Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0505441	05/07/2025
Name of Provider or Supplier	**Street Address, City, State**	
Southwest Skin And Vein Center Pllc	4419 Frontier Trail Suite 110, Austin, TX	

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	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. Standard level deficiencies were cited.
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) (a)(7) Slide, block, and tissue retention-- (a)(7)(i) Slides. (a)(7)(i)(A) Retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). (a)(7)(i)(B) Retain histopathology slides for at least 10 years from the date of examination. (a)(7)(ii) Blocks. Retain pathology specimen blocks for at least 2 years from the date of examination. (a)(7)(iii) Tissue. Preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, slide review, and interview, the laboratory failed to retain slides from its Mohs cases for at least 10 years for one out of 14 cases reviewed from May 2016 - April 2025. Findings follow. A. Review of the laboratory's policy and procedure titled Quality Assurance, revised 08/22/2023, under Procedure stated "... The specimen is checked to make sure that the first cut contains the entire epidermis layer (sections are taken every 10-12 cuts). The slide will contain 3-4 levels per slide. The number of slides prepared depends on the doctor's preference and the size of the specimen. The slide will be labeled as follows: the accession number (which includes doctor initial, clinic location initial, year, and specimen number) will be written at the top of the slide, the next line will have patient last name, followed by first initial; below the name will be the date on the left of the slide and the layer/stage on the right (EX: I,II, III, IV, V, etc.) If more than one slide is prepared, the first will be labeled "A", the next "B", and so on and so forth. For tissue that has been bisected or quadrisected, the number of the piece as designated by

	the map will also be written on the slide (ex: 1, 2, 3, 4)..." And at 5.9 stated, "Slides are maintained for 10 years." B. Review of slides from case number GA24-824 performed on 07/15/2024 had the following slides: IA, IB, IIA, IIB, IID. It was missing slide IIC. C. Interview with the laboratory director on May 7, 2025 at 1200 hours in the office was unsure whether there was a slide IIC, but also confirmed the laboratory did not record the number of slides per case.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of laboratory's policies and procedures, reagent log, manufacturer's instructions, observation, Mohs logs, and interview, the laboratory failed to ensure expired reagents and stains were not used in the laboratory. Findings follow. A. Review of the laboratory's policy and procedure titled Quality Assurance, revised 08 /22/2023, under Procedure at 5.2 stated, "... Further tissue is cut and stained, then checked for adequacy for interpretation by the physician; 2) If the stain remains inadequate for interpretation, additional staining solution containers will be emptied and refilled with new, fresh staining solutions. Further tissue is cut and stained, then reviewed for adequacy of interpretation. If necessary, new source containers of staining chemicals are opened and utilized. This process is repeated until the stains are adequate for interpretation by the physician. Make sure that all chemicals are not expired. If it is suspected that a batch of reagents are contaminated or inadequate for staining, contact the manufacturer. All lot numbers and expiration dates are to be recorded in the H&E Linear Stainline Log...." Review of the laboratory's policy and procedure titled Chemical Hygiene/ Chemical Exposure Plan, revised 08/22/2023, at 5.9 stated, "All commercially purchased chemicals/reagents, stock solutions and working solutions must be used within their indicated expiration dates. Discard when stain deteriorates/becomes less than optimal and the stain can not be re-verified as satisfactory by the dermatologist/ surgeon. Once a chemical has deteriorated and it is no longer acceptable for staining, it must be disposed of according to the Safety Data Sheet and local and federal regulations. If the laboratory identifies a problem with the reagent that was used for patient testing (e.g. expired vial, or reagent subjected to unacceptable storage conditions etc.) the laboratory must evaluate the potential impact on patient test results and maintain records of the evaluation and actions taken. 5.10 A record of lot numbers and expiration dates of reagents being used will be logged on the monthly H&E Linear Stainline Log." B. Review of the reagent log documented on the H&E Linear Stainline form revealed Xylene and 95% Reagent may have been used after their expiration dates. The following entries were observed for the chemicals: March 2024/ Eosin/ Lot 159191/ expiration 10/31/2024 March 2024/ Xylene substitute/ Lot 163900/ expiration 01/31/2025 March 2024/ 95% Reagent/ Lot 165427/ expiration 01/31/2025 No subsequent entries made to date, May, 7, 2025. C. During a tour of the laboratory the following reagents/chemicals were observed as opened but were not documented on the H&E Linear Stainline log: Eosin/ Lot 192130/ expiration 02/28/2026/ opened 03/26/2024 Xylene substitute/ lot 217268/ expiration 01/31/2027/ opened 02/25/2025 95% Reagent/ Lot 176393/ expiration 06 /30/2025/ No open date D. No other Xylene substitute entries were made showing Xylene substitute was used beyond the expiration date of 01/31/2025 - 02/25/2025

	(elapsed time 25 days). Review of the Mohs cases from 02/03/2025 - 02/25/2025 showed cases GA25-110 to GA25- 237 were performed over 8 days of testing. It was unclear whether the 95% Reagent was used beyond its expiration because there was no open date on the bottle in the laboratory. Review of the Mohs cases from 02/03 /2025 - 05/06/2025 (elapsed time 92 days) showed cases GA25-110 to GA25-465 were performed over 23 days of testing. E. Interview with the laboratory director on May 7, 2025 at 1145 hours in the office confirmed the findings.