

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0895787	(X3) Date Survey Completed 11/04/2025
Name of Provider or Supplier Uc Davis Dermatology, Mohs Laboratory	Street Address, City, State 3301 C St, Ste 1356, Sacramento, 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
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of patient testing records, log sheet, final reports, and an interview with the supervisor on November 4, 2025; it was determined that the laboratory failed to follow established policies and procedures to ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. The findings include: 1. The surveyor reviewed ten patient records for Histopathology and found the following discrepancies: a. Patient E24-8, examined on 1/2/2024 had a mismatch on the last name in the Mohs log sheet, differing from the electronic chart, slides, and Mohs map documentation. b. Patient J25-781, examined on 7/25/2025, was recorded in the Mohs log as stage III, while the electronic chart, slides, and Mohs map documented it as stage II. 2. No corrective action or amendment report was available at the time of survey. 3. The supervisor affirmed by an interview on November 4, 2025, at approximately 11:25 a.m. that records were discrepant for the two out of ten patients as mentioned in statement #1. 4. The laboratory's testing volume declaration submitted at the time of survey stated that 1,343 Histopathology tests were performed and reported annually including the time when the discrepancies occurred. .</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p>

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 the surveyor's review of the laboratory's policy and procedure, randomly chosen patient records, lack of proficiency testing records, and an interview with the supervisor, it was determined that the laboratory failed to verify the accuracy of any test or procedure performed at least twice annually for the year 2025 for the testing personnel 2 (TP2). The findings include: 1. The laboratory's policy specified that four cases per surgeon would be selected for proficiency testing each year. However, the records indicated that this policy was not followed, as TP2 did not have Histopathology proficiency testing records for the year 2025. 2. The surveyor reviewed five patient records for Histopathology for each surgeon. Two records for 2025 were potentially affected by the lack of proficiency testing records for TP2. 3. The supervisor affirmed by an interview on November 4, 2025, at approximately 9:50 a.m., that the laboratory lacked proficiency testing records for the TP2 in 2025 as mentioned in the statements above. 4. The laboratory's testing declaration form submitted at the time of the survey stated that 1,343 Histopathology patient test samples were performed annually including the time when proficiency testing records were missed for the year 2025 for TP2. Thus, the reliability and accuracy of patient tests reported cannot be assured. .

D6082

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(1)

(e) The laboratory director must-- (e)(1) 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 lack of corrective action reports for the errors found during patient review and an interview with the supervisor on November 4, 2025, the laboratory director is herein cited for failure to provide quality laboratory services for all aspects of testing especially in the analytic and postanalytic phases of testing. See D5203. .

D6089

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part;

This STANDARD is not met as evidenced by:

Based on surveyor's review of patient test reports, lack of peer review records, and an interview with the supervisor on November 4, 2025; it was determined that the laboratory director failed to ensure that the proficiency testing was performed for the year 2025 as required under subpart H of this part. The findings include: 1. The laboratory lacked proficiency testing records for one out of two testing personnel for the year 2025. See D5217.