Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2220087	02/28/2024
Name of Provider or Supplier	**Street Address, City, State**	
Clark Dermatology Llc	469 Morris Avenue, Elizabeth, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to enroll in an approved PT program for Gram Stain tests in the calender year 2023. The TP confirmed on at 1:40 pm the laboratory was not enrolled in PT for Gram Stain tests.
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 Biannual Assessment (BA) records and interview with the Testing Personnel (TP), the laboratory failed to verify the accuracy of Histopathology testing from 1/20/22 to the date of survey. The TP confirmed on 2/28/24 at 1:30 pm that the laboratory did not perform BA for Histopathology.

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 the Flammable Cabinet and interview with the Testing Personnel (TP), the laboratory used expired 1% Acid Alcohol and Giemsa stain for Acid-Orcein Giemsa (AOG) Histopatholgy testing from 11/30/23 to the date of survey. The findings include: 1) 1% Acid Alcohol lot # 136227 expired 11/30/23. 2) Giemsa Stain # 150966 expired 11/30/23. 3) Approximately 2 patients were run and reported per week. 4) The TP confirmed on 2/28/24 at 1:30 pm that the laboratory used expired reagent.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor review of the Procedure Manual, Proficiency Testing records and interview with the Laboratory Director (LD) failed to provide overall management and direction to the laboratory to ensure that laboratory testing is performed satisfactorily and in compliance with the CLIA regulations from 1/20/22 to the date of the survey. 1. The LD failed to ensure that the laboratory was enrolled in an Centers for Medicare & Medicaid Services (CMS)-approved proficiency testing program for Gram Stain testing. Cross refer to D6091 2. The LD failed to ensure that the laboratory was performing Biannual Assesment (BA) for Histopathology testing. Cross refer to D6091
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on the lack of Biannual Assessment (BA) records, the lack of participation in a Centers for Medicare & Medicaid Services (CMS) approved Proficiency Testing (PT) provider for Gram Stain testing and interview with the testing personal (TP), the Laboratory Director (LD) failed to ensure BA and PT was performed to evaluate the laboratory's performance accurately from 1/20/22 to the date of survey. The TP confirmed on 2/28/24 at 1:00 pm the BA and PT was not performed to evaluate the laboratory's performance accurately.