Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0993620	05/26/2022
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Associates Of Georgia Llc	201 Michael Etchison Road, Monroe, 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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on May 26, 2022. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on the Laboratory Tour and staff interview, the Laboratory failed to ensure that the Fire Extinguisher's were checked for safety from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. The Findings include: 1. During the Laboratory Tour observation of the Fire Extinguisher revealed that the last maintenance check was on September 2020. 2. During an interview with Testing Personnel #2(CMS 209) on May 26, 2022 at approximately 1:45 PM, confirmed that the Laboratory did not maintenace the Fire Extinguisher for safety since September 2020.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of proficiency test(PT) documents and staff review, the laboratory

	failed to perform required correction action for PT results for unacceptable /unsatisfactory evaluations. The Findings include: 1. American Academy of Family Physicians(AAFP) PT document review revealed there was no correction action for the Urinalysis Microscopy Skin Scrap for PT testing in 2021 Event C. 2. During an interview with the Testing Personnel #2(CMS-209) on May 26, 2022 at approximately 2:50 PM, it was confirmed that the TP and LD failed to document a correction action for the PT in 2021 for Event C.
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 and staff interview, the laboratory failed to ensure reagents must not be used after their expiration date as required. Findings include: 1. Observation during the laboratory tour on May 26, 2022 at approximately 1:30 PM, revealed a bottle of Potassium Hydroxide (KOH) 10 percent reagent on the laboratory counter near the microscope which had expired on 12-31-2022. Observation during the same tour at 1:30 p.m. on 1/23/2020 revealed there was no replacement available at the time of survey. 2. During an interview with the Testing Personnel#2(CMS-209) in the hallway of the facility, on May 26, 2022 at approximately 1:30 M, confirmed the KOH solution in use had expired on 12-30-2021, and there was no replacement available at the time of survey.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that 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 Proficiency Testing (PT) document review and staff review, the Technical Supervisor/Laboratory Director(TS/LD) failed to review PT reports as required. The Findings include: 1. American Academy of Family Physicians(AAFP) document review revealed the TS/LD did not review the following PT reports for Dermatophyte Screen and Skin Scraping(Urinalysis---Potassium Hydroxide): PT 2021-C. 2. During an interview with the Testing Personnel #1(CMS-209) on May 26, 2022 at approximately 2:15 PM, confirmed the lack of PT report review by the TS/LD.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed

	when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the laboratory's Proficiency Testing (PT) records and staff interview, the laboratory director (LD) failed to ensure an approved corrective action plan is followed when any PT result is found to be unacceptable/unsatisfactory. Findings include: 1. Review of PT records for 2021 revealed the laboratory received a score of 0% on Events C for the Urinalysis Microscopy Skin Scrap. 2. During an interview with the Testing Personnel # 1(CMS-209) on May 26, 2022 at approximately 2:50 PM, confirmed the LD failed to ensure an approved correction plan was followed for PT results that were unacceptable/unsatisfactory.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on Testing Personnel (TP) document review and staff interview, the Technical Supervisor/Laboratory Director(TS/LD) failed to ensure required TP competencies were performed. The Findings include: 1. TP competency document review revealed the TD/LD failed to perform competencies: Specialty of Potassium Hydroxide (KOH) testing, in 2020, 2021, and thus far 2022, of the following TP listed on the CMS 209 document--- TP #1, TP #3, and TP #4. 2. TP competency document review revealed there was no documentation available at the time of the survey for a Peer Review in 2020, 2021, and thus far 2022 for the providers. 3. During an interview with the Testing Personnel#2(CMS-209) on May 26, 2022 at 2:45 PM, in the hallway of the facility, confirmed the lack of competencies in 2020, 2021, and 2022 for TP #1, TP #3, and TP #4. 4. During an interview with the Testing Personnel #2(CMS-209) on May 26, 2022 at 2:45 PM, in the hallway of the facility, confirmed the lack of documentation for Peer Review in 2020, 2021, and thus far 2022 for the providers.