Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0927575	03/10/2021
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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to verify performance specifications for 1 of 1 Chemistry test systems implemented in 2019. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 03/10/21, at 9:05 a.m. 2. Three Qualigen Fastpack test systems, identified as Units "A", "B", and "C," were observed as present and available for use for Prostate Specific Antigen (PSA) testing during the tour. 3. In an interview on 03/10/21, at 10:55 a.m., TP1 indicated that Unit "C" was put into use for patient PSA testing on 10/14/19. 4. Performance verification (PV) documentation for the Qualigen Fastpack Unit "C" test system was not found in laboratory records. The laboratory was unable to provide PV documents upon request. 5. The PSA patient testing log indicated that patient PSA testing on Unit "C" was initiated in October, 2019. A total of 134 PSA patient specimens were tested on Unit "C" between 10/14/19 and date of survey, 03/10/21. 6. In an interview on 03/10/21, at 10:55 a.m., TP1 confirmed the above findings. .
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)

	(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to establish and follow a system to evaluate and define the relationship between test results obtained from different Chemistry analyzers at least twice annually. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 03/10/21, at 9:05 a.m. 2. Three Qualigen Fastpack test systems, identified as Units "A", "B", and "C," were observed as present and available for use for Prostate Specific Antigen (PSA) testing during the tour. 4. The laboratory's procedure manuals did not include a system to define and evaluate the relationship between PSA test results obtained from different Chemistry analyzers at least twice annually. 5. Documentation of such an evaluation was missing during review of laboratory records for the following time periods: 2019 Performed 4/25/2019 for Units "A" and "B" - Unit "C" not in use at this time. No other records found for 2019. 2020 Performed 7/20 /2020 for Units "A", "B", and "C" No other records found for 2020. 6. In an interview on 03/10/21, at 10:55 a.m., TP1 confirmed the above findings. .