Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2046062	02/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Southwest Skin Laboratory Pllc	1688 E Boston St, Ste 101, Gilbert, 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
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the laboratory's pathology test reports for Biopsy interpretations performed in 2019, 2020 and 2021 and interview with the facility personnel, the laboratory failed to include the gross description on three out of three test reports reviewed during the survey. Findings include: 1. The laboratory performs Biopsy interpretations, including the gross description, under the sub-specialty of Histopathology, with an approximate annual test volume of 4,757. 2. During the survey conducted on February 25, 2022, three out of three pathology test reports reviewed [SW19-0970 from 6/9/19, SW20-1181 from 8/7/20 and SW21-0255 from 2/3 /21] failed to include the gross description. 3. The gross description (including weighing, measuring, describing color, specific orientation for diagnostic interpretation, and other characteristics of the tissue) must be included on the pathology test report. 4. The facility personnel confirmed that the biopsy test reports reviewed during the survey failed to include the gross description as described 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 testing personnel competency evaluation documentation and interview with the facility personnel, it was determined that the technical supervisor failed to evaluate and document the performance of one testing personnel at least annually. Findings include: 1. During the survey conducted on February 25, 2022, no documentation of an annual competency assessment from 2019, 2020 and 2021 was presented for review for one testing personnel who performs the gross description on patient specimens. 2. The facility personnel confirmed that no annual competency evaluation was performed during 2019, 2020 and 2021 for the testing personnel indicated above.