Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0709813	03/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
Obgyn Associates Montgomery	495 Taylor Road, Montgomery, 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 Cobas e411 calibration verification records and an interview with the Technical Consultant, the laboratory failed to perform calibrations verifications at least every six months as per CLIA regulations. This was noted one (2020) out of three (2018-2020) years reviewed by the surveyor. The findings include: 1. A review of the Cobas e411 calibration verification records (2018 - 2020) revealed the following: a) Estradiol, Follicle-Stimulating Hormone (FSH), Beta Human

	Chorionic Gonadotropin (HCG), Insulin, Luteinizing Hormone (LH), Progesterone, and Thyroid-Stimulating Hormone (TSH) last calibration verification was 12/30/2019. It had been 1 year and 2 months since the last calibration verification. b) Prolactin and Thyroxine (T4) last calibration verification was 01/02/2020. It had been been 1 year and 2 months since last calibration verification. c) Free Triiodothyonine (FT3), Free Thyroxine (FT4), T-Uptake, and Testosterone last calibration verification was 06/30 /2020. It had been 8 months since last calibration verification. 2. During an interview on 03/10/2021 at 1:30 PM, the Technical Consultant confirmed the laboratory had not performed calibration verifications since the dates listed above for each analyte. The Technical Consultant also confirmed only two levels are used for each analyte calibration.