Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2006397	06/06/2024
Name of Provider or Supplier	**Street Address, City, State**	
Affiliated Pathologists	20001 S Rancho Way, Rancho Dominguez, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing performance, eight (8) randomly selected patients, and interviews with the laboratory manager (LM) and testing personnel (TP) on 06/06/2024 at approximately 12:00 pm; the laboratory failed to verify the accuracy of histopathology testing at least twice annually. The findings include: 1. The laboratory performed histopathology including Mohs surgery. The laboratory failed to perform evaluation of proficiency testing performance for histopathology for six (6) out of nine (9) testing personnel for the years 2022 and 2023. Therefore, the accuracy of the laboratory's test results cannot be assured. 2. On 06/06/2024 at 12:00 pm, the LM and TP the statement in # 1 above. 3. The laboratory's testing declaration form, signed by the laboratory director on 03/20/24 stated that the laboratory performed 120,921 tests in histopathology annually.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) 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. This STANDARD is not met as evidenced by: Based on the surveyors' review of quality assessment policy and procedure and

	interviews with the laboratory manager (LM) and testing personnel (TP) on 06/06 /2024 at approximately 1:00 pm; the laboratory failed to follow the written policy and procedure to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems for the quality assessment plan. The findings include: 1. The laboratory had an existing protocol for policy for the quality assessment (QA). The laboratory QA (referred by the laboratory as quality improvement) stated that "the laboratory team shall meet to review the prior year as quality improvement program and to structure the program for the following year". The laboratory failed to have any documentation for the annual meeting. Therefore, laboratory cannot ensure the continues improvement. 2. On the day of the survey 06/06/2024 at approximately 1:00 pm, the LM and TP confirmed that the laboratory did not have any documentation for the annual meeting. 3. The laboratory's testing declaration form, signed by the laboratory director on 03/20/24 stated that the laboratory performed 120,921 tests in histopathology and cytology annually.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on the surveyors' review of the preanalytical policy and procedures and interview with the laboratory manager (LM) and testing personnel (TP) on 06/06/2024 at approximately 3:00 pm, the laboratory failed to establish and follow a written policy and procedure for specimen acceptability and rejection criteria. The findings include: 1. The laboratory did not have a written policy for specimen acceptability and rejection. Therefore, laboratory cannot ensure the reliability of the specimens' tests results. 2. On 06/06/2024 at 3:00 pm, the LM and TP confirmed that laboratory did not have a written policy and documentation for rejected specimens. 3. The laboratory's testing declaration form, signed by the laboratory director on 03/20/24 stated that the laboratory performed 120,921 tests in histopathology and cytology annually.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on the surveyor's review of the procedure manuals for analytic systems and interviews with the laboratory manager (LM) on 06/06/2024 at approximately 4:00 pm, the laboratory failed to update all procedure manuals with approval, signature, and date from the current laboratory director (LD) for histopathology and cytology. The findings include: 1. The LD did not sign and date all procedure manuals. Therefore, laboratory cannot verify the procedure manuals are current for tests offered

	by the laboratory. 2. On 06/06/2024 at approximately 4:00 pm, the LM confirmed that the laboratory did not have an updated procedure manual approved by the LD for all current tests offered by the laboratory. 3. The laboratory's testing declaration form, signed by the laboratory director on 03/20/24 stated that the laboratory performed 120,921 tests in histopathology and cytology annually.
D5625	CYTOLOGY CFR(s): 493.1274(c)(3) (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)(3) For each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm, laboratory review of all normal or negative gynecologic specimens received within the previous 5 years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that will affect current patient care, the laboratory must notify the patient's physician and issue an amended report. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interviews with the cytotechnologist (CT), the laboratory failed to establish written policies and procedures to ensure that the search and review of prior negative gynecologic specimens received within the previous five (5) years for each patient with a current HSIL or malignancy was performed. Findings include: 1. On the time of the survey (06/06/2024) the laboratory failed to provide written policies and procedures to describe the laboratory's process for the search and review of all prior negative gynecologic specimens received within the previous five years, for each patient with a current HSIL or malignancy reported by the laboratory. 2. During an interview with the CT on June 6, 20224 at approximately 3:00 p.m., these findings stated in # 1 above were confirmed. 3. 3. The laboratory's testing declaration form, signed by the laboratory director on 03/20/24 stated that the laboratory performed 18,912 tests in cytology annually.
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, lack of statistical records and

	interview with the cytology technologist (CT); the laboratory failed to establish written policies and procedures for the evaluation and comparison statistics. The laboratory failed to document the required annual gynecologic statistics for for the years 2022, 2023, and 2024. Findings include: 1. The surveyors' requested the of statistics report and the laboratory failed to provide written policies and procedures for the evaluation and comparison of required cytology gynecologic statistics which include: a) Cytology cases examined. b) Specimens processed by specimen type. c) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation). d) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison. e) Gynecologic cases where cytology and histology are discrepant; and f) Gynecologic cases where any rescreen of a normal or negative specimen result in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. 3. During an interview with the CT on June 6, 2024, at approximately 3:30 p.m. findings the stated in # 1 above were confirmed. 4. The laboratory's testing declaration form, signed by the laboratory director on 03/20/24 stated that the laboratory performed 18,912 tests in cytology annually.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on the surveyors' review of policies and procedures, eighteen (18) randomly chosen patients' test results (clinical bacteriology, histopathology and cytology), and interviews with the laboratory manager and and testing personnel on June 6, 2024; it was determined that the laboratory director is cited herein due to failure to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of the laboratory testing were monitored. See D 5217, D5291, D5311, D5625, and D5629.
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: The laboratory director is cited herein on the lack of laboratory's written policies approved, dated, and signed by the current laboratory director. Based on the surveyor's review of laboratory records and interview with the laboratory manager it was determined that the laboratory director failed to ensure that an approved, signed, and dated policy manual (policies on all the phases of laboratory testing including: specimen rejection criteria, documents retention policy, panic values, labelling of reagents, proficiency testing policy, validation and verification policy, etc.) was updated when the previous director of operations is no longer a staff member. See D5407.