Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2077017	(X3) Date Survey Completed 03/14/2018
Name of Provider or Supplier Avantic Medical Lab	**Street Address, City, State** 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
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 General Supervisor (GS), the laboratory failed to perform CA correctly on two out of two Testing Personnel (TP) in February 2018. The finding includes: 1. The laboratory did not document when testing personnel were observed, what records were reviewed and how assessment was done. 2. The GS confirmed on 3/14/18 at 10: 20 am that the CA procedure was not performed correctly.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisor (GS), the laboratory failed to review and evaluate coded Hematology PT results obtained from the American Proficiency Institute (API) for 3 of 2017 PT event. The findings include: 1. There was no review or evaluation documented when the laboratory received "Not Graded" results in: a. Hematocrit, Mean Corpuscular Volume and Red Cell Distribution Width tests. 2. The GS confirmed on 3/14/18 at 10:10 am that the laboratory did not evaluate all PT results.

D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on surveyor review of the Test Requisitions (TR) and interview with the General Supervisor (GS), the laboratory failed to ensure that test requisition included relevant and necessary information for accurate and reliable testing and reporting from October 2017 to the date of survey. The findings include: 1. A review of five TR from February 28, 2018 revealed that one out of five did not have collection time. 2. A review of five TR reviewed from March 2018 revealed that two of five did not have collection time. 3. The laboratory did not document any efforts made to get the information. 4. The GS confirrmed on 3/15/18 at 11:40 am that collection time was not on TR.
D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on review of Test Requisition (TR), Laboratory Information System (LIS) and interview with the General Supervisor (GS), the laboratory failed to ensure that information from TR was transcribed accurately into the LIS from October 2017 to the date of survey. The findings include: 1. Review of one out of eight TR revealed that accession number 1803100002 had incorrect birthdate on FR. 2. The GS confirmed on 3/14/18 at 12:15 pm that the laboratory did not ensure information was transcribed accurately.
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: a) Based on surveyor review of the Procedure Manual (PM) and interview with the General Supervisor, the laboratory failed to follow their PM policy for flagging of Hematology results run on the Cell Dyn 3700 from November 2017 to the date of the survey. The finding includes: 1. The PM stated to review a stained smear and follow laboratory's protocol to confirm results for all flagged results but the laboratory did not make a smears on flagged results. 2. The GS confirmed on 3/14/18 at 1:20 pm the PM was not followed. b) Based on surveyor review of the PM, Quality Control (QC) records and interview with the GS, the laboratory failed to follow their policy for QC verification for Hematology QC performed on the Cell Dyn 1700 and Endocrinology QC performed on the Beckman Access 2 analyzer from October 2017 to the date of survey. The finding includes: 1. The PM stated to test the new QC lot three times over three days before putting into use but there was no documented evidence that the laboratory ran the new lot before putting it into use. 2. The GS confirmed on 3/14/18 at 1:50 pm the PM was not followed.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation of the Buffer Solutions (BS) and interview with the General Supervisor (GS), the laboratory failed to put new expiration dates on BS from 12/29/17 to the date of survey. The findings include. 1. The G8 Variant MPI stated that BS expired three months after opening. 2. The laboratory did not put new expration date on BS 1, 2 and 3. 3. The GS confirmed on 3/14/18 at 12:30 am the laboratory failed to put new expiration date on the BS.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records, Manufacture Package Insert (MPI), QC material, and interview with the General Supervisor (GS), the laboratory used expired QC material for all analytes performed on the Beckman Access 2 (BA2) analyzer from 10/19/17 to the date of survey. The findings include: 1. The MPI stated that reconstituted QC material stored at -2 to -8 Celsius (C) expired after seven days for all analytes with the exception of Prostate Specific Antigen (PSA) which expired three days after reconstituting. 2. Lyphochek Immunoassay Plus Control (LIPC) Lot 40341, 40342, and 40343 were reconstituted 10/12/17. A second

	bottle of Level 1 and 2 Lot 40341 and 40342 was reconstituted on 2/28/17. 3. Approximately 105 patients were run and reported with expired QC from 10/19/17 to the date of survey. 4. The GS confirmed on 3/14/18 at 1:35 pm that the laboratory used expired QC material.
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 Specifications (PS) records and interview with the General Supervisor (GS), the laboratory failed to verify accuracy for magnesium tests performed on the Beckman Coulter AU-480 analyzer before reporting patient test results from November 2017 to the date of survey. The GS confirmed on 3/14/18 at 10:50 am the PS was not done.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the General Supervisor (GS), the laboratory failed to report Urinalysis results correctly from 2/20/18 to the date of survey. The finding includes: 1. The laboratory reported units of measurements for qualitative Urinalysis results. 2. The GS confirmed on 3/14/18 at 1:30 pm that urinalysis results were not reported correctly.
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:

	a) Based on surveyor review of the Manufacturers Package Insert (MPI), Final Reports (FR) and interview with the General Supervisor (GS), the laboratory failed to ensure Normal Reference Intervals (RI) were correct on the FR for Endocrinology tests performed on the Beckman Access 2 and Hematology tests performed on the Cell Dyn 3700 from November 2017 to the date of the survey. The findings include: 1. RI were as follows: a. Thyroid Stimulating Hormone (TsH) - the MPI was 0.45-5.33 but the RI on FR was 0.35-4.94. b. White Blood Cells (WBC) - the Reference Range (RR) was 4.5-11.5 for women but the RI on FR was 4.4-11.3 c. Red Blood Cells (RBC) - the Reference Range (RR) was 4.0-5.10 for women but the RI on FR was 4.1-5.1 d. Mean Platelet Volume (MPV) - the Reference Range (RR) was 6.8-10.2 for women but the RI on FR was 7.54-11.24. 2. The GS confirmed on 3/9/18 at 2:15 pm that the laboratory failed to have the correct RI on the FR. b) Based on the surveyor review of the Final Report (FR) and interview with the General Supervisor (GS), the laboratory failed to have a source for Reference Intervals (RI) for Absolute Monocyte, Eosinophil and Basophil tests performed on the Cell Dyn 3700 from November 2017 to the date of the survey. The GS confirmed on 3/14/18 at 2:30 pm that the laboratory did have a source for RI reported on FR.
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 General Supervisor (GS), the GS failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for Routine Chemistry tests performed on the Beckman Coulter AU-480 and G8 analyzers from November 2017 to the date of the survey. The GS confirmed on 3/14/18 at 10:45 am that trends and shifts were not reviewed.