Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0056408	06/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
South Lincoln Hospital District	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
D0000	A recertification survey was completed on 6/17/24. Immediate Jeopardy existed for the following condition-level deficiencies: 42 C.F.R. 493.1100 Condition: Facility Administration 42 C.F.R. 493.1217 Condition: Immunohematology
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on observation, staff interview, and policy and procedure review, the laboratory failed to ensure appropriate equipment was available (D3007) to ensure safe and timely thawing of fresh frozen plasma (FFP) for patient use in the event of an emergency in 1 of 1 blood bank. This failure resulted in a determination of immediate jeopardy.
D3007	FACILITIES CFR(s): 493.1101(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.

	This STANDARD is not met as evidenced by: Based on observation, staff interview, and policy and procedure review, the laboratory failed to ensure appropriate equipment was available to ensure safe and timely thawing of fresh frozen plasma (FFP) for patient use in the event of an emergency in 1 of 1 blood bank. This failure resulted in a determination of immediate jeopardy. The findings were: 1. Observation on 6/12/24 at 8:30 AM and again on 6/13/24 at 2:20 PM showed 3 units of fresh frozen plasma were stored in the Jewett PRF series blood bank freezer. 2. Interview with the technical supervisor (TS) on 6/12/24 at 8:30 AM revealed the hospital's physicians requested FFP be available in the event of an emergency; however, the laboratory did not have the appropriate equipment to ensure safe and timely thawing of the FFP. In an additional interview with the TS on 6/13/24 at 10:13 AM revealed she would not feel comfortable releasing the FFP for patient use and would contact the laboratory's contracted blood and blood product supplier or surrounding hospitals to obtain the blood product. There was no evidence the laboratory had developed an alternative policy and procedure. 3. Review of the "Blood Bank General" policy and procedure, approved on 10/2/23, showed "2. The following blood products are routinely available...Fresh Frozen Plasma (5) 3. All other blood products and blood groups and types are not routinely stocked. The Blood Bank department can obtain these products from American Red Cross in SLC through their online portal. There may be a significant delay in obtaining these products." 4. Review of the "ER Department Clinical Protocol/Procedure Rapid Transfusion Protocol" policy, approved on 10/2/23, showed after the provider had ordered the rapid transfusion protocol the lab would release packed red blood cells as per protocol and immediately begin to thaw two units of FFP. Once the FFP was thawed nursing staff would immediately begin to transfuse the blood product.
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 immunohematology patient records, the blood and blood product storage unit temperature logs, lack of documentation, staff interview, and policy and procedure review, the laboratory failed to ensure a system was in place to monitor proper blood and blood product storage temperatures over a 24-hour period for 6 of 20 months reviewed from October 2022 through June 2024 (October 2023, February 2024, March 2024, April 2024, May 2024, June 2024). In addition, the laboratory failed to ensure the audible alarm was inspected and functioning from October 2022 through June 2024 (D5555) for 3 consecutive survey cycles 9/11/20, 5 /25/22, and 6/17/24. This failure resulted in a determination of immediate jeopardy.
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 CMS (Centers for Medicare and Medicaid Services 209 form, review of personnel records, lack of documentation, staff interview, and policy and procedure review, the technical consultant failed to complete an annual competency assessment (D5209) for two consecutive survey cycles conducted on 5/25/22 and 6/17/24.
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 annual competency assessment for 2 of 2 respiratory therapists for 1 of 2 years reviewed (2023). The findings were: 1. Review of the personnel files for respiratory therapist #1 and of respiratory therapist #2 showed no evidence an annual competency assessment had been completed in 2023. 2. Interview with respiratory therapist #1 on 6/13/24 at 11:30 AM revealed he thought a competency assessment had been completed in 2023; however, he was unable to locate the document. 3. Interview with the technical supervisor on 6/13/24 at 2:21 PM revealed she was unaware she was responsible for completing the competency assessments on the respiratory therapists. 4. Review of the 10/13/23 Employee Competency policy and procedure showed competency assessment should be performed upon initial hire, at 6 months, and then annually. Further review showed "...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 test results promptly, accurately and proficiently..." THIS IS A REPEAT DEFICIENCY, last cited on 5/25/22.
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 proficiency testing records, lack of documentation, staff interview, and review of policy and procedure, the laboratory failed to review proficiency test results that received an artificial score of 100% due to lack of peer group consensus for 2 of 26 American Proficiency Institute (API) proficiency testing events reviewed

	from June 2022 through May 2024. The findings were: 1. Review of the 2023 Immunology/Immunohematology Event #3 comparative evaluation showed the laboratory received an artificial score of 100% for the blood bank compatibility challenge due to lack of peer consensus. There was no documentation the laboratory had performed a self-evaluation. 2. Review of the 2024 Chemistry Core Event #1 comparative evaluation showed the laboratory received an artificial score of 100% for the analyte of total bilirubin due to an increased variance of results. There was no documentation the laboratory had performed a self-evaluation. 3. Interview with the technical supervisor on 6/12/24 at 11:38 AM confirmed an investigation of the ungraded specimens had not been completed. 4. Review of the 7/31/22 API Proficiency Test Procedure showed "PT Survey Summary Report...5...Results that were not graded are compared to the results on the Summary Report. This investigation and comparison are signed by the director and filed with along with the Summary Report..."
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 review of patient test reports, the VITROS XT 7600 analyzer manufacturer's instructions for use, and staff interview, the laboratory failed to follow the manufacturer's instructions to include the prostate specific antigen (PSA) test assay method on 3 of 3 PSA patient test reports (patient #1, patient #2, patient #3) reviewed. The laboratory performed approximately 69 PSA tests per year. The findings were: 1. Review of the VITROS XT 7600 analyzer manufacturer's instructions stated "Different test methods cannot be used interchangeably. PSA results in a given patient sample determined with different tests and from different manufacturers can vary due to differences in test methods and reagent specificity. A change to a different method during serial monitoring of a patient should be accompanied by additional sequential testing to confirm baseline values. The results reported by the laboratory to the physician must include the identity of the PSA test used." Review of the VITROS XT 7600 new instrument verification study showed it was approved by the laboratory director on 8/8/22. The following concerns were identified: a. Review of the PSA test report for patient #1, dated 1/15/24; patient #2, dated 3/8/24; and patient # 3, dated 6/5 /24, showed "This Total PSA was obtained using a One Step Enzyme Immunoassay principle performed on the Vitros 5600 platform. 2. Interview on 6/12/24 at 3 PM with the director of quality and compliance confirmed the test report had not been updated to reflect the change in instrumentation.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity.

	(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 review of the laboratory's environmental records, review of manufacturer's instructions, and staff interview, the laboratory failed to monitor the room temperature and the ambient relative humidity in 2 of 2 reagent and storage areas (main lab, immunohematology room). The findings were: 1. Review of the laboratory's environmental records showed no evidence the room temperature and the ambient relative humidity were monitored and documented. 2. Review of the manufacturer's instructions for the Ortho Workstation, used for performing immunohematology assays, showed the room temperature must be maintained between 15 and 30 degrees Celsius and the relative humidity must be between 15% and 85% (non-condensing). 3. Review of the manufacturer's instructions for the VITROS XT 7600 chemistry analyzer showed the operating temperature must be maintained between 15 and 30 degrees Celsius and the ambient relative humidity must be between 15% and 75%. 4. Interview with the technical supervisor on 6/13/24 at 2:21 PM revealed the laboratory staff would check the temperature of the laboratory; however, nothing was documented.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on new instrument and new test method verification study review, lack of documentation, staff interview, and policy and procedure review, the laboratory failed to confirm the reference values were appropriate for the patient population for 1 of 1 new instrument verification study reviewed (Vitros XT 7600). The laboratory performed approximately 32,127 patients tests annually using the Vitros XT 7600 analyzer. The findings were: 1. Review of the Vitros XT 7600 verification study showed the laboratory director approved the precision, accuracy, and analytical range studies on 8/8/22. There was no evidence the laboratory director had verified the reference intervals were appropriate for the laboratory's population. 2. Interview with the technical supervisor on 6/12/24 at 1:50 PM revealed she was unable to locate the documentation. 3. Review of the Quantitative Test Method Validation policy and procedure showed "...Reference Values...Reference values are evaluated with new analytes, new methodology, or new information from an instrument company..."
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 review of the Ortho Workstation for ID-MTS manufacturer's instructions, staff interview, and review of immunohematology quality control records, the laboratory failed to follow the manufacturer's instructions to perform day of use function checks on the Ortho Workstation for 4 of 19 months reviewed (February 2024, March 2024, April 2024, May 2024). The laboratory performed approximately 145 immunohematology patient tests annually. The findings were: 1. Review of the blood bank quality control sheets from October 2022 through January 2024 showed a section which documented the incubator temperature and the centrifuge revolutions per minute (RPM) of the Ortho Workstation. Review of the February 2024, March 2024, April 2024 and May 2024 quality control sheets showed no acceptable documentation of acceptable incubator temperature and centrifuge RPMS. 2. Interview with the TS on 6/12/24 at 3:48 PM revealed the laboratory had stopped using the quality control forms with the section to document the function checks in February. Further, the TS stated testing personnel would check the Ortho Workstation to ensure it was working properly; however, the data was not documented. 3. Review of the Ortho Workstation for ID-MTS manufacturer's instructions showed "Daily Procedures Centrifuge Display-Speed Check Since the speed of the centrifuge is displayed during operation, Ortho recommends a daily check of the displayed speed. This will ensure the centrifuge speed LED display matches the correct speed of 1032 rpm plus or minus 10 rpm. Incubator Temperature Status Display Check the incubator temperature status display and verify that it is green. This will indicate it is with the correct range."
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of the Ortho Workstation for ID-MTS manufacturer's instructions, lack of documentation, and staff interview, the laboratory failed to define a function check protocol to ensure system performance which was necessary for accurate and reliable test results for the immunohematology Ortho Workstation. The laboratory performed approximately 145 blood banking procedures per year. The findings were: 1. Review of the Ortho Workstation for ID-MTS showed "As Needed Procedures Speed Verification The centrifuge is fully calibrated at the factory. Additional calibration is not necessary. However, an additional speed verification may be performed with an optical or electronic device...as needed. Refer to your local laboratory practices for frequency of speed verification. Ortho recommends that calibration checks be performed with 10 cards. Centrifuge Timing Verification A

	calibrated stopwatch or equivalent is acceptable to check the timer. Verify accuracy of the centrifuge timer according to your organization's standard operating procedures. The manufacturer's instructions also included a procedure for verifying the incubator temperature and timer. 2. Review of the laboratory's documentation showed no evidence the function checks had been performed or a protocol developed. 3. Interview with the technical supervisor on 6/12/24 at 3:48 PM confirmed there was no evidence periodic function checks had been performed and a protocol had not been developed.
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, review of immunohematology patient records, the blood and blood product storage unit temperature logs, lack of documentation, staff interview, and policy and procedure review, the laboratory failed to ensure a system was in place to monitor proper blood and blood product storage temperatures over a 24-hour period for 6 of 20 months reviewed from October 2022 through June 2024 (October 2023, February 2024, March 2024, April 2024, May 2024, June 2024). In addition, the laboratory failed to ensure the audible alarm was inspected and functioning from October 2022 through June 2024. This failure affected 4 patients who received a total of 11 packed red blood cells from February 2024 through May 2024 and resulted in a determination of immediate jeopardy. The findings were: 1. Observation on 6/12/24 at 8:30 AM and again on 6/13/24 at 2:20 PM showed the Jewett blood bank freezer contained 3 units of fresh frozen plasma (FFP) and the blood bank refrigerator contained 12 units of packed red blood cells (PRBC). The storage units were monitored by a SensoScientific monitoring system. The following concerns were identified: a. Interview with the technical supervisor (TS) on 6/12/24 at 8:30 AM revealed the 24-hour monitoring system was currently operational for the blood bank refrigerator; however, the probe in the blood bank freezer was not functioning. Further, the technical supervisor stated the failure of the monitoring unit was discovered the end of March and the laboratory started a daily check of the blood bank refrigerator temperature on 4/1/24. In addition, the TS stated the hospital physicians requested FFP be available for patient use and the units currently in the freezer had arrived from the Red Cross on 6/11/24. b. Review of the October 2023 blood bank refrigerator log sheet showed no temperatures were recorded from 10/11 /23 until 10/24/23. Review of the blood bank freezer log showed the average temperature was minus 19.6 degrees Celsius (C) with the highest temperature documented at 3.7 degrees C on 10/11/24. There was no comment or corrective action noted. c. Review of the February 2024 blood bank refrigerator temperature monitoring log showed the last temperature recorded was on 2/7/24. There were no temperatures recorded for the blood bank freezer. d. There was no record of the temperatures of the blood bank refrigerator or freezer in March 2024. e. Review of the April 2024 blood bank refrigerator log showed the temperature was taken once per day Monday through Friday. A note at the bottom of the log sheet stated the blood bank freezer was not in

	use from 4/1/24 through 4/30/24 due to a probe malfunction. f. Review of the May 2024 blood bank refrigerator temperature log showed manual temperatures were recorded once per day and the 24-hour temperature monitoring probe began recording temperatures on 5/21/24. There was no temperature recorded for the blood bank freezer. g. No temperature was recorded for the blood bank freezer on 6/11, 6/12, or 6 /13 where the FFP was stored. h. Review of the blood bank records showed 1 unit of PRBC was transfused to patient #4 on 2/28/24 and 1 unit of PRBC on 2/29/24; two units of PRBC were transfused to patient #5 on 3/1/24; 2 units of PRBC were transfused to patient #6 on 3/20/24, 2 units on 4/1/24, and 2 units on 5/15/24; and 1 unit of PRBC was transfused to patient #7 on 5/15/24. 2. Review of the laboratory's documentation showed no evidence the audible alarm system had been inspected from October 2022 to June 2024. This was a repeat deficiency last cited on 9/11/20 and 5/25 /22. 3. Interview with the TS on 6/13/24 at 10:13 AM revealed the alarm to the blood and blood product refrigerator/freezer was now programmed to send any temperature failure electronically to her; however, a back-up system had not been developed. The TS confirmed documentation of the inspection of the blood bank audible alarm system could not be located. 4. Review of the 10/10/16 Blood Bank Alarm Checks and Corrective Action policy and procedure showed "Alarm Activation When an alarm sounds in the Blood Bank (refrigerator or freezer), it sounds in the Blood Bank and in the Emergency Room. The Emergency Room staff calls the lab to alert them to the alarm. The technologist on duty then must determine what happened, check the refrigerator or freezer thermometers and document on the temperature chart for the refrigerator or the freezer. This documentation includes: what caused the alarm, the time of activation, the resolution, how long it took the refrigerator or freezer to come back to the correct temperature range, what alternative storage was used (if needed), the date and their initials. If the reason for the alarm cannot be immediately found, call maintenance to come and check the system. Laboratory staff is available at all times...RED BLOOD CELLS (stored at 1 to 6 degrees Celsius) Red Blood Cells can be placed into an American Red Cross shipping container with the appropriate packing...The units can be stored in these containers for up to 24 hours. The temperature needs to be recorded using a thermometer every four hours and documented on the Alternate Temperature Chart. Alternately, the Red Blood Cells may be placed in another refrigerator that can maintain the units at 1 to 6 degrees Celsius. If this method is used, the temperatures still need to be taken every four hours and documented on the Alternate Temperature Chart. FRESH FROZEN PLASMA (stored at less than or equal to minus 18 degrees Celsius) The Fresh Frozen Plasma is to be placed into the freezer in the main lab. The temperature needs to be taken every four hours using a thermometer and documented on the Alternate Temperature Chart... QUARTERLY ALARM CHECKS The alarm on each product storage unit must be checked quarterly. the alarm activation checks both the high and low activation range..." Further review of the procedure showed if the test did not work, the ER did not call, or if another problem exists, the technologist that was doing the test must troubleshoot the problem immediately, If the problem was resolved the blood or blood products may remain in the refrigerator/freezer, however, if a problem was found that would affect the safety, purity or potency of products stored in the refrigerator/freezer the alternate storage procedure should be initiated.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 quality assessment documentation and staff interview, the laboratory director failed to have an ongoing system to identify problems as they occur and to monitor corrective actions taken to ensure their effectiveness. This failure resulted in deficiencies cited at D5555 for three consecutive survey cycles (2020, 2022, 2024). The findings were: 1. Review of the Quality Assurance Monthly Summary Report for the specialty of Immunohematology from October 2022 through May 2024 showed no evidence the laboratory monitored the inspection of the blood bank alarm to ensure it was performed quarterly, as required per laboratory policy. In addition, the summary report failed to include a review of the blood bank refrigerator and freezer temperatures. 2. Interview with the technical consultant on 6/13/24 at 2:21 PM confirmed the Quality Assurance Monthly Summary Report was incomplete.