Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2142370	12/01/2025
Name of Provider or Supplier	**Street Address, City, State**	
Ucla Health Burbank Mohs Lab	2625 W Alameda Ste 404, Burbank, 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	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 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. This STANDARD is not met as evidenced by: Based on the surveyor's review of patient testing records, log sheet, final reports, slides and an interview with the Mohs manager (MM) and office manager (OM) on December 1, 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 seven patient records for Dermatopathology and identified one discrepancy. The specimen location of Patient 4781262 varied across all records, such as the patient log sheet, Mohs map card, slides, and electronic chart. 2. No corrective action or amendment report was available for review at the time of survey. 3. The MM and OM affirmed by interviews on December 1, 2025, at approximately 3:10 p.m. that records were discrepant and was missed to perform a corrective action report as mentioned in statements #1 and #2. 4. The laboratory's testing volume declaration submitted at the time of survey stated that 200 Dermatopathology tests were performed and reported annually including the time when the discrepancies occurred.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1)

	Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on the surveyor's observation during the laboratory's tour and an interview with the Mohs manager (MM) and office manager (OM) on December 1, 2025, it was determined that the laboratory failed to label an open date for various reagent materials used in the laboratory. The findings include: 1. Observations during the tour revealed that all tissue marking dye (TMD) bottles used for Mohs processing of samples and slides lacked opening dates for the following: TMD Lot# a. Green TMD 22234 b. Yellow TMD 693966 c. Blue TMD 586-217150 d. Black TMD 342-127250 e. Red TMD 437-124060 f. Orange TMD 640-124140 2. The laboratory's MM and OM affirmed in an interview on December 1, 2025, at approximately 4:36 p.m., that the TMD mentioned in statement #1 lacked the appropriate label. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory processed and reported approximately 200 Dermatopathology samples. .
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on the surveyor's observation during the laboratory tour, examination of laboratory reagent materials and solutions, and interviews with the Mohs manager (MM) and office manager (OM); it was determined that the laboratory failed in using a tissue marking dye (TMD) when it had exceeded its expiration date. The findings include: 1. The surveyor's observations during the laboratory tour showed that the Green TMD (Lot#22234, expiration date: 8/4/2024) used for Mohs processing of sample was used beyond its expiration for patient testing. 2. The MM and OM affirmed by interviews on December 1, 2025 at approximately 4:36 p.m. that the laboratory used the TMD beyond its expiration date for patient testing without noticing nor checking the label during their quality assessment checks. 3 According to the testing declaration submitted at the time of survey, the laboratory tested and reported approximately 200 patient samples for Dermatopathology annually during the time when the TMD was used past its expiration date. Thus, the quality and accuracy of patient results cannot be assured. .
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by:

	Based on the surveyor's review of the laboratory's policy and procedure, seven Dermatopathology patient test records, preventive maintenance documentation, and interviews with the Mohs manager (MM) and office manager (OM), it was determined that the laboratory failed to follow an established protocol for the cryostat preventive maintenance prior to patient testing. The findings include: 1. The laboratory's protocol stated that the in-use cryostat temperature range was between -18 to -30 degree Celsius. 2. The surveyor reviewed seven patient records for Dermatopathology wherein three out of seven were operated under an out-of-range temperature on three separate ocassions. Further review on these date revealed that a total of ten patients were documented as having undergone Mohs surgery. The records as follows: DATE TEMP PATIENT COUNT 1/22/2025 -31C 1 2/12/02025 -32C 5 3 /12/2025 -33C 4 3. The OM and MM affirmed by interviews on December 1, 2025, at approximately 3:40 p.m. that the laboratory failed to follow their established temperature range for the cryostat prior to patient testing and that no corrective action was documented. The reliability of patient tests reported cannnot be assured. 4. According to the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed and reported approximately 200 Dermatopathology samples including the time when the cryostat was operated on an out-of-range temperature prior to patient testing.
D5821	TEST REPORT CFR(s): 493.1291(k) (k)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 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 surveyor's review of the laboratory's quality assessment (QA) policy and procedure, randomly chosen patient test records, and interviews with the Mohs manager (MM) and office manager (OM); it was determined that the laboratory failed to address errors in patient records prior to finalizing reports. The findings include: 1. The surveyor reviewed seven randomly selected patient test records for Dermatopathology dated from November 8, 2023, to November 12, 2025 and found the following discrepancies: a. Patient 4781262, examined on July 24, 2024 was recorded for the left lower preauricular in the patient log, Mohs map card and slides, but were reported at left cheek in the assessment notes. b. The Mohs map card for Patient 6899701 was not found for its hardcopy and digital copy in the electronic chart. 2. It was the practice of the laboratory to conduct record review at every patient testing day prior to the upload of hardcopy documents and perform corrective actions as necessary. However, none were found for the discrepancies mentioned in statement #1. 3. The MM and OM affirmed by interviews on December 1, 2025, at approximately 3:10 p.m., that the laboratory failed to catch the discrepancies found to perform and document a corrective action or an amendment report. The accuracy and reliability of patient tests reported cannot be assured. 4. According to the laboratory's testing declaration form submitted at the time of the survey, the laboratory performed and reported approximately 200 Dermatopathology tests annually, including the time when the discrepancy in the patient record occured.

D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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 surveyor's review of the laboratory's policy and procedure, randomly selected patient test records and interviews with the Mohs manager and office manager on December 1, 2025; the laboratory director is herein cited due to failure to ensure that quality assessment programs were followed and maintained to assure the quality of laboratory services provided and to identify errors as it occur. The findings include: 1. The laboratory failed to ensure that patient information was matched on all records. See D5203. 2. The laboratory failed to label opening dates on reagent materials and solutions used for patient testing. See D5415. 3. The laboratory used a tissue marking dye beyond its expiration date. See D5417. 4. The laboratory failed to follow the established cryostat temperature and operated in an out-of-range temperature on three separate surgery dates affecting a total of 10 patients. See D5433. 5. The laboratory failed to conduct corrective action report or an amendment report for two out of seven patient records reviewed. See D5821.