Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0698733	07/20/2021
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 proficiency testing (PT) record review and interview with the general supervisor (GS), the laboratory did not ensure that PT was performed at least twice annually for all tests performed in the laboratory. Findings: 1. The laboratory performed testing on urine cytology specimens using the Human Telomerase Reverse Transcriptase (hTERT) telomerase stain. 2. PT record review from 2019 through 2021 showed that there were no PT records for hTERT testing. 3. During an interview on 7 /13/2021 at 2:00 PM, the GS confirmed that the laboratory was not performing PT for the hTERT telomerase test.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the validation data and final report and interview with the polymerase chain reaction (PCR) testing consultant, the laboratory failed to establish

	stability for patient samples tested for microbiology panels using PCR. 1. The document titled "Anne Arundel Stability Study Validation Results" was reviewed and consisted of a single page with two sections for two separate studies. The first study was for analytes tested in semen samples and the second study was for analytes tested in urine samples. 2. The laboratory did not receive and test semen samples for the microbiology panels tested using PCR. The laboratory did test rectal and vaginal swab samples which were not included in the stability study data. 3. Both sections included a brief summary of each study and a table containing the results for the analytes that were tested in each sample matrix. Neither summary included step-by-step instructions detailing how the samples were collected and processed; how and at what concentration each analyte was spiked into the samples; how the samples were tested; the acceptance criteria for evaluating the results; nor how the data was analyzed. 4. For both studies, analytes were tested on days 0, 5, 10, and 14 to determine analyte storage stability by specimen type. According to the final report, the laboratory had a PCR microbiology testing panel that included 19 bacteria, 1 yeast, 1 parasite, 10 antibiotic resistance genes, and the 16S gene. 5. The stability study for semen tested 7 analytes targeting 2 bacteria, 2 antibiotic resistance genes (2 targets per gene), and the 16S gene. Of the 7 analytes tested, 1 had results listed for all 4 days tested, 2 had results listed for day 5, 1 had results listed for day 10, and 3 had results listed for day 0 only so that a standard deviation could not be calculated. 6. The summary for semen samples stated that "All results were within 2 standard deviations except 16S. There were multiple inconsistencies throughout the stability study. Due to these inconsistencies, the length of time shown to be an acceptable limit is 5 days for swab samples." The summary did not explain what the inconsistencies were and how they affected the results nor why 5 days was determined to be an acceptable limit. 7. The stability study for urine tested 13 analytes targeting 5 bacteria, 1 yeast, 4 antibiotic resistance genes (6 total targets), and the 16S gene. Of the 13 analytes, 2 had results listed for all 4 days tested, 7 did not have results listed for day 0, 1 had no results listed at all, and 4 had results listed for day 10 only so that a standard deviation could not be calculated. 8. The summary stated that "All results are within 2 standard deviations except S. marcescens and 16S. Due to these out of range result, the length of time shown to be an acceptable limit is 10 days for urine samples." The summary did not explain why 10 days was determined to be an acceptable limit. 9. During a phone interview on 07/13/2021 at 3:30 PM, the PCR testing consultant confirmed that the written summaries did not detail how the specimens were collected nor how and why the acceptable stability limit of 10 days for urine samples was determined.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on laboratory procedure manual and record review and interview with the general supervisor (GS), the laboratory did not ensure that the laboratory's procedure manual accurately reflected the current practice in the laboratory. Findings: 1. Procedure manual review showed that the laboratory changed its method of staining urine cytology specimens for the Human Telomerase Reverse Transcriptase (hTERT) telomerase stain from its "OligoFISH" method to a new "DiskFISH" method. The

	procedure manual had not been updated to reflect the change; and 2. The procedure, "Quality Assurance," "Histopathology Second Pathologist Review" stated, "As a general rule, any clinically unsuspected malignancy, rare or unusual malignancy, or any case deemed appropriate by the pathologist should be reviewed by a second pathologist." "Reviewed cases will include verification of at least 5 special stains every 6 months." 3. A review of the "Second Opinion Log" from 4/14/2020 to 6/9 /2021 showed that special stains were not included in the slides evaluated for a second opinion. The GS stated at 3:15 PM on the day of the survey that this procedure was not being followed. 4. During an interview on 7/13/2021 at 5:15 PM, the GS confirmed that the laboratory did not ensure that the procedure manual was updated to reflect the current practice of the laboratory.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: I. Based on review of the procedure and interview with the testing person (TP), the laboratory failed to include instructions for corrective actions to take when the negative extraction control for polymerase chain reaction (PCR) testing failed. Findings: 1. The procedure titled "3. DNA Extraction" (AAU-TOP-01.2) was reviewed. Section D, number 4 under "Quality Control" stated that for the negative extraction control, "Any positive result for the assay tested must be resolved/referred to the lab manager." 2. The procedure did not include instructions for what corrective actions need to be taken to resolve any potential reagent contamination or to address patient specimens that were potentially affected by the failed negative extraction control. 3. The procedure did not include instructions for where to document a negative extraction control failure and corrective actions taken to resolve the issue. 4. During an interview on 07/13/2021 at 1:15 PM, the TP confirmed that there was no procedure that defined corrective actions that need to be taken when the negative extraction control fails. II. Based on review of the procedure and interview with the TP, the laboratory's procedure failed to include specimen collection instructions for vaginal swabs for PCR testing. Findings: 1. The procedure titled "1. Specimen Collection and Shipping" (AAU-QM09) was reviewed. 2. The section titled "Collection Procedures" included instructions for collecting urine, rectal swab, and

	semen swab specimens for molecular testing. 3. The TP stated that the only specimens received for PCR testing were urine, rectal swab, and vaginal swab specimens. 4. During an interview on 07/13/2021 at 3:30 PM, the TP confirmed that the procedure did not include instructions for the collection of vaginal swabs. III. Based on review of the procedure and interview with the TP, the laboratory's procedure failed to include clear instructions for storage and transport conditions. Findings: 1. The procedure titled "1. Specimen Collection and Shipping" (AAU-QM09) was reviewed. 2. Section A, number 5 under "Collection Procedures" stated that urine samples "should be refrigerated at 2-8C within 48 hours of collection and can remain at this temperature for up to 72 hours. The urine samples must be tested within 10 days." 3. Section B, number 8 under "Collection Procedures" stated that rectal swab samples "should be refrigerated at 2-8C within 48 hours of collection and can remain at this temperature for up to 72 hours. The swab samples must be tested within 5 days." 4. Section C, number 8 under "Collection Procedures" stated that semen swab samples "should be refrigerated at 2-8C within 48 hours of collection and can remain at this temperature for up to 72 hours. The swab samples must be tested within 5 days." 5. The procedure was not clear as to how the urine, rectal swab, and semen swab samples should be stored or transported after 72 hours and before they must be tested at 10 days and 5 days, respectively, after collection. 6. During an interview on 07/13 /2021 at 3:30 PM, the TP confirmed that the procedure was not clear as to the storage and transport conditions for patient samples after 72 hours and before they must be tested at 5 and 10 days after collection.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on procedure manual review and interview with the general supervisor (GS), the laboratory did not ensure that the laboratory's procedure manuals were signed and dated by the current laboratory director (LD). Findings: 1. The current LD took the position of LD in February 2021. 2. The "Procedure Manual," the "Pathology Safety Manual," and the laboratory's Individualized Quality Control Plan were not approved (signed and dated) by the current LD. 3. During an interview on 7/13/2021 at 5:15 PM, the GS confirmed that the laboratory's procedure manuals were not signed and dated by the current LD.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by:

	I. Based on record review and interview with the practice administrator (PA), the laboratory failed to record relative humidity of the laboratory where total prostate-specific antigen (PSA) testing was performed. Findings: 1. The laboratory used a Qualigen FastPack System to perform Total PSA testing. The instrument manual stated that "the FastPack IP System operates optimally between 15-32 degrees C or 59-90 degrees F at a relative humidity between 10% and 90%." 2. A review of laboratory "Ste 222" temperature logs from January to June 2021 showed that the laboratory was not recording the relative humidity of the laboratory where Total PSA testing was being performed. 3. During an interview on 07/13/2021 at 4:30 PM, the PA confirmed that the laboratory was not recording relative humidity in the laboratory where Total PSA testing was being performed. 43123 II. Based on record review and interview with the general supervisor (GS) and the practice administrator (PA), the laboratory failed to accurately define the acceptable humidity ranges for polymerase chain reaction (PCR) testing. Findings: 1. The "Daily Temperature and Humidity Check" logs for April - June 2021 were reviewed. The logs defined the acceptable humidity range as "Lo - 100%." 2. The laboratory extracted deoxyribonucleic acid (DNA) using a QIAgen QIAcube instrument. Appendix A of the QIAcube User Manual Version 1.3 (March 2018) stated that operating conditions are "Relative humidity 15-75% (noncondensing)." 3. The laboratory amplified the DNA using a Roche LightCycler 480 instrument. Section 2.2 of the LightCycler 480 Instrument - Operator's Manual Version 1.0 stated that "Relative humidity allowed during operation" is "Max. 80% at 32C, no condensation" and "Min. 30%, at +15C to +32C." 4. During the exit interview on 07/13/2021 at 5:30 PM, the GS and PA confirmed that the acceptable humidity ranges listed on the "Daily Temperature and Humidity Check" logs did not match what was specified in the instruments' operator's manuals for PCR testing.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview with the general supervisor (GS), the laboratory did not ensure that histology stains and reagents used for histology testing were labeled with the date that they expire. Findings: 1. During a tour of the laboratory at 9:15 AM, it was observed that the laboratory had small containers of stain and other staining reagents under the fume hood. It was observed that the containers were labeled with the name of the stain or reagent, but were not labeled with the lot number or expiration date. 2. During an interview on 7/13/2021 at 5:15 PM, the GS confirmed that histology stains and reagents were not labeled to indicate the expiration date to ensure that testing materials were not used past their expiration date.
D5453	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iv)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following

	for-- Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the procedure and interview with the testing person (TP), the laboratory failed to test a negative extraction control at least once a day when patient specimens were tested using polymerase chain reaction (PCR). Findings: 1. The procedure titled "3. DNA Extraction" (AAU-TOP-01.2) was reviewed. Section D under "Quality Control" stated "A negative extraction sample must be performed monthly." 2. During an interview on 07/13/2021 at 1:15 PM, the TP confirmed that the negative extraction control for PCR testing was being tested once a month.
D5637	CYTOLOGY CFR(s): 493.1274(d)(1)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary. This STANDARD is not met as evidenced by: Based on procedure manual and cytology record review and interview with the general supervisor (GS), the laboratory did not ensure that the workload limit of each individual performing cytology slide examination was reassessed at least every 6 months and adjusted when necessary. Findings: 1. The procedure, "Cytology" stated, "Workload limits and performance assessment, (as indicated by review of diagnosis correlation), will be reviewed at least every 6 months by the Laboratory Director. Each individual's workload limit will be reassessed and adjusted as necessary every six months." 2. A review of "Cytology Workload Logs" and cytology records from 2019 through 2021 showed that there was no documentation that cytology workload limits had been reevaluated. 3. During an interview on 7/13/2021 at 2:00 PM, the GS confirmed that the laboratory was not reassessing the workload limit of the testing person performing cytology slide examination.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of a final test report for polymerase chain reaction (PCR) testing and interview with the testing person (TP), the laboratory's final test report failed to include the units of measurement, define an abbreviation, and identify that a result

	listed on the report was not determined by testing performed in the laboratory. Findings: 1. A final test report for a urine specimen tested using PCR was reviewed. 2. The results were quantitative and the report stated the units as "Amount per mL." The final test report did not state what unit per mL the amount was referring to. 3. Under a column labeled "Respiration," the abbreviation "FAn" was listed. There was no definition for "FAn" to aid in results interpretation. 4. Under a column labeled "Gram Stain," the report listed "+." The TP explained that the laboratory did not perform a Gram stain and this information was automatically filled into the report based on the characteristics of the pathogen that was identified using PCR testing. 5. During interviews on 07/13/2021 at 1:15 PM and 3:30 PM, the TP confirmed that the amount per mL and abbreviation were not defined and the laboratory did not perform Gram stains.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of a final test report and interview with the testing person (TP), the laboratory failed to include the reference/normal ranges for the amount of deoxyribonucleic acid (DNA) found in specimens tested using polymerase chain reaction (PCR). Findings: 1. A final test report for a urine specimen tested using PCR was reviewed. 2. The test report included a numerical value for "Bacterial Load" and for the pathogen specific DNA that was identified using PCR. 3. The test report did not include a reference/normal range for the amount of "Bacterial Load" or pathogen specific DNA to aid in interpretation of the patient's results. 4. During an interview on 07/13/2021 at 1:15 PM, the TP confirmed that there were no reference/normal ranges for the amount of "Bacterial Load" or pathogen specific DNA found in patient specimens.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel files and interview with the general supervisor (GS), the laboratory director failed to ensure that all testing personnel (TP) received the appropriate training and demonstrated they could perform the polymerase chain reaction (PCR) testing reliably prior to testing patient specimens. Findings: 1. The personnel file for TP#3 contained only the TP's resume. 2. The GS stated that TP#3 was hired in 06/2020 and was performing PCR testing part-time on weekends. 3. During the exit interview on 07/13/2021 at 5:30 PM, the GS confirmed that TP#3's personnel file did not include documentation of the TP's initial training.

D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: The technical supervisor failed to ensure that the negative extraction control for polymerase chain reaction testing was performed on a daily basis and corrective actions required for control failure were clearly defined in the procedure. Cross refer to D5403 I and D5453.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of personnel files and interview with the general supervisor (GS), the technical supervisor failed to ensure that all polymerase chain reaction (PCR) testing personnel (TP) received a competency evaluation semiannually during their first year testing patient specimens. Findings: 1. The personnel file for TP#3 contained only the TP's resume. 2. The GS stated that TP#3 was hired in 06/2020 and was performing PCR testing part-time on weekends. 3. During the exit interview on 07/13/2021 at 5: 30 PM, the GS confirmed that TP#3 did not receive a semiannual competency evaluation during their first year of testing patient specimens.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of personnel files and interview with the general supervisor (GS), the technical supervisor failed to ensure that all histology and cytology testing personnel (TP) received annual competency evaluations. 1. The GS and TP#1 both perform grossing and slide processing for histology and cytology specimens. 2. The personnel files for the GS did not contain documentation of a competency assessment for 2019 or 2020. 3. The personnel files for TP#1 did not contain documentation of a

	competency assessment for 2020. 4. During the exit interview on 07/13/2021 at 5:30 PM, the GS confirmed that competency assessments for the GS were not performed in 2019 or 2020 and for TP#1 were not performed in 2020.
D6175	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(1) Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the TP, the TP did not follow the laboratory's procedure for specimen lysate and DNA retention after polymerase chain reaction (PCR) testing. Findings 1. The procedure titled "4. Storage of Reagents and Specimens and Reagent Handling, Labeling, and Expiration" (AAU-QM07) was reviewed. 2. Section A under "Procedure for Storage of Clinical Specimens" stated "Clinical specimen's lysates will be stored at -12 to -32C for at least one month up to 6 months in a freezer with other patient specimens only." The TP stated that the clinical specimens' lysates were stored in the refrigerator for up to 5 days. 3. Section B under "Procedure for Storage of Clinical Specimens" stated "Clinical sample's DNA [deoxyribonucleic acid] will be stored for at least one month up to a year at -12 to -32C." The TP stated that the clinical samples' DNA were stored in the refrigerator for a week. 4. During an interview on 07/13/2021 at 3:30 PM, the TP confirmed that specimen lysate and DNA retention practices after PCR testing did not match what was stated in the procedure.