

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D2132768	<b>(X3) Date Survey Completed</b>  02/22/2022
<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 Recertification survey was performed on February 22, 2022 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 review of the laboratory's policies, case review records, and interview with personnel, the laboratory failed to ensure the dermatopathologist performing the semi-annual Mohs case reviews documented their findings for one (1) of two (2) years reviewed. Findings: 1. Review of the laboratory's "Proficiency Testing" policy revealed "Semi-annually, the tech or Risk Manager will send two cases containing the original slides, label it with only a surgical case number and send it out for a microscopics examination by a Board Certified Dermatopathologist. NO differential diagnosis will be offered with the specimen. The slide may be labeled 'Proficiency Test' by the sending laboratory for the records of the reference laboratory. Upon receipt of the pathology report from the Dermatopathologist, diagnosis of the slide specimen will be matched to the in-house diagnosis by the physician. Results of each Proficiency Test will be entered in a log and retained as part of the lab's permanent records." 2. Review of the laboratory's "semi-annual case review logs" revealed the following headings: Date of Service Case # Diagnosis Agree ? Comments Reviewer Signature Date 3. Further review of the laboratory's "semi-annual case review" logs for 2020 and 2021 revealed the following six (6) cases from 2020 were submitted to an outside dermatopathologist; however, whether the dermatopathologist agreed with the original diagnosis was not documented: Date of Service: July 8, 2020 Case M20-</p>

066 August 12, 2020 Case M20-078 September 16, 2020 Case M20-085 October 5, 2020 Case M20-096 November 30, 2020 Case M20-119 December 4, 2020 Case M20-121 Reviewer (dermatopathologist) signed "4/20/21" 4. In interview on February 22, 2022 at 12:31 pm, the Office Manager confirmed the reviewing dermatopathologist did not document her findings for the identified 2020 semi-annual case review.

**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's manuals, and interview with personnel, the laboratory failed to monitor the room temperature and humidity of room where the cryostat instrument is located. Findings: 1. Observation by surveyor during laboratory tour on February 22, 2022 at 10:00 am revealed the laboratory did not have a thermometer and humidity monitor where the cryostat and stainer are located (location of processing of histopathology samples). 2. Review of the Leica instrument manuals for the cryostat and stainer revealed the following temperature and humidity requirements: a) Cryostat: "Room temperature 18 C-35 C; Relative humidity, maximum 60 % (non-condensing)" b) Stainer: "Operating temperature range 15 C-30 C; Relative humidity: 20% to 80 % (non-condensing) 3. In interview on February 22, 2022 at 11:21 am, the Office Manager confirmed the room temperature and humidity where the cryostat and stainer are located were not monitored by the laboratory.

**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, review of records, and interview with personnel, the laboratory failed to perform annual preventative maintenance for the cryostat per laboratory policy for two (2) of two (2) years reviewed. Findings: 1. Review of the laboratory's "Cryostat Maintenance" policy revealed "Preventable maintenance and grounding checks are done and documented annually." 2. Review of the laboratory's records revealed the laboratory did not have documentation of the annual preventative maintenance (PM) for 2020 and 2021 for the cryostat. 3. In

interview on February 22, 2022 at 12:31 pm, the Office Manager stated the PM for the cryostat was last performed in 2019.

**D5821**

**TEST REPORT**  
CFR(s): 493.1291(k)

When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's Mohs patient log book, patient visit notes, patient microscope slides, and interview with personnel, the laboratory failed to ensure the correct corresponding case number was utilized for three (3) of eight (8) random selection of patients. Findings: 1. Review of the laboratory's Mohs patient log book, patient microscope slides, and patient visit notes (laboratory's report) the laboratory did not ensure the case number listed in the patient log book corresponded to the microscope slides and visit notes for the following patients: a) January 25, 2021: Patient log book and microscope slides documented as Case Number M21-010, Visit notes had the patient case number documented as M21-009 (duplicate number for a different patient) b) January 27, 2021: Patient log book and microscope slides documented as Case Number M21-011, Visit notes had the patient case number documented as M21-010 c) January 27, 2021: Patient log book and microscope slides documented as Case Number M21-012, Visit notes had the patient case number documented as M21-011 2. In interview on February 22, 2022 at 12:18 pm, the Medical Assistant confirmed for the identified patients the case numbers in the patient visit notes did not match the case numbers listed in the patient log book. The Medical Assistant stated the laboratory did not have corrected patient reports. The Medical Assistant further stated a person who is no longer employed handled the patient logs during the dates of the identified patients.

**D5893**

**POSTANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1299(b)(c)

(b) The postanalytic 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 postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's policies and procedures, patient log book, patient notes, and interview with personnel, the laboratory failed to ensure the quality assessment monitors in place identified issues within the postanalytic system. Findings: 1. Review of the laboratory's "Monthly Patient Quality Assurance Policy" revealed "A monthly patient quality assurance checklist will be performed on the first case of the month. This checklist will evaluate pre-analytical, analytical, and post analytical aspects of the selected case. Any problems concerning the monthly patient

	<p>quality assurance checklist shall be immediately reported to the lab director and documented.." 2. The laboratory failed to ensure the correct corresponding case number was utilized for three (3) of eight (8) random selection of patients. Refer to D5821</p>
<b>D6087</b>	<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 by surveyor, record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to ensure the dermatopathologist performing the semi-annual Mohs case reviews documented their findings for one (1) of two (2) years reviewed. Refer to D5217. 2. The laboratory failed to monitor the room temperature and humidity of room where the cryostat instrument is located. Refer to 5413.</p>
<b>D6094</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>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 assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5893.</p>
<b>D6095</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(6)</p> <p>The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.</p> <p>This STANDARD is not met as evidenced by: Based on review of records and interview with personnel, the Laboratory Director failed to ensure maintenance procedures were maintained to ensure acceptable levels of test performance. Refer to D5433.</p>