Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0940149	02/14/2020
Name of Provider or Supplier	**Street Address, City, State**	
Robert B Seltzer Md	960 E Green St Ste 108, Pasadena, 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
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 Surveyor review of laboratory's policy & procedure, patient test records, quality assessment documents and interview with the laboratory staff, the laboratory failed to have a policy and procedure for any corrective actions necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. The findings include: a. The laboratory did not have any corrective actions policy and procedure in place in order to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. b. The laboratory staff, on 2/14/2020 at 12:00 pm, affirmed that the laboratory did not have any necessary corrective actions policies and procedures. c. The laboratory's testing declaration form, signed by the laboratory Director on 2/14/2020, stated that the laboratory performs 1,500 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 staff, 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: a. The laboratory sends out the skin biopsy tissue samples to another lab for gross descriptions, slide preparations and microscopic readings. However, the laboratory's test report did not indicate the name and address of the other lab where the test was performed. b. The laboratory staff, on 2/14/2020 at 12:10 pm, affirmed that the test was performed at another lab (ASL lab) but the laboratory's test report did not indicate ASL lab. c. The laboratory's testing declaration form, signed by the laboratory Director on 2/14/2020, stated that the laboratory performs 1,500 tests, annually.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, patient & quality control test records, and interview with the Laboratory staff, it was determined that the laboratory director failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. See D5779.