Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D1025374	06/27/2022
Name of Provider or Supplier	**Street Address, City, State**	
Grafton Dermatology	1253 Canal Boulevard, Thibodaux, 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 June 27, 2022 at Grafton Dermatology, CLIA ID # 19D1025374. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 the laboratory's policies, test menu, records, and interview with personnel, the laboratory failed to verify the accuracy of Mycology testing at least twice annually in 2021. Findings: 1. Review of the laboratory's "Potassium-Hydroxide Prep (KOH) & Scabies Prep" policy under "Proficiency Testing" section revealed the following: a) "A form is provided for each provider to complete twice a year." b) "The Laboratory Supervisor is responsible for the policy to be completed twice a year." 2. Review of the laboratory's 2021 "Quality Testing for KOH preps in office" records revealed the Testing Personnel did not space out the performance of the verification of accuracy procedures. The records revealed the following : a) Two cases on October 27, 2021 for the Laboratory Director b) Two cases (one August 12, 2021 and other October 21, 2021) for Testing Personnel 1 c) Two cases (both cases from May 2021) for Testing Personnel 3 were d) Two cases (one June 30, 2021 and other August 23, 2021) for Testing Personnel 4 3. In interview on June 27, 2022 at 11:00 am, the Medical Assistant stated one (1) KOH case is reviewed semi-annually for each personnel reading KOH preps. The Medical Assistant confirmed the laboratory was not performing the KOH twice a year verifications semi-annually as she thought.
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, patient logs, and interview with personnel, the laboratory failed to follow their established procedure for one (1) of seven (7) random selection of patients reviewed for Histopathology. Findings: 1. Review of the laboratory's "Laboratory Procedure" revealed "The specimen is given an accession number and logged in the mohs logbook. Patient name, date, site, diagnosis, stage or layer and number of quadrants per specimen layer." 2. Review of random selection of patients revealed the laboratory did not document the surgical site, diagnosis and stage/number of sections for Case # T22-11. 3. In interview on June 27, 2022 at 11:00 am, the Medical Assistant confirmed the laboratory did not document the identified information per laboratory policy for Case # T22-11. II. Based on review of the laboratory's policies, records, and interview with personnel, the laboratory failed to follow their established procedure for Mycology testing. Findings: 1. Review of the laboratory's "KOH examination"policy revealed "All KOH will be logged in the KOH log book with the patient name and the results will be logged after review. All results are then logged and or dictated in the patient chart." 2. Review of the laboratory's records revealed the laboratory did not have a log book for patients that had potassium hydroxide (KOH) testing performed. 3. In interview on June 27, 2022 at 11:00 am, the Medical Assistant stated the laboratory does not have a KOH prep log book. The Medical Assistant stated the laboratory has a new policy. The laboratory's new policy was not included in the laboratory's policies and procedures manual.
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 policies/procedures and interview with personnel, the laboratory failed to ensure policies and procedures were approved annually per laboratory policy. Findings: 1. Review of the laboratory's "Formal Policy Statement" policy under "Review Policy" section revealed "This procedure manual is reviewed by the Laboratory Director annually and at other times as required by major changes in procedure or other circumstances affecting laboratory performance of the test." 2. Further review of the laboratory's procedures revealed the Laboratory Director did not review the laboratory's policies for 2021. 3. In interview on June 27, 2022 at 11:00 am, the Medical Assistant confirmed the Laboratory Director did not review/sign annually per laboratory policy.
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 manufacturers' requirements, and interview with personnel, the laboratory failed to monitor the room temperature where supplies and test kits are stored. Findings: 1. Observation by surveyor during the laboratory tour on June 27, 2022 at 10:34 am revealed the following items were stored in an area without room temperature monitoring: a) Medline HCG kits, Quantity: one (1) box b) Vacuette blood collection tubes: K2EDTA, Quantity: one (1) pack; Serum clot activator, Quantity: two (2) packs c) BD Vacutainer blood collection tubes, Quantity: one (1) pack 2. Review of the manufacturers' requirements revealed the following temperature requirements: a) Medline HCG: 4-30 degrees Celsius b) Vacuette blood collection tubes: 4-25 degrees Celsius c) BD Vacutainer blood collection tubes: 4-25 degrees Celsius 3. In interview on June 27, 2022 at 10:48 am, the Medical Assistant confirmed the identified items were stored in an area without monitoring of the room temperature.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, maintenance logs, and interview with personnel, the laboratory failed to perform annual preventative maintenance for 2021 as required. Findings: 1. Review of the laboratory's policies and maintenance logs revealed the following: a) Microscope: "Preventative maintenance needs to be completed and documented yearly" b) Cryostat: "According to manufacturer's instructions, lab personnel should oil weekly, grease monthly and/or perform necessary maintenance. There is a service contract on the machines for yearly preventative maintenance. Preventative maintenance and grounding checks are done and documented annually." c) Fume Hood/Air Vent: Grounding to be checked and documented annually." 2. Further review of the laboratory's 2021 maintenance logs revealed the laboratory did not have documented performance of annual preventative maintenance for the following: a) Microscope b) Cryostat c) Fume Hood/Air Vent 3. In interview on June 27, 2022 at 11:43 am, the Medical Assistant confirmed the laboratory did not have annual preventative maintenance performed in 2021 for the identified laboratory equipment.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) 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 performed test methods as required. Findings: 1. The laboratory failed to verify the accuracy of Mycology testing at least twice annually in 2021. Refer to D5217. 2. The laboratory failed to monitor the room temperature where supplies and test kits are stored. Refer to D5413.
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. Findings: 1. The laboratory failed to follow their established procedure for Mycology testing. Refer to D5401 I. 2. The laboratory failed to ensure policies and procedures were approved annually per laboratory policy. Refer to D5407.
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 laboratory personnel performed test methods as required. Refer to D5413.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

	This STANDARD is not met as evidenced by: Based on review of policies, maintenance logs, and interview with personnel, the Laboratory Director failed to ensure maintenance procedures were performed to ensure acceptable levels of test performance. Refer to D5433.
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 review of the laboratory's policies and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings: 1. The laboratory failed to follow their established procedure for one (1) of seven (7) random selection of patients reviewed for Histopathology. Refer to D5401 I. 2. The laboratory failed to ensure policies and procedures were approved annually per laboratory policy. Refer to D5407.