Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0234042	08/14/2024
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
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 with the Laboratory Director/Technical Supervisor the laboratory failed to follow written policies and procedures for an annual statistical evaluation of three of three required nongynecologic laboratory statistics for January through June 2024. Findings include: 1. The laboratory failed to follow the procedure CYTOLOGY LABORATORY STATISTICS, which stated: "PRICIPLE CFR 493.1274 require laboratories performing cytological examination to provide written policies and procedures for the evaluation and comparison of three of three nongynecologic cytology statistics." "POLICY The laboratory manager of Tennessee Urology Associates (TUA) laboratory is required to gather the following statistics monthly with sign off review by the laboratory director. - Total 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 nondiagnostic." 2. The laboratory provided statistics for three of three required annual nongynecologic laboratory statistics for January through June 2024. The laboratory also provided the number of cytology cases documented as reviewed by the Laboratory Director/Technical Supervisor for January through June 2024. The Survey Team compared the statistics with the number of cases documented as reviewed by the Laboratory Director/Technical Supervisor and identified inconsistencies in the numbers. a. The statistics provided for the total number of monthly cytology cases examined did not correspond to the number of cases documented as reviewed to include: -January 2024 statistic = 21 versus number reviewed 160 -February 2024 statistic = 31 versus number reviewed 214 -March 2024 statistic = 27 versus number reviewed 215 -April 2024 statistic = 48 versus number reviewed 230 -May 2024 statistic = 46 versus number reviewed 175 -June 2024 statistic = 37 versus number reviewed 216 b. The statistics provided for the number of specimens processed by specimen type did not correspond to the number of cases documented as reviewed to include: -January 2024 statistic = 21 versus number reviewed 160 -February 2024 statistic = 31 versus number reviewed 214 -March 2024 statistic = 27 versus number reviewed 215 -April 2024 statistic = 48 versus number reviewed 230 -May 2024 statistic = 46 versus number reviewed 175 -June 2024 statistic = 37 versus number reviewed 216 c. The statistics provided for the number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation) did not correspond with the actual number of cytology cases documented as reviewed to include: -January 2024 -No diagnostic categories documented -The number of cases documented as reviewed;160 -February 2024 - -Negative for Malignancy; 22 -Nondiagnostic; 3 -Atypical Urothelial cells suspicious for urothelial neoplasm; 3 -Negative limited; 1 -Atypical Urothelial cells, inconclusive; 1 -Atypical; 1 -The number of cases documented as reviewed; 214 -March 2024- -Negative for Malignancy; 10 -Nondiagnostic; 5 -Atypical Urothelial cells suspicious for urothelial neoplasm; 5 -Negative limited; 5 -Atypical Urothelial cells, inconclusive; 1 -Atypical urothelial cells suspicious for high grade malignancy; 1 -The number of cases documented as reviewe; 215 -April 2024- -Negative for Malignancy; 25 -Nondiagnostic; 7 -Atypical Urothelial cells suspicious for urothelial neoplasm; 5 -Negative limited; 7 -Atypical Urothelial cells, inconclusive; 1 -Atypical urothelial cells suspicious for low grade urothelial malignancy; 2 -Negative for high grade malignancy; 1 -Atypical urothelial cells, inconclusive; 1 -The number of cases documented as reviewed; 230 -May 2024- -Negative for Malignancy; 34 -Nondiagnostic; 4 -Atypical Urothelial cells suspicious for urothelial neoplasm; 6 -Negative limited; 4 -The number of cases documented as reviewed; 175 -June 2024- -Negative for Malignancy; 26 -Nondiagnostic; 4 -Atypical Urothelial cells suspicious for urothelial neoplasm; 4 -Negative limited; 3 -The number of cases documented as reviewed; 216 3. During an interview on August 14, 2024 at 9:15 AM the laboratory's inaccurate statistics were confirmed with 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, lack of workload limit reassessment records and interview with the Laboratory Director/Technical Supervisor the laboratory failed to establish and follow 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. The laboratory failed to provide records of a workload limit reasessment for the Laboratory Director /Technical Supervisor in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. 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 would reassess a maximum workload limit for the Laboratory Director/Technical Supervisor at least every six months and adjust when necessary. The laboratory failed to provide written policies and procedures to detail what performance criteria would be reviewed as part of a workload reassessment. 2. The Survey Team requested and the laboratory failed to provide documentation the Laboratory Director/Technical Supervisor reassessed a maximum workload limit for the Laboratory Director/Technical Supervisor in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. 3. During an interview on August 13, 2024 at 11:35 AM these findings were confirmed with the Laboratory Director/Technical Supervisor.
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 reassessment records and interview with the Laboratory Director/Technical Supervisor, the Technical Supervisor failed to reassess the workload limits at least every six months for one of one Laboratory Director/Technical Supervisor in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and Technical Supervisor failed to provide records of a workload reassessment at least every six months for one of one Laboratory Director /Technical Supervisor in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. (Refer to D5637) 2. During an interview on August 13, 2024 at 11:35 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.
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