Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0927575	06/09/2026
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 9, 2026. The following standard-level deficiencies were cited: 493.1235 Personnel competency assessment policies 493.1236 Evaluation of proficiency testing performance 493.1254 Maintenance and function checks .
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure one of two Technical Consultants (TC) received a competency assessment in 2024 and 2025 which included the specific TC position responsibilities listed in Subpart M. Findings are as follows: 1. The laboratory performed moderate complexity Routine Chemistry testing of Prostrate Specific Antigen (PSA) as confirmed by Testing Personnel 10 (TP10) during a tour of the laboratory at 10:05 a.m. on 06/09/26. 2. Three Qualigen FastPack Systems were observed as present and in use during the tour: 3. A TC competency assessment was not found for TC2 during review of 2024 and 2025 laboratory personnel records. The laboratory was unable to provide the missing competency assessments upon request. 4. A TC competency assessment procedure was not found in Sharepoint, the laboratory's procedure management system. 5. In an interview at 11:30 a.m. on 06/09 /26, TP10 confirmed the above finding. .
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

	CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to investigate one unacceptable Routine Chemistry proficiency testing (PT) result out of fifteen challenges completed in 2025. Findings are as follows: 1. The laboratory performed moderate complexity Routine Chemistry testing of Prostrate Specific Antigen (PSA) as confirmed by Testing Personnel 10 (TP10) during a tour of the laboratory at 10:05 a.m. on 06/09/26. 2. The laboratory performed PT using the American Proficiency Institute (API) proficiency testing provider. 3. The laboratory received one unacceptable PSA PT result of fifteen testing challenges completed in 2025 as indicated in the API 2025 Chemistry - Core - 1st Event Comparative Evaluation report. See below. 2025 - 1st Chemistry Core Event Test: PSA Sample: IA-05 Laboratory result: 13.70 API expected result: 14.89-22.35 4. Unsatisfactory PT result investigation was required as established in the laboratory's Proficiency Testing procedure found in the hard copy Procedure Manual Clinitek and Qualigen document provided by the laboratory. 5. Investigation documentation for the unacceptable PSA score was not found during review of laboratory PT records. The laboratory was unable to provide investigation and corrective action records for this unacceptable PT result upon request. 6. In an interview at 11:25 a.m. on 06/09/26, TP10 confirmed the above finding. .
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with laboratory personnel, the laboratory failed to take corrective action when thermometer function checks failed for one of two refrigerator thermometers in use in 2024 and two of two refrigerator thermometers in use in 2025. Findings are as follows: 1. The laboratory performed moderate complexity Routine Chemistry testing of Prostrate Specific Antigen (PSA) as confirmed by Testing Personnel 10 (TP10) during a tour of the laboratory at 10:05 a.m. on 06/09/26. 2. Fridge/Freezer Thermometers 10782 and 10714 were observed as present and in use in two under-counter refrigerators during the tour. The refrigerators contained PSA test kits and patient specimens. 3. "Failed" was hand written on the 2025 Preferred Medical calibration labels on thermometers 10782 and 10714. 4. Review of Preferred Medical (PM) function check reports from 2024 and 2025 indicated thermometer 10782 failed the 11/22/24 function check. In addition, thermometers 10782 and 10714 failed the 12/22/25 function check. See below. 11/22 /24 Thermometer 10782 Reference reading 7.5 Thermometer reading 6.1 PM documentation - Thermometer Defective 12/22/25 Thermometer 10782 Reference

	reading 11.3 Thermometer reading 8.1 PM documentation - Thermometer Defective Thermometer 10714 Reference reading 3.4 Thermometer reading 4.9 PM documentation - Thermometer Defective 5. The laboratory's equipment policy, found in the Procedure and Safety Manual document located in the laboratory's procedure management system Sharepoint, indicated thermometers were replaced every 2 years. Criteria for acceptable function checks and corrective actions to take when function checks fail were not established in procedure. 6. In interviews at 10:15 a.m. and 1:20 p.m. on 06/09/26, TP10 confirmed the above finding.