Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2077302	05/06/2024
Name of Provider or Supplier	**Street Address, City, State**	
Skin Pathology Center Inc	7091 Sw 47 St, Miami, FL	

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
D0000	A recertification survey conducted on 05/06/2024 found the SKIN PATHOLOGY CENTER INC clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on observation, lack of records and interview, the laboratory failed to monitor the Xylene and Formaldehyde exposure limits for 34 out of 34 months reviewed (2021 (July to December), 2022, 2023 and 2024 (January to April)). Findings include: -During the arrival of the surveyor on site on 05/06/2024 at 10:30 AM, the surveyor noted a strong odor for a chemical product. During the permanence of the surveyor onsite for 3 hours, she could sense the permanence of the strong chemical odor. -Review of procedure manual signed by the laboratory director on 10/16/2023, revealed that the laboratory failed to include a policy to implement the staff monitoring of the exposure to Xylene and Formaldehyde used in the laboratory. -Review of specimen policy revealed that the specimens are received in a 10% formalin bottle. Review of Sakura VIP tissue processor procedure revealed that the laboratory used the 10 % Formalin solution in the first two stations for tissue dehydration and Xylene in the ninth and ten station for clearing. Review of the Hematoxylin and Eosin stain process revealed that the laboratory used Xylene. -Review of Safety Data Sheet for: a) 10% Neutral Buffered Formalin revealed that the OSHA Permissible Limits (PELS) was 0.75 ppm (parts per million). b) Xylene revealed that the OSHA PEL was 100 ppm. During an interview on 05/06/2024 at 12: 30 PM, the laboratory consultant confirmed that the laboratory failed to effectively monitor the Xylene and Formaldehyde exposure.

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 and interview, the laboratory procedure manual failed to include the instruction for making the solutions for alcohol 70% and 80% used for the Sakura VIP Tissue Tek processor. Findings included: -During the tour of the laboratory on 05/06/2024 at 10:30 AM, in the flammable cabinet there was one gallon container of Statlab 100 % Reagent Alcohol lot 192951 and one gallon of Statlab 95 % alcohol lot 14171. During the inspection of VIP processor stations revealed that the laboratory used alcohol 70 and 80%. -Review of the procedure manual signed by the laboratory director on 10/16/2023, in the policy "Specimen Processing VIP-Schedule" stated that the laboratory used alcohol 70% and 80% alcohol. The policy failed to include the instructions of the preparation of the alcohol used. During an interview on 05/06/2024 at 12:00 PM, the laboratory consultant confirmed that the procedure manual failed to include the procedure for preparation of the alcohol 70 and 80% used in the VIP tissue processor.