

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2245027	(X3) Date Survey Completed 06/15/2026
Name of Provider or Supplier Diagnostic Testing Solutions Inc	Street Address, City, State 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
D0000	A complaint survey was conducted on 06/15/2026. The laboratory was found to be out of compliance with the CLIA regulations (42 CFR Part 493) for the following condition-level deficiencies: D5200 - 42 C.F.R. 493.1230 Condition: General laboratory systems; D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6168 - 42 C.F.R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.
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 policies and procedures, manufacturer's instructions for use, the CMS-209 (Laboratory Personnel Report) Form, laboratory records, lack of documentation, and interviews with the technical consultant (TC); the laboratory failed to establish and follow written policies and procedures to ensure optimum integrity of three of six patients' hematology specimens from the time of collection through completion of testing and reporting of results (see D5203), failed to follow written policies and procedures to assess technical consultant competency for one of one TC (see D5209), and failed to follow written policies and procedures for monitoring assessing, and correcting problems identified 2024 through the date of survey, 06/15/2026 (see D5291).

D5203

SPECIMEN IDENTIFICATION AND INTEGRITY
CFR(s): 493.1232

The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, manufacturer's instructions for use (IFU), laboratory records, and interview with the technical consultant (TC); the laboratory failed to establish and follow written policies and procedures to ensure optimum integrity of three of six patients' hematology specimens from the time of collection through completion of testing and reporting of results. Findings include: 1. Review of laboratory policies and procedures revealed the procedure titled "Processing and Testing Patients", which stated, under "Specimen Rejection Criteria", "Testing will be performed only when the minimum identification and safety criteria are met. Specimen will be rejected when: ...sample too old, and no longer appropriate for testing." 2. Review of the manufacturer's IFU for the Diatron Abacus 5 hematology analyzer (Serial Number: (21)510890) revealed, under "8 Sample Measurement 8.1.4 Sample Collection and Handling", "Analyze blood samples within 7 hours of collection." 3. Review of patient test records revealed the laboratory failed to perform the hematologic analysis within the manufacturer's established timeframe for three of six patients reviewed. i) Patient: 3328 Specimen Collected: 08/26/2024 at "09.30" Specimen Received: 08/26/2024 at "12.30" Specimen Analyzed: 08/27/2024 at 3:19 pm ii) Patient: 3740 Specimen Collected: 03/27/2025 at "03.16" Specimen Received: 03/27/2025 at "04.19" Specimen Analyzed: 03/27/2025 at 8:50 pm iii) Patient: 4093 Specimen Collected: 09/04/2025 at "03.12" Specimen Received: 09/04/2025 at "04.34" Specimen Analyzed: 09/04/2025 at 8:31 pm 4. Interview with the TC on 06/15/2026, at 2:58 pm, confirmed the laboratory failed to establish and follow written policies and procedures to ensure optimum integrity of three of six patients' hematology specimens from the time of collection through completion of testing and reporting of results.

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 review of the CMS-209 (Laboratory Personnel Report) Form, laboratory policies and procedures, laboratory records, lack of documentation, and interview with the technical consultant (TC); the laboratory failed to follow written policies and procedures to assess technical consultant competency for one of one TC. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report) Form revealed one technical consultant. 2. Review of laboratory policies and procedures revealed the procedure titled "Personnel Competency", which stated, "Competency assessment is used to ensure that the laboratory personnel are fulfilling their duties as required by regulations." 3. Review of laboratory competency assessment records showed the

	laboratory failed to assess competency for one of one TC. 4. Interview with the TC on 06/15/2026, at 12:35 pm, confirmed the laboratory failed to follow written policies and procedures to assess technical consultant competency for one of one TC.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with the technical consultant (TC); the laboratory failed to follow written policies and procedures for monitoring assessing, and correcting problems identified for 24 of 24 months from 2024 through the date of survey, 06/15/2026. Findings include: 1. Review of laboratory policies and procedures revealed the procedure titled "Quality Assessment", which stated, "Parameters on each of the following systems in our laboratory will be valuated as scheduled to be sure that it meets our quality goals. "Monthly: Quality Control, Maintenance, Calibration Quarterly: Proficiency Testing Every Six months: Personnel Competency, Accuracy/ Cal. Ver. [Calibration Verification] Annually: Personnel Competency, Compliance & Safety, Procedures, Test request (LIS [Laboratory Information System]) Verification" 2. Review of laboratory records revealed a lack of documentation of quality assessment checks performed in the laboratory for the previous 24 months reviewed from June 2024 through June 2026. 3. Interview with the TC on 06/15/2026, at 5:08 pm, confirmed the laboratory failed to follow written policies and procedures for monitoring assessing, and correcting problems identified for 24 of 24 months from 2024 through the date of survey, 06/15/2026.
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 policies and procedures, laboratory records, lack of documentation, and interview with the technical consultant (TC); the laboratory failed to follow written policies and procedures for monitoring assessing, and correcting problems identified for 24 of 24 months from 2024 through the date of survey, 06/15/2026. Findings include: 1. Review of laboratory policies and procedures revealed the procedure titled "Quality Assessment", which stated, "Parameters on each of the following systems in our laboratory will be valuated as scheduled to be sure that it meets our quality goals. "Monthly: Quality Control, Maintenance, Calibration Quarterly: Proficiency Testing Every Six months: Personnel Competency, Accuracy/

	Cal. Ver. [Calibration Verification] Annually: Personnel Competency, Compliance & Safety, Procedures, Test request (LIS [Laboratory Information System]) Verification" 2. Review of laboratory records revealed a lack of documentation of quality assessment checks performed in the laboratory for the previous 24 months reviewed from June 2024 through June 2026. 3. Interview with the TC on 06/15/2026, at 5:08 pm, confirmed the laboratory failed to follow written policies and procedures for monitoring assessing, and correcting problems identified for 24 of 24 months from 2024 through the date of survey, 06/15/2026.
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: Based on direct observation, review of laboratory policies and procedures, and interview with the technical consultant (TC); the laboratory failed to follow policies and procedures regarding hematology, immunology, and chemistry patient specimen retention and disposal, affecting 43 patient specimens. Findings include: 1. Upon a tour of the laboratory on 06/15/2026, at 11:07 am, surveyors observed a rack of 43 patient specimens sitting out at room temperature dated as far back as 06/01/2026 through 06/11/2026. 2. Review of laboratory policies and procedures revealed the procedure titled "Processing and Testing Patients", which stated, under "Specimen Retention & Disposal", "All patient specimens are stored refrigerated for 7 days. Specimens older than 7 days are discarded in regulated waste." 3. Interview with the TC on 06/15/2026, at 1:17 pm, confirmed the laboratory failed to follow policies and procedures regarding hematology, immunology, and chemistry patient specimen retention and disposal, affecting 43 patient specimens.
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: Based on direct observation, review of manufacturer's instructions for use (IFU), and interview with the technical consultant (TC); the laboratory failed to follow the manufacturer's IFU for hematology testing by utilizing the incorrect ethylenediaminetetraacetic acid (EDTA) anticoagulant tube type for specimen collection and processing, affecting 1,600 patients. Findings include: 1. Upon a tour of the laboratory on 06/15/2026, at 11:07 am, surveyors observed BD Vacutainer K2-EDTA anticoagulant purple-top tubes (Reference Number: 367861) being utilized for hematology testing. 2. Review of the manufacturer's IFU for the Diatron Abacus 5 hematology analyzer (Serial Number: (21)510890) revealed, under "8 Sample Measurement 8.1.4 Sample Collection and Handling", "Use only K3-EDTA

	anticoagulated fresh whole blood as sample." 3. Interview with the TC on 06/15/2026, at 2:58 pm, confirmed the laboratory failed to follow the manufacturer's IFU for hematology testing by utilizing the incorrect EDTA anticoagulant tube type for specimen collection and processing, affecting 1,600 patients. 4. Review of the test volume worksheet revealed 1,600 hematology patients were performed in the past 12 months.
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 direct observation, review of laboratory policies and procedures, lack of documentation, and interview with the technical consultant (TC); the laboratory failed to ensure three of three reagents/solutions were labeled to ensure accurate and reliable hematology, immunology, and chemistry testing. Findings include: 1. Upon a tour of the laboratory on 06/15/2026, at 11:07 am, surveyors observed clear liquids in 2 unlabeled urine collection cups and 1 unlabeled BD Vacutainer K2-EDTA anticoagulant purple-top tube. 2. Review of laboratory policies and procedures revealed the policy titled "Reagent, Solutions and Reference materials", which stated, under "Storage and Handling:", "Reagents, solutions, calibrators, and controls used for testing must be stored according to specifications and labeled to identify, -The material -Date received -Date opened and -Expiration date". 3. Interview with the TC on 06/15/2026, at 1:17 pm, confirmed the laboratory failed to ensure three of three reagents/solutions were labeled to ensure accurate and reliable hematology, immunology, and chemistry testing.
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 direct observation, review of laboratory policies and procedures, and interview with the technical consultant (TC); the laboratory failed to ensure reagents, kits, and supplies were not used when they had exceeded their expiration date for five of five routine chemistry Ion-Selective Electrode (ISE) calibrators and one of one hematology differential reagent. Findings include: 1. Upon a tour of the laboratory on 06/15/2026, at 11:07 am, direct observation of laboratory testing supplies found five of five routine chemistry ISE calibrators and one of one hematology differential reagent. Reagent/Supply: High ISE Calibrator Reference #: 55117 Lot #: 1454-DE Expiration Date: 2026-02 Reagent/Supply: High ISE Calibrator Reference #: 55117 Lot #: 1347 Expiration Date: 2024-05 Number of vials: 2 Reagent/Supply: Low ISE Calibrator Reference #: 55117 Lot #: 1347 Expiration Date: 2024-05 Number of vials:

2 Reagent/Supply: Diatron-Diff-SP Reference #: D3021 Lot #: 3022440124
 Expiration Date: 2026-01-31 2. Review of laboratory policies and procedures revealed the policy titled "Reagent, Solutions and Reference materials", which stated, under "Inventories:", "Monthly inventories are checked and ordered. Any expired, spoiled, and contaminated reagents/supply will be properly disposed and replaced." 3. Interview with the TC on 06/15/2026, at 1:17 pm, confirmed the laboratory failed to ensure reagents, kits, and supplies were not used when they had exceeded their expiration date for five of five routine chemistry ISE calibrators and one of one hematology differential reagent.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
 CFR(s): 493.1253(b)(1)

(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 direct observation, review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with the technical consultant (TC); the laboratory failed to demonstrate that it could obtain performance specifications comparable to those established by the manufacturers for 18 of 18 analytes performed on the Envoy 500 chemistry analyzer, eight of eight analytes on the Beckman Coulter Access 2 immunoassay analyzer, six of six analytes on the Diatron Abacus 5 hematology analyzer, and four of four immunology kit tests. Findings include: 1. Upon a tour of the laboratory on 06/15/2026, at 11:07 am, surveyors observed the following tests being performed by the laboratory: Analyzer: Envoy 500 - Routine Chemistry Analytes performed: Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Total Bilirubin, Calcium, Cholesterol, Carbon Dioxide, Creatinine Kinase, Creatinine, Glucose, Iron, HDL (High-Density Lipoproteins), Magnesium, Total Protein, Triglycerides, BUN (Blood Urea Nitrogen), and Uric Acid. Analyzer: Beckman Coulter Access 2 Analytes performed: FT4 (Free Thyroxine), TSH (thyroid-stimulating hormone), T3 (Triiodothyronine), Ferritin, Folate, PSA (Prostate-Specific Antigen), Vitamin B12, and 25-hydroxy vitamin D. Analyzer: Diatron Abacus 5 - Hematology Analytes performed: WBC (White Blood Cell Count), RBC (Red Blood Cell Count), Hemoglobin, Hematocrit, Platelets, and WBC Differential. Manufacturer: Arlington Scientific Kit Tests Analytes performed: Direct RF (Rheumatoid Factor), SLE (Systemic Lupus Erythematosus), and ASO (Anti-streptolysin O). Manufacturer: Germaine Laboratories Kit Test Analyte performed: C-Reactive Protein (CRP) 2. Review of laboratory policies and procedures revealed the policy titled "Method Validation", which stated, "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." 3. Review of laboratory records found no documentation to demonstrate that performance specifications were verified for any of the above-mentioned testing prior to patient testing. 4. Interview with the TC on 06/15/2026, at 1:47 pm, confirmed the laboratory failed to demonstrate that it could obtain performance specifications comparable to those

	established by the manufacturers for 18 of 18 analytes performed on the Envoy 500 chemistry analyzer, eight of eight analytes on the Beckman Coulter Access 2 immunoassay analyzer, six of six analytes on the Diatron Abacus 5 hematology analyzer, and four of four immunology kit tests.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, lack of documentation, and interview with the technical consultant (TC); the laboratory failed to document preventative maintenance for three of three analyzers on 11 of 11 testing dates reviewed from 06/01/2026 through the date of survey, 06/15/2026. Findings include: 1. Upon a tour of the laboratory on 06/15/2026, at 11:07 am, surveyors observed routine chemistry testing performed on the Envoy 500+ analyzer (Serial Number: 43111056), immunoassay testing performed on the Beckman Coulter Access 2 analyzer (Serial Number: 507654), and hematology testing performed on the Diatron Abacus 5 analyzer (Serial Number: (21)510890). 2. Review of the preventative maintenance logs revealed the following required tasks: i. Envoy 500 - Daily: Check Zone Temperatures Check System Supplies Empty Liquid Waste Bottle Inspect Fluidic Module Clean Probe Exteriors Prime Substrate Run Daily Clean System Weekly: Clean Instrument Exterior Inspect Liquid Waste Bottle Check Waste Filter Bottle Inspect/Clean Primary Probe Replace/Clean Aspirate Probes Run System Check ii. Beckman Coulter Access 2 - Daily- AM: Check/Replace Rinse Sol[utio]n. Empty Waste Paper Supply Update Reagents Zero Photometer Clear Alert & Message Daily- PM: Archive 'Specimen Log' Backup Patient Archives Clear Alert & Message Check ISE* Reagents Vol[ume] Suspend Activity Wash Cuvette Wash ISE Module Weekly: Clean Sample Needles Extra Wash Cuvette Shutdown Re[p]lace Saline Diluent iii. Diatron Abacus 5 - Daily: Check Printer Paper Check Reagents Empty Waste Perform and Accept Blank Cycle Run Quality Control Clean Exterior Surfaces Perform Shut Down and Power Off 2. Review of laboratory preventative maintenance logs revealed a lack of documentation of any/all preventative maintenance performance for three of three analyzers on 11 of 11 testing dates reviewed in June 2026. Date of patient testing: Monday, 06/01/2026 Tuesday, 06/02/2026 Wednesday, 06/03/2026 Thursday, 06/04/2026 Friday, 06/05/2026 Monday, 06/08/2026 Tuesday, 06/09/2026 Wednesday, 06/10/2026 Thursday, 06/11/2026 Friday, 06/12/2026 Monday, 06/15/2026 3. Interview with the TC on 06/15/2026, at 3:43 pm, confirmed the laboratory failed to document preventative maintenance for three of three analyzers on 11 of 11 testing dates reviewed from 06/01/2026 through the date of survey, 06/15/2026.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by:

	Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with the technical consultant; the laboratory failed to ensure two levels of quality control (QC) materials were ran each day of patient testing for one of eight patient testing dates reviewed prior to reporting complete blood count (CBC) testing on the Diatron Abacus 5 analyzer in the specialty of hematology and routine chemistry testing on the Envoy 500 analyzer. Findings include: 1. Review of laboratory policies and procedures revealed the procedure titled "Processing and Testing Patients", which stated, under "Testing:", "Daily QC must be performed for each analyzer and non-waived method prior [to] testing patients." 2. Review of laboratory records revealed the laboratory failed to perform/document QC for one of eight testing dates reviewed on the Diatron Abacus 5 hematology analyzer and the Envoy 500 routine chemistry analyzer prior to reporting patient results. Patient: 4771 Date of testing: 06/11/2026 3. Interview with the TC on 06/15/2026, at ___, confirmed the laboratory failed to ensure two levels of QC materials were ran each day of patient testing for one of eight patient testing dates reviewed prior to reporting complete blood count (CBC) testing on the Diatron Abacus 5 analyzer in the specialty of hematology and routine chemistry testing on the Envoy 500 analyzer.
D5805	TEST REPORT CFR(s): 493.1291(c) (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 patient test reports, lack of documentation, and interview with testing personnel (TP) #2; the laboratory failed to include the name and address of the laboratory that performed the complete blood count (CBC) in the specialty of hematology for one of six patient test reports reviewed. Findings include: 1. Review of one of six patient test reports reviewed for CBC testing in the specialty of hematology revealed the laboratory failed to indicate the name and address of the performing laboratory on the final patient test report. Patient: 4628 Collection Date: 05/06/2026 Reported Date: 05/08/2026 2. Interview with TP #2 on 06/15/2026, at 3:20 pm, confirmed the laboratory failed to include the name and address of the laboratory that performed the CBC in the specialty of hematology for one of six patient test reports reviewed.
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 direct observation, review of the CMS-209 (Laboratory Personnel Report) Form, laboratory policies and procedures, laboratory records, lack of documentation, and interviews with the technical consultant and laboratory director (LD); the LD failed to ensure tests performed could obtain performance specifications comparable to those established by the manufacturers (see D6013), failed to ensure two levels of quality control materials were ran each day of patient testing (see D6020), failed to ensure one of two testing personnel were qualified for high complexity testing (see D6029), and failed to ensure competency assessments were completed annually for two of two testing personnel (see D6030).
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 direct observation, review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with the technical consultant (TC); the laboratory director failed to ensure tests performed could obtain performance specifications comparable to those established by the manufacturers for 18 of 18 analytes performed on the Envoy 500 chemistry analyzer, eight of eight analytes on the Beckman Coulter Access 2 immunoassay analyzer, six of six analytes on the Diatron Abacus 5 hematology analyzer, and four of four immunology kit tests (see D5421).
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 review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with the technical consultant; the laboratory director failed to ensure two levels of quality control (QC) materials were ran each day of patient testing for one of eight patient testing dates reviewed prior to reporting complete blood count (CBC) testing on the Diatron Abacus 5 analyzer in the specialty of hematology and routine chemistry testing on the Envoy 500 analyzer (see D5447) and failed to ensure written policies and procedures for monitoring assessing, and correcting problems identified were followed for 24 of 24 months from 2024 through the date of survey, 06/15/2026 (see D5291).
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

	This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory personnel records, and interview with the laboratory director (LD); the laboratory director failed to ensure one of two testing personnel were qualified for high complexity C-Reactive Protein (CRP) Latex testing in the specialty of diagnostic immunology (see D6168).
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) (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 review of the CMS-209 (Laboratory Personnel Report) Form, laboratory policies and procedures, laboratory records, lack of documentation, and interview with the technical consultant (TC); the laboratory director failed to ensure competency assessments were completed annually for two of two moderate complexity testing personnel (TP) performing hematology, chemistry, endocrinology, and immunology testing from 2024 through the date of survey, 06/15/2026 (see D6046).
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on review of the CMS-209 (Laboratory Personnel Report) Form, laboratory policies and procedures, laboratory records, lack of documentation, and interview with the technical consultant (TC); the TC failed to ensure competency assessments were completed annually for two of two moderate complexity testing personnel (TP) performing hematology, chemistry, endocrinology, and immunology testing from 2024 through the date of survey, 06/15/2026. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Report) Form revealed two TP performed moderate complexity testing in the (sub)specialties of hematology, endocrinology, chemistry, and immunology. 2. Review of laboratory policies and procedures revealed the procedure titled "Personnel Competency", which stated, "Director or Designee will perform and document Competency Assessment of staff semiannually from hire and annually thereafter." 3. Review of laboratory personnel records revealed no competency assessments for two of two TP listed on the CMS-209 (Laboratory Personnel Report) Form from 2024 through the date of survey, 06/15/2026. 4. Interview with the TC on 06/15/2026, at 12:36 pm, confirmed the TC failed to ensure competency assessments were completed annually for two of two moderate

	complexity TP performing hematology, chemistry, endocrinology, and immunology testing from 2024 through the date of survey, 06/15/2026.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on direct observation, review of laboratory personnel records, and interview with the laboratory director (LD); the laboratory failed to ensure one of two testing personnel were qualified for high complexity C-Reactive Protein (CRP) Latex testing in the specialty of diagnostic immunology (see D6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on direct observation, review of laboratory personnel records, and interview with the laboratory director (LD); the laboratory failed to ensure one of two testing personnel (TP) were qualified for high complexity C-Reactive Protein (CRP) Latex testing in the specialty of diagnostic immunology. Findings include: 1. Upon a tour of the laboratory on 06/15/2026, at 11:07 am, surveyors observed CRP Latex testing being performed utilizing Germaine Laboratories Aim CRP Test Kit. 2. Review of personnel records revealed one of two TP (TP #2) failed to have qualifying educational documentation for high complexity CRP Latex testing in the specialty of diagnostic immunology. 3. Interview with the LD on 06/15/2026, at 12:35 pm, confirmed the laboratory failed to ensure one of two TP were qualified for high complexity CRP Latex testing in the specialty of diagnostic immunology.