Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0960403	02/08/2022
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 February 8, 2022 at Grafton Dermatology and Cosmetic Surgery, CLIA ID # 19D0960403. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on observation by surveyor, review of test logs, and interview with personnel, the laboratory failed to report sixteen (16) SARS COV-2 results to the state as required. Findings: 1. Observation by surveyor during the laboratory tour on February 8, 2022 at 10:15 am revealed the labotory utilized Quidel Quickvue and Celltrion Distrust COVID-19 Antigen Rapid test kits. 2. In interview on February 8, 2022 at 11: 00 am, the Office Manager stated the laboratory utilizes the identified COVID tests for employees. The Office Manager further stated the results are not reported to the state. 3. In further interview on February 8, 2022 at 11:00 am, the Office Manager stated in 2021 and 2022 a total of sixteen (16) tests were performed.
D5401	PROCEDURE MANUAL

	CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policies, proficiency testing records, and interview with personnel, the laboratory failed to establish and follow policy for twice a year verification of the accuracy of Moh's (Histopathology) testing for one (1) of two (2) years reviewed. Findings: 1. Review of the laboratory's "Proficiency Testing Mohs Micrographic Surgery Skin Specimens" policy revealed "Semi-annually, 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 "Quality Assurance Program" under "Histopathology" section revealed "Proficiency testing is required for this service provided by our physician. It is suggested to submit 3 cases every 6 months to an outside Pathologist." 3. Review of the Mohs proficiency testing records for 2020 and 2021 revealed in 2021 the laboratory submitted one (1) case from February and one (1) from March 2021, not semi-annually per laboratory policy. 4. In interview on February 8, 2022 at 12:06 pm, the Medical Assistant stated she thought as long as two were done a year that was acceptable. The Medical Assistant confirmed the proficiency testing for Mohs was not performed on cases semi-annually. II. Based on review of the laboratory's policies, test menu, and interview with personnel, the laboratory failed to establish written procedures for reporting SARS COV-2 results to the state. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not have written procedures for reporting SARS COV-2 results, to include, but not limited to who is responsible, and frequency of reporting to the state. 2. In interview on February 8, 2022 at 11:00 am, the Medical Assistant confirmed the laboratory did not have a written procedure for the reporting of positive and negative SARS COV-2 results to the state. 3. Review of the laboratory's test menu revealed the laboratory performs twenty five (25) SARS COV-2 tests annually.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures and interview with personnel, the laboratory failed to have the procedures approved and signed by the Laboratory Director. Findings: 1. Review of the laboratory's policies and procedures revealed the Laboratory Director did not approve/sign the procedures. 2. In intereview on February 8, 2022 at 12:40 pm, the Medical Assistant stated the policy manual was updated and confirmed the Laboratory Director did not sign the policy book.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

	The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of manufacturer storage requirements, and interview with personnel, the laboratory failed to monitor the room temperature of the office where SARS COV-2 test kits were stored per manufacturer requirements. Findings: 1. Observation by surveyor during the laboratory tour on February 8, 2022 at 10:50 am revealed the laboratory did not monitor the office where the following supplies were stored: a) Quidel Quickvue SARS Antigen test kits b) Celltrion Diatrust COVID-19 Antigen Rapid test kits 2. Review of the manufacturer storage requirements for the identified test kits revealed the following: a) Quidel Quickvue SARS Antigen test kits: storage requirement 15-30 degrees Celsius b) Celltrion Diatrust COVID-19 Antigen Rapid test kits: 2-30 degrees Celsius 3. In interview on February 8, 2022 at 10:55 am, the Office Manager stated the laboratory does not monitor the temperature of the office where the identified supplies are stored.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation by surveyor and interview with personnel, the laboratory failed to ensure laboratory supplies did not exceed their expiration dates. Findings: 1. Observation by surveyor during laboratory tour on February 8, 2022 at 10:50 am revealed the following expired items: a) Cancer Diagnostics Tissue Marking Dye, Orange, Lot 9255, Expiration date: 2021-09-30, Quantity: One (1) bottle b) Cancer Diagnostics Tissue Marking Dye, Yellow, Lot 9252, Expiration date: 2021-09-30, Quantity: one (1) bottle c) Cancer Diagnostics Tissue Marking Dye, Red, Lot 9249, Expiration date: 2021-09-30, Quantity: one (1) bottle d) Cancer Diagnostics Tissue Marking Dye, Violet, Lot 9246, Expiration date: 2021-09-30, Quantity: one (1) bottle e) Cancer Diagnostics Tissue Marking Dye, Green, Lot 9254, Expiration date: 2021-09-30, Quantity: one (1) bottle f) Cancer Diagnostics Tissue Marking Dye, Blue, Lot 9252, Expiration date: 2021-09-30, Quantity: one (1) bottle g) Cancer Diagnostics Tissue Marking Dye, Black, Lot 9253, Expiration date: 2021-09-30, Quantity: one (1) bottle 2. In interview on February 8, 2022 at 11:16 am. the Medical Assistant confirmed the identified marking dyes were expired.
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease

	nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 form, quality control records, policies and procedures, test menu, and interview with personnel, the laboratory failed to ensure testing personnel documented the stain quality for Hematoxylin and Eosin (H&E) stains for six (6) of eight (8) months reviewed. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the Laboratory Director serves as the Testing Personnel for Mohs (Histopathology). 2. Review of the laboratory's "Quality Control Policies and Documentation" revealed "stains are checked each day for intended reactivity. A control slide is prepared and approved by the physician prior to any testing. The approval is recorded on a QC log." 3. Review of the laboratory's quality control logs for random selection of eight (8) months revealed the laboratory's testing personnel did not document the stain quality for the following six (6) months reviewed: September 2020 December 2020 February 2021 July 2021 November 2021 January 2022 4. Further review of the laboratory's quality control logs revealed the Laboratory Director discontinued documentation of his review of the slides stain quality in September 2020. 5. In interview on February 8, 2022 at 12:40 pm, the Medical Assistant confirmed the Laboratory Director did not document his review of stain quality for the identified months. The Medical Assistant stated it appeared the Laboratory Director stopped documenting his review in 2020. 6. Review of the laboratory's test menu revealed the laboratory performs 1258 Mohs (Histopathology) tests annually.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6054.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

	director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5407.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of policies, personnel records, and interview with personnel, the Technical Consultant failed to evaluate competency annually in 2020 for one (1) of six (6) personnel and six (6) of six (6) personnel in 2021. Findings: 1. Review of the laboratory's policies and personnel records revealed a "KOH Yearly Evaluations by Laboratory Director" form is utilized. 2. Review of personnel records revealed annual KOH competency assessments were not performed for the following: 2020: a) Testing Personnel 2 2021: a) Laboratory Director b) Testing Personnel 1 c) Testing Personnel 2 d) Testing Personnel 3 e) Testing Personnel 4 f) Testing Personnel 5 3. In interview on February 8, 2022 at 12:11 pm, the Medical Assistant stated she did not find the 2021 KOH yearly evaluations for Testing Personnel.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel were performing test methods as required. 1. The laboratory failed to monitor the room temperature of the office where SARS COV-2 test kits were stored per manufacturer requirements. Refer to D5413. 2. The laboratory failed to ensure laboratory supplies did not exceed their expiration dates. Refer to D5417.
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 record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Refer to D5609.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. the laboratory failed to establish and follow policy for twice a year verification of the accuracy of Moh's (Histopathology) testing for one (1) of two (2) years reviewed. Refer to D5401 I. 2. The laboratory failed to establish written procedures for reporting SARS COV-2 results to the state. Refer to D5401 II. 3. The laboratory failed to have the procedures approved and signed by the Laboratory Director. Refer to D5407.