Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2121156	10/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Clark Dermatology	703 Kearny Ave, Kearny, 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
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on survey review of the Procedure Manual (PM), Biannual Assessment Documentation (BAD) and interview with the Office Manager (OM) the laboratory failed to verify the accuracy of Histopathology testing from 11/23/21 to the date of survey. The findings include; 1) The PM states " Cases will be referred to an outside laboratory/physician for complete review of slides and Mohs Map. 2) The laboratory failed to include physician agreement for the biopsy diagnosis of each case submitted for complete review for the Biannual Assessment (BA). 3) The reviewing and referring physicians failed to sign the BAD. 4) There was no documented evidence the Mohs Maps were reviewed for each case submitted. 5) The OM confirmed on 10/17 /23 at 1:30 pm that the laboratory failed to verify the accuracy of Histopathology testing.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). 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 record a discontinuance date for

	procedures not performed in the laboratory from 11/23/21 to the date of survey. The finding includes: 1. The PM had two procedures for slide retention that had different slide retention dates. 2. The OM confirmed on 10/17/23 at 2:15 pm that a discontinuance date was not documented.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 surveyor observation of Histopathology reagents, the Flammable Cabinet, and interview with the Office Manager (OM), the laboratory used and failed to dispose expired Histopathology reagents from 10/4/23 to the date of survey. The findings include: 1. One Eosin Working Solution one gallon container Lot L245-04 expired on 10/4/23. 2. 7 patients were run and reported with the expired reagent. 3. The OM confirmed on 10/17/23 at 2:30 pm that the laboratory used and failed to dispose the expired reagent.