Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2211655	11/04/2022
Name of Provider or Supplier	**Street Address, City, State**	
Southeast Dermatology Specialists	15 Riverbend Drive, Suite 120, Rome, 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 November 04, 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:
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 Proficiency Testing (PT) records review and staff interview, the laboratory failed to enroll in a CMS approved PT program or Peer Review program at least twice a year to verify accuracy of its testing. Findings include: 1. Proficiency Testing (PT) records review revealed no registration with a CMS approved (PT) Agency or a peer review program with a Pathology group or peers at least twice annually in 2021 and 2022. 2. An interview with the Histotech (TP #6 CMS 209) and the laboratory coordinator on 11/04/2022 at approximately 11:30 AM confirmed failure of the laboratory to enroll in a CMS approved (PT) or peer review program in 2021 and 2022.
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 on a monthly or quaterly basis per their QA guidelines as required. The Findings include: 1. Laboratory QA documents review revealed there were no monthly (QA) audits from February 2021 through January of 2022 by the lab director. 2. Daily maintenance logs confirmed Room Temperature, Humidity, Eye wash or Refrigerator logs were not reviewed and signed by the lab director from February 2021 through January 2022. 3. MOHs H and E monthly Quality Control (QC) slides from February 2021 to July 2022 were not reviewed by the lab director. 4. Interviews with the lab coordinator and Histotech (TP #6 CMS 209) on 11/04/2022, at approximately 11:35 AM in the review room confirmed the lack of an adequate QA oversight by the lab director from February 2021 through July of 2022.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory staff, the laboratory director failed to ensure the completion of training and competency assessment for testing personnel (TP) to ensure initial, semi-annual or annual competencies were completed in 2021 and 2022. Finding includes: 1. Review of training and competency assessment records revealed that the laboratory failed to follow their policy which states the "... laboratory director is responsible to ensure or delegate training and competency assesments for all testing personnel...". There were no records for initial training, semi-annual and annual assesments for Testing Personnel (TP#6 CMS 209) in 2021 and 2022. 2. An interview with (TP#6 CMS 209) and the laboratory coordinator on 11/04 /2022, at approximately 12:10 PM in the review room confirmed the abscense of training and competency assesment documents in 2021 and 2022 at the time of survey.