Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D0353637	08/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Associates Of Indiana	1910 N Arlington Ave, Indianapolis, IN	

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 observation, record review, lack of documentation, and interview, the laboratory failed to have policies and procedures that included a step-by-step procedure for grossing and slide reading, storage location and temperature of specimens, and how to perform quality control (QC) for histopathology testing starting 07/08/2022 to the date of the survey and for six of six patients reviewed (PT#1-PT#6). Findings included: 1. During entrance to the laboratory on 8/15/2022 at 9:30 AM, a reference laboratory box outside the office door was observed to be exposed to natural elements. 2. On 08/15/2022 at 12:05 PM, a formalin container for

	tissue transportation was received from SP#1 (Front Office Staff). The container read, "store at room temperature". 3. Review of Lab Policy & Procedures Manual revealed no written documentation of a step-by-step procedure for grossing and slide reading, location and storage temperature of specimens, and quality control procedures for when quality control was completed and how it was documented. 4. Review of "General Specimen Handling, Collection, Labeling" policy, signed by the laboratory director on 7/18/2022, read "3. Specimens are obtained according to the specific protocol for test being performed ... 6. After the specimen is collected, the container is transported and stored in the appropriate location appropriate for specific test being performed." The policy did not include: a) specific protocol for grossing of the specimen, b) the storage or transportation temperature for tissue in formalin, c) the appropriate location for storage of tissue in formalin. d) information on when slides are read after the slides are received from the processing laboratory. 5. Review of "Referral of Specimen", signed by the laboratory director on 7/1/2022, revealed there was no written procedure for how the formalin specimen was to be sent to the referral /reference laboratory for slides to be created. 6. Review of "Quality Assessment Plan", dated 3/23/11, under 2. Analytic Phase: Instruments, read "ii. Check quality control (QC) results and corrective actions by ensuring that: a. QC is performed according to written policies and procedures b. Corrective actions are documented for any compliance not within the minimum acceptable limits c. Verify Laboratory Director has reviewed and signed QC charts monthly." d. This document did not include: 1.) specific protocol for grossing of the specimen, 2.) the storage or transportation temperature for tissue in formalin, 3.) the appropriate location for storage of tissue in formalin. 4.) information on when slides are read after the slides are received from the processing laboratory. 7. Review of PT#1-PT#6 patient records indicated the Dermatology Requestion forms for each patient contained remarks about "stain quality" above the laboratory director's signature. a. PT#1- 7/8, Stain Quality b. PT#2- 7/8, "Stain P 7/15/2022" c. PT#3- 7/8, "Stain Pass 7/15/22" d. PT#4- 7/8, "Stain P 7/15 /2022" e. PT#5- 8/2, "Stain Quality P"- no date f. PT#6- 8/2, "Stain Quality P" - no date 8. During interview on 08/15/2022 at 10:30 AM, SP#1 confirmed there was no storage temperature or storage location policy. 9. During interview on 08/15/2022 at 12:07 PM, SP#1, indicated specimens in formalin put in the "box" at the front of the laboratory for the reference laboratory to pick up around 5:00 PM or 5:30 PM, the reference laboratory will pick up the specimen by 6:30 PM. SP#1 confirmed the box was not insulated to ensure room temperature was maintained. 10. During an interview on 8/15/2022 at 1:30 PM, SP#3 (office manager) confirmed there was no step-by-step procedure for grossing, slide reading, storage temperature, storage location, transportation of specimen, or how to complete quality control. They further indicated that all instructions could be found in the "Quality Assessment Plan" already provided.