/19/23 when installation of the analyzer was completed to the date of the survey. The findings include: 1. The laboratory failed to establish their reportable ranges based on comparing their linearity and Beckman Coulter's Measuring Ranges. 2. The laboratory failed to place those established reportable ranges into use to ensure that patient results outside the ranges would not be reported. 3. The OM confirmed on 3/19/24 at 12:50 pm that the laboratory failed to ensure that PS records were adequate.

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Test Reports (TR) generated from the electronic health record (EHR) for Complete Blood Cell (CBC and Automated Differential testing and interview with the Office Manager (OM), the laboratory failed to have Reference Interval's (RI) on the TR from 12/19/19 to the date of survey. The findings include: 1. The TR did not have RI's for the CBC and Automated Differential. 2. The OM confirmed on 3/19/24 at 1:00 pm the laboratory failed to include RI's for the aforementioned tests.