

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0684217	<b>(X3) Date Survey Completed</b> 12/09/2024
<b>Name of Provider or Supplier</b> Kay Dermatology, Inc	<b>Street Address, City, State</b> 201 S Buena Vista St, Ste 420, Burbank, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3043</b>	<p><b>RETENTION REQUIREMENTS</b> 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 policies and procedures, review of randomly chosen patient test records, and interview with the surgical technician (ST), it was determined that the laboratory failed to provide an approved and signed policy and procedure for retention and storage requirements. Findings include: 1. In reference to the retention requirements in 42 CFR Part 493.1105a, the laboratory is herein cited for the deficient practice of lacking an approved and signed retention and storage requirements policy and procedure. 2. The ST stated during an interview at 11:45 a.m. on December 9, 2024, that the laboratory does not have an official policy and procedure for record retention and storage but kept records for a minimum of seven years. 3. Based on the laboratory's testing declaration submitted at the time of the survey, the laboratory performed 300 Mohs patient samples during the time that no retention and storage policy and procedure was implemented.</p>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <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.</p>

This STANDARD is not met as evidenced by:  
Based on the surveyor's review of the laboratory's policies and procedures, peer review records, five (5) randomly selected patient records, and an interview with the surgical technician (ST); it was determined that the laboratory failed to verify the accuracy of dermatopathology testing at least twice annually for the years 2022, 2023, and 2024. The findings include: 1. Based on the surveyor's review of the laboratory's policies and procedures and 5 randomly selected patient records, no peer review records could be retrieved for the years 2022, 2023, and 2024. Therefore, the accuracy of patient results could not be assured. 2. The ST affirmed by interview on December 9, 2024, at approximately 12:05 p.m., that the laboratory missed performing peer review as mentioned in statement #1. 3. Based on the laboratory's testing declaration form submitted at the time of the survey, the laboratory performed 300 tests in dermatopathology annually during the time that no peer review was performed.

**D5435**

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

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (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. (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 a review of the laboratory's policies and procedures, equipment function check documentation, five (5) randomly selected Mohs patient test records, and an interview with the surgical technician (ST), it was determined that the laboratory failed to ensure function checks performed were monitored and documented properly prior to patient testing. The findings include: 1. Based on the review of equipment function check documentation on December 9, 2024, at approximately 12:30 p.m., the cryostat temperature was out of range on 3/18/2024 prior to patient testing. The acceptable temperature range was between -18C and -30C, and the temperature recorded for the day of the procedure performed was -16C. 2. Based on the review of 5 randomly selected Mohs patient test records, one out of five records, case number M24-071, was performed on 3/18/2024 when the cryostat temperature recorded was out of range (-16C). Upon further review of the log sheet, the temperature on 3/11 /2024 was also out of range (-17C). 3. The ST affirmed by interview at approximately 12:30 p.m. on December 9, 2024, that the laboratory had recorded an out-of-range temperature on the dates mentioned in statement #2 prior to patient testing. 4. Based on the annual testing declaration form submitted at the time of the survey, the laboratory performed and reported approximately 300 patient tests for Mohs, including the time the cryostat temperature was out of range. Thus, the quality and accuracy of patient reports cannot be assured.

**D5779**

**CORRECTIVE ACTIONS**  
CFR(s): 493.1282(a)

Corrective action policies and procedures must be available and followed as necessary

to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's quality assessment policies and procedures, five (5) randomly selected Mohs patient records, and an interview with the surgical technician (ST), it was determined that the laboratory failed to have an established and approved policy and procedure for corrective action. Findings include: 1. Based on the review of the quality assessment policies and procedures, none was found for corrective action, including any criteria necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. 2. Based on the review of five randomly selected Mohs patient records, one out of five was found to be discrepant in the year recorded. The final report for M23-079 was dated 4/24/22, while the rest of the records documented were under 4/24/23. 3. Based on the review of five randomly selected Mohs patient records, two out of five were not completed for review on December 9, 2024, at approximately 12:30 p.m., as slides were unable to be retrieved. On the day of the survey, the ST stated in an interview that during the recent relocation process, the slides from 2014 to 2023 were destroyed and that no corrective action was performed. 4. The ST affirmed by interview that the laboratory did not have a complete policy and procedure for quality assessment that included the corrective action procedure as mentioned in statement #1. 5. Based on the testing declaration submitted at the time of the survey, the laboratory performed and reported 300 tests annually during the time that no corrective action policy and procedure was implemented; thus, the quality and accuracy of patient records cannot be assured.

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's policies and procedures on December 9, 2024, the laboratory director is herein cited for deficient practice for failure to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings include: 1. No peer review for the years 2022, 2023, and 2024. See D5217. 2. Out-of-range cryostat temperature prior to testing. See D5435. 3. No corrective action performed. See D5779.