Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2077017	10/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Avantic Medical Lab	3880 Park Avenue, Edison, 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Operation Manager (OM), the laboratory failed to have Attestation Statements (AS) signed by the analyst and laboratory director for Routine Chemistry, Endocrinology, Urinalysis, and Hematology tests performed with the American Proficency Institute in 1and 2 of 2019 events. The OM confirmed on 10/23/19 at 1:15 pm that the laboratory did not have signed AS.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records and interview with the Operation Manager (OM), the laboratory failed to perform CA correctly on two out of two Testing Personnel (TP) in March 2019. The findings include: 1. The laboratory did not document when testing personnel were observed, what records were reviewed and how assessment was done. 2. CA was not done on each test system. 3. The OM confirmed on 10/23/19 at 11:20 am that the CA procedure was not performed correctly. NOTE: This deficiency was cited in the survey report dated 3/14 /18.
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 surveyor review of the Procedure Manual (PM) and interview with the Operations Manager (OM), the laboratory failed to follow the procedure for reviewing results with flags obtained on the Cell Dyne 3700 analyzer used for Hematology testing from November 2018 to the date of survey. The finding includes: 1. The PM stated to make a smear of samples with a flagged result but a review of ten patient results with flags revealed the laboratory did not make a smear on ten out of ten patients. 2. The OM confirmed on 10/24/19 at 10:00 AM that the laboratory did not follow the procedure for flag review.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor review of the Temperature Logs and interview with the Operations Manager (OM), the laboratory failed to define an acceptable temperature range for Room Temperature (RT) and Humidity where the Tosoh G-8 was kept from November 2018 to the date of survey. The finding includes: 1. The RT and humidity log defined RT as 15-30 Celsius (C) and humidity as 20-80% but the operators manual for the G-8 required RT to be 15-25 C and humidity 40-80%. 2, The OM confirmed on 10/24/19 at 9:30 am that the laboratory did not define appropriate RT and humidity.
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 lack of Performance Specifications (PS) records and interview with the Testing Personnel (TP), the laboratory failed to verify PS for Endocrinology tests performed on the Access 2 analyzer, Routine Chemistry tests performed on the AU 480 analyzer, urinalysis performed on the Clintex Atlas and Hematology performed on the Cell Dyne 3700 when they relocated from November 2019 to the date of survey. The TP #1 listed on CMS form 209 confirmed on 10/23/19 at 12:30 am that the PS were not performed.
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 surveyor review of the Maintenance Record (MR) and interview with the Operations Manager (OM), the laboratory failed to perform and document the six month maintenance as specified by the manufacturer on the Tosoh G-8 analyzer used for Hemoglobin A1C tests from November 2018 to the date of the survey. The OM confirmed on 10/25/19 at 10:55 am that maintenance as specified by the manufacturer was not performed.
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 the Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to ensure that the assayed and unassyed Endocrinology QC material were within acceptable ranges before it was put into use on the Access 2 analyzer from 1118/18 to the date of survey. The findings include; 1. There were no work records for QC verification Lyphochek Immunoassay Plus Controls Lot 40360. 2. The TP #1 listed on CMS form 209 confirmed on 10/24 /19 at 11:00 am that the laboratory did not verify QC. 35471 b. Based on surveyor review of QC records and interview with the Operations Manager (OM), the laboratory failed to verify commercially assayed QC material with each new lot and /or shipment of Hematology and Hemoglobin A1C QC used on the Cell Dyne 3700 and Tosoh G-8 analyzer respectively from November 2018 to the date of survey. The OM confirmed on 10/24/19 at 10:15 am that assayed QC material was not verified before putting in use.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Operations Manager (OM), the laboratory failed to identify problems on the FR for the estimated Glomerular Filtration Rate (eGFR) from November 2018 to the date of the survey. The findings include: 1. The interpretation for eGFR was reported in duplicate under eGFR If African American. 2. The FR interpretation for eGFR stated "Staging of Chronic Kidney Disease (CKD)" with results indicative of CKD but the National Kidney Foundation stated the eGFR determines kidney function. 3. Units for eGFR were reported in Reference and Units columns. 4. The OM confirmed on 10/24/19 at 10:30 am the laboratory did not identify problems on the FR.
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 Procedure Manual (PM), Quality Control (QC) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure a Quality Control (QC) program was maintained for Chemistry and Endocrinology Testing from June 2019 to the date of survey. The findings include: 1. The was no documented evidence of review for Levy Jennings (LJ) charts for routine chemistry from June 2019 until the date of survey. 2. There were no LJ charts for Thyroid Stimulating Hormone, Total Triiodothyronine, Thyroxine, Free Thyroxine, Free Triiodothyronine, and cortisol for August 2019. 3. The was no documented

	evidence of review for LJ charts for endocrinology tests from March 2018 until the date of survey. 4. The TP #1 listed on CMS from 209 confirmed on 10/24/19 at 11:00 am that a QC program was not maintained.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: a) Based on surveyor observation the AU480 analyzer printout and interview with the Testing Personnel (TP), the TP failed to ensure that test analyses performed on the AU 480 series had correct analyte Reference Intervals (RI) programmed on the date of the survey. The findings include: 1. The analyzer printout had Creatine Kinase (CK) RI as -9999 - 9999 U/L. The laboratory RI was 30 - 223 U/L. 2. The analyzer printout had Gamma-Glutamyltransferase (GGT) RI as -9999 - 9999 IU/L. The laboratory RI was 9 - 64 U/L. 3. The TP # 1 listed on CMS form 209 confirmed on 10/23/19 at 12: 30 pm that laboratory failed to follow laboratory procedures for test analyses. b) Based on surveyor observation the analyzer, analyzer printout, Manufactures Package Insert (MPI) and interview with the Testing Personnel (TP), the TP failed to identify problems when results were fagged on the AU 480 series had correct Dynamic Range programmed on the date of the survey. The findings include: 1. The analyzer printout had Bicarbonate test result 31 mEq/L flagged "F" "result higher than dynamic rage" when the dynamic range for the instrument was 2-45 mEq/L. 2. The analyzer printout had Alanine Amino-transferase test result 9 iu/L flagged "G" "result lower than dynamic rage" when the dynamic range for the instrument was 3 - 500 iu/L. 3. The TP # 1 listed on CMS form 209 confirmed on 10/23/19 at 12:30 pm that laboratory failed to identify flag problem.
D6074	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5) Each individual performing moderate complexity testing must be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Operations Manager (OM), the Testing Personal failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the Cell Dyne 3700 and Tosoh G-8 analyzer from November 2018 to the date of the survey. The OM confirmed on 10/23/19 at 1:45 pm that trends and shifts were not reviewed.