

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  17D0452429	<b>(X3) Date Survey Completed</b>  12/08/2021
<b>Name of Provider or Supplier</b>  Clay County Medical Center	<b>Street Address, City, State</b>  617 Liberty Street, Clay Center, 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>D5783</b>	<p><b>CORRECTIVE ACTIONS</b> 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> <p>This STANDARD is not met as evidenced by: Based on observation of the Chemistry EXL instrument and interview with the general supervisor #1 (GS #1), the laboratory failed to evaluate patient test results (patient remediation) since the last acceptable Cardiac Marker Level 1 quality control (QC) on Troponin (TNI) analyte to determine if patient results have been adversely affected and may require corrective action. Findings: 1. QC Range for BioRad Cardiac Plus Level 1 on the TNI analyte: 0.316 - 0.436 ng/mL at time of survey 2. Review of the Chemistry EXL instrument BioRad Cardiac Marker Plus Level 1 QC log for TNI analyte revealed: a. 10/27/21 at 7:00 a.m. Result: 0.438 ng/mL (QC failure) b. 10/27/21 at 7:45 a.m. Result: 0.385 ng/mL (QC valid) c. 10/28/21 at 7:03 a.m. Result: 0.4686 ng/mL (QC failure) d. 10/28/21 at 8:05 a.m. Result: 0.4707 ng/mL (QC failure) e. 10/28/21 at 8:34 a.m. Result: 0.4621 ng/mL (QC failure) f. 10/28/21 at 9:16 a.m. Result: 0.4417 ng/mL (QC failure) g. 10/28/21 at 9:46 a.m. Result: 0.4395 ng/mL (QC failure) h. 10/28/21 at 1:40 p.m. Result: 0.4621 ng/mL (QC failure) i. 10/28/21 at 1:58 p.m. Result: 0.4915 ng/mL (QC failure) j. 10/28/21 at 5:37 p.m. Result: 0.4590 ng/mL (QC failure) k. 10/28/21 at 6:17 p.m. Result: 0.4692 ng/mL (QC failure) l. 10/29/21 at 8:10 a.m. Result: 0.348 ng/mL (QC valid) 3. A request was made to review patient remediation data for 12 patients with 15 TNI tests released during the time frame when the Cardiac Level 1 QC failed and after the Cardiac Level</p>

1 control was valid; No documentation was made available at the time of survey. 4. Interview with GS #1 on 12/08/21 at 1:05 p.m. confirmed, the laboratory failed to evaluate patient test results since the last acceptable test run to determine if patient results have been adversely affected and may require corrective action.