

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D2298665	<b>(X3) Date Survey Completed</b>  01/20/2026
<b>Name of Provider or Supplier</b>  Waukee Surgery Center, Llc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5431</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(2)</p> <p>(a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:</p> <p>This STANDARD is not met as evidenced by: Based on review of the i-STAT operator's manual, lack of thermal probe checks and confirmed by interview with the Quality Improvement Coordinator at 10:32 am on 1/20/2026, the laboratory failed to perform the thermal probe function check every six months for two out of two time periods from 1/1/2025 - 12/31/2025. The findings include: 1. The i-STAT operator's manual states the laboratory must perform the thermal probe function check every six months. 2. The Quality Improvement Coordinator confirmed that the laboratory had not performed the thermal probe function check from 1/1/2025 - 12/31/2025.</p>
<b>D5445</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(1)(2)(g)</p> <p>(d) 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</p>

section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

This STANDARD is not met as evidenced by:

Based on review of the i-STAT Individualized Quality Control Plan (IQCP), quality control (QC) records, patient test records and confirmed by interview with the Quality Improvement Coordinator at 10:32 am on 1/20/2026, the laboratory failed to follow their IQCP plan and perform two levels of external QC monthly and with each new lot and/or shipment of i-STAT cartridges for one out of two months reviewed from 10/1/2025 - 11/30/2025. The findings include: 1. The i-STAT IQCP plan stated the laboratory would perform two levels of external QC monthly and with each new lot number and/or shipment of i-STAT test cartridges. 2. On 10/9/2025, the laboratory performed an arterial blood gas on patient identifier A using lot number 220N252231243 of i-STAT cartridges. 3. The Quality Improvement Coordinator confirmed the laboratory did not have records at the time of the survey, indicating that QC had been performed on lot number 220N252231243 of i-STAT cartridges.