Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2245027	11/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Diagnostic Testing Solutions Inc	4401 N Keeler Ave, Chicago, IL	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the laboratory director (LD), the laboratory failed to enroll in an approved Centers for Medicare and Medicaid Services (CMS) proficiency testing (PT) program for three of three regulated immunology analytes before reporting Antistreptolysin-O (ASO), AntiNuclear antibodies (ANA), and Rheumatoid Factor (RF) patient test results for immunology in 2023. Findings Include: 1. Review of laboratory records revealed the laboratory performed regulated immunology analyte testing of Antistreptolysin-O (ASO), AntiNuclear antibodies (ANA), and Rheumatoid Factor (RF), utilizing the ASI Slide Test latex agglutination assay from the month of January 2023 to the date of survey 11/17/2023. 2. Review of laboratory records revealed no documented evidence of PT enrollment in an approved CMS program for the following three analytes: a) Antistreptolysin-O (ASO) b) AntiNuclear antibodies (ANA) c) Rheumatoid Factor (RF) 3. On 11/17/2023, at 1:30 p.m., the LD confirmed the above findings.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230

	Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the laboratory director (LD), the laboratory failed to monitor and evaluate the overall quality for C-Reactive Protein (CRP) testing at least twice a year in 2023. (Refer to D5217).
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 review of laboratory records, lack of documentation, and interview with the laboratory director (LD), the laboratory failed to evaluate the biannual method accuracy for C-Reactive Protein (CRP) testing at least twice a year in 2023. Findings Include: 1. Review of laboratory records revealed the laboratory performed moderate complexity immunology testing of C-Reactive Protein (CRP), utilizing the ASI Slide Test latex agglutination assay from the month of January 2023 to the date of survey, 11/17/2023. 2. Review of laboratory records and lack of documentation revealed that the laboratory failed to evaluate and document the biannual method accuracy for C-Reactive Protein (CRP) testing in 2023. 3. On 11/17/2023, at 1:30 p.m., the LD confirmed the above finding.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory records, patient test reports, lack of documentation, and interview with the laboratory director (LD) the laboratory: a) failed to demonstrate performance specifications comparable to the manufacturer's characteristics for accuracy, precision, reportable range of test results, and verification of the manufacturer's reference intervals for one of one moderate complexity latex agglutination assay (ASI Slide Test) before reporting four of four moderate complexity immunology (Antistreptolysin-O (ASO), AntiNuclear antibodies (ANA),

	C-Reactive Protein (CRP), and Rheumatoid Factor (RF) analytes in 2023. Affecting 200 patient tests performed (refer to D5421); b) failed to record two control materials of different concentrations performed on the Vital Envoy 500 analyzer (SN: 43111056) for reporting 19 of 19 (Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, Blood Urea Nitrogen, Creatinine, Calcium, Iron (total iron-binding capacity), Total Protein, Albumin, Aspartate Aminotransferase / Serum Glutamic Oxaloacetic Transaminase (AST / SGOT), Alanine Aminotransferase / Serum Glutamic-Pyruvic Transaminase (ALT / SGPT), Alkaline Phosphatase, Total Bilirubin, Total Cholesterol, Triglycerides, High-density lipoprotein (HDL) - Cholesterol, Low-density lipoprotein (LDL) - Cholesterol) moderate complexity chemistry analytes on three of three (01/27/2023, 05/01/2023 and 11/15/2023) patient testing dates (refer to D5447); c) failed to perform positive and negative control procedures on the ASI Slide Test latex agglutination assay for reporting four of four (Antistreptolysin-O (ASO), AntiNuclear antibodies (ANA), C-Reactive Protein (CRP), and Rheumatoid Factor (RF)) moderate complexity immunology analytes on four of four (01/27/2023, 05/01/2023, 08/04/2023 and 11/11/2023) patient testing dates(refer to D5449); d) failed to maintain the instrument run records for 19 of 19 (Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, Blood Urea Nitrogen, Creatinine, Calcium, Iron (total iron-binding capacity), Total Protein, Albumin, Aspartate Aminotransferase / Serum Glutamic Oxaloacetic Transaminase (AST / SGOT), Alanine Aminotransferase / Serum Glutamic-Pyruvic Transaminase (ALT / SGPT), Alkaline Phosphatase, Total Bilirubin, Total Cholesterol, Triglycerides, High-density lipoprotein (HDL) - Cholesterol, Low-density lipoprotein (LDL) - Cholesterol) moderate complexity chemistry analytes utilizing the Vital Envoy 500 analyzer (SN: 43111056) for three of three dates in 2023; the laboratory also failed to maintain the testing records for four of four (Antistreptolysin-O (ASO), AntiNuclear antibodies (ANA), C-Reactive Protein (CRP) moderate complexity immunology analytes utilizing the ASI Slide Test latex agglutination assay for four of four dates in 2023 (refer to D5789).
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 review of laboratory records, lack of documentation, and interview with the laboratory director (LD), the laboratory failed to demonstrate performance specifications comparable to the manufacturer's characteristics for accuracy, precision, reportable range of test results, and verification of the manufacturer's reference intervals for one of one moderate complexity latex agglutination assay (ASI Slide Test) before reporting four of four moderate complexity immunology (Antistreptolysin-O (ASO), AntiNuclear antibodies (ANA), C-Reactive Protein (CRP), and Rheumatoid Factor (RF) analytes in 2023. Affecting 200 patient tests performed. Findings Including: 1. Review of the "Diagnostic Testing Solutions DTS Method Validation 09" revealed the following: "Unmodified, EUA, FDA - cleared or

	approved methods: Each new test / method performance specifications must be verified to substantiate the manufacturer's claim under the laboratory conditions and approved by the laboratory director for patient testing. Patient testing should NOT occur prior training and authorization." 2. Review of laboratory records, and lack of documentation revealed the laboratory failed to demonstrate performance specifications comparable to the manufacturer's characteristics for accuracy, precision, reportable range of test results, and verification of the manufacturer's reference intervals for one of one moderate complexity latex agglutination assay (ASI Slide Test) before reporting four of four moderate complexity immunology analytes in 2023 (affecting 200 patient tests performed): a) Antistreptolysin-O (ASO) b) AntiNuclear antibodies (ANA) c) C-Reactive Protein (CRP) d) Rheumatoid Factor (RF) 3. On 11 /17/2023, at 12:14 p.m., the LD confirmed the above findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the laboratory director (LD), the laboratory failed to perform two control materials of different concentrations for 19 of 19 moderate complexity chemistry analytes for three of three patient testing dates utilizing the Vital Envoy 500 analyzer (SN: 43111056) in 2023. Findings Include: 1. Review of laboratory records and patient test reports identified the laboratory performed testing for 19 (Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, BUN, Creatinine, Calcium, Iron (TIBC),Total Protein, Albumin, AST / SGOT, ALT / SGPT, Alkaline Phosphatase, Total Bilirubin, Total Cholesterol, Triglycerides, HDL - Cholesterol, LDL - Cholesterol) moderate complexity chemistry analytes utilizing the Vital Envoy 500 analyzer (SN: 43111056) in 2023. 2. Review of laboratory records revealed two control materials of different concentrations were not performed on the Vital Envoy 500 analyzer (SN: 43111056) prior to reporting the 19 analytes identified in Finding 1 for three of three dates when patient results were reported. a. REPORT DATE: 01/27/2023 LAB #: 1753 ANALYTE REPORTED: Iron (TIBC) b. REPORT DATE: 05/01/2023 LAB #: 2166 ANALYTE REPORTED: Iron (TIBC) c. REPORT DATE: 11/15/2023 LAB #: 2664 ANALYTES REPORTED: Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, BUN, Creatinine, Calcium, Total Protein, Albumin, AST / SGOT, ALT / SGPT, Alkaline phosphatase, Total Bilirubin, Total Cholesterol, Triglycerides, HDL - Cholesterol, LDL - Cholesterol 3. On 11/17/2023, at 12:14 p.m., the LD confirmed the above findings.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g)

	The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records, patient test reports, lack of documentation, and interview with the laboratory director (LD), the laboratory failed to perform positive and negative control materials for four moderate complexity immunology analytes utilizing the ASI Slide Test latex agglutination assay in 2023. Findings Include: 1. Review of laboratory records and patient test reports identified the laboratory performs testing for four (Antistreptolysin-O (ASO), AntiNuclear antibodies (ANA), C-Reactive Protein (CRP), and Rheumatoid Factor (RF)) moderate complexity immunology analytes utilizing the ASI Slide Test latex agglutination assay in 2023. 2. Review of laboratory records revealed no positive and negative control procedures were performed for the ASI Slide Test latex agglutination assay for four moderate complexity immunology analytes (Antistreptolysin-O (ASO), AntiNuclear antibodies (ANA), C-Reactive Protein (CRP), and Rheumatoid Factor (RF)) corresponding to four of four patient test reports for the following dates: a. REPORT DATE: 01/27 /2023 LAB #: 1753 ANALYTES REPORTED: Antistreptolysin-O (ASO), AntiNuclear antibodies (ANA), C-Reactive Protein (CRP), Rheumatoid Factor (RF) b. REPORT DATE: 05/01/2023 LAB #: 2166 ANALYTES REPORTED: Antistreptolysin-O (ASO), AntiNuclear antibodies (ANA), C-Reactive Protein (CRP), Rheumatoid Factor (RF) c. REPORT DATE: 08/04/2023 LAB #: 2433 ANALYTES REPORTED: Antistreptolysin-O (ASO), AntiNuclear antibodies (ANA), C-Reactive Protein (CRP), Rheumatoid Factor (RF) d. REPORT DATE: 11/11/2023 LAB #: 2662 ANALYTES REPORTED: Antistreptolysin-O (ASO), AntiNuclear antibodies (ANA), C-Reactive Protein (CRP), Rheumatoid Factor (RF) 3. On 11/17/2023, at 12: 14 p.m., the LD confirmed the above findings.
D5789	TEST RECORDS CFR(s): 493.1283(b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on review of laboratory records, patient test reports, lack of documentation, and interview with the laboratory director (LD), the laboratory failed to maintain records of the laboratory information system (LIS) instrument print outs for 19 moderate complexity chemistry analytes utilizing the Vital Envoy 500 analyzer for three of three dates in 2023; and testing records for four moderate complexity immunology analytes utilizing the ASI Slide Test latex agglutination assay for four of four testing dates in 2023. Findings Include: 1. Review of the "Diagnostic Testing Solutions DTS (17) Laboratory Information System (LIS)" manual revealed: "Conclusion: All data from verification must be identical. File all the reports, prints, worklists, and requisitions used as LIS Verification. If any data comparison is unacceptable, contact the LIS support to troubleshoot the problem. Any discrepancy must be resolved before utilizing the LIS to generate patient report." 2. Review of laboratory records revealed the laboratory failed to maintain the instrument run records for 19 moderate complexity chemistry analytes utilizing the Vital Envoy 500 analyzer for three of three testing dates in 2023 (Refer to D5447); the laboratory also failed to maintain the

	testing records for four moderate complexity immunology analytes utilizing the ASI Slide Test latex agglutination assay for four of four testing dates in 2023 (Refer to D5449).
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory records, patient test reports, lack of documentation, and interview with the laboratory director (LD) the laboratory: a) failed to ensure the accuracy of test results entered for 17 moderate complexity chemistry analytes on two of five final patient test reports in 2023 (refer to D5801) b) failed to document the name and location of the referral testing laboratory (NTL Laboratory CLIA #14D2075610) on two of five patient test reports for 29 moderate complexity chemistry analytes; one moderate complexity hematology analyte; and two moderate complexity immunology analytes in 2023 (refer to D5805).
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of laboratory records, and interview with the laboratory director (LD), the laboratory failed to ensure the accuracy of test results entered for 17 moderate complexity chemistry analytes on two of five (5/1/2023 and 8/4/2023) final patient test reports in 2023. Findings Include: 1. Surveyor's review of the "Diagnostic Testing Solutions DTS Processing and Testing Patients 16" manual revealed the following: "Result Reporting: Laboratory test results must be entered correctly to provide optimal patient care. Results that are reported incorrectly may cause unnecessary treatment or loss of life. The data entry must compare LIS report with the instrument prints, tapes, worksheets, and any discrepancy must be resolved or corrected before releasing patient report." 2. Review of laboratory patient reports and "NTL Laboratory" (referral lab CLIA #: 14D2075610) test reports revealed the laboratory failed to ensure the accuracy of test results entered for 17 (Sodium, Potassium, Chloride, Carbon Dioxide, Creatinine, Calcium, Blood Urea Nitrogen, Albumin, Aspartate Aminotransferase, Alkaline Phosphatase, Cholesterol, Total

	Protein, Triglycerides, High-density lipoprotein (HDL) - Cholesterol, Low-density lipoprotein (LDL) - Cholesterol, and Ferritin) moderate complexity chemistry analytes on two of five "Diagnostic Testing Solutions" final patient test reports in 2023. REPORT A: "NTL LABORATORY CLIA #: 14D2075610 - Client Details Name: Diagnostic Testing Solutions Received: 04/29/2023 01:36 Reported: (Not indicated) Name: XXX Requisition # 2304345227 - CHEMISTRY COMPREHENSIVE METABOLIC PANEL" REPORT B: "DIAGNOSTIC TESTING SOLUTIONS - Received Date: 4/27/2023 01.16 Reported Date: 5/1/2023 16:57 Name: XXX Lab # 2166 - CHEMISTRY COMPREHENSIVE METABOLIC PANEL" ANALYTE* REPORT A REPORT B NA 142.9 mmol/L 145 mEq/L K 4.69 mmol/L 4.6 mEq/L CO2 20.7 Low mEq/L 21 mEq/L BUN 62.9 High mg/dL 62 H mEq/L Alb 3.59 g/Dl 3.6 g/dL AST 10.8 Low U/L 11 L U/L ALP 119.9 High U/L 119 H U/L Chol 106.5 mg/dL 106 mg/dL TG 117.5 mg/dL 117 mg/dL HDL 37.33 mg/dL 37 mg/dL LDL 45.7 mg/dL 45 mg/dL Fe 1003.9 High ng/mL 1003 H ng/mL REPORT C: "NTL LABORATORY - Client Details Name: Diagnostic Testing Solutions Received: 08/03 /2023 02:03 Reported: 08/04/2023 12:52 Name: XXX Requisition # 308030028 - CHEMISTRY COMPREHENSIVE METABOLIC PANEL" REPORT D: "DIAGNOSTIC TESTING SOLUTIONS - Received Date: 8/2/2023 12.46 Reported Date: 8/4/2023 16:57 Name: XXX Lab # 2433 - CHEMISTRY COMPREHENSIVE METABOLIC PANEL" ANALYTE* REPORT C REPORT D NA 146.7 High mmol /L 145 mEq/L Cl 107 mEq/L 106 mEq/L Creat 3.88 High mg/dL 2.3 H mg/dL Ca 8.2 Low mg/dL 8.9 mg/Dl TP 5 Low g/dL 5.1 L g/dL 3. On 11/17/2023, at 1:12 p.m., the LD confirmed the above finding. * ANALYTE KEY: NA =Sodium K = Potassium Ca = Calcium CO2 = Carbon Dioxide Cl = Chloride Creat = Creatinine Serum BUN = Blood Urea Nitrogen Alb = Albumin AST = Aspartate Aminotransferase ALP = Alkaline Phosphatase Chol = Cholesterol TP = Total Protein TG = Triglycerides HDL = HDL Cholesterol LDL = LDL Cholesterol Fe = Ferritin
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 review of laboratory records, lack of documentation and interview with the laboratory director (LD), the laboratory failed to indicate the name and location of the referral testing laboratory on two of five (05/01/2023 and 08/04/2023) patient test reports in 2023. Findings Include: 1. Review of laboratory patient reports and lack of documentation revealed the laboratory failed to document the name and location of the referral testing laboratory (NTL LABORATORY CLIA #: 14D2075610 - 8833 Gross Point Rd, Ste 308, Skokie, IL 60077) on two of five patient test reports for 29 (Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, Blood Urea Nitrogen, Creatinine, Calcium, Iron (total iron-binding capacity), Total Protein, Albumin, Aspartate Aminotransferase / Serum Glutamic Oxaloacetic Transaminase (AST / SGOT), Alanine Aminotransferase / Serum Glutamic-Pyruvic Transaminase (ALT /

	SGPT), Alkaline Phosphatase, Total Bilirubin, Total Cholesterol, Triglycerides, High-density lipoprotein (HDL) - Cholesterol, Low-density lipoprotein (LDL) - Cholesterol, Glomerular Filtration Rate (GFR), Hemoglobin A1C, Ferritin, Cortisol, Triiodothyronine (T3), Thyroid-stimulating hormone (TSH), and Free thyroxine (FT4)) chemistry analytes; one (Reticulocyte Count) hematology analyte and two (Hepatitis B Surface Antigen and Hepatitis C Antigen) immunology analytes in 2023. A. Date: 05/01/2023 Patient name: XXX LAB #: 2166 REFERRAL LABORATORY RESULTS: CHEMISTRY: Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, Blood Urea Nitrogen, Creatinine, Calcium, Iron (total iron-binding capacity), Total Protein, Albumin, Aspartate Aminotransferase / Serum Glutamic Oxaloacetic Transaminase (AST / SGOT), Alanine Aminotransferase / Serum Glutamic-Pyruvic Transaminase (ALT / SGPT), Alkaline Phosphatase, Total Bilirubin, Total Cholesterol, Triglycerides, High-density lipoprotein (HDL) - Cholesterol, Low-density lipoprotein (LDL) - Cholesterol, Glomerular Filtration Rate (GFR), Hemoglobin A1C, Ferritin, Cortisol, Triiodothyronine (T3), Thyroid-stimulating hormone (TSH), and Free thyroxine (FT4) HEMATOLOGY: Reticulocyte Count IMMUNOLOGY: Hepatitis B Surface Antigen B. Date: 08/04/2023 Patient name: XXX LAB #: 2433 REFERRAL LABORATORY RESULTS: CHEMISTRY: Sodium, Potassium, Chloride, Carbon Dioxide, Glucose, Blood Urea Nitrogen, Creatinine, Calcium, Iron (total iron-binding capacity), Total Protein, Albumin, Aspartate Aminotransferase / Serum Glutamic Oxaloacetic Transaminase (AST / SGOT), Alanine Aminotransferase / Serum Glutamic-Pyruvic Transaminase (ALT / SGPT), Alkaline Phosphatase, Total Bilirubin, Magnesium, Uric Acid, Creatine Kinase (CK), Total Cholesterol, Triglycerides, High-density lipoprotein (HDL) - Cholesterol, Low-density lipoprotein (LDL) - Cholesterol IMMUNOLOGY: Hepatitis B Surface Antigen and Hepatitis C Antigen 2. On 11/17/2023, at 1:12 p.m., the LD confirmed the above finding.
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 review of laboratory records, lack of documentation, and interview with the laboratory director (LD), the LD: a) failed to ensure the verification of specifications comparable to the manufacturer's characteristics for accuracy, precision, reportable range of test results, and verification of the manufacturer's reference intervals for the latex agglutination assay (ASI Slide Test) before reporting four of four immunology analytes in 2023 (refer to D6013); b) failed to ensure accurate and reliable testing for 19 of 19 chemistry analytes utilizing the Vital Envoy 500 analyzer (SN: 43111056); and four of four immunology analytes utilizing the ASI Slide Test latex agglutination assay in 2023 (refer to D6014); c) failed to ensure the enrollment in an approved Centers for Medicare and Medicaid Services (CMS) proficiency testing (PT) program for three of three regulated assays in 2023 (refer to D6015); d) failed to record and report accurate patient test results for 29 chemistry analytes; one hematology analyte; and two immunology analytes on two of five final patient test reports in 2023 (refer to D6026).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) 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 review of laboratory records, lack of documentation, and interview with the laboratory director (LD), the LD failed to ensure the verification of specifications comparable to the manufacturer's characteristics for accuracy, precision, reportable range of test results, and verification of the manufacturer's reference intervals for latex agglutination assay (ASI Slide Test) before reporting four of four immunology analytes in 2023. Affecting 200 patient tests performed. (Refer to D5421).
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the laboratory director (LD), the LD failed to ensure accurate and reliable testing for 19 of 19 chemistry analytes utilizing the Vital Envoy 500 analyzer (SN: 43111056); and four of four immunology analytes utilizing the ASI Slide Test latex agglutination assay in 2023. Findings Include: 1. The laboratory failed to perform two control materials of different concentrations for 19 of 19 chemistry analytes utilizing the Vital Envoy 500 analyzer (SN: 43111056) in 2023. Refer to (D5447). 2. The laboratory failed to perform positive and negative control materials for four of four immunology analytes utilizing the ASI Slide Test latex agglutination assay in 2023. (Refer to D5449).
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

	This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the laboratory director (LD), the LD failed to ensure the enrollment in an approved Centers for Medicare and Medicaid Services (CMS) proficiency testing (PT) program for three of three immunology analytes in 2023. 200 samples were tested without meeting this mandatory requirement for compliance. (Refer to D2000).
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation, and interview with the LD, the LD failed to ensure that test results included pertinent information required for the interpretation of 29 chemistry analytes; one hematology analyte; and two immunology analytes on two of five final patient test reports in 2023. Findings Include: 1. The laboratory failed to ensure the accuracy of test results required for interpretation of 19 chemistry analytes on two of five final patient test reports in 2023. (Refer to D5801). 2. The laboratory failed to identify testing performed by reference laboratory "NTL LABORATORY CLIA #: 14D2075610" for 29 chemistry analytes; one hematology analyte; and two immunology analytes on two of five final patient test reports in 2023. (Refer to D5805).