Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2269119	08/16/2023
Name of Provider or Supplier	**Street Address, City, State**	
Vera Dermatology	981 W Foothill Blvd, Claremont, 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
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 lack of the laboratory's Mohs reports peer review, review of six (6) randomly chosen histopathology patient's reports, review of submitted laboratory forms, and interviews with the laboratory's office staff (OS) on AUGIST 16, 2023; it was determined that the laboratory failed to verify, at least twice annually, the accuracy of its histopathology tests for the years 2022 and 2023. The findings included: 1. The laboratory could not provide documentation showing that it had verified its histopathology Mohs tests' accuracy for the years 2022 and 2023 for the dermatopathologist performing slide reading and providing patients' diagnosis. Therefore, the accuracy of the laboratory's test results for patients' histopathology procedures, cannot be assured. 2. Corrective Action form submitted to surveyor on August 27,2023 from Vera Dermatology states, "No peer review of dermatology because zero cases of dermatopathology performed 2022-2023" Surveyor did review 6 randomly selected patients which were tested within this time frame. 3. The OS confirmed at approximately 12:00 p.m., that the laboratory did not have any record to verify its Mohs test accuracy for the years 2022 and 2023. 4. The laboratory's testing declaration form signed by the laboratory director, stated that the laboratory performs approximately 200 histopathology tests annually.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) 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 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. The laboratory must 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 surveyor observation, lack of maintenance protocol, and interview with the Office Staff (OS); it was determined that the laboratory failed to establish and follow a maintenance protocol for the AMSscope microscope that ensures its continued performance necessary for accurate and reliable test results. The findings included: 1. Based on the surveyor observation on August 16,2023, at 11 am. there was no evidence or records found for the microscope maintenance or calibration. 2. Preventative maintenance record for the microscope submitted to surveyor on August 27, 2023 from Vera Dermatology shows maintenance and alignment started on October 4, 2022. Patient testing started in June 14, 2022. 3. For 2 of 6 patients randomly selected for review by surveyor, accurate and reliable test results could not be established. 4. The OS confirmed by interview on August 16,2023, at 11am. that the laboratory failed to establish manufacturer recommendation and follow a maintenance protocol for the AMSscope microscope used for histopathology examinations. 5. Based on the laboratory's yearly testing declaration submitted at the time of the survey, the laboratory analyzed and reported approximately 200 samples.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must 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 review of the laboratory's records for policies and procedures, patient review records, direct observation by the surveyors during the lab tour, and interviews with Office staff on August 16, 2023; it was determined that the laboratory director failed to ensure that several aspects of the preanalytical, and analytic phases of laboratory testing were monitored. See D5433, and D5217.