

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D1016491	(X3) Date Survey Completed 04/17/2019
Name of Provider or Supplier Mankato Clinic At Daniels Health Center	Street Address, City, State 1901 Old Minnesota Avenue, Saint Peter, MN	
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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to to establish and follow a procedure for the ongoing monitoring of the effectiveness of an Individualized Quality Control Plan (IQCP). Findings are as follows: 1. The laboratory performed qualitative serum HCG* testing as confirmed by Technical Consultant 1 (TC1) during a tour of the laboratory on 4/17/19 at 10:05 a.m. 2. A Beckman Coulter ICON 25 hCG Test kit was observed as present and available for use during the tour of the laboratory. 3. In an interview on 4/17/19 at 12:15 pm, TC1 confirmed that an IQCP to reduce the frequency of QC performance from each day of patient testing for qualitative serum HCG was established and implemented in 2016. 4. Annual reviews of the qualitative serum HCG IQCP for 2017 and 2018 were not found in laboratory records. The laboratory was unable to provide the documentation upon request. 5. In an interview on 4/17/19 at 12:15 pm, TC1 confirmed the above findings. *HCG = human chorionic gonadotropin .</p>