

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0679423	(X3) Date Survey Completed 09/28/2023
Name of Provider or Supplier Crete Area Medical Center	Street Address, City, State 2910 Betten Drive, Crete, NE	
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
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of quality control (QC) records, review of patient testing, and interview with the laboratory manager the laboratory failed to perform daily QC for electrolyte sedimentation rate (ESR) testing performed for one day of two months of patient testing reviewed. Findings are: 1. Review of external QC records from 8/1 /2023 - 9/28/2023 revealed level 2 of quality control was not performed on 9/5/2023. 2. Review of patient testing revealed three patients tested for ESR on 9/5/2023. 3. Interview with the laboratory manager confirmed the laboratory did not run level 2 on 9/5/2023 and three patients ESR testing was performed.</p>
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of quality control (QC) records, review of patient testing, and interview with the laboratory manager the laboratory failed to have quality control</p>

result meet the criteria for acceptability before reporting patient test result for electrolyte sedimentation rate (ESR) testing performed for one day of two months of patient testing reviewed. Findings are: 1. Review of external QC records from 8/1/2023 - 9/28/2023 revealed level 2 out of range on 8/28/2023. 2. Review of patient testing revealed one patient tested for ESR on 8/28/2023. 3. Interview with the laboratory manager confirmed the laboratory failed to have quality control meet the criteria for acceptability before reporting ESR patient test result on 8/28/2023.