Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2093926	10/13/2021
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) and interview with the Testing Personnel (TP), the laboratory failed to achieve a score of 80% or more for Hematology tests performed with the American Proficiency Institute (API). The finding includes: 1) The laboratory scored 20% for Lymphocytes % event 2-2021 with the API. 2) The laboratory scored 60% for Lymphocytes % event 1-2021 with the API.
D2130	HEMATOLOGY CFR(s): 493.851(f)

	Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) and interview with the Testing Personnel (TP), the laboratory failed to achieve a score of 80% or more in two out of three events for for Hematology tests performed with the American Proficiency Institute (API). The findings include: 1) The laboratory scored 20% for Lymphocytes % event 2-2021 with the API. 2) The laboratory scored 60% for Lymphocytes % event 1-2021 with the API.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), and interview with the Testing Personnel (TP), the laboratory failed to follow procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems from January 2021 to the date of the survey. The findings include: 1. The laboratory failed to follow the PM for supervisor review of Quality Control (QC) reports on the Sysmex XN-550 analyzer. 2. The PM stated "The supervisor reviews the following QC reports at the following intervals": a. Insight IQAP every month or applicable. b. Exception Report every month or applicable. c. Summary Report every month or applicable. d. Detailed Daily Verification report every month or applicable. e. Parameter Report every month or applicable. 3. There was no documented evidence the laboratory performed the aforementioned procedures. 4. The TP#1 listed on CMS form 209 confirmed 10/13/21 at 12:00 pm that the laboratory failed to follow procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the lack of the Maintenance Records (MR) and interview with the Tetsing Personnl (TP), the laboratory failed to perform and document preventative maintenance as specified by the manufacturer on the Sysmex XN-550 used for

	Hematology tests from January 2021 to the date of the survey. The TP #1 listed on CMS form 209 confirmed on 10/13/21 at 12:15 pm that preventative maintenance as specified by the manufacturer was not performed.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of Calibration Verification (CV) records, Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to perform and document Calibration procedures at least once every six months for Hematology Tests performed on the Sysmex XN-550 analyzer from 12/18/21 to the date of the survey. The findings include: 1. A review of CV records revealed that the laboratory did not perform "Precision Check" as requireed prior to CV. 2. A review of CV records revealed CV was not run every six months. 3. The TP #1 of CMS form 209 confirmed on 10/13/21 at 10:30 am that the laboratory failed to perform and document CV.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to have available defined statistical parameters of commercially assayed Hematology QC material with each new lot and /or shipment used on the Sysmex XN-550 analyzer from January 2021 to date of survey. The findings include: 1. XN- Control lot 11831401, 11831402, 11831403 had

	no Manufacturers Package Insert with QC values prior to running QC to verify if the QC was in range prior to putting them in use. 2. The TP#1 listed on CMS form 209 confirmed on 10/13/21 at 11:00 am that all assayed QC material was not verified before putting in use.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual PM, the lack of Quality Control (QC) records and interview with the Testing Personnel (TP) the TP, failed to follow the laboratory's Corrective Action (CA) policy and document CA to ensure accurate and reliable patient results were reported from January 2021 to the date of survey. The finding includes: 1. The PM stated "All trouble shooting actions are logged in the activity log (Reference the Beyondcare quality monitor user manual)." but the laboratory did not have the Beyondcare quality monitor user manual. 2. The laboratory did not have an activity log. 3. The TP#1 on CMS form 209 confirmed on 10/13/21 at 11:00 am that the laboratory failed to follow the laboratory's CA policy.
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. (c) The laboratory must document all analytic systems assessment activities. 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 and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from January 2021 to the date of survey. The findings include: 1. The laboratory did not have a policy with criteria on when to repeat a patient test. 2. TP could not generate Insight QC reports at the time of survey. 3. The TP#1 listed on CMS from 209 confirmed on 10/13/21 at 11:45 am that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

	This CONDITION is not met as evidenced by: Based on surveyor review of the Laboratory records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory from 12/18/18 to the date of survey. The findings include: 1. The LD failed to achieve a score of 80% or more for Hematology tests. Cross refer D2016 2. The LD failed to achieve a score of 80% or more in two out of three events. Cross refer D2130 3. The LD failed to ensure that PS procedures performed on the Sysmex XN-550 analyzer were adequate. Cross refer D6013 4. The LD failed to ensure that the QC program is maintained. Cross refer to D6020. 5. The LD failed to establish a QA plan. Cross refer to D6021.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that PS procedures performed on the Sysmex XN-550 analyzer were adequate from January 2021 to the date of survey. The finding includes: 1. The LD did not perform precision. 2. The TP#1 listed on CMS from 209 confirmed on 10/13/2021 at 10:20 am that PS records were not adequate.
D6020	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 the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that the QC program is maintained for laboratory services provided from 12/18/18 to the date of the survey. The findings include: 1. There was no documented evidence that Complete Blood Count (CBC) QC was reviewed. 2. There was no documented evidence that QC verification was reviewed. 3. The TP # 1 listed on CMS form 209 confirmed on 10/13 /21 at 12:00 pm the LD did not ensure the QC program was maintained.
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 a lack of a Quality Assurance (QA) plan and interview with the Testing Personnel (TP), the Laboratory Director failed to establish a QA plan from 12/18/18 to the date of the survey. The TP confirmed 10/13/21 at 11:00 am that a QA plan had not been established.