

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  17D0047197	<b>(X3) Date Survey Completed</b>  09/26/2023
<b>Name of Provider or Supplier</b>  Lincoln County Hospital	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5807</b>	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of approved reference ranges in the laboratory Hematology procedure manual and interview with the Laboratory Director (LD), the laboratory failed to ensure the test report included correct normal ranges as determined by the laboratory Hematology policy at time of survey. Findings: 1. Review of the patient reports from the Laboratory Information System (LIS), CPSI, revealed 9 out of 15 parameters for normal ranges did not correctly match those reference ranges for the complete blood count (CBC) test in the laboratory "Lab-1532 Sysmex XN-450/XN-550 Complete Blood Count and Parameters - Whole Blood" procedure manual. LIS (CPSI) patient report: (Male Adult &gt;18 y/o) WBC 4.0-11.00 K/uL RBC 3.0-6.00 K/uL HGB 11.0-16.0 g/dL HCT 35.0-50.0 % MCV 80 -104 fL MCH 25.0-36.0 pg MCHC 31 - 37 g/dL PLT 150-450 K/uL RDW-CV 11.0-16.0 % Procedure Manual Parameters: (Male Adult &gt;18 y/o) WBC 3.7-10.4 K/uL RBC 4.50-5.80 K/uL HGB 13.6-16.7 g/dL HCT 41-50 % MCV 82-99 fL MCH 27-32 pg MCHC 32-36 g/dL PLT 140-385 K/uL RDW-CV 11.8-15.6 % 2. Interview with Laboratory Director on 9/26 /2023 at 10:40 a.m. confirmed, the laboratory failed to ensure the correct reference ranges approved in the "Lab-1532 Sysmex XN-450/XN-550 Complete Blood Count and Parameters - Whole Blood" procedure manual were in correlation with the LIS (CPSI) patient report.</p>
<b>D6049</b>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii)</p>

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Sysmex CA-600 Maintenance documentation and interview, the technical consultant (TC) / Laboratory Director (LD) failed to ensure the maintenance was reviewed regularly for five months for Daily, Weekly, Quarterly and Yearly Maintenance on the Sysmex CA-600 (s/n: 23473) coagulation instrument at time of survey. Findings: 1. Review of the April, May, June, July and August 2023 "Sysmex CA-600 Maintenance Checklist" showed no evidence that the TC performed a review of the Daily, Weekly, Quarterly and Yearly Maintenance Sysmex CA-600 coagulation analyzer. 2. Interview with the Laboratory Director on September 26, 2023 at 11:15 a.m. confirmed the technical consultant (TC) failed to ensure the maintenance was reviewed regularly for Daily, Weekly, Quarterly and Yearly Maintenance on the Sysmex CA-600 coagulation instrument.