Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 05D0603818	**(X3) Date Survey Completed** 03/23/2022
Name of Provider or Supplier Bruce R Carlton Md Inc	**Street Address, City, State** 2101 Vale Rd, Ste 301, San Pablo, 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**
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 patients test records and interview with the laboratory personnel on March 23, 2022, at 11:40 am, the laboratory failed to indicate the report date on the test report. The findings include: 1. The laboratory performed skin biopsies and later read the biopsied tissue slides that were prepared at the APMG laboratory. The laboratory generated the final test report after microscopic slide reading, however, did not indicate the report date on the test report, instead it indicated the service date (biopsy date) on the test report. The date of the test report is the date results were generated as a final report. On the other hand, the laboratory sent out the slides to another laboratory to verify its reading accuracy. Since the laboratory did not indicate the report date on the final test report, it can not be verified if the laboratory generated the report before sending out to the other laboratory or after receiving the results from the other laboratory. Therefore, the slide reading accuracy can not be assured. 2. The laboratory personnel on March 23, 2022, at 11:40 am, affirmed that the laboratory did not indicate the report date on the test report. 3. The laboratory's testing declaration form, signed by the laboratory director on 3/11/2022, stated that the laboratory performs approximately 173 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 patients test records and interview with the laboratory personnel on March 23, 2022, at 11:40 am, the laboratory director failed to ensure the laboratory's compliance with the CLIA regulations. The findings include: See D5805.