Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0591542	03/09/2026
Name of Provider or Supplier	**Street Address, City, State**	
Menlo Dermatology Medical Group	888 Oak Grove Ave Ste 8, Menlo Park, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish 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 the laboratory's policy and procedure, patient record, lack of personnel competency documentation, and an interview with the office manager (OM) on March 9, 2026, as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to perform the personnel competency assessment prior to patient testing. The findings include: 1. The laboratory had an existing competency assessment protocol for the tests under provider-performed microscopy (PPM) which included the potassium hydroxide (KOH) and scabies tests but was not followed since 2023 resulting to lack of records for all testing personnel (TP) performing the tests. 2. The surveyor reviewed the KOH patient test record and determined that the test performed for the PPM test was performed by the TP without any record of competency assessment documentation for the years 2023, 2024 and 2025. 3. The OM affirmed in an interview on March 9, 2026, at approximately 4:20 p.m. that the laboratory lacked competency assessments for the years 2023, 2024 and 2025 for all testing personnel performing PPM tests. 4. The quality and reliability of patient samples processed and reported could not be assured due to lack of personnel competency assessment as required in this subpart. .
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 and procedure, preventive maintenance (PM) documentation, seven patient records, and an interview with the office manager (OM), it was determined that the laboratory failed to ensure performed tests and function checks were documented or maintained prior to patient testing. The findings include: 1. It was the practice of the laboratory to have a biennial PM service for the microscope, Olympus EH, serial number: 250423. However, this was not followed as the last service found was documented on 6/9/2023 but had no follow-up PM since 6/9/2025. 2. No corrective action documentation was available at the time of survey. 3. The OM affirmed by an interview on March 9, 2026, at approximately 3:50 p.m. that the PM was overlooked and no corrective action documentation was performed. 4. According to the testing declaration form submitted at the time of the survey, the laboratory performed and reported approximately 310 tests annually, which included the period when the PM was missed as mentioned in this deficiency. .
D5603	HISTOPATHOLOGY CFR(s): 493.1273(b)(f) (b) The laboratory must retain stained slides, specimen blocks, and tissue remnants as specified in 493.1105. The remnants of tissue specimens must be maintained in a manner that ensures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under 493.1449(b), (f), or (g). This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's retention policy and procedure, six patient testing records and an interview with the office manager (OM) on March 9, 2026, it was determined that the laboratory failed to retain the patient's slide with the least frequency required. The findings include: 1. It was the practice of the laboratory to retain histopathology slides at least ten years as specified in 493.1105(a)(7)(i)(B). 2. The surveyor reviewed six patient testing records wherein one record was missing for the patient case number: 23-11199, examined on 6/15/2023. 3. No corrective action report was available for review at the time of survey. 4. The OM affirmed by an interview on March 9, 2026, at approximately 4:20 p.m., that the patient's slide was missing and no corrective action documentation is available for review. Thus, the quality and reliability of patient tests reported cannot be assured. 5. According to the laboratory declaration form submitted at the time of survey, the laboratory performed and reported 309 patient cases annually including the time when the laboratory failed to retain patient slides. .
D5988	PPM LABORATORY DIRECTOR RESPONSIBILITIES (c) Evaluate the competency of all testing personnel and ensure that the staff maintains their competency to perform test procedures and report test results promptly, accurately, and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to- (c)(1) Direct observations

	of routine patient test performance, including, if applicable, specimen handling, processing, and testing; (c)(2) Monitoring the recording and reporting of test results; (c)(3) Review of test results or worksheets; (c)(4) Assessment of test performance through testing internal blind testing samples or external proficiency testing samples; and (c)(5) Assessment of problem-solving skills; and This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policy and procedure, preventive maintenance records, patient test record and an interview with the office manager on March 9, 2026, this deficiency in herein cited for the laboratory director due to failure to ensure that competency assessments were performed for all testing personnel. See D5209. .
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, lack of preventive maintenance records, and an interview with the office manager on March 9, 2026, this deficiency in herein cited for the laboratory director due to failure to ensure that the quality system assessment records were followed and retained with the least frequency required in 493.1105. The findings include: 1. The laboratory failed to follow their policy for the equipment maintenance and function check of the microscope used for testing. See D5435. 2. The laboratory failed to retain the patient slide as required in 493.1105. See D5603.