Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0960403	10/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Grafton Dermatology & Cosmetic Surgery	327 Bayou Gardens Blvd, Houma, LA	

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	A Recertification survey was performed on October 17, 2023 at Grafton Dermatology & Cosmetic Surgery, CLIA ID # 19D0960403. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and twice a year verification records as well as interview with laboratory personnel, the laboratory failed to follow their quality assessment policy for twice a year verification of the accuracy of Moh's (Histopathology) testing for three (3) of three (3) events reviewed. Findings: 1. Review of the laboratory's "Proficiency Testing" policy revealed "Semi-annually, dated 6 months apart on each case, the tech or Risk Manager will send two cases containing the original slides, label it with only the surgical case number, and send it our {sic} for a microscopic examination by a Board Certified Dermatopathologist." 2. Review of the laboratory's 2022 Moh's proficiency testing records revealed the laboratory sent two (2) cases from February 2022 and two (2) cases from August 2022 out for verification of accuracy, but the four cases were not sent for verification until January 2023. 3. In interview on October 17, 2023 at 10:57 a.m., the Lab Supervisor stated for 2022 she pulled two (2) cases from the first half of the year and two (2) cases from the second half of the year and sent them out together in January 2023 to the outside Dermatopathologist for verification. 4. Further review of the laboratory's 2022 proficiency testing records revealed the cases were not

	reviewed by the outside Dermatopathologist until September 2023. 5. Review of the laboratory's 2023 Moh's proficiency testing records revealed the laboratory did not send cases for verification for the first half 2023. 6. In interview on October 17, 2023 at 10:57 a.m., the Lab Supervisor stated she was waiting to send four (4) cases from 2023 together. She confirmed she did not send the cases semi-annually for 2022 and the first half of 2023.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on review of patient test records and interview with personnel, the laboratory failed to ensure the correct patient case number was recorded on patient test results for one (1) of eight (8) patients reviewed. 1. Review of the laboratory's patient logs, slides, and Moh's maps revealed the following one (1) patient had an incorrect case number recorded on the Moh's map: June 29, 2022 - Case M22-151 recorded in patient log book and on slides. Moh's map case number recorded as M22-155 2. In interview on October 17, 2023 at 11:41 a.m., the Lab Supervisor confirmed the case number on the Moh's map was incorrect. She confirmed the Moh's map case number did not match the case number in the log book and on the slides.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's patient test records and quality assurance records, as well as interview with personnel, the laboratory failed to ensure the quality assessment monitors in place identified issues within the postanalytic system. Findings: 1. Review of the laboratory's patient test records for Moh's testing revealed the case number on the Moh's map was not correct for (1) of eight (8) patients reviewed. Refer to D5801. 2. Review of the laboratory's "Monthly Patient Quality Assurance Checklist" revealed the laboratory performed the following postanalytic checks on one case per month: - Slides were reviewed by surgeon - Map and slides were properly reported by surgeon 3. In interview on October 17, 2023 at 11:41 a.m., the Lab Supervisor confirmed the laboratory's current quality assessment monitors did not identify the issue with patient case number on the Moh's map.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Findings: 1. The laboratory failed to follow their quality assessment policy for twice a year verification of the accuracy of Moh's (Histopathology) testing for three (3) of three (3) events reviewed. Refer to D5291. 2. The laboratory failed to ensure the quality assessment monitors in place identified issues within the postanalytic system. Refer to D5893.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure final reports included required pertinent information. Refer to D5821.