Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2263712	07/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Amedix Diagnostic	1500 Cardinal Dr, Little Falls, 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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on surveyor observation of the laboratory's New Jersey Clinical Laboratory License and an in office review of the laboratory's requirements for a NJCLL under New Jersey Statutes Annotated: N.J.S.A. 45:9-42.26. License; necessity; categories, the laboratory performed unauthorized patient testing under the subspecialty General Immunology from 1/1/25 to 7/9/25. The findings include: 1. Surveyor observation of the laboratory's NJCLL revealed the laboratory was only authorized to perform the below indicated specialties from 1/1/25 to 12/31/25: a) Chemistry b) Endocrinology c) Hematology d) Urinalysis 2. The laboratory performed approximately 2,500 unauthorized patient tests under the General Immunology subspecialty. 3. A surveyor from the NJCLL program confirmed on 7/11/25 at 1:00 pm, he laboratory was not authorized to perform testing under the General Immunology subspecialty.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by:

	Based on surveyor review of the Proficiency Testing (PT) records and interview with the Techincal Consultant (TC) laboratory failed to verify the accuracy of Folate test results obtained from the American Proficiency Institute (API) for the Chemistry-Core 2nd event 2025. The findings include: 1. The laboratory received a score of 100% but received a code "9" for Folate samples IA-07 and AI-09. 2. API reported the range for Folate sample IA-07 as 3.7-7.1 ng/mL. 3. The laboratory reported Sample IA-07 as out of range for Folate with 7.4 ng/mL. 4. The TC confirmed on 7/9/25 at 10:20 am accuracy of the PT results were not verified.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (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), Unassayed Quality Control Verification Sheet (UQCVS) and interview with the Technical Consultant (TC), the laboratory failed to have a complete procedure for "Establish or verify the criteria for acceptability of all control materials" from 7/5/22 to 7/9/25. The findings include: 1. The PM stated, "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." 2. The above procedure doe not state how the Quality Control (QC) material will be "verified." 3. The PM stated, "Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control material previously determined statistical parameters." 4. The above procedure does not state how new unassayed QC lots will be verified before being put into use for patients testing. 5. The TC confirmed on 7/9/25 at 11:30 am that the laboratory did not have the above mentioned procedures. B) Based on surveyor review of the Procedure Manual (PM), lack of Levy Jennings Graphs (LJG) and interview with the Technical Consultant (TC), the laboratory failed to follow their procedure for "Quality Control" from 7/5/22 to 7/9/25. The findings include: 1. The PM stated "The supervisor is to monitor on a monthly basis adherence to QC frequency, monitor any failed runs and corrective action taken", "corrective actions are to be reviewed and trends monitored." 2. LJG were printed adhoc during the survey. 3. There was no documented evidence QC was monitored on a monthly basis. 4. The TC confirmed on 7/9/25 at 11:30 am that the laboratory did not follow the above mentioned procedures. C) Based on surveyor review of the Procedure Manual (PM), and interview with the Techncal Consultant (TC), the laboratory failed to have a procedure for the calculation of Estimated Glomerular Filtration Rate (eGFR) from 7/5/22 to 7/9/25. The TC confirmed on 7/9/25 at 11:30 am that the laboratory failed to have the above mentioned procedure.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 Standard Operating Procedures Manual (SOPM) and interview with the Technical Consultant (TC) the laboratory failed ot provide complete procedures for Quality Control (QC). The findings include: 1. The laboratories Quality Control (QC) procedures lacked a criteria for acceptability and what corrective action to take when QC results fail to meet a criteria for acceptability from 7/5/22 to 7/9/25. 2. The TC confirmed on 7/9/25 at 1:45 pm, that the PM lacked criteria for QC acceptability and correction action for failures.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: A) Based on surveyor observation of the Specific Gravity (SG) calibration material, surveyor review of the Manufacturers package insert (MPI), maintenance records and interview with the Technical Consultant (TC), Testing Personnel (TP) did not follow the MPI for performing SG calibration used in Urinalysis testing performed on the Arkray Aution Max analyzer from 5/28/25 to 7/9/25. The findings include: 1. The MPI for the SG Calibrator states, "Transfer the entire solution from each bottle into the measurement container, and use in accordance with operating manual for the analyzer. Do not reuse." 2. The SG calibrator in the refrigerator, lot 4F05, had an opened date of 12/23/24 with solution still in the bottle. 3. The TC confirmed on 7/9 /25 at 11:30 am, TP did not follow the MPI. B) Based on surveyor observation of Quality Control (QC) material in use, review of the Manufactures Package Insert (MPI), Procedure Manual (PM) and interview with the Technical Consultant (TC), the laboratory did not follow the MPI for QC material used for the Beckman Coulter Access 2 analyzer from 6/2/25 to 7/9/25. The findings include: 1. Surveyor observation of the freezer revealed the laboratory aliquotted BioRad Liquichek Immunoassay Plus QC, lot # 85390, on 6/2/25 and refroze the QC material. The refrozen QC material was labeled with an expiration date of 2/28/26. 2. The MPI

	states "This product is shipped under frozen conditions. Once thawed, do not refreeze this product." Once thawed and opened, most of the analytes for the Biorad Liquichek Immunoassay QC have a stability of 14 days. 3. The laboratory used expired QC material for the Beckman Coulter Access 2. Approximately 20 patients results were reported during the above mentioned time frame. 4. The TC confirmed on 7/9/25 at 1: 30 pm, TP did not follow the MPI.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation of the Quality Controls (QC) in use, review of the Manufacturers Package Insert (MPI) and interview with the Technical Consultant (TC), the laboratory failed to put open and expiration dates on QC material in use for Urinalysis tests from 7/1/25 to 7/9/25. The finding includes: 1. The MPI states, "QC material for the DxU has an Open expiration: 30 days." 2. DxU QC, lot 033-25, was not labeled with opened or new expiration dates. 3. The TC confirmed on 7/9/25 at 1: 35 pm, the laboratory did not label the QC in use with opened or new expiration dates.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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, Manufacturers Instructions for Use (MIU) and interview with the Techincal Consultant (TC), the laboratory used expired QC material for Routine Chemistry testing performed on the Beckman Coulter AU480 from 4/15/25 to 7/9/25. The findings include: 1. The MIU for Bio-Rad Liquid Unassayed Multiqual QC material stated, "Aliquot Frozen: once aliquoted and stored in tightly capped amber vials at -20 to -80 degrees Celcius this product will be stable as follows, All analytes 14 days." 2. The laboratory reconstituted and aliquoted Bio-Rad Liquid Unassayed Multiqual QC material on 4/1 /25. 3. The QC expired 4/15/25. 4. Approximately 250 patients had Routine Chemistry testing performed and reported. 5. The TC confirmed on 7/9/25 at 1:00 pm that the laboratory used expired QC material.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or

	specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of the Specific Gravity (SG) Calibration records, Procedure Manual (PM), and interview with the Technical Consultant (TC), the laboratory failed to document the SG calibrators lot numbers used for calibration procedures performed on the Arkray Aution Max analyzer from 7/1/24 to 1/1/25. The findings include: 1. The laboratory did not document which lot numbers of reference material were used for SG calibration. 2. The TC confirmed on 7/9/25 at 11:15 am, the laboratory failed to document the lot numbers of calibration material used when SG calibration was performed.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC), Procedure Manual and interview with the Technical Consultant (TC) the laboratory failed to have control procedures that detect immediate errors that occur due to operator performance for routine chemistry testing perform on the Beckman coulter AU480 from 7/5/22 to 7/9/25. The findings include: 1. The laboratory Assayed control material Bio-Rad Liquid Unassayed Multiqual QC Lot # 56760 on 10/21/24. 2. The laboratories assayed results for Bio-Rad Liquid Unassayed Multiqual QC Lot # 56760 did not match what was entered into the Laboratory Information System (LIS) as follows. a) Aspartate aminotransferase (AST) Lot # 56761 Assayed value was 32.98 U/L - 36.02 the LIS was 33-37 U/L. b) AST Lot # 56762 Assayed value was 87.4-92.30 U/L the LIS was 86-94 U/L. c) Total Bilirubin (TBIL) Lot # 56761 Assayed value was .674-7.26 mg /dL the LIS was .625-.677 mg/dL. d) TBIL Lot # 56762 Assayed value was 1.56-176 mg/dL the LIS was 1.46-1.86 mg/dL. e) Chloride (CL) Lot # 56761 Assayed value was 71-76 mEq/Lthe LIS was 67-79 mEq/L. f) CL Lot # 56762 Assayed value was 96.37-98.77 mEq/L the LIS was 94-102 mEq/L. g) Calcium (CA) Lot # 56761 Assayed value was 5.3-5.684 mg/dL the LIS was 5.2-5.8 mg/dL. h) CA Lot # 56762 Assayed value was 9.53-9.93mg/dL the LIS was 9.3-10.1 mg/dL. i) Bicarbonate (CO2) Lot # 56761 Assayed value was 14.28-17.72mEq/L the LIS was 15-17 mEq/L.

	j) CO2 Lot # 56762 Assayed value was 16.25-20.25 mEq/L the LIS was 18-20 mEq /L. 3. The TC confirmed on 6/1/21 at 12:30 pm that the laboratory failed to have control procedures that detect immediate errors that occur due to operator performance.
D5807	TEST REPORT CFR(s): 493.1291(d) (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 Test Reports (TR), Procedure Manual (PM) and interview with the Technical Consultant (TC), the laboratory failed to have accurate Reference Intervals (RI) on the TR's for Routine Chemistry tests performed on the Beckman Coulter AU480 analyzer from 4/30/25 to 7/9/25 The findings include: 1. The PM and TR had different RI for the following analytes: a) The PM had Sodium as 136-145 mmol/L, but TR had the RI as 134-146 mmol/L. b) The PM had Potassium as 3.5-5.1 mmol/L, but TR had the RI as 3.4-5.4 mmol/L . c) The PM had Chloride as 98-107 mmol/L, but the TR had the RI as 96-108 mmol/L. d) The PM had Ferritin as Male 23.9-336.2, but TR had the RI for Male as 10.0-440.0 ng/mL. e) The PM had Vitamin B12 as 180-914 pg /mL, but TR had the RI as 241-897 pg/mL. f) The PM had Folate as 5.9 to >24.8 ng/mL, but the TR had the RI as 2.9-17.7 ng/mL. 2. The TC confirmed on 7/9/25 at 1:45 pm, the laboratory did not not have accurate RI.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor review of the Laboratory records and interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory from 7/5/22 to 7/9/25. The findings include: 1. The LD failed to failed to ensure that Performance Specification (PS) procedures performed on the Beckman Coulter DxH 560 analyzer were adequate, Cross refer to D6013. 2. The LD failed to ensure that the quality assessment programs are maintained. Cross refer to D6020. 3. The LD failed to identify problems that may affect test performance. Cross refer to D6074.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by:

	Based on surveyor review of the Performance Specification (PS) records and interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to ensure that PS procedures performed on the Beckman Coulter DxH 560 analyzer were adequate from 5/15/24 to 7/9/25. The finding includes: 1. There was no reference range study performed for the normal population range. 2. The reportable ranges were not verified or established before being used for patient testing. 3. The TC confirmed on 7/9/25 at 11:20 am, the LD failed to ensure the PS were adequate before being used for patient testing.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment 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 surveyor review of Quality Assessment (QA) records and the Procedure Manual (PM), the Laboratory Director (LD) failed to ensure that the quality assessment programs are maintained for routine chemistry performed on the Beckman Coulter AU480 from 7/25/22 to 7/9/25. Cross refer to 5441.
D6074	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(5) (b)(5) 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; and This STANDARD is not met as evidenced by: Based on the surveyor review of Quality Control (QC) records and interview with the Technical Consultant (TC), the Laboratory Director (LD) failed to identify problems that may affect test performance by not reviewing and evaluating trends and/or shifts for tests performed on the Beckman coulter AU 480 analyzer from 7/5/22 to 7/9/25. Cross refer to D5401(B).