Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0698733	05/15/2023
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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of test reports sent for accuracy verification and interview with the general supervisor (GS), the laboratory failed to document the steps taken when the pathologist's results did not agree with the results reviewed by a peer pathologist. Findings: 1. The procedure titled "Urothelial OligoFISH, Cytology and Telomerase Outside Review" stated that "The pathologist will randomly select two cytology, two FISH and two telomerase specimens semi-annually. These will be reviewed by a peer pathologist." 2. The procedure stated that if the pathologist "does not agree with the peer pathologist, arrangements will be made for the slides to be sent to a third party for resolution. 3. There were four case reports that were sent to an outside laboratory for peer review: 4339192, 4339177, 4339182, and 4339195. 4. A note stating "Disagree, diagnosis not confirmed by FISH" was handwritten on each report and dated 01/25/2023. 5. There was no additional documentation explaining if patient results were affected by the disagreement in diagnosis, what corrective actions were taken, and if the results were sent to a third party for resolution as stated in the procedure. 6. During the survey on 05/15/2203 at 5:00 PM, the GS confirmed that there was no additional documentation explaining the next steps taken when results sent for outside peer pathologist review did not agree with the pathologist results.
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 have the individual proficiency test results for each unknown sample (evaluated by the proficiency test provider) for the 3rd event of 2022 for PSA (prostate specific antigen) proficiency testing. Findings: 1. The laboratory documented the review of the PSA proficiency testing for the 3rd event of 2022 on the summary evaluation provided by the proficiency test provider, The laboratory did not have the proficiency test providers evaluation showing the scores for each individual unknown sample.
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 review of reagent logs and interview with the general supervisor (GS), the laboratory failed to document lot numbers, dates in use, and expiration dates for histopathology and cytology reagents to ensure they were not used beyond defined expiration dates. Findings: 1. The laboratory used "Lot Numbers" logs to record the reagent name, lot number, date in use, and expiration date. 2. The logs for the following reagents showed that the last lot numbers documented on the logs were expired: a. 1M MgCl2: Lot 19034100 was put into use on 03/23/2022 and expired on 07/16/2022. b. Activator: Lot 1924500 was put into use on 02/02/2022 and expired on 12/15/2022. c. Cellay Control Slides: Lot 21334 expired on 12/20/2022. The date in use was not documented. The previous lot, 21131, was put into use on 12/30/2021 and expired on 05/11/2022. d. DAB/SUB/CHROM: Lot 220202 was put into use on 07/28 /2022 and expired on 12/31/2022. e. DAPI Antifade: Lot 22034 was put into use on 07 /30/2021 and expired on 08/03/2022. f. Decal STAT: Lot 129131 expired on 09/30 /2024. The date in use was not documented. The previously lot, 068930, was put into use on 01/18/2019 and expired on 08/2021. g. Detergent (Cellay): Lot 19355400 was put into use on 07/27/2022 and expired on 01/27/2023. h. Hematoxylin: Lot 220324 was put into use on 08/20/2021 and expired on 12/31/2022. i. HRP Polymer - A/B/C: Lot 220324 was put into use on 08/20/2021 and expired on 12/31/2022. j. Isothermal Denaturing Solution: Lot 19184300 was put into use on 02/09/2022 and expired on 10 /04/2022. k. Mounting Medium Toluene: Lot 1243 was put into use on 01/10/2022 and expired on 08/31/2022. l. OligoFISH Probe: Lot 59.119 was put into use on 05/19 /2022 and expired on 04/30/2023. Lot to lot verification documentation showed that lot 59.121 was received on 06/24/2022 and lot 59.122 was received on 10/10/2022. Neither lot was recorded on the reagent log. m. 10% PBS: Lot 19148200 was put into use on 04/14/2022 and expired on 09/08/2022. n. Tissue Marking Dye: Lot 104400E was put into use on 04/20/2021 and expired on 03/2023. o. Tubing Cleaning Kit (Z1 & Z2): Lot 210802 was put into use on 02/02/2022. The expiration date was not documented. 3. The following logs showed a gap in time between when one lot expired and the next lot was put into use. a. 1M MgCl2: Lot 18754400 expired on 02 /13/2022 and the next lot was not put into use until 03/23/2022. b. Detergent (Cellay): Lot 18544100 expired on 10/22/2021 and the next lot was not put into use until 04/07 /2022. c. Isothermal Denaturing Solution: Lot 18348600 expired on 06/12/2021 and the next lot was not put into use until 02/09/2022. 4. During the survey on 05/15/2023 at 5:00 PM, the GS confirmed that the reagent logs were not up to date.

D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of staining quality control (QC) records and interview with the general supervisor (GS), the laboratory failed to document pathologist approval of the staining material for intended reactivity and staining characteristics. Findings: 1. The laboratory stained histology and cytology patient slides using hematoxylin and eosin (H&E), acid hematoxylin (AH), immunohistochemistry (IHC), and Papanicolaou (Pap) stains. 2. The laboratory was to document staining QC on monthly logs titled "Daily Staining QC Log." 3. The log included columns for H&E, AH, Pap, and IHC stains and columns for technologist and pathologist initials of approval. 4. The log stated "Y = Yes adequate staining." The logs were filled in with a "Y" in the stain type columns on days that the stain was prepared and then initialed by the technologist who prepared the stains. 5. The column for the initials of the pathologist who evaluated the stained slides for patient results was blank. 6. During the survey on 05/15/2023 at 5:00 PM, the GS confirmed that the pathologist evaluating patient results was not documenting approval of daily stain QC for intended reactivity and staining characteristics.
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 (QA) plan, review of incident report forms, and interview with the general supervisor (GS), the laboratory director failed to document review of incident reports and ensure the forms were complete. Findings: 1. The QA plan stated that department personnel were responsible for data collection and reporting which would be reviewed by the supervisor and medical director on a monthly basis. The plan also stated that major incidents affecting patient and/or patient specimen outcome would be documented on the incident report forms. 2. The incident report forms included sections to document the date of the incident, patients involved, personnel identifying the incident, whether the patient clinic was contacted, the "Problem," the "Effect on the Patient care," the "Performance Standards Failure," the "Assessment & Identification of Causes," the "Action Plan," the personnel completing the form, and the review/approval signatures and dates from the medical director and the lab administrator. 3. A total of 10 incident report forms from 06/24 /2022-04/13/2023 were reviewed. Of the 10 incident reports, 2 were clearly signed by the medical director. 4. The reports did not consistently have all sections completed. For example, the report form for the incident that occurred on 02/14/2023 did not identify the personnel who filled out the form and did not contain the signature and

	date of review/approval from the medical director and lab administrator. 5. The laboratory supplied prostate biopsy kit boxes that included 12 separate collection vials for separate prostate biopsy cores. On 02/14/2023 the laboratory was notified that when staff went to put a patient's 2nd prostate biopsy core specimen into a specimen vial, the vial already contained a prostate biopsy core from an unknown patient. 6. The incident report form did not identify which clinic the incident was reported from. An attachment to the incident report form stated that the laboratory spoke with a contact at the Greenbelt clinic to inform them of the incident. The date and time of contact was not documented. 7. The attachment stated that the differences between the clinic and the pathology lab's procedures for retaining or discarding unused collection vials was discussed. 8. The "Performance Standards Failure" section was not completed, and it was unclear if collection procedures were not followed. 9. The "Assessment & Identification of Causes" section was not completed, and it was unclear if the root cause of the error was identified or if the unknown core was able to be identified. 10. The "Action Plan" section was not completed, and it was unclear if changes in processes or procedures would be applicable, and if so, were implemented. 11. During the survey on 05/15/2023 at 5:00 PM, the GS confirmed that the incident report forms were not consistently being signed as reviewed by the medical director and all sections on the report from the 02/14/2023 were not completed.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review, the technical supervisor did not ensure competency checks were performed and documented. Findings: 1. General supervisor # 1 (as identified on the personnel report signed 4/19/23) performs tissue grossing. On March 14, 2022 General Supervisor #2 (as identified on the personnel report signed 4/19/23) performed the competency check for General Supervisor #1. The competency check (performed on March 14, 2022) was not performed by a technical supervisor (as reported on the personnel report) as required. 2. General supervisor # 1 (as identified on the personnel report signed 4/19/23) took an ergonomics quiz and a spill response quiz (as part of the competency check) that evaluated and scored, but the person who scored the quiz was not identified and the quiz did not have a date when taken or scored. 3. The laboratory written procedure titled Molecular policy and Procedure Manual under the heading Technologist Competency Test states that the laboratory supervisor can evaluate competency, but does not state that the evaluating supervisor must also qualify as a technical supervisor.