Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0666021	03/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Urological Associates, Pc	3319 Spring Street, Davenport, IA	

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
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 review of AAB proficiency testing (PT) attestation statements for 2016-2017 and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 03/08/2018, the laboratory failed to maintain a copy of the attestation statement signed by the laboratory director and testing personnel for six out of six PT testing events (2016 events 1, 2, and 3; 2017 events 1, 2, and 3) in 2016-2017 . The findings include: 1. The laboratory director did not sign the attestation statements for the following testing events: *2016 event 1- Chemistry, Comprehensive *2016 event 1- Special Chemistry *2016 event 1- Basic Chemistry *2016 event 1- Hematology *2016 event 2- Hematology *2016 event 3- Chemistry, Comprehensive *2016 event 3- Special Chemistry *2016 event 3- Basic Chemistry *2016 event 3- Hematology *2017 event 1- Chemistry, Comprehensive *2017 event 1- Special Chemistry *2017 event 1- Basic Chemistry *2017 event 1- Hematology *2017 event 2- Chemistry, Comprehensive *2017 event 2- Special Chemistry *2017 event 2- Basic Chemistry *2017 event 2- Hematology *2017 event 3- Chemistry, Comprehensive *2017 event 3- Special Chemistry *2017 event 3- Basic

	Chemistry *2017 event 3- Hematology 2. The laboratory director and testing personnel did not sign the attestation statements for the following testing events: *2016 event 2- Chemistry, Comprehensive *2016 event 2- Special Chemistry *2016 event 2- Basic Chemistry
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 proficiency testing records and confirmed by laboratory personnel identifier #5 (refer to the Laboratory Personnel Report) at approximately 12:15 pm on 03/08/2018, the laboratory failed to verify the accuracy for reading biopsy slides and cytology slides twice annually for two out of two time periods in 2017. At the time of the survey, laboratory personnel identifier #5 confirmed that the laboratory did not verify the accuracy for reading biopsy slides and cytology slides in 2017.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of maintenance records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 11:20 am on 03/08/2018, the laboratory failed to perform and document monthly maintenance on the ACE Axcel Clinical Chemistry System for three out of 12 months (July, August, and September) in 2017. The findings include: 1. The ACE Axcel Clinical Chemistry System maintenance log listed the following as monthly maintenance items: * Rinse probe and fluid lines with 10% bleach * Clean bottle caps and cap connectors * Clean ISE sample port * Perform touch plate assembly cleaning procedure 2. At the time of the survey, the laboratory did not have documentation of monthly maintenance performed in July, August, and September of 2017.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or

	negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: Based on lack of statistical records and confirmed by laboratory personnel identifier #5 (refer to the Laboratory Personnel Report) at approximately 10:30 am on 03/08 /2018, the laboratory failed to document an annual statistical evaluation including: the number of cytology cases examined, the number of specimens processed by specimen type, and the number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation) for 2017.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) 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 records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 9:20 am on 03/08/2018, the laboratory director failed to ensure that prior to testing patient specimens, all testing personnel performing moderate complexity testing received the appropriate training for one out of one new testing personnel (laboratory personnel identifier #6). The findings include: 1. The laboratory hired personnel identifier #6 in September 2017. The testing personnel currently performs post vasectomy testing. 2. At the time of the survey, the laboratory did not have post vasectomy testing training records available for laboratory personnel identifier #6.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of personnel records, and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 9:20 am on 03/08/2018, the laboratory failed to assess and document the competency of individuals performing post vasectomy testing at least annually for three out of three testing personnel (identifiers #2, #3, and #4) as part of their competency assessments in 2016 and 2017. At the time of the survey, laboratory personnel identifier #2 confirmed that annual competency assessments did not include post vasectomy testing.