

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0660929	(X3) Date Survey Completed 09/30/2021
Name of Provider or Supplier Kane County Hospital	Street Address, City, State 355 N Main, Kanab, UT	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on record review, direct observation, and interview with the technical supervisor, humidity of the laboratory was not monitored. The laboratory performs approximately 160,732 tests annually. Findings include: 1. Record review did not include recorded humidity on the maintenance log. There was no written policy for the monitoring of room humidity. 2. No hygrometer was present in the laboratory during observation on 09/29/2021 at approximately 4:00 PM. 3. Sysmex CA-600 Series analyzer requires 30-80% humidity. 4. In an interview on 09/29/2021 at approximately 4:30 PM, the technical supervisor confirmed humidity was not monitored.</p>
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result</p>

reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
Based on records review, direct observation, and interview with the Technical Supervisor (TS) the laboratory failed to perform function checks on all laboratory pipettes and thermometers. Laboratory thermometers are used to insure the stability of calibrators, controls, and reagents stored in freezers and refrigerators. Laboratory pipettes are used for various proposes throughout the laboratory. The laboratory performs approximately 160,732 test annually. Findings include: 1. Record review found no pipette calibration and function checks for precision and accuracy of laboratory pipettes and laboratory thermometers. 2. Record review did not find a policy for regular pipette function checks and laboratory thermometers. 3. Visual inspection on 09/30/2021 at approximately 10:00 AM, showed no calibration stickers on thermometers or pipettes. 4. The lab failed to follow the manufactures instructions for calibrating and performing function checks for laboratory pipettes and laboratory thermometers. 5. In an interview on 09/30/2021 at approximately 10:03 am, the TS confirmed that the lab does not perform function checks of laboratory pipettes and thermometers.

D5553

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

(b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (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 record review and interview with the Technical Supervisor (TS) the laboratory failed to properly complete cross match tag paperwork for issuing a blood unit to patient. The laboratory performs tests for approximately 60 transfusions annually. Findings include: 1. Record review showed on 08/28/2020 component tag paperwork was not completed prior to issuing blood unit to the patient. 2. The laboratory did not follow its pretransfusion testing procedure on documenting paperwork prior to checking out blood units. 3. In an interview on 09/30/2021 at approximately 11:30 am, the TS confirmed that the paperwork had not been filled out properly before issuing the blood unit to the patient.