

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0960403	(X3) Date Survey Completed 09/18/2019
Name of Provider or Supplier Grafton Dermatology & Cosmetic Surgery	Street Address, City, State 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 performed on September 18, 2019 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.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to verify the accuracy of Mycology and Histopathology testing at least twice annually. Findings: 1. Review of the laboratory's test menu revealed the laboratory performs Potassium Hydroxide (KOH) preps and Histopathology testing. 2. Review of the laboratory's records revealed the laboratory did not verify the accuracy of testing for the following: a) KOH preps: verification not performed in 2018 b) Histopathology: verification not performed in 2018 3. In interview on September 18, 2019 at 2:15 pm, the Medical Assistant Supervisor stated the Laboratory Director thought the twice a year verification for Mohs (Histopathology testing) was no longer needed since the laboratory no longer does the diagnosis portion. 4. In further interview on September 18, 2019 at 2:18 pm, the Medical Assistant Supervisor stated the laboratory was unaware KOH preps required a verification of accuracy of its performance.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks</p>

may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include the following: a) Twice a year verification for accuracy of KOH testing to include frequency, acceptability criteria, and corrective action plan 2. In interview on September 18, 2019, the Medical Assistant Supervisor confirmed the laboratory did not include the identified policy.

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 record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D5217.

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 D5401.

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 record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D5217.