Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2057459	10/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Specialists, The	176 Mountain Avenue, Hackettstown, NJ	

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	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 surveyor review of the Procedure Manual (PM) and interview with the Office Manager (OM) via telephone, the laboratory failed to have all procedures needed for Histopathology tests from 1/15/19 to the date of the survey. The findings include: 1. The laboratory failed to have a procedure for: a. Slide retention b. Quality Control for Hematoxylin and Eosin Stain 2. The OM confirmed via telephone on 10/12 /21 at 10:00 am that the laboratory did not have the above procedures.
D5407	PROCEDURE MANUAL

	CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Office Manager (OM) via telephone, the laboratory failed to have an approved, signed and dated PM by the Laboratory Director from 1/15/19 to the date of the survey. The OM confirmed via telephone on 10/12/21 at 10:00 am a PM signed by the LD was not available.
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 lack of maintenance records and interview with the Office Manager (OM) via telephone, the laboratory failed to perform and document annual maintenance on the microscope used in laboratory testing from January 2019 to the date of the survey. The OM confirmed via telephone on 10/12/21 at 10:00 am there was no documented evidence that annual maintenance was performed on the microscope from January 2019 to the date of the survey.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on surveyor review of the lack of Quality Control (QC) records and interview with the Office Manager (OM) via telephone, the laboratory failed to document Hematoxylin and Eosin (H&E) control slide reaction from 1/15/19 to the date of the survey. The findings include: 1. The laboratory did not document H&E stain QC reaction for reading of biopsy slides. 2. The laboratory read and reported approximately 1600 patient slides. 3. The OM confirmed via telephone on 10/12/21 at 10:00 am that the laboratory did not document H&E QC stain reaction.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established

	and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Office Manager (OM) via telephone, the Laboratory Director failed to maintain a Quality Control (QC) program for Hematoxilyn and Eosin (H&E) stain reaction from January 2019 to the date of survey. The OM confirmed on 10/12/21 at 10:00 am that a QC program was not maintained.