

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0930920	(X3) Date Survey Completed 05/22/2023
Name of Provider or Supplier Albany Ivf Fertility & Gynecology Pllc	Street Address, City, State 399 Albany Shaker Rd, Loudonville, NY	
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
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For 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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's thermometer calibration procedure titled, "Equipment Calibration and Verification SOP", the "Monthly Surface Thermometer Calibration" records, and an interview with the technical supervisor, the laboratory failed to follow the laboratory's approved Boston IVF Equipment Calibration and Verification standard operating procedure and document refrigerator/freezer temperatures for December 2022. FINDINGS: 1. The technical supervisor confirmed on May 22, 2023, at approximately 11:00 A.M. that the laboratory failed to follow the established "Equipment Calibration and Verification SOP" and document the ICSI1 and ICSI2 refrigerator/freezer temperature thermometer readings on the December 2022 Monthly Surface Thermometer Calibration.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p>

This STANDARD is not met as evidenced by:
Based on review of the Makler Quality Control (QC) records and an interview with the technical supervisor, the laboratory director failed to document review of the Makler quality control results performed from October 28, 2020, through April 13, 2022. FINDINGS: 1. The technical supervisor confirmed on May 22, 2023, at approximately 11:30 A.M. that the laboratory director failed to review and document approval of the Makler QC performed from October 28, 2020, through April 13, 2022.