

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0384720	(X3) Date Survey Completed 09/23/2022
Name of Provider or Supplier Community Memorial Hospital	Street Address, City, State 909 West First Street, Sumner, IA	
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
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on observations made during the survey, lack of quality control (QC) records, review of the Cardinal Health human chorionic gonadotropin (HCG) Combo test kit package insert, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 3:30 pm on 09/23/2022, the laboratory failed to perform a negative and positive control at least each day of patient testing for one out of one lot number of Cardinal Health HCG Combo test kit (lot number HCG1112034, expiration 2023-10-31). The findings include: 1. Observations made during a tour of the laboratory revealed that the laboratory uses the Cardinal Health HCG Combo test kit to perform serum HCG qualitative patient testing. 2. At the time of the survey, the laboratory had in use Cardinal Health HCG Combo kit lot number HCG1112034 (expiration 2023-10-31). 3. The HCG Combo kit package insert stated that for serum testing, federal, state, and local guidelines should be followed. 4. At the time of the survey, personnel identifier #1 confirmed that the laboratory had not performed controls on the Cardinal Health HCG Combo kit lot number HCG1112034 (expiration 2023-10-31).</p>