Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2132768	12/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Matherne Dermatology, Llc	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Recertification survey was performed on December 19, 2023 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.
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, review of the laboratory's policies and temperature logs, as well as interview with personnel, the laboratory failed to define acceptable temperature limits for operation of the cryostat. Findings: 1. Observation by surveyor during the laboratory tour on December 19, 2023 at 9:57 a.m. revealed the laboratory utilized a Leica cryostat. 2. Review of the laboratory's policies revealed the following two policies with differing acceptable temperature ranges for the cryostat: a) Mohs Procedure - "To begin a Moh's procedure the cryostat needs to be turned to -21C to -30 C." b) Cryostat Maintenance - "The cryostats should be maintained at -20 degrees Celsius to no colder than - 27 degrees Celsius for best Moh's sectioning." 3. Review of the laboratory's cryostat temperature logs revealed an acceptable temperature of -20 to - 27 degrees Celsius. 4. In interview on December 19, 2023 at 11:26 a.m., the Office Manager confirmed the policies identified above had different acceptable temperature ranges for the cryostat.

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on observation, review of the laboratory's policies and temperature logs, as well as interview with personnel, the laboratory failed to document corrective actions performed when the cryostat temperature was documented as outside of the laboratory's acceptable range for forty-four (44) of two hundred thirty (230) days of patient testing reviewed. Findings: 1. Observation by surveyor during the laboratory tour on December 19, 2023 at 9:57 a.m. revealed the laboratory utilized a Leica cryostat. 2. Review of the laboratory's "Cryostat Maintenance" policy revealed "The cryostats should be maintained at -20 degrees Celsius to no colder than - 27 degrees Celsius for best Moh's sectioning. Any variance out of range will be recorded and reported to the supervisor immediately. If the range variance cannot be repaired, the console will not be used until serviced." 3. Review of the laboratory's temperature records revealed the laboratory defined the acceptable temperature range of the cryostat as - 20 to - 27 degrees Celsius. 4. Further review of the laboratory's temperature logs from April 1, 2022 through December 18, 2023 revealed the cryostat temperature was documented as outside of the laboratory's acceptable range on the following days of patient testing: April 20, 2022 temperature documented as - 28 degrees Celsius December 5, 2022 temperature documented as - 28 degrees Celsius December 9, 2022 temperature documented as - 28 degrees Celsius December 12, 2022 temperature documented as - 28 degrees Celsius December 16, 2022 temperature documented as - 28 degrees Celsius December 19, 2022 temperature documented as - 28 degrees Celsius December 21, 2022 temperature documented as - 28 degrees Celsius January 6, 2023 temperature documented as - 28 degrees Celsius January 9, 2023 temperature documented as - 28 degrees Celsius January 11, 2023 temperature documented as - 28 degrees Celsius January 13, 2023 temperature documented as - 28 degrees Celsius January 16, 2023 temperature documented as - 28 degrees Celsius January 18, 2023 temperature documented as - 28 degrees Celsius January 25, 2023 temperature documented as - 28 degrees Celsius January 27, 2023 temperature documented as - 28 degrees Celsius January 30, 2023 temperature documented as - 28 degrees Celsius February 3, 2023 temperature documented as - 28 degrees Celsius February 6, 2023 temperature documented as - 28 degrees Celsius February 13, 2023 temperature documented as - 28 degrees Celsius February 24, 2023 temperature documented as - 19 degrees Celsius February 27, 2023 temperature documented as - 18 degrees Celsius March 1, 2023 temperature documented as - 19 degrees Celsius March 3, 2023 temperature documented as - 18 degrees Celsius March 8, 2023 temperature documented as - 18 degrees Celsius May 1, 2023 temperature documented as - 28 degrees Celsius May 3, 2023 temperature documented as - 28 degrees Celsius May 5, 2023 temperature documented as - 28 degrees Celsius May 8, 2023 temperature documented as - 28 degrees Celsius May

	10, 2023 temperature documented as - 28 degrees Celsius May 15, 2023 temperature documented as - 28 degrees Celsius June 2, 2023 temperature documented as - 28 degrees Celsius June 5, 2023 temperature documented as - 28 degrees Celsius September 27, 2023 temperature documented as - 28 degrees Celsius September 29, 2023 temperature documented as - 28 degrees Celsius October 4, 2023 temperature documented as - 28 degrees Celsius October 6, 2023 temperature documented as - 28 degrees Celsius October 18, 2023 temperature documented as - 28 degrees Celsius November 3, 2023 temperature documented as - 28 degrees Celsius November 29, 2023 temperature documented as - 28 degrees Celsius December 1, 2023 temperature documented as - 28 degrees Celsius December 4, 2023 temperature documented as - 28 degrees Celsius December 6, 2023 temperature documented as - 28 degrees Celsius December 13, 2023 temperature documented as - 28 degrees Celsius December 15, 2023 temperature documented as - 28 degrees Celsius 5. In interview on December 19, 2023 at 11:26 a.m., the Office Manager confirmed the laboratory did not document corrective actions on the dates identified above.
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, record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Refer to D5413.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5781.