Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 05D0932547	**(X3) Date Survey Completed** 05/12/2021
Name of Provider or Supplier Ocean Skin And Vein Institute Inc	**Street Address, City, State** 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**
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 onsite survey on May 12, 2021 at Noon, including observation of Mohs slides, review of laboratory records, the lack of 2020 laboratory records and documents, and interview with laboratory personnel, it was determined that in 2020, the laboratory failed to at least twice annually verify the accuracy of Mohs procedures. Findings included: 1. Laboratory records documented four Testing persons performed Mohs procedures in 2020. 2. A laboratory policy stated that the accuracy of Mohs procedures are verified at least twice annually. 3. The laboratory failed to provide for review documents that at least twice annually verified the accuracy of the Mohs procedures performed by each Testing person in 2020, including 6 out of 6 as follows: Date ID Testing person ---------- 2/17/20 JP - R shin SC 6/30/20 AP - R dorsal wrist DS 8/31/20 MM - L ant. lower leg prox AL 10/13/20 JP - R nose ala NT 11/09/20 HW - L chin AL 12/15/20 KH - R ear helix NT 4. A laboratory person affirmed (5/12/21 at Noon) the laboratory failed to maintain the policy for 2020. 5. The reliability and quality of the Mohs procedures performed in 2020 could not be assured when the laboratory failed to at least twice annually verify accuracy. Approximately 200 Mohs procedures were performed by the four Testing persons in 2020.
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 observation of Mohs slides, review of EMR and laboratory records for Mohs procedures in 2020 - 2021 that revealed inconsistencies, and interview with a laboratory person on 5/12/21 at Noon, it was determined that the laboratory failed to establish and follow written policy/procedure to monitor, assess, identify, and correct problems in postanalytic systems. Findings included: 1. Mohs slides and maps documented 2 Stages were performed for each procedure, as follows: Date ID EMR 6 /30/20 AP - R dorsal wrist (a) 1/18/21 DR - R buccal cheek (b) 3/01/21 JD - L temple (b) 4/12/21 EH - R cheek infraorbital (b) 2. The patient's electronic medical record stated: a) "Total # of Mohs Stages: 1" b) For these three cases -- instead of stating "Total # of Mohs Stages: 2", the EMR stated 1 Stage, twice. For example: "Mohs: Right Cheek - Buccal: 1.3 x 1.1 cm. Total #Mohs Stages: 1", then "Mohs: Right Cheek - Buccal: 1.5 x 1.2 cm. Total # of Mohs Stages: 1". 3. The laboratory person affirmed (5/12/21 at Noon) the EMR were irregular and the failure to have an established internal audit to monitor, assess, identify, and correct problems post-analytically. 4. The reliability and quality of the EMR system could not be assured when the laboratory failed to establish and follow a written policy to perform internal audits post-analytically to monitor, assess, identify, and correct problems.