Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0701721	11/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Women's Health Group, Pa, The	1620 Charles Place, Manhattan, KS	

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 review of 2017, 2018 calibration verification documentation and interview with the technical consultants, the laboratory failed to perform and document calibration verification procedures for progesterone(Prog), follicle stimulating hormone(FSH), thyroid stimulating hormone(TSH), hepatitis B surface antigen (HBsAG), and human immunodeficiency virus(HIV). Findings: 1. Review of 2017, 2018 calibration documentation for the Architect chemistry analyzer revealed the

	laboratory failed to perform at least a 3 point calibration, including at least a minimal, mid-point, and maximum value every 6 months for Prog, FSH, TSH, HBsAG, and HIV. 2. Interview with the technical consultants on November 2, 2018 at 12:30 PM confirmed the laboratory failed to perform at least a 3-point calibration verification for Prog, FSH, TSH, HBsAG, and HIV.