Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2097023	02/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Urology Associates Of Green Bay, Sc	2720 Cahill Rd, Marinette, WI	

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 surveyor review of calibration verification records, patient logs and interview with a clinical supervisor, staff A, the laboratory did not perform calibration verification every six months on the Qualigen FastPack immunoassay analyzer in 2022. Finding include: 1. Review of calibration verification records showed calibration verification performed on the Qualigen FastPack immunoassay analyzer on August 25, 2021, and August 9, 2022. Further review showed no evidence of

	additional calibration verification performed on the analyzers in 2022 when calibration verification was due on February 25, 2022. 2. Review of patient logs showed one hundred fifteen patient tests were performed between February 25, 2022, and August 9, 2022. 3. Interview with the staff A on February 14, 2023, at 10:05 AM confirmed the laboratory did not perform calibration verification every six months on the Qualigen FastPack immunoassay analyzer in 2022.