Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2012104	08/08/2024
Name of Provider or Supplier	**Street Address, City, State**	
Southwest Skin Specialists, Ltd	5010 E Shea Blvd, Ste 130, Scottsdale, AZ	

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
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on lack of corrective action documentation, review of laboratory policy and interview with testing personnel (TP-3), the laboratory failed to follow established corrective action policies and procedures to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. Findings include: 1. The laboratory's established policy states, "Corrective action will be implemented and documented for each significant problem that is found. Quality assessment monitoring, errors and problems will all be documented by the laboratory using the lab SharePoint site Discrepancy and Internal Quality Improvement forms. All corrective actions will be reveiwed after an acceptable amount of time to ensure their effectiveness and to take additional steps if needed." 2. TP-3 interviewed on 8/08/24 at 1:55 PM stated, "There was a specimen that was mislabeled (in the lab) within the last 7 months." 3. The laboratory failed to produce evidence of corrective action documentation for the error indicated above. 4. TP-3 interviewed on 8/08/24 at 2:00 PM confirmed that laboratory failed to document corrective actions as indicated in laboratory policy, including the mislabeling error referenced above. 5. The laboratory's reported annual test volume for the subspecialty of Histopathology is 46,190.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all

	personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on lack of initial training documentation for three out of four testing personnel and interview with testing personnel (TP-3), the laboratory director failed to ensure that all testing personnel receive the appropriate training and demonstrate that they can perform all testing operations reliably and accurately prior to testing patients' specimens. Findings include: 1. No initial training documentation was presented for review for three out of four testing personnel (TP-1, TP-3, TP-4) who began grossing patients' specimens in July 2022, September 2022 and February 2024 (respectively), in the subspecialty of Histopathology. 2. TP-3 interviewed on 8/08/24 at 12:20 PM confirmed the laboratory failed to have documentation of initial training for the testing personnel indicated above. 3. The laboratory's reported annual test volume for the subspecialty of Histopathology is 46,190.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on lack of documentation of a semiannual competency evaluation for 3 of 3 testing personnel and interview with testing personnel (TP-3), the technical supervisor failed to evaluate and document the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Findings include: 1. No evidence of a semiannual competency evaluation was presented for review for three out of three testing personnel (TP-1, TP-2, TP-3) who perform grossing on patients' specimens. 2. TP-3 interviewed on 8/08/24 at 12: 25 PM confirmed the technical supervisor failed to document a semiannual competency evaluation for the testing personnel indicated above.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on lack of documentation of an annual competency evaluation from 2023 and interview with the Testing Personnel (TP-3), the technical supervisor failed to evaluate and document the performance of 1 out of 3 individuals responsible for high complexity testing at least annually after the first year the individual tested patient

	specimens. Findings include: 1. No evidence of an annual competency evaluation was presented for review from 2023 for one out of three testing personnel (TP-3) who performs grossing on patients' specimens. 2. TP-3 interviewed on 8/08/24 at 12:26 PM confirmed the technical supervisor failed to document an annual competency evaluation for the testing personnel indicated above.