Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0927575	06/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Minnesota Urology Plymouth	2855 Campus Dr #650, Plymouth, MN	

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
D0000	The Minnesota Urology Plymouth laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F. R. part 493) upon completion of the recertification survey performed on June 20, 2024. The following standard-level deficiencies were cited: 493.1251 Procedure Manual 493.1255 Calibration and calibration verification procedures .
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory director failed to approve all procedures in use by the laboratory in 2022, 2023, and 2024. Findings are as follows: 1. The laboratory performed moderate complexity Chemistry testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:15 a.m. on 06/20/24. 2. Three Qualigen FastPack test systems were observed as present and available for use during the tour. The laboratory performed Prostate-Specific Antigen testing using the FastPack systems during the time period reviewed; July 2022 through June 2024. 3. Laboratory procedures were found in the Procedure and Safety Manual and the Clinitek, Qualigen, and Orchard Procedure Manual, both located in the Education, Training, Competency 3-ring binder. 4. Laboratory Director approval of laboratory procedures located in the above procedure manuals was not found on date of survey: 5. In an interview at 11:35 a.m. on 06/20/24, the TC confirmed the above finding. .
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 observation, document review, and interview with laboratory personnel, the laboratory failed to perform and document Chemistry analyzer calibration verification at least once every 6 months in 2023. Findings are as follows: 1. The laboratory performed moderate complexity Chemistry testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:15 a.m. on 06/20/24. 2. Three Qualigen FastPack test systems were observed as present and available for use during the tour. The laboratory performed Prostate-Specific Antigen testing using the FastPack systems during the time period reviewed; July 2022 through June 2024. 3. FastPack system method verification (calibration verification) was required every six months as established in the Qualigen procedure found in the Clinitek, Qualigen, and Orchard Procedure Manual. 4. Calibration verification was performed on 10/30 /22 and 10/13/23 as indicated in laboratory records. Eleven months and thirteen days elapsed between these calibration verification dates. 5. Calibration verification documentation was not found in laboratory records from between 10/30/22 and 10/13 /23. The laboratory was unable to provide records for a calibration verification during this time period upon request. 6. In an interview at 12:10 p.m. on 06/20/24, the TC confirmed the above finding. .