Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2173568	06/21/2024
Name of Provider or Supplier	**Street Address, City, State**	
Em Dimitri Do Pmc-Dba Dimitri Dermatology	2104 Gause Blvd West, Suite A, Slidell, 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 at Dimitri Dermatology, CLIA ID 19D2173568, on June 21, 2024. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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: **Repeat deficiency from survey on October 18, 2022** Based on review of the laboratory's policies and interview with personnel, the laboratory failed to ensure policies and procedures were approved annually per laboratory policy in 2022 and 2023. Findings: 1. Review of the laboratory's "Review Policy" revealed "This procedure manual is reviewed by the Laboratory Director annually and at other time as required by major changes in procedure or other circumstances affecting laboratory performance of the test." 2. Further review of the "Review Policy" revealed the Laboratory Director did not review the policies in 2022 and 2023. 3. In interview on June 21, 2024 at 11:01 am, the Operations personnel confirmed the laboratory did not have documentation of the Laboratory Director's annual review of policies for 2022 and 2023.
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: I. Based on review of the laboratory's policies, maintenance records, and interview with personnel, the laboratory failed to perform the microscope grounding check monthly per policy for seventeen (17) of seventeen (17) months reviewed. Findings: 1. Review of the "Equipment Quality Control for Microscopes" policy revealed "grounding check is monitored monthly." 2. Review of the laboratory's "Maintenance Record for Microscopes" revealed the laboratory did not perform the microscope grounding check for the following sixteen (16) months: January 2023 February 2023 March 2023 April 2023 May 2023 June 2023 July 2023 August 2023 September 2023 October 2023 November 2023 December 2023 January 2024 February 2024 March 2024 April 2024 May 2024 3. In interview on June 21, 2024 at 11:44 am, the Operations personnel stated the Laboratory Director did not document the performance of the microscope monthly grounding check for the identified months. II. Based on review of the laboratory's policies, maintenance records, and interview with personnel, the laboratory failed to establish the frequency of performance of the microscope cleaning in their written policy. Findings: 1. Review of the laboratory's "Equipment Quality Control for Microscopes" policy revealed "Microscope stage and ocular eye pieces are to be cleaned monthly. Stage is to be cleaned with alcohol or similar cleaner and ocular eye pieces are to be cleaned with lens paper. " 2. Review of the laboratory's "Maintenance Record for Microscopes" revealed the laboratory performs the stage and ocular cleanings each day of use, not monthly. 3. In interview on June 21, 2024 at 11:44 am, the Operations personnel stated the Laboratory Director performs the microscope cleaning each day of use, not monthly as their policy stated. The Operations personnel confirmed the laboratory's written policy did not match what was in practice.
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 review of the laboratory's policies, temperature logs, and interview with personnel, the laboratory failed to perform corrective actions when the room temperature was not maintained between 65-76 degrees Fahrenheit per the laboratory's policy for nine (9) of sixty six (66) days reviewed. Findings: 1. Review of the laboratory's "Quality Control Program" policy under the "Facilities" section revealed "The environment in the working area of the laboratory will be controlled by the commonly used heating, air-conditioning and ventilation equipment used

	throughout the entire medical office, which will maintain a working temperature of 65 to 76 degrees Fahrenheit. Temperatures will be taken by an employee in the laboratory and recorded. If a temperature is outside the desired range, the Laboratory Director will be notified as soon as possible, and before any patient result is reported. Appropriate corrective action will be taken and documented. It is the responsibility of the Laboratory Director to determine the severity of the problems and the effect on the testing process." 2. Review of the laboratory's "Temperature Monitor Log for Room, Refrigerators, Freezers, Cryostat" revealed the room temperature was documented outside of normal limits without corrective actions for the following dates: a) November 28, 2023: 61.2 degrees Fahrenheit b) December 12, 2023: 60.4 degrees Fahrenheit c) January 9, 2024: 64.6 degrees Fahrenheit d) January 16, 2024: 60.1 degrees Fahrenheit e) January 30, 2024: 62.2 degrees Fahrenheit f) February 20, 2024: 61.4 degrees Fahrenheit g) February 27, 2024: 63.5 degrees Fahrenheit h) March 12, 2024: 63.3 degrees Fahrenheit i) March 29, 2024: 61.9 degrees Fahrenheit 3. In interview on June 21, 2024 at 11:44 am, the Operations personnel confirmed the laboratory did not perform corrective actions for the identified temperatures outside of the acceptable limits.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the laboratory's policies, random selection of patient slides, patient test reports, and interview with personnel, the laboratory failed to maintain a labeling system to ensure positive identification of patient samples for one (1) of eight (8) patients reviewed. Findings: 1. Review of the laboratory's "Preparation and Labeling" policy revealed "Slides will be labeled as FS year, dash, and then the order of the slide taken. The corresponding slide will be logged with the patient's full name on a worksheet which can be used to quickly reference specific slides." 2. Observation by surveyor on June 21, 2024 at 10:56 am revealed a slide holder labeled "BB" on the outside and the following labeling on the cover: a) Position 5 labeled with the patient's name and "FS24-76" b) Position 7 labeled with the patient's name and "FS24-76 with a line drawn through the 76" and corrected to "FS24-77." 3. Further observation by surveyor on June 21, 2024 at 10:56 am revealed the patient slides were labeled as: a) Position 5: "FS24-76" b) Position 7: "FS24-76" There was not a corresponding slide labeled "FS24-77." 4. Review of the patient test report for the patient listed in position 7 revealed the patient identification number referenced was "FS24-77." 5. In interview on June 21, 2024 at 10:56 am, the Medical Assistant stated the patient slide was mislabeled, but the slide holder was labeled correctly. The Medical Assistant stated the slide in position 7 should have been corrected to "FS24-77."
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)

	(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of records, and interview with personnel, the laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Findings: 1. The laboratory failed to ensure policies and procedures were approved annually per laboratory policy in 2022 and 2023. Refer to D5407. 2. The laboratory failed to perform the microscope grounding check monthly per policy for seventeen (17) of seventeen (17) months reviewed. Refer to D5433 I. 3. The laboratory failed to establish the frequency of performance of the microscope cleaning in their written policy. Refer to D5433 II. 4. The laboratory failed to perform corrective actions when the room temperature was not maintained between 65-76 degrees Fahrenheit per the laboratory's policy for nine (9) of sixty six (66) days reviewed. Refer to D5781. 5. The laboratory failed to maintain a labeling system to ensure positive identification of patient samples for one (1) of eight (8) patients reviewed. Refer to D5787.
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, review of patient slides, records, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5787.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) 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. 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 established to assure the quality of laboratory services provided. Refer to D5791.
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 the laboratory's policies, maintenance records, and interview with personnel, the Laboratory Director failed to ensure maintenance procedures were established and followed to ensure acceptable levels of test performance. Findings: 1. The laboratory failed to perform the microscope grounding check monthly per policy for seventeen (17) of seventeen (17) months reviewed. Refer to D5433 I. 2. The laboratory failed to establish the frequency of performance of the microscope cleaning in their written policy. Refer to D5433 II.
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 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.
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: **Repeat deficiency from survey on October 18, 2022** 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. Refer to D5407.