Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 53D0056408	**(X3) Date Survey Completed** 05/25/2022
Name of Provider or Supplier South Lincoln Hospital District	**Street Address, City, State** 711 Onyx Street, Kemmerer, WY	
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: . Based on review of proficiency testing records, lack of documentation, and staff interview, the individual testing the proficiency testing samples and/or the laboratory director failed to attest to the routine integration of the American Proficiency Institute (API) proficiency tests into the patient workload for 3 of 18 proficiency testing events reviewed from September 2020 through May 2022. The findings were: 1. Review of the proficiency testing records showed attestation statements with the following concerns: a. 2021 API Immunohematology Event #1 was not signed by the laboratory director. b. 2021 API Immunohematology Event #2 was not signed by the testing personnel performing the tests. c. 2022 API Hematology Event #1 was not signed by the laboratory director. 2. Interview with the laboratory manager on 5/24/22 at 11:44 AM revealed she was not the laboratory manager at the time of the 2021 proficiency testing events. In addition, the laboratory manager confirmed the 2022 API Hematology Event #1 attestation statement was incomplete. .
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) 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. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: . Based on review of proficiency testing records and staff interview, the laboratory failed to maintain a copy of the testing results and the attestation statements for the API (American Proficiency Institute) proficiency testing samples for 4 of 18 proficiency testing events reviewed from September 2020 through May 2022. The findings were: 1. Review of the proficiency testing records showed no evidence of the following documentation: a. 2021 API Miscellaneous Chemistry Event #1 was missing the attestation statement and documentation of the testing results. b. 2021 API Immunohematology Event #2 was missing the attestation statement. d. 2021 API Hematology Event #1 was missing documentation of the testing results. e. 2021 API Hematology Event #3 was missing documentation of the testing results. 2. Interview with the laboratory manager on 5/24/22 at 11:44 AM revealed she was not the laboratory manager at the time of the 2021 proficiency testing events; however was able to confirm the documentation was unavailable. .
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: . Based on review of the Centers for Medicare and Medicaid Casper 155 report, review of the American Proficiency Institute (API) evaluation reports, and staff interview, the laboratory failed to successfully participate in two consecutive API Hematology proficiency testing events for the white blood cell differential (2021 Event #3, 2022 Event #1). Refer to D2130. .
D2130	HEMATOLOGY CFR(s): 493.851(f)

	Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: . Based on the review of the Centers for Medicare and Medicaid Services (CMS) Casper 155 report, review of the American Proficiency Institute (API) evaluation reports, and staff interview, the laboratory failed to successfully participate in two consecutive API Hematology proficiency testing (PT) events for the white blood cell differential which included basophils, eosinophils, lymphocytes, monocytes, and neutrophils (2021 Event #3, 2022 Event #1). The findings were: 1. Review of the CMS Casper 155 report and the API Hematology PT evaluations showed the laboratory failed to successfully obtain a passing score for the white blood cell differential on the following API testing events: a. 2021 Event #3 showed the laboratory scored a 0% b. 2022 Event #1 showed the laboratory scored a 0%. 2. Interview with the laboratory manager on 5/24/22 at 11:44 AM revealed she was not the laboratory manager at the time the 2021 API Hematology Event #3 was tested and was unaware of the failure. In addition, the laboratory manager confirmed the 2022 Event #1 had failed and the cause of the failure had not been investigated. .
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: . Based on lack of documentation and staff interview, the laboratory failed to retain the instrument printouts for blood gas testing on the Abbott i-STAT analyzer for 2 of 2 years of testing reviewed (2021, 2022). The laboratory performed approximately 60 blood gas tests per year. The findings were: 1. Review of the laboratory's records showed no evidence the Abbott i-STAT instrument printouts had been retained. 2. Interview with the laboratory manager on 5/25/22 at 11:17 AM revealed the respiratory therapists performed the blood gas testing and manually entered the results into the patient's medical record. Further, the laboratory manager stated the instrument printouts for the blood gases had not been saved. .
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on observation, review of the Abbott i-STAT operator's manual, lack of documentation, review of the Abbott i-STAT patient testing log sheets, review of quality control (QC) records, review of the laboratory's individualized quality control plan (IQCP), and staff interview, the laboratory failed to ensure manufacturer's instructions were followed to perform function checks as required on the Abbott i-

	STAT instrument (D5431); failed to ensure calibration verification was performed on the Abbott i-STAT instrument every 6 months (D5439); and failed to ensure QC was performed as outlined in the IQCP for blood gas analysis (D5445). .
D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1271, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on observation, review of patient test reports, lack of documentation, policy and procedure review, and staff interview, the laboratory failed to ensure the emergency release of uncrossmatched blood was signed by the ordering physician (D5551) and failed to ensure the audible alarm system on the blood and blood product storage units were functioning properly (D5555) for two consecutive surveys conducted on 9/11/20 and 5/25/22. .
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 the Centers for Medicare and Medicaid Services (CMS) 209 Laboratory Personnel Report, review of policy and procedures, lack of documentation, review of proficiency testing records, review of the laboratory's test menu, and staff interview, the laboratory failed to complete an initial competency assessment (D5209), failed to review and evaluate proficiency testing results (D5211), failed to at least twice annually verify the accuracy of test results (D5217), and failed to monitor, assess, and correct problems in the general laboratory system (D5291). .
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 (Centers for Medicare and Medicaid Services) 209 Laboratory Personnel Report, lack of documentation, review of policy and procedure, and staff interview, the technical supervisor failed to complete an initial competency assessment for 1 of 1 testing personnel prior to independently testing patient samples

	(TP #1). 1. There was no evidence the technical supervisor had completed an initial competency assessment prior to TP #1 independently testing patient samples. 2. Interview with TP #1 revealed she was hired on 11/14/21 and confirmed a competency assessment had not been completed prior to her independently testing patient samples. 3. Review of the policy titled "Employee Competency" showed "(b) The Technical Supervisor is responsible for: (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report tests results promptly, accurately and proficiently..." .
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: . Based on review of API (American Proficiency Institute) proficiency testing records, lack of documentation, and staff interview, the laboratory failed to review and evaluate proficiency testing results for 9 of 18 testing events reviewed from November 2020 to May 2022. The findings were: 1. Review of the API proficiency testing (PT) reports failed to include documentation the laboratory had evaluated test scores of less than 100%. The following concerns were identified: a. Review of the 2020 API Chemistry Core Event #3 showed the laboratory scored an 80% on sodium, an 80% on lactic acid, and a 40% on lipase. There was no documentation the laboratory had evaluated the proficiency testing results. b. Review of the 2021 API Chemistry Core Event #1 showed the laboratory scored an 80% on chloride and an 80% on free triiodothyroxine (FT3). There was no documentation the laboratory had evaluated the proficiency testing results. c. Review of the 2021 API Chemistry Core Event #2 showed the laboratory scored an 80% on triglyceride and an 80% on FT3. There was no documentation the laboratory had evaluated the proficiency testing results. d. Review of the 2021 API Hematology Event #1 showed the laboratory scored a 60% on monocytes. There was no documentation the laboratory had evaluated the proficiency testing results. e. Review of the 2021 API Hematology Event #2 showed the laboratory scored a 60% on lymphocytes. There was no documentation the laboratory had evaluated the proficiency testing results. f. Review of the 2021 API Immunohematology Event #3 showed the laboratory scored a 40% on antibody detection and a 40% on compatibility testing. There was no documentation the laboratory had evaluated the proficiency testing results. g. Review of the 2021 API Chemistry Core Event #3 showed the laboratory scored an 80% on pH, pCO2, and chloride. There was no documentation the laboratory had evaluated the proficiency testing results. h. Review of the 2021 API Miscellaneous Chemistry Event #1 showed the laboratory scored 0% on microalbumin. There was no documentation the laboratory had evaluated the proficiency testing results. i. Review of the 2021 API Miscellaneous Chemistry Event #2 showed the laboratory scored 0% due to lack of participation. There was no documentation the laboratory had evaluated the proficiency testing results. 2. Interview with the laboratory manager on 5/24/22 at 11: 44 AM revealed she was new to the position and was unaware of the results of the PT events. .
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 the laboratory's test menu and staff interview, the laboratory failed to at least twice annually verify the accuracy of the C-reactive protein (CRP) analyte for 2 of 2 years reviewed (2020, 2021). The laboratory performed approximately 800 CRP patient tests annually. The findings were: 1. Review of the laboratory test menu showed the laboratory performed CRP testing. 2. Interview with the laboratory manager on 5/24/22 at 11:44 AM revealed she was new to the position and had assumed CRP was included in the proficiency testing program. .
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 policy and procedure review, lack of documentation, and staff interview, the laboratory failed to follow written procedures to monitor, assess, and correct problems in the general laboratory system for 2 of 2 years reviewed (2021, 2022). The findings were: 1. Review of the last quality assessment documentation was dated 12/31 /2020. 2. Interview with the laboratory manager on 5/25/22 at 11:30 AM revealed she was new to the position and was unaware of any quality assessment documentation. 3. Review of the policy and procedure titled "Quality Assessment Program" last reviewed by the laboratory director on 10/28/21 showed "Purpose The laboratory has an ongoing Quality Assessment Program that is designed to monitor, evaluate and improve the quality of laboratory performance and ensures the reliability of test data, and to evaluate the competency of the laboratory staff. The lab will identify and resolve any problems that may affect lab performance and thus patient care...The following Quality Assurance monitors are actively evaluated to maintain an established standard of laboratory performance and compliance. Data from each monitored area is collected, recorded and analyzed...When required, appropriate corrective action will be implemented and documented. Monitoring will be continued to assure that the action taken was appropriate and resulted in correction of any problems found. At a minimum, quarterly meetings are held to review the monitored area reports." The following Quality Assurance Monitors were outlined in the policy: Proficiency Testing, Quality Management, Laboratory Record Retention, Equipment /Centrifuge Maintenance, Temperatures, Reporting of Results, Laboratory Director, Quality of Water, Test Method Validation, Reference Ranges, Personnel, and Safety. .
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: . Based on review of the CMS (Centers for Medicare and Medicaid Services) 116 form, lack of documentation, and staff interview, the laboratory failed to have a written procedure for reporting SARS-CoV-2 test results to the appropriate agencies. The laboratory performed approximately 550 SARS-CoV-2 tests annually. The findings were: 1. Review of the CMS-116 form showed the laboratory performed SARS-CoV-2 testing using the Abbott BinaxNow antigen test system. 2. Review of the laboratory's procedure manuals showed no evidence the laboratory had developed a policy and procedure for reporting SARS-CoV-2 test results to the appropriate agencies. 3. Interview with the laboratory manager on 5/24/22 at 4 PM confirmed the laboratory did not have a written procedure for reporting SARS-CoV-2 patient test results. .
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on lack of documentation, review of the laboratory's Abbott i-STAT patient testing log sheets, review of the Abbott i-STAT operator's manual, and staff interview, the facility failed to follow the Abbott i-STAT manufacturer's instructions to perform a function check every 8 hours for the CG4+ test cartridge (pH, partial pressure of oxygen (PO2), partial pressure of carbon dioxide (PCO2), and lactate), and every 24 hours for Troponin I and the CHEM 8+ (sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, total carbon dioxide, hematocrit, and hemoglobin) test cartridge for 142 days of patient testing reviewed (1/3/22 through 5/25/22). The laboratory tested approximately 60 blood gas tests using the CG4+ cartridge, 13 CHEM 8+ panels, 10 Troponin I, and 4 Lactate tests on the Abbott i-STAT instrument during this timeframe. The findings were: 1. Review of the Abbott i-STAT testing log sheets showed no documentation the laboratory had verified the performance of the Abbott i-STAT instrument by using the internal or external Electronic Simulator every 8 hours or every 24 hours as specified by the manufacturer. 2. Interview with the laboratory manager on 5/24/22 at 3:26 PM confirmed the laboratory did not perform the function checks as required. 3. Review of the Abbott i-STAT operator's manual showed "Verify the performance of each handheld in the i-STAT System using the internal or external Electronic Simulator every 24 hours of use, or as needed for regulatory compliance. In the USA, verification is required every 8 hours for blood gases, hematocrit..." .
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)

	-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: . Based on lack of documentation and staff interview, the laboratory failed to verify the reportable range at least every 6 months using testing materials with values at the zero or minimal level, the mid-level, and the upper-level of the reportable range for the CHEM8+ test cartridge (sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, total carbon dioxide, hematocrit, and hemoglobin), the CG4+ test cartridge (pH, partial pressure of oxygen (PO2), partial pressure of carbon dioxide (PCO2), lactate) and the Troponin I test cartridge analyzed on the Abbott i-STAT instrument for 2 of 2 years of testing (2020, 2021) reviewed. The findings were: 1. Review of the laboratory's records showed no documentation the reportable range of the analytes on the Abbott i-STAT instrument had been verified. 2. Interview with the laboratory manager on 5/24/22 at 3:36 PM confirmed the calibration verification had not been completed. .
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on review of patient testing logs, review of quality control (QC) records, lack of documentation, review of the laboratory's individualized quality control plan (IQCP), and staff interview, the laboratory failed to perform two levels of control with each new lot number or shipment for the CHEM8+ test cartridge (sodium, potassium, chloride, ionized calcium, glucose, blood urea nitrogen, creatinine, total carbon dioxide, hematocrit, and hemoglobin), the CG4+ test cartridge (pH, partial pressure of oxygen (PO2), partial pressure of carbon dioxide (PCO2), and lactate) and the Troponin I test cartridge analyzed on the Abbott i-STAT instrument for 142 days of

	patient testing reviewed (1/3/22 through 5/25/22). The findings were: 1. Review of the patient testing logs showed the following concerns: a. CHEM8+ lot #461181 was used for patient testing on 1/1/22 and twice on 1/3/22. There was no evidence QC had been performed on the lot number prior to patient testing. b. CHEM8+ lot #40181 was used for patient testing three times on 3/6/22 and 3/7/22, 3/29/22, 4/25/22, 5/4/22, and 5/10 /22. There was no evidence QC had been performed on the lot number prior to patient testing. c. Troponin I lot #03214 was used for patient testing on 1/1/22, 1/3/22, and 1/6 /22. There was no evidence QC had been performed on the lot number prior to patient testing. d. Troponin I lot #91214 was used for patient testing on 1/12/22 and 4/14/22. There was no evidence QC had been performed on the lot number prior to patient testing. e. Troponin I lot #830214 was used for patient testing on 4/21/22, 5/4/22, 4/25 /22, and 5/11/22. There was no evidence QC had been performed on the lot number prior to patient testing. f. CG4+ lot #20243 was used for patient testing on 1/20/22. There was no evidence QC had been performed on the lot number prior to patient testing. g. CG4+ lot #10243 was used for patient testing for the analyte of lactate on 3 /3/22, 4/16/22, and 4/25/22. There was no evidence QC had been performed on the lot number prior to patient testing. h. There was no documentation of the CG4+ test cartridge patient results and the lot number of cartridge used for performing the test. 2. Review of the IQCP showed QC should be performed once per lot number or shipment prior to testing patient samples. 3. Interview with the laboratory manager on 5/24/22 at 3:26 PM confirmed no further documentation of QC was available. .
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on lack of documentation, review of the Abbott Cell Dyn Ruby operator's manual, and staff interview, the laboratory failed to verify the statistical parameters of quality control material prior to use for 3 of 3 test systems reviewed (hematology, coagulation, chemistry). The findings were: 1. There was no documentation the laboratory had verified a new lot of quality control material prior to being used for the hematology, chemistry, and coagulation analyzers. 2. Interview with the laboratory director on 5/24/22 at 3:18 PM revealed she was unaware of the requirement. 3. Review of the Abbott Cell Dyn Ruby operator's manual showed "New control material lots should be analyzed in parallel with current lots prior to their expiration dates. To accomplish the transition to a new lot of control material, follow your laboratory's protocol or proceed as follows:..." .
D5547	HEMATOLOGY

	CFR(s): 493.1269(c)(d) (c) For manual coagulation tests-- (c)(1) Each individual performing tests must test two levels of control materials before testing patient samples and each time a reagent is changed; and (c)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: . Based on observation, review of coagulation records, lack of documentation, and staff interview, the laboratory failed to establish a normal patient Prothrombin time mean prior to utilizing the reagent for patient testing for 1 of 1 lot number of thromboplastin reviewed. The findings were: 1. Observation of the Stago Satellite coagulation analyzer on 5/24/22 at 2:27 PM showed Neoplastin (thromboplastin) lot #257795 with an ISI (International Sensitivity Index) of 1.32 was in use. A mean patient Prothrombin time of 13.5 was being utilized to calculate the INR (International Normalized Ratio). 2. There was no documentation to show the laboratory had established the mean patient Prothrombin time prior to using the reagent to test patient samples. 3. Interview with the laboratory manager on 5/24/22 at 2:27 PM revealed she was unaware of the requirement. .
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. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: . Based on review of patient test records and staff interview, the laboratory failed to ensure the emergency release of uncrossmatched blood was signed by the ordering physician requesting an emergency release of blood for 1 of 1 patients reviewed. The findings were: 1. Review of the test record for patient #1 showed 1 unit of O negative blood was released on 4/17/22 due to an emergency. There was no documentation the physician had signed the emergency release form accepting responsibility for any adverse patient reaction that may occur. 2. Interview with the laboratory manager on 5 /24/22 at 1:52 PM revealed she had the physician sign the form using an electronic platform, however the system had failed to save the signature. .
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is

	regularly inspected. (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. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: . Based on observation, lack of documentation, review of policy and procedure, and staff interview, the laboratory failed to ensure the audible alarm system of the blood and blood product storage units were functioning properly and the appropriate staff were notified when the alarm sounded for 2 of 2 years reviewed (2021, 2022). The findings were: 1. Observation of the blood and blood product storage units showed they were monitored using the SensoScientific monitoring system. There was no documentation the alarm system had been inspected. 2. Review of the Blood Bank Alarm Checks policy showed "The alarm on each product storage unit must be checked quarterly. The alarm activation checks both the high and low activation range." "Quarterly alarm checks" had been crossed out with no corresponding signature or date. 3. Interview with the laboratory manager on 5/24/22 at 1:45 PM revealed she was new to the position and was unaware of the requirement. THIS IS A REPEAT DEFICIENCY, last cited on 9/11/20. .
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 American Proficiency Institute proficiency testing (PT) records, lack of documentation, and staff interview, the laboratory director failed to attest to the routine integration of API proficiency tests into the patient workload (D6089), failed to review and evaluate PT records (D6091), and failed to ensure an effective corrective action plan was developed to prevent reoccurrence of failed proficiency testing events (D6092). .
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: . Based on review of proficiency testing records, lack of documentation, and staff interview, the laboratory director failed to attest to the routine integration of American Proficiency Institute proficiency tests into the patient workload for 3 of 18 proficiency testing events reviewed from September 2020 through may 2022. Refer to D2009. .
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii)

	The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: . Based on review of American proficiency Institute proficiency testing (PT) records, lack of documentation, and staff interview, the laboratory director failed to review and evaluate PT records for 9 of 18 testing events reviewed from November 2020 to May 2022. Refer to D5211. .
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure 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 American Proficiency Institute (API) evaluation reports and staff interview, the laboratory director failed to ensure an effective corrective action plan was developed to prevent reoccurrence of the failed white blood cell differential which included basophils, eosinophils, lymphocytes, monocytes, and neutrophils for 2 consecutive API Hematology proficiency testing events (2021 Event #3, 2022 Event #1). Refer to D2130.