Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2257859	11/13/2024
Name of Provider or Supplier	**Street Address, City, State**	
Atlas Diagnostics	926 S Elmora Ave, Elizabeth, 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
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Technical Supervisor (TS), the laboratory lacked copies of all PT records for testing performed with the American Proficiency Institute (API) for the 2nd Coagulation PT event of 2024. The findings include: 1. The laboratory lacked the work records and the attestation page for the 2nd Coagulation PT event of 2024. 2. The TS confirmed on 11/13/24 at 11:30 am, all PT records were not retained.
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: A) Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Supervisor (TS), the laboratory failed to review PT performance codes "See note [20]", " Response was not formally graded due to insufficient peer group data. Please see the participation summary for additional information" results obtained for PT performed with the College of American Pathologists (CAP) in the calendar year 2024 The findings include: 1. "See note [20]" results were received for event K-B 2024 Ligand-Generaln as follows: a) Triiodthyronie (T3) samples K-06, K-07, K-08, K-09, K-10. b) Free Triiodthyronie (FT3) samples K-06, K-07, K-08, K-09, K-10. c) Thyroxine (T4) samples K-06, K-07, K-08, K-09, K-10. d) free Thyroxine

	(FT4) samples K-06, K-07, K-08, K-09, K-10. e) Thyroid Stimulating Hormone (TSH) samples K-06, K-07, K-08, K-09, K-10. f) Vitamin B-12 samples K-06, K-07, K-08. 2. "See note [20]" results were received for event K-A 2024 Ligand-General as follows: a) Triiodthyronie (T3) samples K-01, K-02, K-3, K-04, K-05. b) Thyroxine (T4) samples K-01, K-02, K-3, K-04, K-05. 3. The TS confirmed on 11/12/24 at 11:30 am that the laboratory failed to evaluate PT performance codes. 48354 B) Based on surveyor review of the PT records and interview with the TS, it was revealed that the laboratory failed to review PT performance codes "See note [30]" (Scientific committee decision) results obtained for PT performed with the College of American Pathologists (CAP) for Urine Drug Screening (UDS) event A of 2024. The findings include: 1. Ethanol samples UDS 01,02,03,04, and 05 and had coded results for see note 30 which were not evaluated. 2. The TS confirmed on 11/13/24 at 2:15 pm, the laboratory did not evaluated coded results for PT results obtained for UDS event A of 2024
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 the surveyor review of the Procedure Manual (PM) and interview with the Technical Supervisor (TS), the PM lacked all applicable procedures for Coagulation tests performed from 9/7/24 to 11/13/24. The findings include: 1) The PM lacked a procedure to establish new normal patient mean and reference ranges with each new lot of thromboplastin. 2) The TS confirmed on 11/13/24 at 2:20 pm, the above mentioned procedure was not available for review.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

	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 PM lacked Reference Intervals (RI) and established Reportable Ranges (RR) for Complete Blood Count (CBC) tests performed on the Beckman Coulter DxH 560 analyzer from 9/1/23 to 11/13/24 The findings include: 1. The PM lacked RI and a source for CBC tests performed on the DxH 560 analyzer. 2. The PM lacked established RR for CBC tests performed on the DxH 560 analyzer. 3. The TS confirmed on 11/13/24 at 1:00 pm, the PM lacked RI and RR for CBC tests.
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 review of the Quality Control (QC) Records and interview with the Technical Supervisor (TS), the laboratory failed to document preparation and expiration dates on QC material for Endocrinology testing performed on the Siemens Immulite 2000 analyzer from September 2024 to 11/13/24. The findings include: 1. The QC material expiration date changed once opened. 2. Bio-Rad Lyphochek Immunoassay Plus Controls were stable as follows: a) After reconstituting and storing tightly capped at 2-8 degrees Celcius that product will be stable - all analytes for 7 days. Folate and Prostate-Specific Antigen (PSA) 3 days. 3. Bio-Rad Lyphochek Immunoassay Plus Controls 1 Lot # 40441 and 3 Lot # 40443 had no open or expiration dates documented. 4. The TS confirmed on 11/13/24 at 11:00 am, the laboratory did not document preparation and expiration dates on QC material used for Endocrinology testing. 48354 B) Based on surveyor review of the Procedure Manual (PM), Manufacturers Package Insert (MPI) for DxH 560 control material, the QC currently in use and interview with the TS, the laboratory failed to document expiration dates on QC material used for the Hematology tests performed on the Beckman Coulter DxH 560 analyzer. The finding includes: 1. The PM states " if expiration date after opening is different from the expiration of the unopened product, the new expiration date should be written on the label." 2. The DxH 500 series control MPI states the QC material has an open stability time of 16 days. 3. QC lot # 352416511, 352416512 and 352416513 did not have new expiration dates written on them. 4. The TS confirmed on 11/13/24 at 2:00 pm, the laboratory did not document expiration dates on QC material for Hematology testing.
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 Technical Supervisor (TS), the laboratory used expired QC material for Toxicology testing from to 10/10/24 to 11/13/24. The findings include: 1. QC material expiration date changes once opened. 2. MAS DOA Total Drugs of abuse QC material was stable for 30 days after opening. 3. MAS DOA Total Drugs of abuse level 4 lot # DAT260854B and 5 lot DAT26084A expired 10/10/24. 4. Approximately 31 patients were run and reported. 5. The GS confirmed on 11/13/24 at 11:00 am 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 the Sysmex CA 600 Performance Specification (PS) records and interview with the Technical Supervisor (TS), the laboratory failed to ensure that all PS records were adequate for all analytes run on the Sysmex CA 600 for Coagulation tests from 10/27/24 to 11/13/24. The findings include: 1. The laboratory failed to calculate and implement their normal patient mean used for coagulation tests performed on the Sysmex CA 600 before patient testing. 2. There was no documented evidence the laboratory information system (LIS) was verified with the Sysmex CA 600 before patient use. 3. The TS confirmed on 11/13/24 at 10:50 am, the laboratory failed to ensure that all PS records were adequate.
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 Verification (QCV) records and interview with the Technical Supervisor (TS), the laboratory failed to verify QC material before paitent testing for toxicology tests performed on the Horiba Yumizen CL1200 from

	September 2024 to 11/13/24. The findings include: 1) There was no documented evidence that QCV was performed on the aforementioned analyzer. 2) The GS confirmed 11/13/2024 at 1:15 pm there was no documented evidence that QC material was verified before patient testing.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Quality Control Records (QCR) and interview with the Technical Supervisor (TS), the laboratory failed to follow the Corrective Action (CA) policy for Quality Control (QC)for Hematology tests performed from 10/17/24 to 11/13/24. The finding includes: 1. The "Quality Control Corrective Action Chart" stated if one QC level out, rerun QC from same bottle, if QC result not in, rerun with fresh QC, if QC result not in then recalibrate. 2. QC lot # 362416412 Normal QC value for Mean Platelet Volume (MPV) failed six times on 10/15/24 and two times on 10/17/24 before the analyzer was recalibrated. 3. The TS confirmed on 11/13/24 at 1:45 pm, the laboratory failed to follow the laboratory's CA policy.
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, Observation in the analyzer and interview with the Technical Supervisor (TS), the laboratory failed to take Corrective Action (CA) when controls were out of range for Toxicology tests performed on the Horiba Yumizen C1200 analyzer from 11/7/24 to 11/13/24. The findings include: 1. A review of the QC records for MAS DOA Total 4 control failed for negative Amphetamine on 11/7/24. 2. There was no documented evidence the laboratory peformed corrective action for the above mentioned QC failure. 3. Approximately 5 patients were run and reported. 4. The TP confirmed on 11/13/24 at 1:30 pm that corrective action on failed QC was not performed and documented.
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 surveyor review of the Procedure Manual and interview with Technical Supervisor (TS), the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from 4/12/22 to 11/13/24. The finding includes: 1. The laboratory lacked a Quality Control Verification (QCV) procedure for all specialties performed by the laboratory. 2. The TS confirmed on 11/13/24 at 11:45 am that the laboratory failed to have a QCV procedure for all specialties.
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 Test Reports (TR) for Chemistry and Endocrinology tests sent to reference laboratories and interview with the Technical Supervisor (TS), the laboratory failed to ensure the TR included all the required information from September 2024 to 11/13/24. The findings include: 1. TR did not specify which analytes tested where sent to a reference laboratory. 2. The TS confirmed on 11/12/24 at 12:00 pm, the laboratory failed to ensure the TR included all the required information. Note: This deficiency was corrected onsite. 48354 Based on surveyor review of the Sysmex CA 600 Test Records (SCATR) , Test Reports (TR) and interview with the TS, the laboratory failed to ensure that the FR had accurate results for Coagulation tests performed on the Sysmex CA 600 from 9/7/24 to 11/1 /24. The finding includes: 1. A review of patient SCATR and TR revealed four out of four patient reports had inaccurate test results for international normalized ratio. The results from the SCATR and TR were as follows: a) Accession number 4133 had an INR of 0.969 from the SCATR but was reported as 1 on the TR. b) Accession number 4185 had an INR of 0.0.948 from the SCATR but was reported as 1 on the TR. c) Accession number 3961 had an INR of 0.886 from the SCATR but was reported as 1 on the TR. d) Accession number 3868 had an INR of 0.958 SCATR but was reported as 1 on the TR. 2. The TS confirmed on 11/13/24 at 1:45 pm, patient TR for coagulation tests had inaccurate results.
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), Performance Specifications (PS) for the Sysmex CA 600, Procedure Manual (PM),Test Records (TR) from the analyzer and interview with the Technical Supervisor (TS), the laboratory failed to have accurate Reference Intervals (RI) for Coagulation tests from 9/7/24 to 11/1/24. The findings include: 1. The PS stated the international normalized ratio (INR) established was 0.80- 1.10 2. Review of patient FR revealed that four out of four patient reports had an INR RI of 1-1. 3. The TS confirmed on 11/13/24 at 1:00 pm, the laboratory did not implement the established RI for INR.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records and interview with the Technical Supervisor (TS), the Laboratory Director (LD) failed to ensure that PS were adequate to perform Chemistry tests performed on the Horiba Yumizen C1200 analyzer from September 2024 to 11/13/24. The findings include: 1. The laboratory failed to perform linearity for hemoglobin A1C and Vitamin D. 2. The TS confirmed on 11/12/24 at 11:15 am, that the LD failed to ensure the PS were adequate.