

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0453756	(X3) Date Survey Completed 04/30/2025
Name of Provider or Supplier Saint Paul Vi Institute National Women's	Street Address, City, State 6901 Mercy Rd, Omaha, NE	
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>(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 lack of calibration verification records and interview with the technical consultant, the laboratory failed to perform calibration verification every 6 months on their chemistry instrument, Siemens Immulite 1000, for 2023 and 2024. 1. Laboratory records of their chemistry instrument, Siemens Immulite 1000, lacked calibration verification records. 3. Interview with the technical consultant on 4/30/2025 at 10:52 AM, confirmed the laboratory failed to perform calibration verification every six months for 2023 and 2024.</p>