

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2230568	(X3) Date Survey Completed 10/19/2023
Name of Provider or Supplier Innovative Fertility Specialists Of Alabama	Street Address, City, State One Inverness Center Parkway, Suite 210, Birmingham, AL	
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
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on a review of calibration verification (C-V) records, Quality Control (QC) policy and procedures, and an interview with Testing Personnel #1, the laboratory failed to ensure C-V was documented on the Tosoh AIA-900 Immunoassay analyzer the second half of 2022 and all of 2023 (three of four 2022-2023 C-V's documentation missed). The findings include: 1. A review of the records for the Tosoh AIA-900</p>

Immunoassay analyzer revealed a C-V was performed on February 22, 2022. No documentation of C-V performed the second half of 2022 and first and second half of 2023 to review for the following analytes with two point calibrators: a) Beta Human Chorionic Gonadotropin (hCG) b) Follicle Stimulating Hormone (FSH) 2. A review of the QC policy and procedures revealed, "FSH and hCG analytes with 2-point calibration are required to have Calibration Verification performed." Also, analytes calibrated with less than three calibrators must have a semi-annual C-V, as per CLIA regulatory requirements. 3. During an interview on October 19,2023, at 12:45 PM, Testing Personnel #1 stated the three calibration verifications had been performed but the documentation cannot be located.