Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2176553	09/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Nikko Dermatology	27150 Us-290 Suite 100, Cypress, TX	

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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a random review of patient's test records, and staff interview, it was revealed the laboratory failed to retain the Mohs maps for four of seven patients reviewed between February 2020 and August 2021. Findings include: 1. A review of the laboratory's policy titled 'Test Procedures' revealed the following: "Documentation required for each test performed: - Laboratory Test Log - Test Requisition - Mohs Map - Pathology Report - Operative Report Completing and retaining all documentation is not only required by CLIA, but is also necessary for insurance audits." 2. A random review of patient test records from February 2020 to August 2021 revealed the following four patient's records did not include the Mohs map: Case number: M20-012 Procedure date: 2/26/20 Case number: M20-015 Procedure date: 4/15/20 Case number: M20-018 Procedure date: 5 /22/20 Case number: M20-030 Procedure date: 10/23/20 3. An interview with testing person #3 (as indicated on the CMS 209 form) on 9/21/21 at 9:50 a.m. in the nurse's station, after review of the records, confirmed the above findings.

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 a review of the laboratory's accuracy assessment records from 2020 and staff interview, it was revealed the laboratory failed to have documentation of performing two of two twice annual accuracy assessments for Mohs slide interpretations in 2020. Findings include: 1. A review of the laboratory's accuracy assessment records revealed the laboratory failed to have documentation of verifying the accuracy of the Mohs slides at least twice annually in 2020. 2. An interview with testing person #3 (as indicated on the CMS 209 form) on 9/21/21 at 9:00 a.m. in the nurse's station, after review of the records, confirmed the above findings.