

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D2132768	<b>(X3) Date Survey Completed</b>  09/18/2019
<b>Name of Provider or Supplier</b>  Matherne Dermatology, Llc	<b>Street Address, City, State</b>  416 Hwy 308, Thibodaux, LA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Certification survey was performed on September 18, 2019 at Matherne Dermatology, LLC, CLIA ID # 19D2132768. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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 the performance of Mycology testing at least twice annually. Findings: 1. Review of the laboratory's test menu revealed the laboratory performs KOH preps. 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a written policy for verification of the accuracy of Mycology testing, KOH preps. 3. Review of the laboratory's records revealed the laboratory did not have documentation of verification of the accuracy for Mycology testing for 2018. 4. In interview on September 18, 2019 at 9:45 am, the Laboratory Director stated that KOH was not included in the twice a year verifications performed.</p>
<b>D5403</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step</p>

performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:  
 \*\*Repeat deficiency from survey conducted on December 29, 2017\*\* 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 it did not include the following: Quality control: who is responsible for performing and acceptability requirements 2. In interview on September 18, 2019, the practice manager stated the medical assistants and Laboratory Director performs stain checks. The practice manager confirmed the laboratory's policy did not define who is responsible for performing quality control.

**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 and interview with personnel, the laboratory failed to ensure laboratory supplies and reagents had not exceeded their expiration date. Findings: 1. Observation by surveyors during the laboratory tour on September 18, 2019 revealed the following expired items: a) Surgipath Tissue Marking Dye-Violet, Lot # 05102017, Expiration date: 2018-05, Quantity: one (1) bottle b) Surgipath Tissue Marking Dye-Orange, Lot # 05092017, Expiration date: 2018-05, Quantity: one (1) bottle c) Healthlink KOH Solution, Lot # 1724108, Expiration date: 2018-08-29, Quantity: two (2) bottles 2. In interview on September 18, 2019 the practice manager confirmed the identified items were expired.

**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.

	<p>This STANDARD is not met as evidenced by: Based on observation, 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 the performance of Mycology testing at least twice annually. Refer to D5217. 2. The laboratory failed to ensure laboratory supplies and reagents had not exceeded their expiration date. Refer to D5417.</p>
<p><b>D6087</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(3)(iii)</p> <p>The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5417.</p>
<p><b>D6106</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by: **Repeat deficiency from survey conducted on December 29, 2017** Based on record review 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. Refer to D5403.</p>