Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0965359	02/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Columbus Center For Reproductive	2323 Whittlesey Road, Columbus, GA	

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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on February 8, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 surveyor review of calibration records of testing performed on the Tosoh

	AIA-900 Automated Immunoassay Analyzer and interview with the testing personnel (TP), the laboratory failed to perform and document calibration verification of the three analytes using less than a three point calibration, Beta Human Chorionic Gonadotropin, (BHCG), Follicle Stimulating Hormone, (FSH), and Prolactin, at least once every 6 months. The findings include: 1. Calibration records for BHCG, FSH, and Prolactin performed on the Tosoh AIA-900 Automated Immunoassay Analyzer revealed calibration does not contain at least 3 points including a zero, midpoint and high value near the cut-off range. 2. Review of calibration records from June 2017 through January 2018 revealed no documentation showing calibration verification for BHCG, FSH, and Prolactin was performed at least once every 6 months. 3. TP #2 (see CMS 209) confirmed on 2/8/18 at 10:30AM, in a holding area, that the laboratory did not document or perform calibration verification or use 3 levels of calibration materials for BHCG, FSH, and Prolactin performed on the Tosoh AIA-900 Automated Immunoassay Analyzer from June 2017 through January 2018.