

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0455707	(X3) Date Survey Completed 07/28/2021
Name of Provider or Supplier Providence Medical Center	Street Address, City, State 1200 Providence Road, Wayne, 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 log records, and interview with the general supervisor the laboratory failed to perform daily QC for d-dimer and human chorionic gonadotropin (HCG) quantitative testing performed. Findings are: 1. Review of external QC records from September 2020 through July 2021 revealed QC performed once every twenty eight days or new lot for d-dimer. 2. Review of patient logs revealed patient testing was performed starting September 2020 for d-dimer. 3. Review of external QC records from October 2020 through July 2021 revealed only one level of QC performed every fourteen days or new lot for HCG, quantitative. 4. Review of patient logs revealed patient testing was performed starting October 2020 for HCG, quantitative. 5. Interview with the general supervisor on 7/28/2021 at 1:25 PM confirmed the laboratory had not performed QC testing at least once a day when patient specimens are tested. The general supervisor confirmed no individual quality control plan had been implemented for d-dimer and HCG, quantitative.</p>