Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D2298665	(X3) Date Survey Completed 08/13/2024
Name of Provider or Supplier Waukee Surgery Center, Llc	**Street Address, City, State** 1025 Se Tallgrass Ln, Ste 110, Waukee, 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	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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. This STANDARD is not met as evidenced by: Based on lack of Individualized Quality Control Plan (IQCP) records, review of quality control (QC) records, and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at 10:25 am on 08/13/2024, the laboratory failed to perform two levels of quality control each day of patient testing for the GEM Hemochron 100 test system. The findings include: 1. The laboratory performed activated clotting time (ACT) testing on the GEM Hemochron 100 test system. 2. The laboratory performed QC with each new shipment of test cartridges and monthly for the GEM Hemochron 100 test system. 3. Laboratory personnel identifier #3 indicated that the laboratory intended to follow the manufacturer's instructions for performing QC. 4. At the time of the survey, the laboratory did not have an IQCP for the GEM Hemochron 100 test system.