

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0382523	(X3) Date Survey Completed 12/20/2022
Name of Provider or Supplier Doran Clinic For Women	Street Address, City, State 1015 Duff Avenue, Ames, 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
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 lack of an Individualized Quality Control Plan (IQCP), review of quality control (QC) records, and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 3:15 pm on 12/20/2022, the laboratory failed to perform a positive and negative control each day of patient testing for the BD Affirm test system. The findings include: 1. The laboratory performed a positive and negative control with each new lot and shipment of tests and weekly for the BD Affirm test system. 2. Laboratory personnel identifier #1 indicated that the laboratory intended to follow manufacturer's instructions for performing QC. 3. At the time of the survey, the laboratory did not have an IQCP for the BD Affirm test system.</p>