

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0884685	(X3) Date Survey Completed 02/20/2024
Name of Provider or Supplier Southern Calif Permanente Medical Group	Street Address, City, State 9449 E Imperial Hwy Ste 310, Downey, 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
D3043	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7)</p> <p>The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of retention policies and procedures for Mohs slides, test procedures, analytical systems record, quality assessment records, and test reports, review of eight (8) randomly chosen Mohs patients test records, and interview with the administration representative (AR) and laboratory director (LD); the laboratory failed to have a retention policy for Mohs documents. The findings included: 1. On the day of survey, February 20, 2024, at approximately 11:30 a.m. no policy for retention of documents and records were found for Mohs including test procedure, analytical systems record, quality assessment records, and test reports at the time of survey. 2. The AR and LD confirmed by interview on February 20, 2024, at approximately 11:30 a.m. that the laboratory did not have a retention policy for Mohs. 3. The laboratory reports signed and dated by the LD performed and reported approximately 1,049 for Mohs procedures annually.</p>
D5821	<p>TEST REPORT CFR(s): 493.1291(k)</p> <p>When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue</p>

corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.

This STANDARD is not met as evidenced by:

Based on the surveyors' review of eight (8) Mohs patient records, interviews with the administration representative (AR) and laboratory director (LD), the laboratory failed to maintain their slides for all the Mohs phases reported. The findings included: 1. The surveyors reviewed eight (8) Mohs patient records. One (1) out of eight (8) records was discrepant in the number of slides recorded in the report and the number of slides presented at the time of survey. 2. On the laboratory's lab record log, it showed a total of four (4) slides that were prepared. However, at the time of the survey, only three (3) out of four (4) slides were located. Phase IIA was missing. 3. During an interview with the survey team, the AR and LD affirmed that the discrepancy in number 1 above was possibly due to a misplacement during storing. Further investigation is needed to be performed. Also, no corrective action was available at the time of the survey. 4. The laboratory reported approximately 1,049 Mohs cases performed 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 surveyor's review of the laboratory's records, policies and procedures, patients' test results records, quality assessment documentation, and interviews with the laboratory's administration representative (AR) and laboratory director (LD) on February 20, 2024; it was determined that the laboratory director failed to ensure that several aspects of the preanalytic and analytic phases of the laboratory testing were monitored. See D3043, D5821.