Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0960403	01/24/2018
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 Certification Survey was conducted on January 24, 2018 at Grafton Dermatology and Cosmetic Surgery-CLIA ID # 19D0960403. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
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: ***REPEAT DEFICIENCY from survey November 11, 2015*** Based on observation, record review and interview with personnel, the laboratory failed to document the temperature of the Cryostats for three (3) of seven (7) days reviewed. Findings: 1. Observation by surveyor during laboratory tour on January 24, 2018 revealed the laboratory utilizes the following Cryostats: Leica CM 1510S Leica Avantik QS 11 2. Review of the laboratory's 2017 Cryostat temperature logs revealed the laboratory did not document the temperature in December 2017 for the following three (3) of seven (7) days: December 18, 2017 December 20, 2017 December 22, 2017 3. In interview on January 24, 2018 at 11:30 am, Personnel 7 stated she did not know how documentation after December 15, 2017 was missed. Personnel 7 confirmed the laboratory did not document the Cryostat temperatures for the identified dates.

D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to document the performance of a control slide for Hematoxylin and Eosin (H&E) Staining utilized for Histopathology slides for three (3) of seven (7) days reviewed. Findings: 1. Review of the laboratory's "Stain Maintenance" policy revealed "A QC worksheet is documented daily on the stain quality and any corrections or changes made." 2. Review of H&E quality control records and MOHS patient logs for December 2017 revealed the laboratory did not document the performance of H&E quality control (QC) for the following three (3) days involving seventeen (17) patients: December 18, 2017: Patients 1 -4 December 20, 2017: Patients 5-12 December 22, 2017: Patients 13-17 3. In interview on January 24, 2018 at 11:30 am, Personnel 7 stated she reviews the books and did not know how documentation after December 15, 2017 was missed. Personnel 7 confirmed the laboratory did not document H&E QC performance for the identified dates.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic 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 analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory's Quality Assurance monitors failed to identify and correct quality issues. Findings: 1. Review of the laboratory's temperature logs and quality control records revealed the laboratory's QA monitors did not identify the following issues: a) The laboratory failed to document the temperature of the Cryostats for three (3) of seven (7) days reviewed. Refer to D5413. b) The laboratory failed to document the performance of a control slide for Hematoxylin and Eosin (H&E) Staining utilized for Histopathology slides for three (3) of seven (7) days reviewed. Refer to D5601. 2. In interview on January 24, 2018 at 11:40 am, Personnel 6 stated the laboratory has checks in place to identify issues. Personnel 6 confirmed the laboratory did not identify the issues found.
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: ***REPEAT DEFICIENCY from survey November 11, 2015*** Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Refer to D5413.
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 quality control programs are maintained in Histopathology. Refer to D5601.
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: ***REPEAT DEFICIENCY from survey November 11, 2015*** Based on observation, record review and interview with laboratory personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5793.