Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2173568	10/18/2022
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 on October 18, 2022 at EM Dimitri DO PMC (DBA Dimitri Dermatology), CLIA ID # 19D2173568. 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: 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. 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 2021. The Laboratory Director's documented review was December 2019. 3. In interview on October 18, 2022 at 2:00 pm, the Operations personnel confirmed the laboratory did not have documentation of the Laboratory Director's annual review of policies for 2021.
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: **Repeat deficiency from survey performed February 9, 2021 ** Based on observation by surveyor, review of policies, and interview with personnel, the laboratory failed to ensure reagents did not exceed their expiration dates. Findings: 1. Observation by surveyor during the laboratory tour on October 18, 2022 at 1:01 pm revealed the following expired items: a) Gill's Hematoxylin III stain solution, Lot 125623, Expiration Date: 2022-07-31, Quantity: four (4) bottles 2. Review of the laboratory's "Storage, Use and Handling" policy revealed " Do not use reagent after expiration date." 3. In interview on October 18, 2022 at 2:00 pm, the Laboratory Director and Operations personnel confirmed the identified items were expired.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and interview with personnel, the laboratory failed to have documentation of the cryostat's annual performance of preventative maintenance (PM) for 2021. Findings: 1. Review of the laboratory's service report records revealed the laboratory did not have documentation of performance of preventative maintenance for their cryostat for 2021. 2. In interview on October 18, 2022 at 2:25 pm, the Operations personnel stated the service order for the PM was initiated December 2021; however, service did not perform the task until January 2022. The Operations personnel confirmed the laboratory did not have documentation of the annual PM for the cryostat for 2021.
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: **Repeat deficiency from survey performed February 9, 2021 ** Based on review of the laboratory's policies, corrective action records, temperature logs, and interview with personnel, the laboratory failed to document corrective actions performed when the cryostat temperature was documented outside of acceptable range for six (6) of ten (10) dates. Findings: 1. Review of the laboratory's "Equipment Quality control for Cryostats" policy revealed "Temperature range is -10 degrees C to -30 degrees C. Corrective action is taken and documented if temperature exceeds range." 2. Review

	of the laboratory's temperature logs in 2021 and 2022 revealed the following six (6) dates the cryostat's temperature exceeded acceptable limits without documented corrective actions: a) August 17, 2021 recorded temperature -31 degrees Celsius b) August 24, 2021 recorded temperature 31 degrees Celsius c) April 19, 2022 recorded temperature 30 degrees Celsius d) April 26, 2022 recorded temperature 30 degrees Celsius e) October 4, 2022 recorded temperature -31 degrees Celsius f) October 11, 2022 recorded temperature -31 degrees Celsius 3. Review of the laboratory's "Corrective Action Request Form" dated March 2, 2021 revealed "Incorrect cryostat temp" was addressed in the laboratory's staff meeting on March 19, 2021. The problem indicated was "The cryostat temperature was recorded incorrectly at '30 C'. Personnel will ensure correct documentation." 4. In interview on October 18, 2022 at 2:05 pm, the Laboratory Director and Operations personnel confirmed the laboratory did not have documentation of corrective actions for temperatures that exceeded acceptable limits.
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, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Refer to D5417.
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 records and interview with personnel, the Laboratory Director failed to ensure maintenance procedures were maintained to ensure acceptable levels of test performance. Refer to D5429.
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 the 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: 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.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Supervisor failed to provide technical and scientific oversight for the laboratory. Findings: 1. The laboratory failed to ensure reagents did not exceed their expiration dates. Refer to D5417. 2. The laboratory failed to have documentation of the annual performance of the cryostat's preventative maintenance (PM) for 2021. Refer to D5429.
D6118	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(5) The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D5781.