Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2005357	12/05/2023
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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on the lack of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to document all pertinent information and retain manufacturers' assay information sheets for QC material and Xpert Xpress CoV-2/Flu /RSV plus kits used in Virology testing performed on the Cepheid GeneXpert DX analyzer from 8/29/22 to the date of survey. The finding includes: 1. The laboratory failed to document all pertinent information for Zeptometrix NATrol QC used in Virology testing performed on the Cepheid GeneXpert DX analyzer. 2. The laboratory failed to retain all Certificates of Analysis received for Zeptometrix NATrol QC. 3. The laboratory failed to document all pertinent information for Xpert Xpress CoV-2 /Flu/RSV plus kits used in Virology testing performed on the Cepheid GeneXpert DX analyzer. 4. The TP # 2 listed on the CMS-209 form confirmed on 12/5/23 at 11:45 am that all QC records were not retained.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. 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 review coded results for

	Hematology Testing performed with the College of American Pathologists (CAP) in the calendar years 2022 and 2023. The findings include: 1. The laboratory received coded results (Code 26 -Educational Challenge) for Urine Chemistry- General for event U-A- 2023. a) Urine albumin/creati ra samples U-04, 05, 06 received code 26. 2. The laboratory received coded results (Code 27 - Lack of participant or referee consensus) for Urine Drug Testing (Screening) even UDS-A 2023. a) Immunochromatography Medtox Cut-Off 500 sample UDS-05 was coded see note 27. 3. The laboratory received coded results (Code 28 - Response qualifies with a great than or less than sign: unable to quantitative) for S-A 2023 Diagnostic Immunology. a) Antistreptolysin O (ASO) quant sample ASO-02, 04,05 were coded 28, there was no documented evidence of peer group comparison performed. 4. The laboratory received coded results (Code 28 - Response qualifies with a great than or less than sign: unable to quantitative) and unacceptable results for S-B 2023 Diagnostic Immunology. a) Antistreptolysin O (ASO) quant sample ASO-08, 09 were coded 28, there was no documented evidence of peer group comparison performed. b) Rheumatoid Factor (RF) Screening, quant samples RF-07, 10 were graded Unacceptable. 5. The laboratory received coded results (Code 26 -Educational Challenge) for Coagulation, Limited for event CGL-B 2023. a) Prothrombin Time (PT) qual samples CGL-06, 07, 08 ,09,10 received code 26. b) Active Partial thromboplastin Time (PTT), qual samples CGL-06, 07, 08 ,09,10 were graded "see note 26" 6. The laboratory received coded results (Code 26 -Educational Challenge) for Urine Chemistry- General for event U-B- 2023. a) Urine albumin/creati ra samples U-10,11,12 were graded "see note 26" 7. The laboratory received coded results (Code 26 -Educational Challenge) for Blood Cell ID, Photographs for event KP-C 2022. a) Blood Cell ID upgraded sample BCP-26, 27 ,28 ,29, 30 were graded "see note 26" 8. There was no documented evidence that aforementioned coded PT results were reviewed. 9. The TP confirmed on 12/5/23 at 1:15 pm that the laboratory did not review coded PT results.
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 Cepheid GeneXpert Dx and Sentosa SX101 Operator's Manuals (OM) and Vela ViroKey Virus Total Nucleic Acid Kit package insert, the room temperature and humidity logs and interview with the Technical Supervisor (TS), the laboratory failed to provide accurate acceptable ranges for room temperature and humidity consistent with the manufacturer's requirements in the main laboratory, PCR room #3 and storage area from 4/7/20 to the date of the survey. The findings include: 1. The room temperature and humidity logs used in all rooms stated the acceptable ranges were 15-28C for room temperature and 20-80% for humidity. 2. The OM for the Cepheid GeneXpert Dx located in the main laboratory defined the room temperature requirement as 20-25C. 3. The OM for the Sentosa SX101 located in PCR room #3 defined the room humidity requirement as 55-75%. 4. The package

	insert for the Vela ViroKey Virus Total Nucleic Acid Kits located in the storage area defined the room temperature requirement as 15-25C. 5. The TS confirmed on 12/5/23 at 2:00 pm that the laboratory failed to provide accurate acceptable ranges for room temperature and humidity consistent with the manufacturer's requirements on all room temperature and humidity logs.
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 Quality Control Materials (QCM) and interview with the Testing Personnel (TP), the laboratory failed to appropriately label QCM used for Virology tests performed on the Cepheid GeneXpert DX analyzer from 8/29 /22 to the date of the survey. The findings include: 1. The Positive QCM was observed in a container labeled as "FLU/RSV/SARS Positive Control 3/3/23". It did not indicate an expiration date, lot number, storage requirements or other pertinent information required for proper use. 2. The Negative QCM was observed in an unlabeled container that did not have an identity, expiration date, lot number, storage requirements or other pertinent information required for proper use. 3. The TP #2 as listed on CMS form 209 confirmed on 12/5/23 at 11:30 am that the QC materials used were not labeled appropriately.
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 the lack of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment of Zeptometrix NATrol QC used on the Cepheid GeneXpert DX analyzer for Virology testing from 8/29/22 to the date of the survey. TP #2 as listed on the CMS-209 form confirmed on 12/5/23 at 1:10 pm that the QC material was not verified before putting into use.

D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the lack of Quality Control (QC) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure the QC program was established and maintained from 8/29/22 to the date of the survey. The findings include; 1. The LD failed to ensure there were QC Verification procedures for Virology tests performed on the Cepheid GeneXpert DX analyzer. 2. The LD failed to ensure the laboratory documented all QC procedures performed with all pertinent information. 4. The TP #2 as listed on the CMS- 209 form confirmed on 12/5/23 at 12: 00 PM the LD failed to ensure the QC program was established and maintained.