Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0441688	03/23/2026
Name of Provider or Supplier	**Street Address, City, State**	
Sullivan County Memorial Hospital Laboratory	630 W 3rd St, Milan, MO	

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
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records for 2024, 2025 and to date 2026 and interview with the technical supervisor (TS) #2, the laboratory failed to maintain copies of all PT records including attestation statements for two of eight PT testing events. Findings: 1. Review of PT records for 2024 showed the laboratory could not provide attestation statements for the following proficiency testing events: 2024 Association of Bioanalysts Medical Laboratory Education (AAB-MLE) M1 2024 AAB-MLE M2 2. Interview with the TS #2 on March 18, 2026 at 12:00 PM confirmed the laboratory could not provide attestation statements for two PT testing events in 2024.
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 review of 2024, 2025 and to date 2026 proficiency testing (PT) results, and interview with the technical supervisor (TS) #2, the laboratory failed to evaluate PT results that did not reflect laboratory test performance for one of eight PT events. Findings: 1. Review of American Proficiency Institute (API) PT records showed no corrective action documentation was available to show the laboratory investigated ungraded PT results for the following events: 2026 API Chemistry Core 1st Event-Total Bilirubin CH-05 2. Interview with the TS #2 on March 18, 2026 at 12:00 PM confirmed the laboratory failed to evaluate PT results that did not reflect the laboratory test performance in 2026.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of 2024, 2025 and to date 2026 proficiency testing (PT) records, and interview with the technical supervisor (TS) #2, the laboratory failed to document evaluation for one of eight proficiency testing activities. Findings: 1. Review of American Association of Bioanalysts Medical Laboratory Education (AAB-MLE) 2024 M2 event showed no documentation of evaluation of proficiency testing. 2. Interview with the TS #2 on March 18, 2026 at 12:00 PM confirmed the laboratory failed to document evaluation of proficiency testing for one proficiency testing activity in 2024.
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 observation of the laboratory safety hood, Abbott i-STAT 1 room and blood bank room, lack of temperature logs and humidity logs, review of Abbott i-STAT 1 system manual, blood bank gel card manual, performance verification procedures for the Sysmex XN 450 hematology analyzer, Ortho Diagnostics Vitros 5600 chemistry analyzer quality control (QC) records, blood bank procedures, blood bank patient logs, blood bank quality control (QC) logs, blood bank alarm check log, laboratory procedures, patient reports and patient results and interview with technical supervisor (TS) #2, the laboratory failed to meet the condition of analytic systems. The laboratory failed to define criteria for the i-STAT testing area and blood bank testing area in 2024 and to date March 18, 2026 (Refer to D5413); the laboratory failed to verify performance specifications prior to reporting patient test results (Refer to D5421); the laboratory failed to define, perform and document maintenance for the

	laboratory safety hood in 2025 and to date 2026 (Refer to D5429); the laboratory failed to document how criteria was established for acceptability of control materials providing quantitative results for alkaline phosphatase (Refer to D5469); the laboratory failed to document QC for four patient testing days from January 2024 to date March 18, 2026 (Refer to D5551); the laboratory failed to perform blood bank refrigerator alarm inspections quarterly for 2024 (Refer to D5555); the laboratory failed to ensure the procedure reference ranges matched the reference ranges on the patient reports (Refer to D5807).
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation of the Abbott i-STAT 1 room and blood bank room, lack of temperature logs, lack of humidity logs, review of Abbott i-STAT 1 system manual, review of blood bank gel cards manual, and interview with the technical supervisor (TS) #2, the laboratory failed to define criteria for the i-STAT testing area and blood bank testing area for room temperature and humidity in 2024 and to date March 18, 2026. Findings: 1. Observation of Abbot i-STAT 1 room revealed the laboratory was not taking room temperature or humidity for January 2024 to date March 18, 2026. 2. Review of the Abbott i-STAT 1 system manual states, "Relative humidity 10-90% non-condensing" and temperature range "61-86 degrees Fahrenheit". 3. Lack of i-STAT temperature logs and humidity logs showed no documentation of temperature and humidity. 4. Observation of blood bank room revealed the laboratory was not taking room temperature or humidity for January 2024 to date March 18, 2026. 5. Review of blood bank gel cards manual states, "operating/room temperature 18 degrees Celsius to 25 degrees Celsius" an humidity "5-80%" 6. Lack of blood bank temperature logs and humidity logs showed no documentation of temperature and humidity. 7. Interview with the TS #2 on March 18, 2026 at 1:00 PM confirmed the laboratory failed to define criteria for the i-STAT testing area and blood bank testing area for room temperature and humidity.
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 review of the performance verification procedures for the Sysmex XN 450 hematology analyzer, patient results and interview with the technical supervisor (TS) #2, the laboratory failed to verify performance specifications prior to reporting patient test results. Findings: 1. Review of the performance verification procedures for the Sysmex XN 450 hematology analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: white blood cell (WBC), red blood cell (RBC), hemoglobin, hematocrit (HCT), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), red blood cell distribution width (RDW), platelets, mean platelet volume (MPV), percent neutrophils, percent lymphocytes, percent monocytes, percent eosinophils, percent basophils, absolute neutrophils, absolute lymphocytes, absolute monocytes, and absolute basophils prior to the beginning of patient testing in November 2024. 2. The laboratory performs approximately 36,240 hematology patient tests annually. 3. Interview with the TS #2 on March 18, 2026 at 10:30 AM confirmed the laboratory failed to verify performance specifications prior to reporting patient test results.
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 observation of the laboratory safety hood and interview with the technical supervisor (TS) #2, the laboratory failed to define, perform and document maintenance for the laboratory safety hood in 2025 and to date 2026. Findings: 1. Observation of the laboratory safety hood showed no documentation of maintenance for the laboratory safety cabinet in 2025 and to date 2026. 2. Interview with the TS #2 on March 18, 2026 at 9:00 AM confirmed, the laboratory failed to perform and document maintenance for the laboratory safety hood in 2025 and to date 2026.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(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. (d)(10)(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. (d)(10)(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. This STANDARD is not met as evidenced by: Based on review of the Ortho Diagnostics Vitros 5600 chemistry analyzer quality control (QC) records for 5 of 33 analytes, and interview with the technical supervisor

	(TS) #2, the laboratory failed to document how criteria was established for acceptability of control materials providing quantitative results for alkaline phosphatase. Findings: 1. Review of the Ortho Diagnostics Vitros 5600 chemistry analyzer QC records showed the laboratory used unassayed QC. The laboratory could not show how they established, documented, and defined statistical parameter criteria (mean and standard deviations) for acceptability of quantitative QC for the analytes albumin, alkaline phosphatase, ALT AST, direct bilirubin, total bilirubin, calcium, chloride, HDL cholesterol, carbon dioxide, creatine phosphokinase, glucose, iron, lactic acid, LDL cholesterol, lipase, magnesium, phosphorus, potassium, sodium, total protein, triglyceride, blood urea nitrogen, uric acid, beta HCG, thyroid stimulating hormone (TSH), free T4, free T3, troponin I, and b-type natriuretic peptide (BNP). 2. Review of chemistry QC in the computer where testing personnel accept QC results showed the range for alkaline phophastase level 1 27.58-31.38 and alkaline phophatase level 3 237.36-267.84. 3. Review of acceptable QC ranges established in the laboratory's QC log book showed alkaline phosphatase level 1 34.21-39.33 and alkaline phosphatase level 3 246.40-281.0. The laboratory could not address the discrepancy in alkaline phosphatase ranges. 4. Interview with the TS #2 on March 18, 2026 at 12:10 PM confirmed the laboratory failed to establish criteria for acceptability of control materials providing quantitative results.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. This STANDARD is not met as evidenced by: Based on review of blood bank procedures, blood bank patient logs, blood bank quality control (QC) logs, and interview with the technical supervisor (TS) #2, the laboratory failed to document QC for four patient testing days from January 2024 to date March 18, 2026. Findings: 1. Review of the laboratory's procedure "Gel Test System Reagent Quality Control" states "Blood Bank Quality Control in this Laboratory is to be processed on the day a Blood Bank Procedure is requested. All Quality Control Materials Results MUST produce Expected Reactions prior to testing patient specimens". 2. Review of blood bank patient testing logs showed no documented QC on: July 3, 2024 one patient tested: type and screen December 16, 2024 one patient tested: type, screen, and compatibility testing with 2 units packed red blood cells (PRBC's) given, unit # W182424070567 and unit #W182424070644 March 27, 2025 one patient tested: type, screen, and compatibility testing with 2 units PRBC's given unit #W181125270038 and unit #W182425116768 April 10, 2025 one patient tested: type and screen 3. Interview with the TS #2 on March 18, 2026 at 12:30 PM confirmed the laboratory failed to document quality control each day of patient testing.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f)

	(c) Blood shall be stored in a clean and orderly environment in a manner to prevent mix-ups. Expired blood must not be in the routine inventory. Unacceptable units must be segregated from routine inventory. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. This STANDARD is not met as evidenced by: Based on review of blood bank alarm check log, and interview with the technical supervisor (TS) #2, the laboratory failed to perform blood bank refrigerator alarm inspections quarterly for 2024. Findings: 1. Review of the laboratory's blood bank alarm check log showed no blood bank refrigerator alarm inspections were completed in 2024. 2. Interview with the TS #2 on March 18, 2026, at 11:00 AM confirmed, the laboratory failed to perform blood bank refrigerator alarm inspections quarterly in 2024.
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: Based on review of laboratory procedures, patient reports, and interview with the technical supervisor (TS) #2, the laboratory failed to ensure the procedure reference ranges matched the reference ranges on the patient reports. Findings: 1. Review of the "Sullivan County Memorial Hospital Clinical Laboratory Complete Blood Count on Sysmex XN-450" procedure showed the following reference ranges: Female Reference Range WBC (x10^3/uL) 3.98-10.04 RBC (x10^6/uL) 3.93-5.22 HGB (g /dL) 11.2-15.7 HCT (%) 34.1-44.9 MCV (fL) 79.4-94.8 MCH (pg) 25.6-32.2 MCHC (g/dL) 32.2-35.5 PLT (x10^3/uL) 182-369 RDW-CV (%) 11.7-14.4 RDW-SD (fL) 36.4-46.3 MPV (fL) 9.4-12.3 Neut % 34.0-71.1 Lymph % 19.3-51.7 Mono % 4.7-12.5 Eo% 0.7-5.8 Baso% 0.1-1.2 Neut # (x10^3/uL) 1.56-6.13 Lymph # (x10^3/uL) 1.18-3.74 Mono # (x10^3/uL) 0.24-0.86 Eo # (x10^3/uL) 0.04-0.36 Baso # (x10^3/uL) 0.01-0.08 Male Reference Range WBC (x10^3/uL) 4.23-9.07 RBC (x10^6/uL) 4.63-6.08 HGB (g/dL) 13.7-17.5 HCT (%) 40.1-51.0 MCV (fL) 79.0-92.2 MCH (pg) 25.7-32.2 MCHC (g/dL) 32.3-36.5 PLT (x10^3/uL) 163-337 RDW-CV (%) 11.6-14.4 RDW-SD (fL) 35.1-43.9 MPV (fL) 9.4-12.4 Neut % 34.0-67.9 Lymph % 21.8-53.1 Mono % 5.3-12.2 Eo% 0.8-7.0 Baso% 0.2-1.2 Neut # (x10^3/uL) 1.78-5.38 Lymph # (x10^3/uL) 1.32-3.57 Mono # (x10^3/uL) 0.30-0.82 Eo # (x10^3/uL) 0.04-0.54 Baso # (x10^3/uL) 0.01-0.08 2. Review of "Siemens CA-660 Reference Interval" procedure showed the following reference ranges: aPTT (secs) 24.5-32.8 PT (secs) 9.3-11.4 3. Review of patient reports showed the following reference ranges: WBC (x10^3/uL) female 5.02-12.95 male 4.29-12.18 RBC (x10^6/uL) female 3.49-5.17 male 3.81-5.87 HGB (g/dL) female 10.92-15.34 male 11.89-17.50 HCT (%) female 32.76-43.82 male34.92-51.80 MCV (fL) female 80.47-96.93 male 83.14-96.37 MCH (pg) female 27.39-33.40 male 28.25-33.70 MCHC (g/dL) female 32.17-36.36 male 32.97-36.04 PLT (x10^3/uL) female 192-365 male 142-313 RDW-CV (%) female 11.88-15.15 male 11.6-15.33 MPV (fL) female 8.80-11.72 male 8.58-12.23 Neut % female 39.44-78.67 male 41.00-82.23 Lymph % female 13.05-48.64 male 9.18-45.26 Mono %

	female 4.40-10.32 male 4.51-12.60 Eo% female 0.00-6.69 male 0.00-5.10 Baso% female 0.00-0.75 male 0.00-1.10 Neut # (x10^3/uL) female 1.40-6.13 male 1.91-5.38 Lymph # (x10^3/uL) female 1.23-4.13 male 0.48-3.97 Mono # (x10^3/uL) female 0.40-0.89 male 0.35-1.03 Eo # (x10^3/uL) female 0.00-0.61 male 0.00-0.37 Baso # (x10^3/uL) female 0.00-0.07 male 0.00-0.08 aPTT (secs) 23.3-35.3 PT (secs) 9.1-12.1 4. Interview with the TS #2 on March 18, 2026 at 11:30 AM confirmed the procedure reference ranges did not match the reference ranges on the patient reports.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of 2024 to date March 18, 2026 blood bank "Transfusion Service Record" patient logs, blood bank procedures, 2024, 2025 and to date 2026 proficiency testing (PT) records, immunohematology patient testing logs, immunohematology records, quality assessment (QA) program, performance verification procedures for the Siemens CA-660 coagulation analyzer and the Sysmex XN 450 hematology analyzer, training and competency documents, and personnel records and interview with the technical supervisor (TS) #2, the laboratory director (LD) failed to provide overall management and direction of the laboratory. The LD failed to ensure that testing personnel documented and recorded test results accurately and proficiently (Refer to D6079); the LD failed to ensure the blood bank compatibilty test is developed to ensure quality laboratory testing through to the transfusion of packed red blood cells(Refer to D6082); the LD failed to ensure an approved corrective action plan is followed when any PT result is found to be unacceptable or unsatisfactory for two of eight PT events (Refer to D6092); the LD failed to ensure immunohematology QC programs and QA programs are maintained to assure the quality of laboratory services and to identify failures in quality as they occur (Refer to D6093); the LD failed to employ a sufficient number of laboratory personnel with the appropriate training to accurately perform the volume testing performed (Refer to D6101); the LD failed to identify and document initial training needs for six of six testing personnel performing coagulation and hematology testing (Refer to D6102).
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

	This STANDARD is not met as evidenced by: Based on review of 2024 to date March 18, 2026 blood bank "Transfusion Service Record" patient logs and interview with the technical supervisor (TS) #2, the laboratory director failed to ensure that testing personnel documented and recorded blood bank test results accurately and proficiently. Findings: 1. Review of blood bank 2024 patient logs showed: -March 6, 2024 a patient was given one unit of blood and the "Transfusion Service Record" log was not completely filled out. The donor unit release record has no documentation of issued by, visual inspection, issue date and time. -March 24, 2024 a patient was given one unit of blood and the transfusion service record was not completely filled out. The donor unit release record has no documentation of issued by, visual inspection, issue date and time. 2. Review of the "Transfusion Service Record" patient logs showed on July 24, 2024 a patient A was typed, screened and compatibility testing was performed. The laboratory places patient stickers on the log that has patient name and a place for tech initials, date to be filled in when done and time when completed. The "Transfusion Service Record" log for July 24, 2024 with patient "A" the patient sticker has the date as 7/22/24 and time 0910 which is 48 hours before patient testing was actually performed. 3. Interview with TS #2 on March 18, 2026 at 11:00 AM confirmed the laboratory director failed to ensure that testing personnel documented and recorded blood bank test results accurately and proficiently.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) (e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on review of blood bank procedures, review of blood bank "Transfusion Service Record" patient log, and interview with the technical supervisor (TS) #2, the laboratory director failed to ensure the blood bank compatibility test is developed to ensure quality laboratory testing through to the transfusion of packed red blood cells (PRBC's). Findings: 1. Review of procedures revealed no procedure for length of time between compatibility testing and transfusion of PRBC's to the patient. 2. Review of "Transfusion Service Record" patient log from March 21, 2024 showed compatibility testing was performed on 2 units of PRBC's for patient "B". Patient "B" received the first unit #W181124039989 on March 24, 2024. Patient "B" received the second unit of PRBC's #W181124046568 on March 29, 2024 with out performing compatibility testing again. 3. Interview with TS #2 on March 18, 2026 at 11:00 AM confirmed the laboratory director failed to ensure the blood bank compatibility test is developed to ensure quality laboratory testing through to the transfusion of PRBC's.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by:

	Based on review of the 2024, 2025 and to date 2026 proficiency testing (PT) records and interview with the technical supervisor (TS) #2, the laboratory director failed to ensure an approved corrective action plan is followed when any PT result is found to be unacceptable or unsatisfactory for two of eight PT events. Findings: 1. Review of American Association of Bioanalysts Medical Laboratory Education (AAB-MLE) 2024 M3 PT record showed the laboratory obtained a score of 80% on Unexpected Antibody Detection and a score of 80 % on Compatibility Testing. 2. Review of AAB-MLE 2025 M3 PT record showed the laboratory obtained a score of 80% on Hematology-Hematocrit and a score of 50% on Urine Sediment. 3. No corrective action documentation was available to show the laboratory investigated the unacceptable PT results. 4. Interview with the TS #2 on March 18, 2026 at 12:00 PM confirmed the laboratory director failed to ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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 immunohematology patient testing logs "Transfusion Service Record", review of immunohematology records, and interview with the technical supervisor (TS) #2, the laboratory director failed to ensure immunohematology QC programs and QA programs are maintained to assure the quality of laboratory services and to identify failures in quality as they occur. Findings: 1. Review of immunohematology patient testing logs "Transfusion Service Record", from January 2024 to date March 18, 2026 showed immunohematology patient testing logs were changed for ABO testing on reverse grouping. The reverse grouping values were marked through and changed to "NT" when performing compatibility testing on units on the following dates: July 11, 2024 two units of packed red blood cells (PRBC's) given unit #W181124081466 and unit #W181124086590 August 6, 2024 one unit of PRBC's given unit # W181124104737 August 12, 2024 two units of PRBC's given unit #W184024093131 and unit #W184024049796 March 4, 2025 one unit of PRBC given unit #181125277247 2. Review of immunohematology records from January 2024 to date March 18, 2026 showed no documentation on July 11, 2024, August 6, 2024, August 12, 2024 and March 4, 2025 for why the immunohematology patient testing logs were changed. 3. Interview with the TS #2 on March 18, 2026 at 12:10 PM confirmed the laboratory director failed to ensure immunohematology QC and QA programs are maintained to assure the quality of laboratory services and to identify failures in quality as they occur.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) (e)(11) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

	This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the technical supervisor (TS) #2, the laboratory director failed to employ a sufficient number of laboratory personnel with the appropriate training to accurately perform the volume of testing performed. Findings: 1. Review of personnel records on March 18, 2026 showed the laboratory had five full-time and one laboratory manager, appropriately trained testing personnel for testing in the laboratory that is open 24 hours a day, 365 days a year. Testing personnel perform all laboratory testing and phlebotomy services. The laboratory performs approximately 93,423 laboratory tests per year and approximately 3,312 phlebotomies per year. 2. Interview with the TS #2 on March 18, 2026 at 12:00 PM confirmed the laboratory director failed to employ a sufficient number of laboratory personnel with the appropriate training to accurately perform the volume of testing performed.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) 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 review of the performance verification procedures for the Siemens CA-660 coagulation analyzer and the Sysmex XN 450 hematology analyzer, review of training and competency documents and interview with the technical supervisor (TS) #2, the laboratory director (LD) failed to identify and document initial training needs for six of six testing personnel (TP) performing coagulation and hematology testing. Findings: 1. Review of the performance verification procedures for the Siemens CA-660 coagulation analyzer showed the laboratory began patient testing on January 15, 2025. 2. Review of the performance verification procedures for the Sysmex XN 450 hematology analyzer showed the laboratory began patient testing on November 15, 2024. 3. Review of training and competency documents showed the laboratory could not provide documentation for initial training and competency for TP #1, TP #2, TP #3, TP #4, TP #5, and TP #6 for the Siemens CA-660 coagulation analyzer and the Sysmex XN 450 hematology analyzer. 4. Interview with the TS #2 on March 18, 2026 at 11:30 AM, confirmed the laboratory director failed to identify and document training needs for six TP performing testing on the Siemens CA-660 coagulation analyzer and the Sysmex XN 450 hematology analyzer.