

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0245307	(X3) Date Survey Completed 08/25/2025
Name of Provider or Supplier Southeastern Dermatology, Pa	Street Address, City, State 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
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and interview with the Operations Manger 08/25/2025, the laboratory's procedure manual was not complete and current for the testing performed. Findings: Review of the laboratory's procedure manual revealed no written procedure for the manual staining of Hematoxylin & Eosin (H & E) slides. During interview at approximately 2:01 p.m., the Operations Manger confirmed no written procedure for the manual staining of H & E slides.</p>

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of personnel records for 2025, and interview with the Operations Manager 08/25/2025, the Laboratory Director (LD) failed to specify in writing the duties and responsibilities for the Technical Supervisor (TS) involved in the daily operation of the laboratory. Findings: Review of personnel records revealed the absence of a job description for the TS position. During interview at approximately 4:45 p.m., the Operations Manager confirmed no position description available for the TS.