Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2093926	12/18/2018
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
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. 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 the laboratory failed to attain at least 80% or more for Hematology/coagulation performed with the American Proficiency Institute (API) for event 2-2017. The findings include: 1. The laboratory received a grade of 0% white blood cell differential all analytes. 2. The laboratory received a 60% for MCHC. 3. The corrective action written on the "performance review and corrective action" sheet provided by (API) was illegible. 4. The TP stated that the corrective action that was performed was "a correlation study between Newton hospital and the Physicians office lab (POL) was conducted. 5. There was no documented evidence the failures mentioned above were investigated. 6. The TP #1 listed on CMS form 209 confirmed on 12/18/18 at 11:20 am that the laboratory did not perform and document an evaluation of unacceptable PT results.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 review of Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to have a written procedure for lot to lot Quality Control (QC) verification for all tests performed Abaxis Piccolo Xpress analyzer from 10/16 /16 to the date of survey. The findings include: 1. This deficiency was previously cited. a)The plan of corrections stated "The laboratory now has a written procedure for lot to lot quality control verification for all tests performed on the Abaxis Piccolo Xpress analyzer". 2. There was no evidence of a written procedure 3. The TP #1 on CMS form 209 confirmed on 12/18/18 at 10:40 AM that the procedure mentioned above was not in the PM.
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: a) Based on surveyor review of Quality Control (QC) records, Manufactures Package Insert (MPI) and interview with the Testing Personnel (TP), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment for Basic Metabolic Panel Plus tests performed on the Piccolo Xpress analyzer from 6/15/17 the date of survey. The finding includes: 1. The TP stated that she "did not know QC verification needed to be performed on the Piccolo". 2. The laboratory did not verify QC materials used in 2017 and 2018. 3. The TP #1 listed on CMS form 209 confirmed on 12/18/18 at 11:00 am that the assayed values of QC materials were not verified before putting in use. b)Based on surveyor review of QC records, MPI and interview with the TP, the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment for Hematology testing performed on the Sysmex XS 10001 analyzer from on the date of survey. The finding includes: 1. There was no documented evidence that QC verification was performed. 2. The TC confirmed on 12 /18/18 at 11:00 pm that the assayed values of QC materials were not verified before putting in use.
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 the surveyor review of the Final Reports (FR) and interview with the Testing Personnel (TP), the laboratory failed to have a Reference Range (RR) for Complete Blood Count (CBC) tests on the FR from 6/15/17 from 6/15/17 to the date of survey. The TP confirmed on 12/18/18 at 11:40 am CBC tests did not have a RR on the FR.