Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0932547	08/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Ocean Skin And Vein Institute Inc	13420 Newport Ave Ste G, Tustin, 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
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of lack the laboratory's records, and interview with the laboratory staff, it was determined that the laboratory failed to retain all laboratory quality system assessment records for at least 2 years. The findings included: a. The laboratory performed Mohs surgery onsite. b. Interview with the laboratory staff at 8/9 /2022 @ 10:10 am onsite, no laboratory records including but not limited to evaluation of proficiency testing performance/peer review were available onsite. c. The laboratory failed to retain laboratory quality system assessment records for at least 2 years
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory Mohs maps, and interview with the laboratory staff, it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the post analytic systems The findings included: a. Review of 6 patient Mohs maps as follows: ACCESSION NUMBER = AN, tissue Site = ST L = left, R =

	right DATE AN ST 1) 2/21/22 S22-000617 L Nose 2) 2/21/22 S22-000126 L post scalp 3) 5/23/22 Blank L lateral forehead 4) 5/23/22S22-0007(?)42L cheek-infraorbital 5) 7/18/22 S22-002801 R lower leg-anterior 6) 8/8/22 S22-003407 L inferior eyelid b. One of 6 Mohs maps, the laboratory failed to provide a slide account number in Mohs map, 3) 5/23/22 with Left lateral forehead, to ensure the consistency of the patient-specific data was accurately and reliably recorded or transcribed to Mohs map.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory records, Mohs maps, and interview with the laboratory staff, it was determined that the laboratory director failed to ensure and maintain the quality control programs and the quality of laboratory services provided. The findings included: a. The laboratory director failed to ensure and maintain the quality control programs and quality of laboratory services provided. b. The laboratory failed to retain laboratory quality system assessment records for at least 2 years see D-3039. c. One of 6 Mohs maps, the laboratory failed to provide a slide account number in Mohs map, and to ensure the consistency of the patient-specific data was accurately and reliably recorded or transcribed to each Mohs map, see D-5891.