Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2214982	01/31/2023
Name of Provider or Supplier	**Street Address, City, State**	
Clark Dermatology	55 Newton Sparta Road, Newton, 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 the Procedure Manual (PM), Biannual Assessment (BA) records and interview with the Office manager (OM), the laboratory failed to verify the accuracy and reliability of Moh's testing twice a year from 2/26/21 until the date of survey. The finding includes: 1. Three out of three BA assessments were not dated 2. Two out of three BA assessments did not have slide numbers. 3. Two out of three BA assessments did document the referring physicians review. 4. The OM confirmed on 1/31/23 at 12:30 pm that the laboratory did not verify the accuracy of Moh's testing twice a year.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. 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 have a complete procedure for Biannual Assessment (BA) on the date of survey. The findings include: 1) The BA procedure does not include the name and credentials of the reviewing physician. 2)

	The BA procedure does not include not the name and credentials of the third party reviewing physician. 3) The OM confirmed on 1/31/23 at 12:00 pm that the laboratory did not have the aforementioned procedure.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: (a) Based on surveyor review of the Temperature Log (TL) and interview with the Office Manager (OM), the laboratory failed to define an acceptable Room temperature and humidity range where Histopathology tests are performed on the date of survey. The finding include: 1. The TL did not have an acceptable range for Temperature or Humidity. 2. The OM confirmed on 1/31/23 at 12:35 pm that an acceptable range was not defined. (b) Based on surveyor review of TL and interview with the OM the laboratory failed to define an acceptable Cryostat Temperature (CT) that was used for Mohs testing on the date of survey. The OM confirmed on 1/31/23 at 12:35 pm that an acceptable range was not defined.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of Stain Maintenance and Quality Control (QC) Log (SMQCL) and interview with the Office Manager (OM), the laboratory failed document all control procedures performed on each day of Mohs testing on the date of survey. The findings include: 1) The SMQCL did not specify what slide was reviewed for Hematoxylin and Eosin (H&E) control reaction 2) The OM confirmed on 1/31/23 at 12:10 pm that the laboratory failed document all control procedures stated above.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and

	identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Office Manager (OM) the laboratory failed to ensure that the FR included the name and address of the laboratory where testing was performed from 2/26/21 to the date of survey. The finding includes: 1) Five out of five FR did not havethe name and address of the laboratory where testing was performed 2) The OM confirmed on 1/31/23 at 10: 00 am that the FR did not have name and address of the laboratory where testing was performed.