Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0591209	08/29/2019
Name of Provider or Supplier	**Street Address, City, State**	
Paul D Hartman Md	1860 El Camino Real Ste 401, Burlingame, 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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of patient testing logs, the laboratory's quality assessment (QA) policy/procedures and interview with the laboratory director on August 29, 2019, the laboratory failed to follow established written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. The findings included: a. During a random review of patient testing logs, and slide review for the period of 01/01/ 2018 through 08/29/2019, the laboratory failed to document review of one patient case twice annually as the laboratory's QA policy/procedure had established. b. The laboratory QA policy and procedure states "The Medical Director of the lab will review one case when needed at random twice a year to check all the information pertaining to the patient's specimen preparation, collection and preservation. For the following years, (2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019) the laboratory had documentation of just one patient case review for each of the years. c. During the random sampling of nine (9) patients tested during the period of 01/01/2018 to 08/09/ 2019, the laboratory failed to note and correct the testing date for one (1) patient slide collection date which had been recorded incorrectly . Date Patient 12/11/2018: 18-8010 Date labeled as collected on 12/12/2018 (two patients tested on same date). d. The laboratory director and staff confirmed on August 29, 2019 at approximately 11:15 a.m., the failure to follow established QA policy's, and the failure to identify and correct the labeling of (1) out of (1) patient slides reviewed on 12/11/2018, and the failure to retain specimen slides as required in 493.1105(a)(7)

	(B). see D5603. e. The laboratory reports performing approximately 564 histopathology patient slide reviews annually.
D5603	HISTOPATHOLOGY CFR(s): 493.1273(b)(f) (b) The laboratory must retain stained slides, specimen blocks, and tissue remnants as specified in 493.1105. The remnants of tissue specimens must be maintained in a manner that ensures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under 493.1449(b), (l), or (m). (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's histopathology patient logs and a random selection of of nine (9) patient slides from 01/09/2018 to 08/29/2019, the laboratory failed to retain stained slides, as specified in 493.1105. The findings included: a. During the random sampling of nine (9) patients tested during the period of 01/01 /2018 to 08/09/ 2019, the laboratory failed to retain specimen slides as required in 493. 1105(a)(7)(B) for one (1) out of (9) patient slides on the day of survey. Date Patient 05 /02/2018: 18-3272 Slide missing (five patients were tested on same date of patient). b. The laboratory documents sending the slide out for verification on 05/02/2018 to another laboratory. c. The laboratory director and staff had no documentation as to the location or receipt of the slide from the reference laboratory. d. The laboratory director confirmed by interview on August 29,2019 at approximately 11:15 a.m. the failure to ensure that the slide was received back from the reference laboratory. e. The laboratory reports performing approximately 568 dermatopathology slide reviews annually.