Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0047197	02/08/2022
Name of Provider or Supplier	**Street Address, City, State**	
Lincoln County Hospital	624 North 2nd Street, Lincoln, KS	

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
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the policy "Quality Assessment Plan", the lack of available quality assessment (QA) documents, and interview with testing personnel #1 (TP#1), the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems. Findings: 1. The "Quality Assessment Plan" required a mechanism of review to verify that test requisitions include all relevant information, specimen collection, handling, transport and storage procedures are followed, and specimen rejection criteria was adhered to. 2. No documents were made available for requisition review and specimen rejection monitoring at the time of survey. 3. Interview with TP#1 on 2 /8/22 at 11:55 a.m. confirmed, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test

	results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature logs, stated temperature ranges, temperature entries, lack of corrective action documentation and interview with TP #1, the laboratory failed to document corrective action when temperatures were out of set ranges. Findings: 1. Review of the "Temperature Log" documentation showed the laboratory failed to document any corrective action for the months of August 2021 thru November 2021 for the following number of days per month for the Big Refrigerator" established temperature range 2-8 degrees Celsius, "Small Refrigerator" established temperature range 2-8 degrees Celsius, and "Incubator" established temperature range 36-40 degrees Celsius. a. August 2021- One day of no temperature readings recorded for 7 of 7 thermometers. b. September 2021-Five days of temperature recorded was outside of acceptable range for the Big Refrigerator, one day of temperature recorded was outside of acceptable range for the Incubator, and one day of no temperature readings recorded for 7 of 7 thermometers. c. October 2021- Thirteen days of temperature recorded was outside of acceptable range for the Big Refrigerator, one day of temperature recorded was outside of acceptable range for the Small Refrigerator, and nine days of temperature recorded was outside of acceptable range for the Incubator. d. November 2021-Four days of temperature recorded was outside of acceptable range for the Big Refrigerator, and one day of temperature recorded was outside of acceptable range for the Incubator. 2. Interview with TP#1 on 2/8/22 at 11:30 am confirmed, the laboratory failed to document corrective action when temperatures were out of set ranges.
D5807	TEST REPORT CFR(s): 493.1291(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 normal ranges in the laboratory procedure manual, patient reports and interview, the laboratory failed to ensure the test report included normal ranges as determined by the laboratory. Findings: 1. Review of the patient reports from the EMR revealed that the normal ranges for two of two analytes and one of one calculated values did not match the normal ranges as stated in the procedure manual. 2. Review of the procedure manual for activated partial thromboplastin time (APTT) found the expected values or normal range was 21-29 seconds. 3. Review of the patient report for APTT contained a normal range of 18.9 to 30.9 seconds. 4. Review of the procedure manual for protime (PT) found the expected values or normal range was 10.0-13.0 seconds. No expected value or normal range was found for the International Normalized Ratio (INR) in the procedure. 5. Review of the patient report for PT contained no normal range for protime and a normal range of 0.00-3.50 for INR. 6. Interview with the technical consultant (TC) on 2/8/22 at 11:00 a.m. confirmed, the laboratory failed to ensure the test report included normal ranges as determined by the laboratory.

D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on the review of "Quality Assessment Monitors" for Urinalysis, Hematology, Coagulation, Serology, and Chemistry, lack of review documentation, and missing entries, the technical consultant (TC) failed to ensure that parameters for acceptable levels of analytic performance were maintained throught the entire testing process. Findings: 1. Review of QA monitors for Urinalysis, Hematology, Coagulation, Serology, and Chemistry show no documentation of review by the TC for the calendar year 2021. 2. Review of the monitor for urinalysis shows "Urine centrifuge calibration checked (every six months)" has only one entry in January. 3. Review of QA monitors for coagulation show no entries on: a. "Documentation of corrective action for QC problems" for January, February and March. b. "Patient Normal Mean Study performed with each change of reagent & results are available-all months of 2021. c. "Verify that INR calculation uses current pt. normal mean results" -all months of 2021. d. "Centrifuge Calibration Checked every 6 months-no entries for all months except February. 4. Review of QA monitors for chemistry show no entries on: a. "Every 6 months-Centrifuges-RPMs & Timers checked"-no entries for all months except April. 4. Interview with the TC 2/8/22 at 10:45 a.m. confirmed, the technical consultant (TC) failed to ensure that parameters for acceptable levels of analytic performance were maintained through the entire testing process.