

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0695714	(X3) Date Survey Completed 02/19/2019
Name of Provider or Supplier Cheyenne County Hospital	Street Address, City, State 210 W First Street, St Francis, 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of Kendro CO2 incubator Hercell 150 operating manual and interview with the General Supervisor #2 and Testing Personnel #3, the laboratory failed to follow the manufacturer's instructions for operating the CO2 incubator in Microbiology. Findings included: 1. Review of the operator's manual for the Kendro CO2 incubator Hercell 150 indicated a CO2 comparison measurement has to be performed every three months to determine the exact measured value of the device-integral CO2 sensor. 2. Review of the Microbiology maintenance logsheet indicated no comparison measurement of CO2 for the incubator. 3. Interview with General Supervisor #2 and Testing Personnel #3 confirmed the laboratory failed to follow the manufacturer's instructions for the correct maintenance of the CO2 incubator.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation and interview with General Supervisor #2, the laboratory</p>

failed to ensure reagents and stains were used before they had exceeded their expiration date. Findings Include: 1. Direct observation of the laboratory testing area on the date of survey at 1:30 PM found a bottle of Potassium Hydroxide (KOH) solution with the lot number of 63028985 and expiration date of September 30, 2018. 2. General Supervisor #2 confirmed the bottle of Potassium Hydroxide (KOH) solution was expired and was currently used in patient testing. The interview occurred February 19, 2019 at 1:35 PM.

D5559

IMMUNOHEMATOLOGY
CFR(s): 493.1271(e)(f)

(e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (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 review of the laboratory's immunohematology policies and procedures and 30 patient test records, the laboratory failed to document all immunohematology control procedures performed in one out of 30 instances. Findings include: 1. Review of the laboratory's immunohematology policy titled "Blood Bank Quality Control" found the following instructions for Quality Control (QC). DAY OF USE Perform QC once each day of use that a Blood Bank procedure is performed. 2. Review of the Transfusion Service Testing Log indicated a patient was typed and crossmatched for two units on February 9, 2019. The two units were not transfused. 3. Review of the Laboratory's Blood Bank Assessment Form in the LIS found no quality control (QC) documentation for ABO/Rh and antibody screening cells on February 9, 2019. 4. Interview with the General Supervisor #2 on February 9, 2019 at 11:30 AM confirmed that there was no documentation of QC for ABO/Rh and antibody screening cells in the LIS on February 9, 2019.