Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0505441	03/21/2019
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
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: Review of policies and procedures, laboratory records and interview facility personnel found that the laboratory failed to verify the accuracy of results for DTM, scabies and potassium hydroxide (KOH) direct amount examinations at least twice each year in 2018. The findings included: 1. Review of the policies and procedures found: DTM - "at least twice annually, the laboratory director and testing personnel will complete the proficiency testing form and will demonstrate proficiency regarding the accuracy of interpretation for the presence or absence of growth of yeast for dermatophytes." Scabies Prep : "at least twice annually, the laboratory director and testing personnel will complete the proficiency testing form and will review scabies prep test specimens that each of the other has interpreted, to see if there is any discrepancy in interpretation." potassium hydroxide (KOH) direct amount examinations:"at least twice annually, the laboratory director and testing personnel will complete the proficiency testing form and will review scabies prep test specimens that each of the other has interpreted, to see if there is any discrepancy in interpretation." 2. Review of laboratory records for the verification of accuracy of results found that the laboratory verify the accuracy of DTM, KOH and scabies exam one of two expected times in 2018. Scabies exam were concluded on March 2, 2018 KOH exams were completed on March 16, 2018 and DTM was completed on March 6, 2018. 3. Interview of testing person three listed on the CMS report 209 laboratory personnel report conducted on March 21, 2019 at 9:31 AM confirmed that no other results were available to ensure that the laboratory had verify the accuracy of results a second time in 2018.

D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Observations, review of reagent labels and interview of facility personnel found that the laboratory failed to store the reagents and solutions used for Hematoxylin and Eosin (H and E) staining of tissue specimens as specified by the manufacturer for three of four reagents. The findings included: 1. Observations made during the tour the facility found that the laboratory stored all reagents and solutions used for H and E staining in the cabinet below the sink in the laboratory. 2. Review of the manufacturer's labels found: Stat-Lab EOSIN -Y ALCOHOLIC 0.25% lot 069671 expiration 2020-10-01 - "storage store in a dry, cool and well ventilated place. Keep container closed when not in use. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep in fireproof place." Fisher brand HistoPrep 95% Reagent Alcohol Lot 456246 Expiration 06/2022 - "Storage: store locked up. Store in a well ventilated place. Keep container tightly closed." Stat-Lab XS-3 Xylene Substitute - "storage store in a dry, cool, locked to place. Keep/store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store in a well ventilated place. Keep container tightly closed in a fireproof place." 3. Interview of testing person three on the CMS report 209 laboratory personnel report conducted on March 21, 2019 at 9:43 AM confirmed that the laboratory did not have a fireproof cabinet to store reagents and solutions used for H&E staining of tissue specimens.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Review the CMS 209 laboratory personnel report, laboratory records and interview of facility personnel found that the laboratory director failed to specify in writing the responsibilities and duties for each testing person performing moderate and high complexity testing procedures. The findings included: 1. Review of this CMS 209 laboratory personnel report found that the laboratory designated to testing personnel performing high complexity testing and one testing person performing moderate complexity testing. 2. Review of laboratory records found no written delegation of responsibilities and duties for three of three testing personnel. 3. Interview of testing person three conducted on March 21, 2019 at 10:21 AM confirmed that written delegation of duties were not available for three of three testing personnel.