Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2165927	03/02/2022
Name of Provider or Supplier	**Street Address, City, State**	
Southeast Dermatology Specialists	400 Brookstone Parkway, Suite 500, Columbus, 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 March 2, 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:
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on quality assessment (QA) document review and staff interview, the laboratory failed to document quality assessment activities as required. The Findings include: 1. Laboratory QA documents review revealed the lack of a QA checklist and documentation from 2019 to 2022. 2. No accurate normal ranges on room Temperature (15 - 46 Degree C), Humidity(No normal ranges), Cryostat (30 - 70 %) and refrigerator(0 - 10 degree C) logs. 3. No evidence of maintenance logs review by the laboratory director or TS (Technical Supervisor) from 2019 to 2022. 4. Interviews with the Laboratory coordinator and office manager on 03/02/2022 at 12:15 PM in the conference room confirmed the lack of adequate QA checklist and QA documents review from 2019 and 2022.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory

	must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the laboratory tour and staff interview, the laboratory failed to perform annual professional maintenance on the current Microscope in use as required. Findings include: 1. Observation during the laboratory tour revealed that the Microscope (AM Scope by Tension Scientific) in use was NOT calibrated annually as required. The last calibration was performed on 01-09-2020. 3. Interviews with the laboratory coordinator and office manager on 03/02/2022 during the lab tour at approximately 10:15 AM, confirmed the lack of the aforementioned professional maintenance on the Microscope.