Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2272192	09/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Clark Dermatology	3461 Us-22d, Branchburg, NJ	

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 surveyor review of Biannual Assessment (BA) records, Procedure Manual (PM) and interview with the Office Manager (OM),the laboratory failed to follow their procedure and verify the accuracy and reliability of Mohs testing twice annually from 5/15/24 to 9/6/24. The findings include: 1. The PM states "the Mohs Surgeon will select at least two Mohs cases for QA review approximately every 6 months. 2. There was only one case selected and not two cases as stated in the PM for the first BA review. 3. The OM confirmed on 9/3/24 at 10:30 am that the laboratory did not follow the BA procedure to verify the accuracy and reliability of Mohs testing.
D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on surveyor review of Test Reports (TR), Electronic Medical Records (EMR), Procedure Manual and interview with the Office Manager (OM), the laboratory failed to have an ongoing mechanism to ensure the accuracy of manual entries by personnel into a laboratory information system (LIS) from 5/15/24 to 9/3/24. The findings include: 1. The laboratory failed to have a procedure for manually transcribed TR and

	other pertinent information into the LIS. 2. The OM confirmed on 9/3/24 at 11:10am the laboratory failed to verify the accuracy of manual entries by personnel into the LIS.
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 review of the Procedure Manual (PM) and interview with the Office Manager (OM), the laboratory failed to establish a maintenance protocol for the Linistat Stainer used for Histopathology tests from 5/14/24 to 9/3/24 The findings include: 1. The PM did not have a maintenance protocol for the Linistat Stainer used for Histopathology tests. 2. The OM confirmed on 9/3/24 at 11:00 am the laboratory did not have a maintenance protocol for the Linistat Stainer.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on surveyor review of the Mohs Patient Log (MPL), Test Records and interview with the Office Manager (OM), the laboratory failed to maintain an accurate information system for Histopathology tests from 6/19/24 to 9/6/24. The findings include: 1. A review of five entries on the MPL revealed: a) Case # 24-014 had one stage documented on the MPL but had two stages documented on the MOHS map and final report. b) Case # 24-013 had two stages documented on the MPL but had one stage documented on the MOHS map and final report. 2. The OM confirmed at 11:00 am on 9/3/24 the laboratory failed to maintain an accurate information system.