Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0398942	10/23/2022
Name of Provider or Supplier	**Street Address, City, State**	
Minnesota Urology, Pa	6025 Lake Road, Suite 200, Woodbury, 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
D5034	CLINICAL CYTOGENETICS CFR(s): 493.1225 If the laboratory provides services in the specialty of Clinical cytogenetics, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1276, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on laboratory record review, direct observation, and interview with laboratory personnel, the laboratory failed to meet the requirements as specified in 493.1256 for Clinical cytogenetics. Findings are as follows: 1. The laboratory failed to check Clinical cytogenetic fluorescent stains for positive reactivity 115 of 115 days of use in 2021 and 2022. Refer to D5475. .
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 ensure five of five reviewed reportable ranges obtained during the single performance verification (PV) activity completed in 2022 were adopted by

	the laboratory. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel 3 during a tour of the laboratory at 8:10 a. m. on 10/19/22. 2. A Beckman Coulter DxH 500 hematology analyzer was observed as present and available for use during the tour of the laboratory. The laboratory began performing Complete Blood Counts with Automated Differentials on this analyzer on 08/30/22. 3. PV activities on the DxH were completed in August 2022 as indicated in laboratory records found in the Performance Verification Data Manual DxH 500. Five analytes were reviewed for reportable range accuracy as indicated below. WBC - White Blood Cells RBC - Red Blood Cells HGB - Hemoglobin PLT - Platelets HCT - Hematocrit 4. The upper and/or lower reportable range limits adopted by the laboratory did not reflect the actual reportable range values obtained by the laboratory during the PV as indicated in the PV documents and the CBC with Automated Leukocyte Differential Beckman Coulter DxH procedure found in the DxH 500 Instructions for Use and SOP's manual. The Technical Consultant indicated the values found in the procedure were the analytical measuring ranges provided by the manufacturer. See below. Analyte PV Procedure WBC 0.03-103.0 0.05-400.0 RBC 0.01-7.95 0.005-8.5 HGB 0.01-19.3 0.10-25.5 PLT 0.9-1800.0 3.0-3000.0 HCT 28.4-53.8 Not in procedure 5. In an interview at 2:15 p.m. on 10/19/22, the TC confirmed the above finding. .
D5475	CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to check Clinical cytogenetic fluorescent stains for positive reactivity 115 of 115 days of use in 2021 and 2022. The laboratory performed approximately 367 Clinical cytogenetics tests on patient samples annually. Findings are as follows: 1. The laboratory performed Clinical cytogenetic fluorescence in-situ hybridization (FISH) testing as confirmed by Testing Personnel 3 during a tour of the laboratory at 8:10 a.m. on 10/19/22 2. Positive and negative quality control (QC) slide testing was required with each batch of FISH testing as indicated in the Bladder Cancer FISH Analysis using CELLAY Probes procedure found in the FISH Procedure manual. 3. The Bladder Cancer Fluorescence In-Situ Hybridization Scoring Sheets, found in the Fluorescence In-Situ Hybridization Binder, were used to document QC testing. The scoring sheets did not include documentation of positive QC slide testing from January 2021 through October 2022. Scoring sheets for negative QC slide testing were found for this time period. 4. The Clinic Operations Director (COD) discussed this issue with Testing Personnel 1 (TP1) at 4:30 p.m. on 10/19/22. Per the COD, TP1 stated positive QC slides were not tested with each batch of FISH testing in 2021 and 2022. 5. The laboratory performed FISH testing on 589 patient samples over 115 days of testing between 01/01/21 and 10/19/22 as indicated on an internal report generated by the laboratory on 10/19/22. 6. In an interview at 4:35 p.m. on 10 /19/22, the Technical Consultant confirmed the above finding.