Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2144906	05/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
Skin Solutions Dermatology	800 Saundersville Rd, Hendersonville, TN	

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
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 review of laboratory records, patient test results, and staff interview, the laboratory failed to retain analytic system records including hematoxylin and eosin (H and E) stain quality control (QC) logs, daily patient logs, reagent logs, maintenance logs, temperature logs, and quality assurance (QA) for patient comparison records for MOHS testing for a period of two years in 2022 and 2023. The findings include: 1. Review of laboratory records including H and E control logs, daily patient logs, reagent logs, maintenance logs, temperature logs, QA logs (patient comparison with outside pathology) revealed the following: A. Lack of all records from January 2022 through September 2022 (last patient slide 09/08/2022). B. Lack of reagent logs, and maintenance logs, from 02/09/2023 through 04/12/2023. C. Lack of H and E quality control logs from 02/28/2023 through 04/12/2023. 2. Review of patient test results from randomly selected dates revealed MOHS testing was performed on patients in 2022 and 2023 as follows: 04/07/2022 patient MH22-092 05/19/2022 patient MH22-122 06/16/2022 patient MH22-145 09/08/2022 patient MH22-207 02/09/2023 patient MH23-001 03/02/2023 patient MH23-033 3. Interview on 05/22/2023 at 1:00 pm with the Chief Clinical Officer and laboratory personnel (non-testing) confirmed the laboratory failed to maintain analytic system records for two years in 2022 and 2023.
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 laboratory records, laboratory policy, and staff interview, the laboratory failed to verify accuracy of the histopathology MOHS testing procedure twice per year in 2022 (one of three years reviewed). The findings include: 1. Review of laboratory records revealed no documentation of verification of accuracy for the histopathology MOHS testing procedure performed in 2022. 2. Review of the laboratory policy titled " Quality Assurance Manual" revealed "Any test performed in the laboratory for which proficiency testing is not available will be verified at least twice a year, and the results will be reviewed by the Laboratory Director." 3. Interview on 05/22/2023 at 1:00 pm with the Chief Clinical Officer and laboratory personnel (non-testing) confirmed the laboratory did not verify the accuracy of histopathology MOHS testing procedure in 2022.
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 random review of histopathology slides and staff interview the laboratory failed to retain stained histopathology daily quality control slides for 10 years (six of seven dates reviewed) for dates when MOHS patient testing was performed in 2021, 2022, and 2023. The findings include: 1. Random review of stained histopathology slides on 05/22/2023 of the following dates revealed daily quality control slides for 2021, 2022, and 2023 were not retained with patient slides. 11/16/2021 patient reported MH21-285 04/07/2022 patient reported MH22-092 05/19/2022 patient reported MH22-122 06/16/2022 patient reported MH22-145 09/08/2022 pateint reported MH22-207 02/09/2023 patient reported MH23-001 2. Interview with the Chief Clinical officer on 05/22/2023 at 1:00 pm confirmed the laboratory failed to retain the stained daily quality control slides for histopathology MOHS testing for 10 years.
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 laboratory Quality Assurance (QA) policy, lack of records available, and staff interview, the laboratory failed to follow it's own QA policy in 2021, 2022,

	and 2023 (19 of 21 total months reviewed) when patient testing for MOHS procedures were performed. The findings include: 1. Review of the laboratory policy titled "Quality Assurance Manual" revealed the following; "The Laboratory Director reviews quality control charts and logs on at least a monthly basis." "Any test performed in the laboratory for which proficiency testing is not available will be verified at least twice a year, and the results will be reviewed by the Laboratory Director." "...all quality assurance records be maintained for a period of two years.." 2. Request on 05/22/2023 for QA records revealed the documents were not available for 2021 (May through December), 2022 (January through September), February 2023, and March 2023. 3. Interview on 05/22/2023 at 1:00 pm with the Chief Clinical Officer and laboratory personnel (non-testing) confirmed the laboratory failed to follow it's own policy for Quality Assurance in 2021, 2022, and 2023.