Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0245307	01/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Southeastern Dermatology, Pa	4390 Fayetteville Rd, Lumberton, NC	

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
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 review of 2019, 2020, and 2021 laboratory records and interview with nurse manager 1/13/22, the laboratory failed to verify the accuracy of the potassium hydroxide(KOH)/Wet Prep test at least twice annually in 2019, 2020 and 2021, a period of approximately 3 years. Findings: Review of 2019, 2020, and 2021 laboratory records revealed no documentation the laboratory had performed a verification of accuracy for the KOH/Wet Prep test in 2019, 2020 and 2021. Interview with nurse manager at approximately 11:40 a.m. confirmed the laboratory had not performed a twice annual verification of accuracy for the KOH/Wet Prep test in 2019, 2020, and 2021. She stated the physician does not perform them that often.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or

	control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory procedure manual and interview with nurse manager 1 /13/22, the laboratory procedure manual failed to include the laboratory's system for entering results in the patient medical record. Findings: Review of laboratory procedure manual revealed the manual failed to include a procedure for the laboratory's system of entering results into the patient medical record. Interview with nurse manager at approximately 11:40 a.m. confirmed the procedure manual failed to include how test results were entered into the patient medical record.