

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0875883	(X3) Date Survey Completed 09/09/2025
Name of Provider or Supplier Skin Cancer And Dermatologic Surgery	Street Address, City, State 421 N Rodeo Dr, Ste T-7 2nd Fl, Beverly Hills, 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 office manager (OM) on September 9, 2025; it was determined that the laboratory failed to follow established 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. The findings include: 1. Review of patient log for potassium hydroxide (KOH) and scabies revealed the following discrepancies as follows: a. Patient #1335729 and Patient #1545165 were not documented in the final report for the test performed, including the interpretation of the results. b. Patient #1536125 was recorded in the patient log as examined at the abdomen, while the final report indicated preumbilical skin. 2. The OM affirmed by interview on September 9, 2025, at approximately 3:40 p. m. that records were discrepant for the three out of five patients as mentioned in statement #1. 3. No corrective action was performed not documented. 4. The laboratory's testing volume declaration submitted at the time of survey stated that 200 KOH and 100 scabies tests were performed and reported annually including the time when the discrepancies occurred.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish</p>

and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of five Mohs patient records, lack of personnel competency documentation, and an interview with the office manager (OM); as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to perform competency assessment for all personnel involved in patient testing. The findings include: 1. The laboratory utilized three HTs to assist with Mohs Micrographic Skin Cancer Surgeries for processing and staining. One out of the three HT failed to have any record for 2025 which was due last April. 2. The laboratory lacked competency records for all testing personnel involved in potassium hydroxide (KOH) and scabies testing for the years 2023, 2024, and 2025. 3. The quality and reliability of patient samples processed and reported could not be assured. 4. According to the testing declaration form submitted at the time of the survey, the laboratory reported and performed approximately 200 KOH, 100 scabies, 2,500 Histopathology patient samples annually including the time when competency assessment for all testing personnel were missed.

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 the surveyor's review of the laboratory's policy and procedure, patient record documentation, lack of proficiency testing (PT) documentation and an interview with the office manager (OM); it was determined that the laboratory failed to verify the accuracy of any test or procedure performed at least twice annually for the years 2023, 2024, and 2025. The findings include: 1. The laboratory was missing a protocol to conduct proficiency testing for all provider performed microscopy (PPM) tests that included potassium hydroxide (KOH) and scabies test at least twice annually. 2. The laboratory lacked proficiency testing for all providers performing PPM tests for the years 2023, 2024, and 2025. 3. The OM affirmed by an interview on September 9, 2025, at approximately 2:40 p.m., that the laboratory missed to perform proficiency testing for all providers as mentioned in the statements above. 4. The laboratory's testing declaration form submitted at the time of the survey stated that 200 tests for KOH and 100 scabies test samples annually including the time when proficiency testing were not performed for the years 2023, 2024, and 2025. Thus, the reliability and accuracy of patient tests reported cannot be assured.

D5435

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(2)

(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
 Based on the surveyor's review of the laboratory's policy/procedure, preventive maintenance (PM) documentation, patient records and an interview with the office manager (OM); it was determined that the laboratory failed to follow an established policy and procedure in place for the PM as defined by the manufacturer, with at least the frequency recommended for the laboratory's equipment prior to patient testing. The findings include: 1. The laboratory failed to provide PM documentation for the year 2023 for the microscope used at the facility according to manufacturer's requirements, to be performed annually. 2. The surveyor reviewed five Mohs patient records from October 3, 2023 to August 12, 2025. One out of five (1118756) was missing records for the cryostat PM, cryostat temperature, and stain PM. Three patients, including 1118756, were seen on October 3, 2023, and were affected. 3. No corrective action reports were available for review at the time of the survey. 4. The OM affirmed by an interview on September 9, 2025, at approximately 3:40 p.m., that the laboratory was missing 2023 PM records, which influenced the findings mentioned in statements #1 and #2. 5. According to the testing volume declaration submitted at the time of survey, the laboratory performed and reported approximately 2,500 tests annually for Histopathology including the time when 2023 records were missing.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
 Based on the surveyor's review of the laboratory's policy and procedure, personnel reports (CMS-209 and LAB-116), lack of personnel competency documents, and an interview with the office manager; the laboratory director is herein cited for failure to perform and document competency evaluation for all personnel involved in patient testing. See D5209.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the laboratory policy/procedure, patient test records, lack of personnel competency and preventive maintenance records, and an interview with the office manager; it was determined that the laboratory director is cited for failure to provide oversight and management of the laboratory. The findings include: 1. Specimen Identification and Integrity. See D5203 2. Lack of proficiency testing. See D5217

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 surveyor's review of the laboratory's policies and procedures, patient test records, proficiency testing (PT) documentation, and an interview with the laboratory manager; it was determined that the laboratory director is herein cited for failure to provide oversight and management of the laboratory. The findings include: 1. Lack of preventive maintenance records. See D5435