Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0698733	12/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
Anne Arundel Urology Pa	600 Ridgely Ave Ste 210, Annapolis, MD	

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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on record review, the laboratory did not document its review of the proficiency testing evaluations for Fluorescence in situ hybridization (FISH) testing for events CYI-B of 2023 and CYI-A and CYI-B both of 2024. The laboratory proficiency test records did not show that the results returned from the proficiency test provider were reviewed by the laboratory director and appropriate staff.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on record review and interview with the testing person (TP), the laboratory failed to document the lot number, expiration date, and in use date of reagents used for the molecular urinary tract infection (UTI) panel assay. Findings: 1. The laboratory performed extraction and amplification procedures for the UTI panel assay. 2. Reagent lot numbers were documented on the lot-to-lot verification worksheets, but these did not capture the date the lots were put into use for patient testing. 3. There was a section on the electronic batch worksheet to capture the lot number and expiration date used for each batch tested for both the extraction and amplification reagents. The two batch worksheets that were reviewed did not have the lot numbers

	documented. 4. During the survey on 12/11/2024 at 1:10 PM, the TP confirmed that the lot numbers and expirations dates for the UTI panel reagents were not documented on the electronic batch worksheets and there was no other reagent log that captured the dates the reagents were put into use.
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 record review and interview with the testing person (TP), the laboratory failed to ensure that test results from two polymerase chain reaction (PCR) analyzers were compared at least twice a year. Findings: 1. The laboratory performed patient testing using two QuantStudio 5 PCR analyzers. 2. During the survey on 12/11/2024 at 1:15 PM, the TP confirmed that there was no policy or procedure to compare test results from the two PCR analyzers at least twice a year.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the "Quality Assurance Worksheet" records for the monthly reporting of the quality activities associated with the prostate-specific antigen (PSA) test, the laboratory did not report the month that the quality assurance review was conducted for, on the worksheet. this was confirmed during interview on 12/11/24 at 12:30 pm with laboratory staff.