Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0968423	06/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Natural Image Lenore Sikorski Md	25500 Rancho Niguel Rd, Ste 290, Laguna Niguel, 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 review of the laboratory's evaluation of proficiency testing performance (EP) records, and interview with the laboratory personnel, it was determined that the laboratory failed to verify the accuracy of Mohs surgery histopathology testing it performed that is not included in subpart I of 42 C.F.R. part 493. The findings included: a. The laboratory performed Mohs surgery which includes histopathology examination for the removal of the cancer skin tissues. b. The histopathological testing is not listed in the CLIA regulations' subpart I. c. To ensure the accuracy of this histopathological examination, the laboratory must perform evaluation of proficiency testing performance at least twice annually by peer review or split samples. d. The laboratory failed to perform EP in the year of 2019 and only once on 12/29/2020. d. The laboratory performed Mohs surgery including histopathological slides examination in approximately 17 patient cases monthly.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's written policy and procedure (P&P), Verification of Test Accuracy, review of the laboratory's evaluation of proficiency testing performance (EP) records, and interview with the laboratory personnel, it was determined that the laboratory failed to follow its written P&P and failed to perform EP at least twice annually. The findings included: a. The laboratory failed to follow its P&P, Verification of Test Accuracy to perform "Peer Review Policy of Lenore Sikorski MD". b. The Verification of Test Accuracy under title as [MOHS HISTOPATHOLOGY "PEER REVIEW" POLICY], stated: "It is the Peer Review Policy of Lenore Sikorski MD to send a minimum of one Mohs case, two times per year, for review/blind testing by a Board Certified Dermatologist or Pathologist". c. The laboratory sent slides on 12/29/2020 to a qualified Board Certified Dermatologist or Pathologist for peer review only once in 2020 but did nothing in the year of 2019. d. The laboratory affirmed (6/8/21 @11:45 am) that the laboratory mis-performed the peer review for 2019 and only one time for 2020.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure (P&P) for Verification of Test Accuracy, and review of the evaluation of proficiency testing performance records, and interview with the laboratory personnel, it was determined that the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for Mohs surgery's histopathological examination system. The findings included: a The laboratory performed Mohs surgery including histopathological examination for the removal of skin tissues. b. The laboratory failed to perform evaluation of proficiency testing performance for histopathological testing at least twice annually to ensure the accuracy of the testing system, see D-5217. c. The laboratory failed to follow its written policy and procedure (P&P) for Verification of Test Accuracy, see D-5791.