

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2193603	(X3) Date Survey Completed 07/22/2022
Name of Provider or Supplier Southeast Dermatology Specialists	Street Address, City, State 100 Market Place Boulevard, Suite 300, Cartersville, 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	An initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on July 22, 2022. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(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.</p> <p>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 on a monthly or quarterly basis per their QA guidelines as required. The Findings include: 1. Laboratory QA documents review revealed the laboratory did not have a monthly or quarterly quality checklists in 2021 thru date of survey (07/22/2022). 2. Monthly reviews of maintenance logs including: Room Temperature, Humidity, Refrigerator, Freezer and Cryostat were not documented by the Lab director who is also the General Supervisor (GS) and Technical Supervisor. 3. An interview with the laboratory coordinator, on 07/22/2022, at 11:25 AM in the review room confirmed the lack of adequate QA checklist and maintenance logs review by laboratory director in 2021 thru date of survey 07/22/2022.</p>
D6022	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p>

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)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on Quality Assurance(QA) documents review and staff interview, the Lab Director(LD) failed to ensure that proper QA guidelines were followed including regular review of (QA) data to identify and fix problems in the laboratory as required by Clinical Laboratory Improvement Amendments (CLIA). Findings include: 1. (QA) documents review revealed the laboratory director did not review maintenance logs nor a (QA) checklist to identify and correct problems in the laboratory as they occur in 2021 thru date of survey 07/22/2022. 2. An interview with the laboratory coordinator in the review room on 07/22/2022, at approximately 11:05 AM, confirmed the LD did not review the aforementioned (QA) logs in 2021 thru the date of survey 07/22/2022.