Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0234042	01/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Tennessee Urology Associates Pllc	800 Oak Ridge Turnpike, Suite A-101, Oak Ridge, TN	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, and an interview it was determined that the laboratory failed to establish written policies and procedures to assess the competency of one of one Laboratory Director/Technical Supervisors in 2016, 2017 and 2018 to the date of the survey. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the competency assessment of one of one Laboratory Director /Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessment for one of one Laboratory Director /Technical Supervisors in 2016, 2017 and 2018 to the date of the survey. 3. During an interview on January 16, 2018 at 11:35 AM the Laboratory Director/Technical Supervisor confirmed that there were no written policies and procedures for competency assessments of the Laboratory Director/Technical Supervisor.
D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.

	This STANDARD is not met as evidenced by: Based on review of final test reports and corresponding test requisitions and interview it was determined that the laboratory failed to ensure that the specimen source and patient gender was transcribed accurately into the Laboratory Information System (LIS) for five of thirty specimens sampled from January through October 2017 Findings include: 1. The Survey Team compared thirty final test reports with corresponding test requisitions. Cases reviewed included U17-00090, U17-00092 through U17-00100, U17-05141 through U17-05150 and U17-05081 through U17-05090. a. Four of the thirty final test reports had an incorrect specimen source transcribed into the LIS. Reports include: U17-00094 U17-00095 U17-00096 U17-05147 b. One of thirty final test reports had an incorrect patient gender transcribed into the LIS. Report includes: U17-05087 2. During an interview on January 18, 2018 at 10:00 AM, the Laboratory Director/Technical Supervisor confirmed these findings.
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 review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures for an annual statistical evaluation of three of three required statistics for nongynecologic cytology specimens in 2016 and 2017. Findings include: 1. The Survey Team requested and the laboratory failed to provide a written policy and procedure for an annual statistical laboratory evaluation of three required statistics for the nongynecologic specimens: a. The number of cytology cases examined; b. The number of specimens processed by specimen type; c. The number of patient cases reported by diagnosis, to include unsatisfactory. 2. The Survey Team requested and the laboratory failed to provide an annual statistical evaluation from 2016 and 2017 for the three required statistics. 3. During an interview on January 16, 2018 at 11:35 AM the Laboratory Director/Technical Supervisor confirmed that there were no written policies and procedures for documenting and evaluating annual statistics.
D5633	CYTOLOGY CFR(s): 493.1274(d)(1) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening.

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that a maximum workload limit was established by the Laboratory Director/Technical Supervisor. There was no workload limit established for one of one Laboratory Director/Technical Supervisors when performing primary evaluation of cytology specimen slide preparations in 2016, 2017 and 2018 to the date of the survey. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that a maximum workload limit was established by the Laboratory Director/Technical Supervisor for the Laboratory Director/Technical Supervisor. 2. The Survey Team requested and the laboratory failed to provide an established maximum workload limit for the Laboratory Director/Technical Supervisor for 2016, 2017 and 2018 to the date of the survey. 3. During an interview on January 16, 2018 at 11:35 AM the Laboratory Director/Technical Supervisor confirmed that there were no written policies and procedures for the establishment of maximum workload limits for the Laboratory Director/Technical Supervisor.
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 review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that one of one Laboratory Director/Technical Supervisor's workload limits were reassessed at least every six months and adjusted when necessary in 2016, 2017 and 2018 to the date of the survey. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies or procedures to ensure that a workload limit reassessment for the Laboratory Director/Technical Supervisor would occur every 6 months. 2. The Survey Team requested and the laboratory failed to provide records that the Laboratory Director/Technical Supervisor reassessed a maximum workload limit for the Laboratory Director/Technical Supervisor every six months in 2016, 2017 and 2018 to the date of the survey. 3. During an interview on January 16, 2018 at 11:35 AM the Laboratory Director/Technical Supervisor confirmed there were no policies or procedures to reassess workload limits.
D5641	CYTOLOGY CFR(s): 493.1274(d)(2)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined;

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to establish written policies and procedures to ensure that the workload limit for the Laboratory Director/Technical Supervisor, when examining slides in less than an 8-hour workday, would be prorated using a period of eight hours to determine the number of slides that may be examined in each day for 2016, 2017 and 2018 to the date of the survey. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure the workload limits would be prorated for the Laboratory Director/Technical Supervisor, when examining slides in less than an 8-hour workday or on activities other than primary examinations of cytology slides. 2. During an interview on January 16, 2018 at 11:35 AM the Laboratory Director/Technical Supervisor confirmed these findings.
D5645	CYTOLOGY CFR(s): 493.1274(d)(3) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview, it was determined that the laboratory failed to establish written policies and procedures to ensure that the laboratory would maintain records for the one of one Laboratory Director/Technical Supervisors of the total number of slides examined and the number of hours devoted to examining slides in 2016, 2017 and 2018 to the date of the survey. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure that the laboratory would maintain records of the total number of slides examined and the number of hours devoted to examining slides during each 24-hour period for the Laboratory Director/Technical Supervisor. 2. During an interview on January 16, 2018 at 11:35 AM the Laboratory Director /Technical Supervisor confirmed there were no records maintained of the time spent examining slides in each twenty-four hour period in 2016, 2017 and 2018 to the date of the survey.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: The Laboratory Director failed to fulfill the responsibility for the overall operation of the laboratory and failed to ensure compliance and oversight with applicable

	regulations (refer to D6079). The cumulative effect of these practices resulted in the Laboratory Director's inability to provide overall management and direction of cytology in accordance with 493.1445 of this subpart.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory including assuring compliance with applicable regulations by having cytology procedures and programs established and followed. Cross Refer to D5209, D5309, D5629, D5633, D5637, D5645 and D6115
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on the review of 255 negative non-gynecologic cases from 2017 and confirmation by the Laboratory Director/Technical Supervisor on January 17, 2018 it was determined that the Laboratory Director/Technical Supervisor failed to verify the accuracy of one non-gynecologic cytology test result. Case Includes: 1. U17-00091 January 10, 2017 Urine LABORATORY DIAGNOSIS: Negative for Malignancy SURVEY TEAM DIAGNOSIS: Urothelial Cell Carcinoma LABORATORY DIRECTOR/TECHNICAL SUPERVISOR DIAGNOSIS: Atypical Urothelial Cells Suspicious for High Grade Neoplasia
D6130	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3) (c) In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary.

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, and interview it was determined that the Technical Supervisor failed to establish an individual workload limit in 2016, 2017 and 2018 to the date of the survey for the Laboratory Director/Technical Supervisor. The Technical Supervisor also failed to reassess the workload limits at least every six months and make adjustments when necessary in 2016, 2017 and 2018 to the date of the survey for the Laboratory Director /Technical Supervisor. Cross Refer to D5633 and D5637
D6133	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(6) In cytology, the technical supervisor or the individual qualified under 439.1449(k)(2), if responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides. This STANDARD is not met as evidenced by: Based on interview and lack of laboratory records it was determined that one of one Technical Supervisors failed to document the number of slides screened and the number of hours devoted to screening slides during each 24-hour period for any date in 2016, 2017 or 2018 to the date of the survey. Cross refer to D5645
D9999	By agreement between ASCT Services, Inc. and CMS, information provided for CMS's completion of CMS Form 670 are ASCT Services, Inc. averages only. This information is confidential and proprietary to ASCT Services, Inc., is exempt under the Freedom of Information Act (5 U.S.C. 552 et seq.), and shall be used for federal government purposes only.