Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0398942	(X3) Date Survey Completed 10/12/2023
Name of Provider or Supplier Minnesota Urology, Pa	**Street Address, City, State** 6025 Lake Road, Suite 200, Woodbury, MN	

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, statistical records and interviews with the Laboratory Director/Technical Supervisor A and the Laboratory Manager, the laboratory failed to follow written policies and procedures for the evaluation and comparison of one of three nongynecologic cytology statistics. The laboratory failed to document one of three required annual nongynecologic statistics in 2021 and 2022. Findings include: 1. The laboratory failed to follow the policy CYTOLOGY/HISTOLOGY QUALITY ASSURANCE: QUARTERLY REPORT which stated: "Quarterly report will contain the following metrics: Cytology Statistics; Total number of cytology cases, and a percentage of each diagnostic category (Negative for High-Grade Urothelial Carcinoma (NHGUC) , Atypical Urothelial Cells (AUC), Suspicious for High-Grade Urothelial Carcinoma (SHGUC), High-Grade Urothelial Carcinoma (HGUC), Low-Grade Urothelial Neoplasia (LGUN), Other Primary and Metastatic Malignancy and Unsatisfactory." a. During an interview on

	October 11, 2023 at 3:00 PM with the Laboratory Director/Technical Supervisor A and the Laboratory Manager it was stated that the QUARTERLY REPORT STATISTICS for the second and third quarters of 2023 were for Facility A and Facility B combined. b. The laboratory was not following the policy to compile statistics for cytology cases that were examined only at this facility (Facility A). 2. The Survey Team requested and the laboratory failed to provide records of one of three required annual nongynecologic statistics in 2021 and 2022. Statistics include: - Number of nongynecologic cases reported by diagnosis, including the number reported as unsatisfactory. a. The laboratory provided 2021 ANNUAL LAB STATISTICS AND 2022 ANNUAL LAB STATISTICS, which did not include the number of cases reported as unsatisfactory. 3. During an interview on October 11, 2023 at 3:00 PM the Laboratory Director/Technical Supervisor A confirmed these findings.
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