

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0319976	(X3) Date Survey Completed 02/04/2022
Name of Provider or Supplier Southern Women's Health DbA	Street Address, City, State 1012 Biglane Dr, Brookhaven, MS	
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 review of calibration records for the Qualigen Fast Pack IP System since the last survey on 11/14/19 and interview with Testing Personnel #1, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, on 2/4/22 at 1:00 p. m., the laboratory failed to document, as performed, calibration verification for thyroid stimulating hormone (TSH) and human chorionic gonadotropin (HCG) testing at least once every six months since 11/14/19. Findings include: Review of calibration</p>

records for the Qualigen Fast Pack IP System since the last survey on 11/14/19 revealed calibration of TSH and HCG testing was performed with two calibrators. There was no documentation of calibration verification performed for TSH and HCG testing since the last survey on 11/14/19. Interview with Testing Personnel #1, listed on the CMS 209 personnel form, on 2/4/22 at 1:00 p.m. revealed calibration verification for TSH and HCG testing had not been performed since 11/14/19.