

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0984309	(X3) Date Survey Completed 06/27/2023
Name of Provider or Supplier Univ Of Ks Health System - Great Bend Campus, The	Street Address, City, State 514 Cleveland, Great Bend, 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
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of chemistry Beckmen Coulter DXC 600 and Abbott iStat Chem 8+; Immunohematology Ortho-Clinical Diagnostics ID-Micro Typing System and Manual Blood Bank Tube method procedures, lack of comparison records and interview, the laboratory failed to evaluate and define the relationship between test results using different methodologies and instruments twice annually (every six months). Findings include: 1. Review of chemistry analytes Sodium, Potassium, Chloride, Carbon Dioxide, Urea Nitrogen, Creatinine and Glucose showed they are performed with two methods: the Beckmen Coulter DXC 600 and the Abbott iStat Chem 8+. a. No procedure was available on how to evaluate and define the relationship between the chemistry test results twice annually (every six months). b. No comparison testing records performed twice (every six months) annually from January 1, 2022 to June 27, 2023 were made available at the time of survey. 2. Review of Immunhematology analytes ABO and Rh showed they are performed with two methods: Ortho-Clinical Diagnostics ID-Micro Typing System and Manual Blood Bank Tube method. a. No procedure was available on how to evaluate and define the relationship between the Immunohematology results twice annually (every six months). b. No comparison testing records performed twice annually (every six months) from January 1, 2022 to June 27, 2023 were made available at the time of survey. 3. Interview with the general supervisor#2 on June 27, 2023 at 12:18 PM confirmed the laboratory failed to</p>

evaluate and define the relationship twice annually (every six months) between the Beckmen Coulter DXC 600 and Abbott iStat Chem 8+; Immunohematology Ortho-Clinical Diagnostics ID-Micro Typing System and Manual Blood Bank Tube method procedures.

D5803

TEST REPORT
CFR(s): 493.1291(b)

Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's emergency blood release paper documents and electronic medical record (EMR), Sunquest, the final patient forms and interview, the laboratory failed to show the State Surveyor (SA) the completed emergency blood release documents (paper) in the patient's EMR which is the hospital information system (HIS), Sunquest. There was not an adequate data entry system(s) review in place that ensured test results were accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to the patient's electronic medical record (EMR). Findings: 1. No documentation could be provided to the State Surveyor (SA) in patients' EMR of twelve or twelve patients' emergency release of blood products paper documents at time of survey. 2. An entry system review request made available at the time of survey for the emergency release (paper) reports from August 17, 2021 to June 27, 2023. None of the twelve patient emergency release of blood products completed forms were entered into the patient's EMR of the HIS Sunquest. 3. Interview with general supervisor #2 and the Laboratory Director on June 27, 2023 at 1:57 p.m. confirmed, the laboratory failed to show the State Surveyor (SA) the completed emergency blood release documents (paper) in the patient's EMR and have an adequate data entry system(s) review in place that ensured test results were accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to the electronic medical record (EMR).

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 approved reference ranges in the laboratory "Hematology Reference Range" procedure manual and interview with the general supervisor #2 (GS#2), the laboratory failed to ensure the test report included correct normal ranges and unit of reports as determined by the laboratory "Reference Range" policy at time of survey. Findings: 1. Review of the patient reports from the Laboratory Information System (LIS) revealed 4 out of 18 parameters for normal ranges and unit of reports did not correctly match those reference ranges for the complete blood count (CBC) test in the laboratory "Reference Range" procedure manual. Reference Range and Unit of Report, LIS patient report (Unisex): Absolute Neutrophil Count: None, No Unit of Report Absolute Lymph Count: None, No Unit of Report Absolute Eosinophil Count: None, No Unit of Report Absolute Basophil Count: None, No Unit of Report

Procedure Manual Parameters (Unisex): Neut# 1.8 - 7.0, No Unit of Report Lymph# 1.0 - 4.8, No Unit of Report Eos# 0.0 - 0.45, No Unit of Report Baso# 0.0 - 0.2, No Unit of Report 2. Interview with GS#2 on June 27, 2023 at 12:18 p.m. confirmed, the laboratory failed to ensure the correct reference ranges and unit of reports for 4 of 18 parameters approved in the "Reference Range" procedure manual were in correlation with the LIS patient report.