Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2007503	12/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
S.C. Pathology Services	22214 Evening Star Ct, Santa Clarita, CA	

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: Based on Surveyor review of laboratory's policy & procedure, patient, quality control and test accuracy verification records, and interview with the laboratory director on December 10, 2021 at 12:10 pm, the laboratory failed to verify, at least twice annually, the accuracy of its slide readings for the years of 2020 and 2021. The findings include: 1. The laboratory read dermatopathology slides prepared in another lab. However, the laboratory did not have any documentation showing that it had verified its slide reading accuracy, at least twice annually. Hence, the accuracy of the reported results could not be assured and thus might have harmed patients. 2. The laboratory director on December 10, 2021 at 12:10 pm, affirmed that the laboratory did not verify its dermatopathology slide reading accuracy, twice yearly. 3. The laboratory's testing declaration form, signed by the laboratory Director on 12/10/2021, stated that the laboratory performs 2,500 tests, annually.
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 Surveyor review of laboratory's policy & procedure, patient test records, and interview with the laboratory director on December 10, 2021 at 12:10 pm, the laboratory failed to indicate on its test report the name and address of the laboratory location where the test was performed. The findings include: 1. The laboratory read and interpreted dermatopathology slides at 22214 Evening Star Ct., Santa Clarita, CA 91390 which was prepared in another location at 44215 15th St., W., Ste. 309, Lancaster, CA 93534. The test report was generated in the laboratory at 44215 15th St., W., Ste. 309, Lancaster, CA 93534 where the sample was processed and stained. However, the test report did not have the name and address at where the slides were read, and the results were generated. 2. The laboratory director on December 10, 2021 at 12:10 pm, affirmed that the test report did not have the name and address of the laboratory at where the results were generated. 3. The laboratory's testing declaration form, signed by the laboratory Director on 12/10/2021, stated that the laboratory performs 2,500 tests, annually.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, patient, quality control and test accuracy verification records, and interview with the laboratory director on December 10, 2021 at 12:10 pm, it was determined that the laboratory Director failed to assure compliance with the applicable regulation. See D5217 and D5805.