Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0056408	05/07/2018
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
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 proficiency testing records review, lack of documentation, lack of written delegation of director's duties to the qualified technical consultant, and interview with staff, the director failed to attest to the routine integration and testing of proficiency samples for 8 of 26 American Proficiency Institute (API) proficiency testing events reviewed from May 2016 to May 2018. Findings include: 1. API proficiency testing records review failed to include the director's signature and date attesting Chemistry, Hematology, Microbiology, and Immunohematology proficiency tests were performed in the same manner and number of times patient tests were routinely performed for: Chemistry events - 1 of 2016 and 3 of 2017; Hematology events 1 of 2017 and 1 of 2018; Immunohematology events 1 and 3 of 2016 and events 1 and 3 of 2017. 2. The laboratory lacked a written delegation of duty by the director to authorize a qualified technical consultant or technical supervisor to sign the attestation in lieu of the director. 3. In an interview conducted on 05/07/2018 at approximately 7:00 P.M. staff confirmed the laboratory director had not signed the attestation statements listed and that the laboratory did not have a written delegation by the director for qualified

	technical supervisors of Chemistry, Hematology, and Microbiology to sign the attestation statement in the director's absence (only the director qualifies to sign Immunohematology attestation statements).
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control records review, lack of documentation, and interview with staff, the laboratory failed to monitor quality control records over time for test accuracy and precision for approximately 30 tests performed on the Vitros 5600, 3 of 3 tests performed on the Stago satellite coagulation instrument, and 6 of 6 tests performed on the Ruby 5 complete blood count instrument. Findings include: 1. Quality control records review failed to include documentation for evaluations of quality control performance overtime to detect shifts or trends controls may demonstrate and may need corrective actions. 2. In an interview with staff on 05/07 /2018 at approximately 6:30 P.M., staff stated the laboratory did not have a process to monitor quality control results over time for precession and accuracy evaluation and to observe shifts and trends in test results. Based on direct observation, manufacturer's package insert review, lack of documentation, and interview with staff, the laboratory failed to follow Neoplastine Cl manufacturer's instructions for International Normalized Ratio (INR) calculation for 1 of 1 new lot numbers of reagents received for 2 years of prothrombin time (PT)/ INR testing reviewed. The laboratory performed approximately 600 tests per year. Findings include: 1. Direct observation of the current Neoplastine Cl reagent lot number in use on 05/07/2018 at approximately 9:00 A.M. was identified as 251527 expiring on 12/31/2018. The manufacturer's package insert review for lot number 251527 stated the reagent International Sensitivity Index (ISI) was 1.26. Direct observation on 05/07/2018 at approximately 5:30 P.M., of Stago satellite coagulation analyzer data entered for lot number 113908, ISI was 1.27, and normal patient mean the analyzer used to calculate the INR was 13.2. 2. The laboratory failed to document they followed the manufacturer's instructions to perform patient normal range studies using the new lot number of Neoplastine Cl with the assigned ISI of 1.26 to accurately calculate the INR for the current lot number of Neoplastine Cl. 3. In an interview conducted on 05/07/2018 at approximately 5:40 P. M., staff stated they did not perform a new patient normal range study, change the ISI to 1.26, or enter the changes into the instrument data storage for INR calculation for the time tests were performed since the lot number was changed.
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 lack of documentation, patient test records review, and interview with staff, the laboratory failed to follow their quality control procedure to perform Arterial Blood Gas (pH, pCO2, and pO2) and lactic acid quality control with each new lot number of iSTAT CG4+ test cartridges and monthly. The laboratory performed approximately 5 arterial blood gas tests per year. Findings include: 1. The laboratory lacked iSTAT quality control records for new lot numbers of test cartridges received from May 2016 to May 2018. 2. Patient test records review included documentation the laboratory performed and reported lactate results for patient #10008467 on 04/16 /2018 using lot number 210D180090243. 3. In an interview with staff on 05/07/2018 at approximately 6:15 P.M. staff confirmed they failed to document at least 2 levels of liquid quality control performance with each new lot number of CG4+ test cartridges or monthly for Arterial Blood Gas and Lactate tests performed from May 2016 to May 2018.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory failed to document they checked each new lot number or shipment of blood culture media used for detection of aerobic and anaerobic bacterial growth on the Bactec XS 40 instrument for 2 of 2 years of testing performed. The laboratory performed approximately 4 to 8 cultures per month. Findings include: 1. The laboratory failed to document they performed sterility and growth checks for each lot number and shipment of Bactec blood culture media received from May 2016 to May 2018. (The number of shipments or lot numbers of media received was not determined but estimated to be 2 to 3 per year). 2. In an interview conducted on 05/07/2018 at approximately 7:00 P.M., staff stated they had not checked blood culture media for its ability to sustain aerobic and anaerobic growth and ensure media was sterile prior to reporting patient test results from May 2016 to May 2018.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d)

	(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory failed to ensure two levels of quality control were performed with each change of coagulation reagents for Prothrombin Time (PT) and Activated Partial Thromboplastin Time (APTT) tests reviewed. The laboratory performed approximately 2 to 6 tests per day (900 PT and PTT tests per year). Findings include: 1. Laboratory quality control records failed to include documentation the laboratory ensured quality controls were performed each 8 hours of testing and following each change of protime and activated partial thromboplastin time reagents. The laboratory was opened from 8:00 A.M. to 8: 00 P.M. and on call for PT and PTT testing 24 hours per day. 2. In an interview conducted on 05/07/2018 at approximately 9:45 A.M., staff stated they did not document when reagents were changed and that 2 levels of QC materials were tested following each reagent change to ensure the change of reagents did not alter testing performance. The number of reagent changes could not be determined without documentation for when the laboratory made reagent additions or quality control performance after reagents were changed.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that 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 proficiency testing records review, lack of documentation, and interview with staff, the laboratory director failed to ensure proficiency tests were reviewed to identify problems that require corrective actions for 6 of 8 failed proficiency testing analysts reviewed [Serum pregnancy (hCG), Thyroid Stimulating Hormone (TSH), partial pressure oxygen (pO2), prostate specific antigen (PSA), and Vancomycin]. Findings include: 1. Proficiency testing records review included documentation the laboratory scored less than 100% for American Proficiency Institute (API) tests performed for: The laboratory reported test problems for pO2 and pCO2 testing the 1st event of 2016. The laboratory self graded their results versus the acceptable ranges for pO2 to find their score would have been 0%. 0% for PSA event 1 of 2016, 60% for Serum pregnancy and 20% for TSH the 1st event of 2017, and 40% for Vancomycin for event 2 of 2017. 2. The laboratory failed to document corrective actions taken to identify problems and make corrective actions to prevent recurrence for the failed proficiency tests scores listed in finding 1. 3. In an interview conducted

	on 05/07/2018 at approximately 6:30 P.M., staff confirmed the laboratory lacked documentation of corrective actions for proficiency testing failures and scores of less than 100% for hCG, TSH, pO2, PSA and Vancomycin tests.