

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1048982	(X3) Date Survey Completed 06/25/2024
Name of Provider or Supplier Affiliated Pathologists	Street Address, City, State 1010 Murray Ave, San Luis Obispo, 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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of five (5) randomly chosen patient sampling covering a period from 5/25/2022 to 6/7/2024, review of proficiency testing documents, biopsy notes, final reports, quality assurance, turn-around- time, and interview with the laboratory's director and testing personnel (TP); it was determined that the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory testing systems. The findings included: 1. On the day of the survey 6/25 /2024 at approximately 3:15 p.m. no documentation could be retrieved to show that the laboratory had written policies and procedures for turn-around time, microscope preventive maintenance, retention of documents, safety, and quality assessment and assurance. 2. The correction process involves written policies specific for Affiliated Pathology for turn-around time, microscope preventive maintenance, retention of documents, safety, quality assessment and assurance, and policies for preventing problems that have been identified. 3. The LD on 6/25/2024 at approximately 3:30 p. m. that the laboratory did not have written policies and procedures that reflect the current practice for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. Policies stated in 2 above. 4. The testing declaration submitted on 6/25/2024 signed and dated by the LD estimated 9,436 tests performed annually.</p>
D5401	PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on the lack of laboratory written policies for histopathology, cytology, sample rejection, etc., and interviews with the laboratory director (LD); it was determined that the laboratory failed to have available and follow written procedures for all test performed in the laboratory. The findings included: 1. On the day of the survey on June 25, 2024, at approximately 3:00 p.m. the laboratory failed to provide written policies and procedures specific for Affiliated Pathologists of the Central Coast approved and signed by the LD for all the test performed in the laboratory. 2. For five (5) out of five (5) random patient test results reviewed for histopathology and non-GYN cytology test ordered, processed, analyzed, and reported for which the laboratory had no written policies and procedures available. 3. The LD confirmed on 06/25/2024 at approximately 3:30 p.m. that the laboratory did not have written policies and procedures available for histopathology and non-Gyn tests performed in the laboratory.

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 (LD); it was determined that the laboratory failed to establish written policies and procedures for an annual statistical evaluation of three of three required cytology statistics. The laboratory failed to document one (1) of three (3) required annual statistics for 2022, and 2023. Findings include: 1. The surveyor requested, and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of three (3) of three (3) required 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

surveyor requested, and the laboratory failed to provide the number of specimens processed by specimen type annual statistic for the years 2022 and 2023. 3. The LD confirmed by interview that findings stated in 1 and 2 are correct.

D6106

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:
Based on review of records and interview with the laboratory director on the day of the survey (June 25, 2024), the laboratory director failed to ensure that approved, signed, and dated, procedure manuals and policies reflecting the current practice at Affiliated Laboratory are available to all personnel responsible for any aspect of the testing process. Findings include: D5291, D5401 and 5629.