Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2005357	06/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Apple Diagnostic Lab	233 Durham Avenue, South Plainfield, 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 Technical Supervisor (TS), the laboratory failed to perform CA correctly on two out of two Testing Personnel (TP) in 2018. The findings include: 1. All specialty tests performed by TP were not evaluated. 2. The laboratory did not document what records were reviewed and how assessment was performed. 3. The TS confirmed on 6 /13/18 at 11:00 am that CA 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 records and interview with the Technical Supervisor (TS), the laboratory failed to evaluate coded results obtained in 1, 2 and 3 of 2017 and 1of 2018 events for Hematology tests performed with the American Proficiency Institute (API). The finding includes: 1) The laboratory did not evaluate Not Graded 2 (lack of consensus) results for Hematocrit, Mean Corpuscular Volume and Red Cell Distribution Width for all samples in each event. 2) The TS confirmed on 6/13/18 at 9:50 am that the laboratory failed to evaluate coded results.

D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on surveyor review of the Biannual Assessment (BA) records and interview with the Technical Supervisor (TS), the laboratory failed to verify the accuracy of Urinalysis testing twice annually from 12/15/15 to the date of the survey. The TS confirmed on 6/13/18 at 1:00 pm the laboratory did not verify the accuracy of Urinalysisy testing twice annually.
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), observation of centrifuge and interview with the Technical Supervisor (TS), the laboratory failed to follow Urine Microscopic procedure from 12/15/15 to the date of survey. The finding includes: 1. The ME procedure stated to "Spin urine specimen for 5 minutes but the laboratory spun for 10 minutes. 2. The laboratory did not have a source for microscopic procedure. 3. The TS confirmed on 6/13/18 at 1:30 pm that the laboratory did not follow the PM instructions. 35471 b) Based on surveyor review of the Procedure Manual (PM), observation of centrifuge and interview with the Testing Personnel (TP), the laboratory failed to follow the Coagulation (Coag) procedure from 12/15/15 to the date of survey. The finding includes: 1. The PM stated to "Spin Coag specimens at "3000 RPMs for 15 minutes" but the TP stated Coag samples were spun at 4000 RPMs for 10 minutes. 2. The TP #2 listed on CMS form 209 confirmed on 6 /13/18 at 1:30 pm that the laboratory did not follow the PM. c) Based on surveyor review of the PM, Quality Control (QC) records and interview with the TP, the laboratory failed to follow the QC verification procedure for QC used on the Coulter LH 750, Sysmex CA 500 and Premier Trinity Biotech 9210 from 12/15/15 to the date of the survey. The findings include: 1. This was cited on the previous survey and the Plan of Correction stated "QC are correlated concurrent with the old lot using a minimal of ten data points for each level of QC over a five day period". 2. A review of the QC verification revealed the laboratory ran new QC five times over two days. 3. The TP #2 listed on CMS form 209 confirmed on 6/13/18 at 11:55 am that the laboratory did not follow the PM. d) Based on surveyor review of the PM and interview with the TP, the laboratory failed to follow the Quality Management (QM) procedure from 12/15/15 to the date of the survey. The finding includes: 1. The QM stated a Quality Assurance review was to be performed monthly but there was no documented evidence that it was performed. 2. The TP #2 listed on CMS form 209 confirmed on 6/13/18 at 2:15 pm that the laboratory did not follow the PM.
D5409	PROCEDURE MANUAL

	CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to record a discontinuance date on "Quality Control (QC) Material Lot Change Procedure" from 12/15/15 to the date of the survey. The finding includes: 1. The laboratory had two procedures for QC Lot Change but there was no discontinuance date documented on either procedure. 2. The TP #2 on CMS form 209 confirmed on 6/13/18 at 1:30 pm that a discontinuance date was not recorded.
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: a) Based on surveyor observation of the Quality Control (QC) material and interview with the Testing Personnel (TP), the laboratory failed to put open and new expiration dates on Routine Chemistry, Endocrinology, Hematology and Hemoglobin A1C QC material at the time of survey. The findings include. 1) The expiration date of control material shortens once opened. 2) The laboratory did not put new expiration dates on Lyphocheck Immunoassy Plus Control, Lyphocheck Liquid Assayed Multiqual Control, and Liquichek Urine Chemistry Control QC in use. 3) The laboratory did not put new expiration dates on Lyphocheck Coagulation Control, Glycolated Hemoglobin and Streck Para 12 Plus QC in use. 4) The TP #2 listed on CMS form 209 confirmed on 6/13/18 at 2:30 pm the laboratory failed to put new expiration dates on the control material. 35471 b) Based on surveyor observation of the Coagulation reagents and interview with the TP, the laboratory failed to label the cleaning reagent used on the Sysmex CA 500 with pertinent information required for proper use on the date of the survey. The findings include: 1. A small bottle with a white cap was not labeled as to its identification, storage requirements, preparation and expiration date. 2. The TP stated it was cleaning reagent for the CA 500. 3. The TP #2 listed on CMS form 209 confirmed on 6/13/18 at 2:35 pm all reagents were not labeled.
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 and interview with the Testing Personnel (TP), the laboratory used expired QC material for Prostate Specific Antigen (PSA) testing from 6/10/18 to 6/13/18. The findings include: 1. QC material expiration date changes once opened. 2. The laboratory was unaware that PSA QC material was stable for 3 days. 3. PSA QC material was opened 6/7/18 and expired 6 /10/18. 4. One patient was run and reported after 6/10/18. 5. The TP #2 on CMS form 209 confirmed on 6/13/18 at 2:30 pm that the laboratory used expired QC material.
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: a) Based on surveyor observation of the Analyzer Maintenance Screen (AMS) and interview with the Testing Personnel (TP), the laboratory failed to perform and document maintenance on the Advia Centaur analyzer used for Special Chemistry and Endocrinology testing from 8/25/17 to the date of the survey. The findings include: 1. A review of AMS revealed monthly maintenance was not performed as follows: a. Monthly Cleaning - due 8/25/17 b. Replace cleaning solution - due 5/21/18 c. Empty water trap - due 5/21/18 d. Clean water bottle & reservoir - due 5/21/18 e. Prime water form reservoir to manifolds - due 5/2/18 f. Clean exterior of ancillary probes - due 5 /24/18 g. Clean exterior of aspirate probes - due 5/24/18 h. Clean exterior of reagent probes - due 5/24/18 i. Clean or replace air filter - due 5/24/1 2. The TP #2 on CMS form 209 confirmed on 6/13/18 at 1:10 pm that maintenance was not performed. 35471 b) Based on surveyor review of the Maintenance Records (MR) and interview with the TP, the laboratory failed to perform and document yearly maintenance as specified by the manufacturer on the Sysmex CA 500 analyzer used for Coagulation tests from 12/15/15 to the date of the survey. The TP #2 listed on CMS form 209 confirmed on 6/13/18 at 2:45 pm that maintenance as specified by the manufacturer was not performed.
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: Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to take corrective action when two out of three levels of control were out of range for platelet tests performed on the Cell Dyn analyzer from 1/2/18 to the date of the survey. The findings include: 1. Streck Para 12 Plus QC Low and Normal were out of range on 1/2/18 and there was no evidence of

	corrective action taken. 2. Approximately ten patient results were reported. 3. The TP #2 listed on CMS form 209 confirmed on 6/13/18 at 3:00 pm that no corrective action was taken for out of range QC on 1/2/18.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on surveyor review of the Urinalysis work records and interview with the Technical Supervisor (TS), the laboratory failed to maintain work records with the identity of the personnel who performed Urinalysis testing from 12/15/15 to the date of survey. The TS confirmed on 6/13/18 at 1:45 pm that identity of personnel was not on the work records.
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 the surveyor review of the Procedure Manual, Patient Results and interview with the Testing Personnel (TP), the laboratory failed to establish a written policy to monitor and assess problems with Coagulation tests performed on the Sysmex Ca 500 from 12/15/18 to the date of the survey. The finding includes: 1. The laboratory could not explain why the comments listed below were on the FR: INR Therapeutic Ranges for Coumadin Treatment: a. Prophylactic for Deep Vein Thrombosis 2.0-2.5 b. Hip Surgery/ Fractured Femur, Open 2.0-3.0 c. Treatment of DVT, PE, or TIA 2.0-3.0 d. Recurrent DVT or PE 3.0-4.5 2. The TP #2 listed on CMS form 209 confirmed on 6/13 /18 at 2:40 pm the laboratory did not have a procedure to monitor and assess problems on the FR.
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: a) Based on surveyor review of the Final Reports (FR) and interview with the Technical Supervisor (TS), the laboratory failed to ensure that the Test Report Date (TRD) was indicated on the FR from 12/15/15 to the date of survey. The TS confirmed on 6/13/18 at 1:45 pm that the TRD was not on the FR. b) Based on surveyor review of the FR and interview with the TS, the laboratory failed to ensure that the name and the address of the reference laboratory where send out tests were performed was on the FR from 12/15/15 to the date of survey. The TS confirmed on 6 /13/18 at 2:00 pm that the reference laboratory name and the address was not on the FR. 35471
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 surveyor review of the Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to identify the source of the Reference Interval (RI) used for Hemoglobin A1C (A1C) tests on the FR from 12/15/15 to the date of survey. The TP #2 listed on CMS form 209 confirmed on 6/13/18 at 2:55 pm that there was no documented source for the A1C RI on the FR.
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 Reports (FR) and interview with the Testing Personnel (TP), the laboratory failed to correct problems in the postanalytic system from 12/15/15 to the date of the survey. The finding includes: 1. A review of FR revealed a Complete Blood Count (CBC) with Auto Differential was reported when a CBC with a Manual Differential was performed. 2. Red Blood Cell (RBC) Morphology was reported as RBC normal on the FR. 3. The TP #2 listed on CMS form 209 confirmed on 12/15/15 at 2:45 pm that the laboratory did not correct problems in the FR.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Technical Supervisor (TS), the laboratory director failed to establish competency procedure as required by the regulation from 12/15/15 to the date of survey. The findings include: 1. The Performance Assessment procedure stated "Evaluate competency of the operator by direct observation". 2. There were no other tools listed and was not in detail. 3. The TS confirmed on 6/13/18 at 11:00 am that competency procedure was not established correctly.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. 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 TP failed to document corrective action taken when Endocrinology, Special Chemistry and Routine Chemistry controls were reran on the Dimension RXL and Advia Centaur analyzer respectively from 12/15/15 to the date of survey. The TP #2 on CMS form 209 confirmed on 6/13/18 at 1:00 pm that corrective action was not documented on out of range controls.
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 Levy Jennings (LJ) records and interview with the Testing Personnel (TP), the TP failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for Hemoglobin A1C tests performed on the Premier Trinity Biotech 9210 and Complete Blood Cell test performed on the Cell Dyn 3700 analyzer from 12/15/15 to the date of the survey. The TP confirmed on 6/13/18 at 1:45 pm that trends and shifts were not reviewed.