Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2137386	(X3) Date Survey Completed 11/12/2019
Name of Provider or Supplier Fertility Institute Of North Alabama	**Street Address, City, State** 808 Turner Street Sw, Huntsville, 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	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) 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. This STANDARD is not met as evidenced by: Based on a review of the calibration and calibration verification (C/V) records for the Roche Cobas e-411 Immunoassay Chemistry analyzer and an interview with Testing Personnel #1, the surveyor determined the laboratory failed to perform calibration verifications every six months. The findings include: 1. A review of the records for the Roche Cobas e-411 Immunoassay Chemistry analyzer revealed all analytes are routinely calibrated with two-calibrator kits. Analytes calibrated with less than three

	calibrators must have a calibration verification (C/V) performed every six months. 2. A review of the Chemistry records revealed "Cal Checks" (individual kits for each specific analyte with three or five calibrator levels) were performed in April 2018, with review and approval by the Technical Consultant on 4/12/2018. There was no documentation of other "Cal Checks" (C/V) until 2/5/2019 and 8/15/2019. 3. During an interview on 11/12/2019 at 5:45 PM, Testing Personnel #1 confirmed the testing personnel had not performed the second "Cal Check" (C/V) in 2018. SURVEYOR ID #32558 Licensure and Certification Surveyor