Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 44D0234042	**(X3) Date Survey Completed** 03/22/2023
Name of Provider or Supplier Tennessee Urology Associates Pllc	**Street Address, City, State** 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, lack of competency assessment records and interview with the Laboratory Director/Technical Supervisor, the laboratory failed to establish written policies and procedures to assess the competency of the Laboratory Director/Technical Supervisor. The laboratory failed to assess the competency of one of one Laboratory Director/Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the process to assess the competency of the Laboratory Director/Technical Supervisor. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessment for one of one Laboratory Director /Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Laboratory Director/Technical Supervisor includes: -Laboratory Director/Technical Supervisor 3. During an interview on March 22, 2023 at 8:32 AM, the Laboratory Director /Technical Supervisor confirmed these findings.
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: Based on review of ten laboratory policies and procedures and interview with the Laboratory Director/Technical Supervisor, the laboratory failed to establish written policies and procedures for two laboratory test processes. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's step-by-step process for reporting final nongynecologic test results. 2. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail the process of filing, storing and disposal of nongynecologic cytology specimen slides. a. During an interview on March 21, 2023 at 7:25 AM, the Survey Team asked Staff A how long the nongynecologic cytology specimen slides were kept onsite. Staff A stated, "the slides are kept for ten years then disposed of". 3. During an interview on March 22, 2023 at 8:32 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, statistical records and interview with the Laboratory Director/Technical Supervisor, the laboratory failed to establish written policies and procedures for the evaluation and comparison of three of three nongynecologic cytology statistics. The laboratory failed to document one of three required annual nongynecologic statistics for 2021 and 2022. Findings include:

	1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the evaluation and comparison of three of three nongynecologic cytology statistics. Statistics include: -Number of nongynecologic cytology cases examined -Number of nongynecologic specimens processed by specimen type -Number of nongynecologic cases reported by diagnosis, including the number reported as unsatisfactory 2. The Survey Team requested and the laboratory failed to provide records for one of three required annual statistics for 2021 and 2022. Statistics include: -Number of nongynecologic cases reported by diagnosis, including the number reported as unsatisfactory a. During an interview on March 21, 2023 at 8:30 AM, the Laboratory Manager stated, "we have no statistics by diagnostic category". 3. During an interview on March 22, 2023 at 8:32 AM, the Laboratory Director /Technical Supervisor confirmed these findings.
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, lack of workload limit records and interview with the Laboratory Director/Technical Supervisor, the laboratory failed to follow written policies and procedures to ensure maximum workload limits were established for the Laboratory Director/Technical Supervisor who performed primary screening of nongynecologic cytology specimen slides in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The laboratory failed to follow the policy titled CYTOLOGY QUALITY/WORKLOAD LIMIT which stated: "The Laboratory Director (LD)/Technical Supervisor (TS) shall establish workload limit." 2. The Survey Team requested and the laboratory failed to provide individual maximum workload limits for one of one Laboratory Director/Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Laboratory Director/Technical Supervisor includes: -Laboratory Director/Technical Supervisor 3. During an interview on March 22, 2023 at 8:32 AM, the Laboratory Director/Technical Supervisor confirmed these findings.
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 with the Laboratory Director/Technical Supervisor, the laboratory failed to establish written policies and procedures to reassess and adjust, when necessary, a maximum workload limit at least every six months for the Laboratory Director/Technical Supervisor. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the Laboratory Director/Technical Supervisor's workload limits would be reassessed at least every six months and

	adjusted when necessary. 2. During an interview on March 22, 2023 at 8:32 AM, the Laboratory Director/Technical Supervisor confirmed these findings.
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, lack of workload limit records and interview with the Laboratory Director/Technical Supervisor, the laboratory failed to establish written policies and procedures to ensure that the workload limit for the Laboratory Director/Technical Supervisor would be prorated when examining slides in less than an eight-hour work day. The laboratory failed to provide documentation of a prorated workload limit for one of one Laboratory Director/Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prorate the workload limit for the Laboratory Director/Technical Supervisor when examining slides in less than an eight-hour day. 2. The Survey Team requested and the laboratory failed to provide records of a prorated workload limit for one of one Laboratory Director/Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Laboratory Director/Technical Supervisor includes: -Laboratory Director /Technical Supervisor 3. During an interview on March 22, 2023 at 8:32 AM, the Laboratory Director/Technical Supervisor confirmed these findings.
D5647	CYTOLOGY CFR(s): 493.1274(d)(4) (d) Workload limits.The laboratory must establish and follow written policies and procedures that ensure the following: (d)(4) Records are available to document the workload limit for each individual. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of workload limit records and interview with the Laboratory Director/Technical Supervisor, the laboratory failed to establish written policies and procedures to ensure records were available to document the workload limit for one of one Laboratory Director/Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. The laboratory failed to provide records of individual workload limits for one of one Laboratory Director/Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure records were available to document the workload limit for the Laboratory Director/Technical Supervisor who performed primary screening of nongynecologic cytology specimen slides. 2. The Survey Team requested and the laboratory failed to provide records of individual workload limits for one of one

	Laboratory Director/Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Laboratory Director/Technical Supervisor includes: -Laboratory Director /Technical Supervisor 3. During an interview on March 22, 2023 at 8:32 AM, the Laboratory Director/Technical Supervisor confirmed these findings.
D5655	CYTOLOGY CFR(s): 493.1274(e)(4) (e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview with the Laboratory Director/Technical Supervisor, the laboratory failed to establish written policies and procedures to ensure unsatisfactory nongynecologic cytology specimen slides were identified and reported as unsatisfactory. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure unsatisfactory nongynecologic cytology specimen slides were identified and reported as unsatisfactory. 2. During an interview on March 22, 2023 at 8:32 AM, the Laboratory Director/Technical Supervisor confirmed these findings.
D5657	CYTOLOGY CFR(s): 493.1274(e)(5) (e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(5) The report contains narrative descriptive nomenclature for all results. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interview with the Laboratory Director/Technical Supervisor, the laboratory failed to establish written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to define the criteria used and the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results. 2. During an interview on March 22, 2023 at 8:32 AM, the Laboratory Director /Technical Supervisor confirmed these findings.
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 written policies and procedures, lack of workload limit records

	and interview with the Laboratory Director/Technical Supervisor, the Technical Supervisor failed to establish individual workload limits and to reassess the workload limits at least every six months for one of one Laboratory Director/Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. Cross refer to D5633 and D5637 Findings include: 1. The Survey Team requested and the Laboratory Director/Technical Supervisor failed to provide documentation that the Technical Supervisor established a maximum workload limit for one of one Laboratory Director /Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. (Refer to D5633) Laboratory Director/Technical Supervisor includes: -Laboratory Director /Technical Supervisor 2. The Survey Team requested and Laboratory Director /Technical Supervisor failed to provide records of a workload reassessment at least every six months for one of one Laboratory Director/Technical Supervisor in 2021, 2022 and to the date of the survey in 2023. (Refer to D5637) Laboratory Director /Technical Supervisor includes: -Laboratory Director/Technical Supervisor 3. During an interview on March 22, 2023 at 8:32 AM, the Laboratory Director/Technical Supervisor confirmed these findings.
D9999	