Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2093926	01/16/2024
Name of Provider or Supplier	**Street Address, City, State**	
Atlantic Medical Oncology	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: A. Based on surveyor review of the Insight Quality Control Report (IQCR) for the Sysmex XN analyzer and interview with the Testing Personnel (TP), the laboratory failed to perform and document corrective action from 10/25/23 to the date of survey. The findings include: 1. The IQCR states "if your Coefficient of Variation (CV) is 1.5 times greater than the group CV, your result is presented in bold and an investigation is warranted." 2. The following analytes were in bold for the IQCR for Lot 3293 from 10/25/23 to 1/5/24 a) Neut % Level 1 had a CV of 4.5 b) Lymph % Level 1 had a CV of 7.9 c) Mono% Level 1 had a CV of 12.5 d) Lymph # Level 1 had a CV of 9.0 3. There was no documented evidence for corrective action for the above mentioned analytes and control lot number. 4. TP #1 as listed on the CMS-209 form, confirmed on 1/16/24 at 11:00 am the laboratory failed to perform and document all corrective action. B. Based on surveyor review of the Calibration Verification Report (CVR) for the Sysmex XN analyzer and interview with the Testing Personnel (TP), the laboratory failed to perform and document corrective action from 10/25/23 to the date of survey. The findings include: 1. The CVR states "Your CV will be bolded along with a 1 appearing in notes column if your CV exceeds the CV% limit." 2. The following analytes in the CVR were bold and had a 1 appearing in the notes column for Lot 3293 from 10/25/23 to 1/30/24: a) Neut % Level 1 had a CV of 4.5 b) Lymph

	% Level 1 had a CV of 7.9 c) Mono% Level 1 had a CV of 12.5 d) Lymph # Level 1 had a CV of 9.0 3. There was no documented evidence for corrective action for the above mentioned analytes and control lot number.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that all PT results that were graded as unacceptable had corrective action performed for Hematology and Chemistry tests performed with the American Proficiency Institute (API) in the calendar years 2022 and 2023. The findings include; 1. The following PT analytes were graded as unacceptable: a. Sample Identification (ID) XE-05 for Mean Platelet Volume (MPV) for the 1st Hematology PT event of 2023. b. Sample ID XE-14 for Basophils for the 3rd Hematology PT event of 2022. c. Sample ID CH-13 for Potassium for the 3rd Chemistry PT event of 2023. d. Sample ID CH-11, CH-12, and CH-14 for Albumin for the 3rd Chemistry PT event of 2022. e. Sample ID CH-06 and CH-10 for Bilirubin for the 2nd Chemistry PT event of 2022 f. Sample ID CH-01 for Albumin for the 1st Chemistry PT event of 2022. 2. There was no documented evidence that corrective action was performed on the above mentioned analytes. 3. TP #1 as listed on the CMS-209 form confirmed on 1/16/24 at 11:30 am that the LD failed to ensure corrective action was performed on analytes graded as unacceptable.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the lack of a Quality Assessment (QA) plan, review of the Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to establish a QA program to assure the quality of laboratory services provided from 10/13/21 to the date of the survey. TP #1 as listed on the CMS-209 form, confirmed on 1/16/24 at 11:30 am that the LD failed to establish a QA program. Note: This deficiency was previously cited on 10/13/21