Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2160298	03/26/2024
Name of Provider or Supplier	**Street Address, City, State**	
Hudson Dermatology Pc	155 White Plains Road - Suite 109, Tarrytown, NY	

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 review of the current, approved standard operating procedures (SOPs) and interview with the Laboratory Coordinator (LC), the laboratory failed to draft, approve instructions and criteria for pathology specimen send outs. FINDINGS: 1. The laboratory utilized Aurora Diagnostics Laboratory of Dermatopathology, 33D0143814, for pathology specimens requiring special staining. 2. The current, approved SOPs did not include instructions and criteria for pathology specimen

	special staining, distribution to Aurora Diagnostics Laboratory of Dermatopathology, as well as specimen return and result reporting. 3. The LC confirmed the findings on March 26th, 2024, at 11:30 A.M.