Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0505441	03/29/2023
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 found NOT to be in compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements. The condition not met was: D6168 - 42 C.F.R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, quality control records, patient testing logs, and interview, the laboratory failed to document the results of the internal controls for the Consult Diagnostics hCG (human chorionic gonadotropin) Urine Test Cassette for 125 patients tested from Sept 2022 - March 2023. Findings follow. A. Review of the McKesson Consult Diagnostics hCG Urine Test Cassette, Rev 00 12 /15, under Quality Control stated, "Internal procedural controls are included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result..." B. Attempted review of quality control records showed none available for review. Quality control records were requested on March 23, 2023, at 1630 hours but not provided. C. Review of the Urine Pregnancy Test Log showed from 09/14/2021 - 03/21/2023, 125 patients were tested. D. Interview with the Office Manager on March 23, 2023, at 1630 hours confirmed the internal quality control was not documented.

D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policies and procedures, accuracy assessments, patient testing logs, and interview, the laboratory failed to perform twice a year accuracy assessment of Mohs (clear margins) for 1 of 3 events reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Quality Assurance, revised 09/24/2021, at 5.5 stated, "At least once annually, Mohs surgeons will submit samples of Mohs histopathology slide specimens and maps to either a Mohs surgeon or Dermatopathologist for an in-depth, peer-review-style proficiency testing..." The procedure required annual accuracy assessments versus twice a year accuracy assessment. B. Review of the accuracy assessments from 2021 and 2022 showed 1 event performed in 2022 on 12/20/22. Additional accuracy assessments were requested on March 23 at 1400 hours but not provided. C. Review of the Mohs case log for 2022 showed the laboratory reported 1258 cases, GA22-01 - GA22-1258. D. Interview with the Laboratory Director on March 23 at 1400 hours in the office confirmed one accuracy assessment for Mohs and frozen section biopsies were performed in 2022 because they were told they only had to perform one if they previously had no issues. II. Based on review of the laboratory's policies and procedures, accuracy assessments, patient testing logs, and interview, the laboratory failed to perform twice a year accuracy assessment of frozen section biopsies for the dermatopathology interpretations (diagnosis) for 1 of 3 events reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Quality Assurance, revised 09/24/2021, at 5.6 stated, "At least once annually, samples of frozen section tissue specimen slides, along with the surgeon's diagnostic interpretations, will be sent to another Mohs Surgeon or Dermatopathologist for peer review..." The procedure required annual accuracy assessments versus twice a year accuracy assessment. B. Review of the accuracy assessments from 2021 and 2022 showed 1 event performed in 2022 on 12/20/22. Additional accuracy assessments were requested on March 23 at 1400 hours but not provided. C. Review of the Frozen Section Biopsies log for 2022 showed the laboratory reported 12 frozen section biopsy cases, FGA22-01 - FGA22-12. D. Interview with the Laboratory Director on March 23 at 1400 hours in the office confirmed one accuracy assessment for Mohs and frozen section biopsies were performed in 2022 because they were told they only had to perform one if they previously had no issues.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of educational credentials and interview, the laboratory failed to employ testing personnel that met the educational requirements for two of five testing personnel performing high complexity testing in Histopathology. See D6171.

D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet

	the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of educational credentials and interview, the laboratory failed to employ testing personnel that meet the educational requirements for two of five testing personnel performing high complexity testing in Histopathology. Findings follow. A. Review of education credentials for testing personnel # four and five, on the CMS form 209, showed the following: 1. Testing personnel #4 was lacking a diploma or transcript. A diploma was requested on March 23, 2023 at 1415 hours but not provided. 2. Review of the transcript for Testing personnel #5 showed she was lacking 2 hours in chemistry and 3 hours in either a chemistry, biology, or medical laboratory technician (MLT) course. B. Interview with the Laboratory Director on March 23, 2023 at 1340 hours acknowledged testing personnel #4 & 5 performed inking in Mohs testing. Interview with the Laboratory Director on March 29, 2023 at 1605 via phone confirmed the findings for both testing personnel after a review of the findings.