Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D1054342	05/19/2021
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Affiliates Pc	3131 Maple Drive, Suite 102, Atlanta, GA	

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
D0000	On July 23, 2021 an off site followup review was completed. The report revealed that corrective action was found to be acceptable and corrected. The facility is now in compliance with with all regulations surveyed.
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 Testing Personnel (TP) document review and staff interview, the laboratory failed to verify at least twice annually, the accuracy of testing performed for Moh's. Findings include: 1. TP document review revealed there were no twice annual peer reviews performed on the Technical Supervisor(CMS 209) for Moh's testing in 2019, 2020, and 2021 thus far. 2. During an interview with the Practice Manager in the Moh's laboratory on May 19, 2021 at approximately 10:45 AM, it was confirmed the lack of peer review was performed for Moh's testing.
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 observation during the lab tour and staff interview, the laboratory failed to ensure reagents and solutions were not used after their expiration date as required.

	Findings include: 1. During the laboratory tour on May 19, 2021 at approximately 11: 30 AM, observation revealed the following reagents expired, in the flammables cabinet: Scott tap water, Lot no. 2012117 Exp. date: 05-04-2021, Acetone, Lot no. 4423-00 Exp. date: March 2018, and Scott tap water, Lot no. E122-09 Exp. date: 05-07-2017. 2. Interview with the Practice Manager in the Moh's laboratory on May 19, 2021 at approximately 12:00 PM, confirmed the reagents listed above were expired during the laboratory tour.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on laboratory competency document review and interview with the Practice Manager, the Laboratory Director (LD) failed to perform annual competency on all testing personnel (TP). The Findings include: 1. Laboratory competency review revealed the LD failed to perform an annual competency for the Technical Supervisor (TS) and testing personnel (TP). 2. Interview with the Practice Manager on May 19, 2021 at approximately 10:55 AM, in the MOHS lab, confirmed the LD failed to perform annual competencies on all required personnel.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory policy and procedure manual (SOP) and staff interview, the laboratory director (LD) failed to specify in writing the duties and responsibilities of each individual engaged in the performance of all phases of testing as required. Findings include: 1. SOP review revealed the lack of a Duties and Responsibilities policy and procedure for the General Supervisor, Technical Consultant, and the Clinical Consultant. 2. Interview with the Practice Manager on

	May 19, 2021, in the Moh's laboratory at approximately 10:30 AM, confirmed the SOP did not contain the Duties and Responsibilities for the following positions: General Supervisor, Technical Supervisor, and Clinical Consultant.