Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0698733	12/14/2018
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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record and patient sample log review and interview with the general supervisor (GS), the laboratory did not handle PT specimens in the same manner as patient samples. Findings: 1. Patient samples for pathology testing are recorded on a patient log. 2. A review of pathology patient logs from 2017 to 2018 showed that samples from 4 of 4 PT events were not recorded on the patient log. 3. During an interview on 12/14/18 at 1:45 PM, the GS confirmed that PT samples were not recorded on the patient log in the same manner as patient specimens.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing

	samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. 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 a copy of all PT records were maintained for a minimum of two years from the date of the PT testing event. Findings: 1. A review of cytology PT records from 2017 to 2018 showed that cytology instrument printouts from 4 of 4 PT events were not available for review at the time of the survey. 2. During an interview on 12/14/18 at 1:45 PM, the GS confirmed that the cytology printouts from the PT events listed above were not maintained with the PT records reviewed.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on temperature log record review and interview with the general supervisor (GS), the laboratory failed to document corrective action when refrigerator and freezer temperatures were out of range. Findings: 1. The temperature range for the laboratory refrigerator is 2 - 10 degrees Celsius; the temperature range for the laboratory freezer is -20 - -10 degrees Celsius; and 2. From February to August, 2018 the refrigerator temperatures were out of range 1 out of 149 times recorded and the freezer temperatures were out of range 40 out of 149 times recorded. 3. There were no corrective actions documented for these dates. 4. During an interview on 12/14/18 at 1:45 PM, the GS confirmed that there were no corrective actions documented for the days that the refrigerator and freezer temperatures were out of range.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the general supervisor (GS), the laboratory director (LD) did not ensure that all PT reports were

	reviewed and evaluated to identify any problems that require corrective action. Findings: 1. A review of PT records from 2017 and 2018 showed that the PT reports for 4 of 4 events were not signed by the LD, showing that he/she had evaluated the laboratory's performance. 2. During an interview on 12/14/18 at 1:45 PM the GS confirmed that the LD had not signed PT results, indicating that they had been reviewed to identify any problems that require corrective action.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the general supervisor (GS), the laboratory director (LD) did not ensure that corrective actions were performed when cytology PT was found to be unacceptable. Findings: 1. The laboratory is enrolled in PT for "FISH for Urothelial Carcinoma" through the College of American Pathologists. A review of 4 PT events in 2017 and 2018 showed that for the first event (CYI-A) of 2018, the laboratory's grade was unacceptable for 1 of 2 tests performed. 2. The PT results were not signed or reviewed by the LD and no investigation or corrective actions were performed for the failed PT. 3. During an interview on 12/14/18 at 1:45 PM the GS confirmed that the LD did not ensure that a corrective action plan was followed when cytology PT results were unacceptable.
D6178	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(4) Each individual performing high complexity testing must follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance. This STANDARD is not met as evidenced by: Based on temperature log record review and interview with the general supervisor (GS), the testing personnel did not follow the laboratory's procedure for when refrigerator or freezer temperatures are out of range. Findings: 1. Laboratory staff record refrigerator and freezer temperatures on the laboratory's "Daily Lab Equipment Temperature QC Log." The log states, "If any value falls below minimum or above maximum allowable value adjust the temperature and record new reading. Document all out of range readings and actions taken to resolve, if temperature cannot be adjusted then the instrument should be taken out of use until rectified." 2. A review of temperature logs from February to August, 2018 showed that refrigerator and freezer temperatures were out of range with no corrective action documented. See D5781. 3. During an interview on 12/14/18 at 1:45 PM the GS confirmed that testing personnel did not follow the laboratory's policy for handling out of range refrigerator temperatures.