

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0678657	(X3) Date Survey Completed 01/11/2023
Name of Provider or Supplier Tpmg Laboratory Stockton	Street Address, City, State 7373 West Lane, 1st Flr, Stockton, CA	
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	<p>CYTOLOGY CFR(s): 493.1274(c)(5)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, statistical records and interviews the laboratory failed to establish written policies and procedures for an annual statistical evaluation of three of three required nongynecologic cytology statistics. The laboratory failed to document three of three required nongynecologic annual statistics for 2020, 2021 and 2022. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of three of three required nongynecologic cytology statistics. Statistics include: -The number of cytology cases examined -The number of specimens processed by specimen type -The number of patient cases reported by diagnosis, including the number reported as unsatisfactory 2. The Survey Team requested and the laboratory failed to provide the three required nongynecologic annual statistics for 2020, 2021 and 2022. Statistics include: -The number of cases examined -The number of specimens processed by specimen type -The number of</p>

patient cases reported by diagnosis, including the number reported as unsatisfactory. a. The Survey Team reviewed records ANNUAL CYTOLOGY STATISTICS YEAR: 2021 and CAP NG AND FNA SRC AND DX period selected - Month 202112 MDs: All CVL. The statistics on the records were combined statistics for multiple laboratories and were not specific to the laboratory being surveyed. 3. During an interview on January 10, 2023 at 2:30 PM, the Laboratory Manager and the Chief of Pathology/Technical Supervisor confirmed that the nongynecologic statistics were for multiple laboratories and were not specific to the laboratory being surveyed. 4. During a telephone interview on January 11, 2023 at 11:30 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor.

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