

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 17D0453224	<b>(X3) Date Survey Completed</b> 01/09/2018
<b>Name of Provider or Supplier</b> Stanton County Hospital	<b>Street Address, City, State</b> 404 North Chestnut Street, Johnson, 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>D5413</b>	<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: A review of Temperature and humidity logs and interview with staff revealed the laboratory failed to document the humidity for the laboratory as the Dimension EXL the chemistry analyzer requires Findings were as follows: a. Based upon review of manufacture's operators guide the laboratory failed to document the humidity 20% to 80% for the laboratory . b. At the time of the survey 01/09/2018 the laboratory failed to produce documentation of humidity, This was confirmed by the General Supervisor from the CMS 209 form on 01/09/2018 at 15:30 hours.</p>
<b>D5783</b>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p>

This STANDARD is not met as evidenced by:

A review of the Quality Control (QC) procedure and interview with staff revealed the laboratory failed to produce a policy concerning a failed QC concerning patient results. Findings were as follows: a. Interview with general supervisor 01/09/2018 at 14:30 hrs. confirmed the laboratory failed to have the policy, (All patients test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected).