Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1037117	05/19/2026
Name of Provider or Supplier	**Street Address, City, State**	
Dermatopathology Consultants Llc	104 White Horse Pike, Haddon Heights, 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) (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. This STANDARD is not met as evidenced by: Based on surveyor review of the written procedure manual and interview with the histotechnologist (HT), the laboratory failed to have all applicable procedures for histopathology, technical and professional components, testing in the written procedure manual from 10/17/23 to 5/19/26. The findings include: 1. The laboratory failed to provide a written procedure for reporting histopathology patient results in their laboratory information system (LIS). 2. The laboratory failed to include a back-up plan including storage, sending out and/or staining and reading histopathology

	slides by other methods occurs in case the equipment becomes inoperable, reagents /stains are not available or any other emergency situation occurs where staining and histopathology slide reading cannot be performed. 3. The HT confirmed on 5/19/26 at 11:00 am that the laboratory did not provide the aforementioned written procedures.
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. This STANDARD is not met as evidenced by: Based on the lack of Quality Control (QC) records and interview with the Histotechnologist (HT), the laboratory failed to document daily control slide reactions for histopathology testing from 10/17/23 to 5/19/26. The findings include: 1. The laboratory did not document daily stain QC reactions during the time period stated above. 2. The laboratory stained and/or read histopathology slides for approximately 44,000 patients in the above time period. 3. The HT confirmed on 5/19/26 at 12:30 pm that the laboratory did not document QC stain reactions.