Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2173568	02/09/2021
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	An Initial survey was performed on February 9, 2021 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.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policies and procedures, personnel records, and interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for the Technical Supervisor were complete. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not have a written policy for assessment of competency, including frequency of performance, for the Technical Supervisor. 2. Review of personnel records for the Technical Supervisor revealed the Laboratory Director did not perform a competency assessment for the duties of the Technical Supervisor. 3. In interview on February 9, 2021 at 3:00 pm the Laboratory Director confirmed he did not perform a competency assessment for the Technical Supervisor. The Laboratory Director confirmed the laboratory did not have a written policy for assessment of competency for the Technical Supervisor. II. Based on review of the laboratory's policies and procedures, CMS-209 form, and interview with personnel, the laboratory failed to establish written policies and procedures to assess competency of Testing Personnel. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the Laboratory Director serves as Testing Personnel. 2. Review of the laboratory's policies and procedures revealed the laboratory did not have a written

	policy for competency assessments of testing personnel that included frequency of performance and the minimal requirement of the following six (6) procedures: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 3. In interview on February 9, 2021 at 3:00 pm, the Laboratory Director confirmed the laboratory's policy and procedure manual did not include a written policy for competency assessment for testing personnel.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policies and procedures 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 the laboratory did not include the following: a) Verification of accuracy of Histopathology testing to include corrective action for results that do not agree with secondary dermatopathologist b) Acceptable room temperature range 2. In interview on February 9, 2021 at 1:29 pm, the Laboratory Director confirmed the laboratory did not have a written policy related to corrective action for verification of accuracy of Histopathology testing. 3. In interview on February 9, 2021 at 2:25 pm, the Medical Assistant stated the laboratory's acceptable room temperature range was 60-77 degrees Fahrenheit. This range did not match the "working temperature of 65 to 76 degrees Fahrenheit" that was indicated in the laboratory's policy manual under the "Facilities" section. II. Based on direct observation, review of the laboratory's policy, and interview with personnel, the laboratory failed to follow their established policy for labeling of slides. Findings: 1. Review of the laboratory's policy revealed "Slides are labeled with number, full patient name, date, and type." 2. Observation by surveyor on February 9, 2021 at 1:57 pm revealed the following five (5) patient slides were not labeled per laboratory policy: Date of Service: December 17, 2019: Account 211063 Date of Service: February 11, 2020: Account 214125 Date of Service: June 16, 2020: Account 155715 Date of Service: July 28, 2020: Account 89695 Date of Service: December 29, 2020: Account 148047 3. In interview on February 9, 2021 at 2:25 pm, the Medical Assistant stated the slides are labeled with the patient name and part. The Medical Assistant confirmed the patient slides were not labeled as their laboratory policy indicated.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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 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: Based on review of the laboratory's policies and procedures and interview with personnel, the laboratory failed to have complete policies and procedures for quality control (QC). Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not include the following written procedures: a) Quality Control: to include but not limited to corrective action to take when results for stain quality do not meet acceptability criteria 2. In interview on February 9, 2021 at 1:31 pm, the Laboratory Director confirmed the laboratory did not have a policy related to corrective actions for unacceptable QC.
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 policy and procedure manual and interview with personnel, the laboratory failed to have the policy and procedure manual approved and signed by the Laboratory Director. Findings: 1. Review of the laboratory's "Mohs /Histology Laboratory Compliance Manual" revealed the manual was not approved and signed by the Laboratory Director. 2. In interview on February 9, 2021 at 1:57 am, the Laboratory Director confirmed he had not signed the laboratory's policy and procedure manual.
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 direct observation by surveyor and interview with personnel, the laboratory

	failed to ensure solutions did not exceed their expiration date. Findings: 1. Direct observation by surveyor during laboratory tour on February 9, 2021 at 1:10 pm revealed the following expired item: USP Normal Saline 0.9 Sodium Chloride, Lot # 1806034, Expiration Date: 2020-06-14, Quantity: one (1) bottle 2. In interview on February 9, 2021 at 1:10 pm, the Medical Assistant confirmed the identified item was expired.
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of patient test records, policy and procedure manual, test menu, and interview with personnel, the laboratory failed to ensure testing personnel documented the stain quality for Hematoxylin and Eosin (H&E) stains. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the Laboratory Director serves as the testing personnel. 2. Review of the laboratory's " Quality Control" policy revealed " A control slide will be made and evaluated each day that a frozen section is prepared. A record of the control slide will be maintained." 3. In interview on February 9, 2021 at 2:29 pm, the Medical Assistant stated the Laboratory Director does not document the stain quality of control slides. 4. Review of random selection of patients from December 2019 through December 2020 revealed the laboratory did not have documented QC assessment of stain quality for the following five (5) dates reviewed: Date of Service: December 17, 2019 (Total of four patients reported) Date of Service: February 11, 2020 (Total of three patients reported) Date of Service: June 16, 2020 (Total of four patients reported) Date of Service: July 28, 2020 (Total of four patients reported) Date of Service: December 29, 2020 (Total of three patients reported) 5. Review of the laboratory's test menu revealed the laboratory performs seventy two (72) H&E stains for Mohs testing annually.
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 temperature logs, policies, and interview with personnel, the laboratory failed to document corrective actions performed when the cryostat temperature was documented outside of acceptable range for twenty three (23) of twenty three (23) days reviewed in January 2020 through December 2020.

	Findings: 1. Review of the laboratory's policy revealed the cryostat's acceptable temperature range was "-20 degrees C to -30 degrees C." 2. Further review of the laboratory's policy revealed "Corrective action is taken and documented if temperature exceeds range." 3. Review of the laboratory's temperature logs for 2020 revealed the following twenty three (23) dates the cryostat's temperature exceeded acceptable limits without documented corrective actions: January 7, 2020 recorded temperature 30 degrees Celsius (C) January 14, recorded temperature 30 degrees C January 21, 2020 recorded temperature 30 degrees C January 28, 2020 recorded temperature 30 degrees C February 4, 2020 recorded temperature 30 degrees C February 11, 2020 recorded temperature 30 degrees C March 10, 2020 recorded temperature 30 degrees C March 24, 2020 recorded temperature 30 degrees C April 7, 2020 recorded temperature 30 degrees C April 21, 2020 recorded temperature 30 degrees C May 5, 2020 recorded temperature 30 degrees C May 19, 2020 recorded temperature 30 degrees C June 2, 2020 recorded temperature 30 degrees C June 16, 2020 recorded temperature 30 degrees C June 30, 2020 recorded temperature 30 degrees C August 8, 2020 recorded temperature 30 degrees C August 25, 2020 recorded temperature 30 degrees C September 22, 2020 recorded temperature 30 degrees C October 6, 2020 recorded temperature 30 degrees C October 20, 2020 recorded temperature 30 degrees C November 3, 2020 recorded temperature 30 degrees C November 17, 2020 recorded temperature 30 degrees C December 1, 2020 recorded temperature 30 degrees C 4. In interview on February 9, 2020 at 3:00 pm, the Medical Assistant stated she recorded the cryostat temperature incorrectly. The Medical Assistant confirmed the laboratory did not have documentation of corrective actions for the temperatures that exceeded acceptable limits.
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, record review, and interview with personnel, the laboratory failed to establish complete procedures to monitor, assess, and correct problems, identified with the analytic system. Findings: 1. Review of the laboratory's "Quality Assurance" policy revealed "The lab director will monitor all aspects of the laboratory and make certain that all testing complies with the individual testing policy and procedure protocols." The policy did not define what monitors are in place or frequency of performance to ensure compliance. 2. The laboratory did not identify the following issues with the analytic system: a) The laboratory failed to have a complete policy and procedure manual. Refer to D5401 I. b) The laboratory failed to follow their established policy for labeling of slides. Refer to D5401 II. c) The laboratory failed to have complete policies and procedures for quality control (QC). Refer to D5403. d) The laboratory failed to have the policy and procedure manual approved and signed by the Laboratory Director. Refer to D5407. e) The laboratory failed to ensure solutions did not exceed their expiration date. Refer to D5417. f) The laboratory failed to ensure testing personnel documented the stain quality for Hematoxylin and Eosin (H&E) stains. Refer to D5609. g) The laboratory failed to

	document corrective actions performed when the cryostat temperature was documented outside of acceptable range for twenty three (23) of twenty three (23) days reviewed in January 2020 through December 2020. Refer to D5781.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patient final reports, test menu, and interview with personnel, the laboratory failed to include the laboratory's address on patient final reports. Findings: 1. Review of the following five (5) patient final test reports revealed the address of the laboratory performing the testing was not included: Date of Service: December 17, 2019: Account 211063 Date of Service: February 11, 2020: Account 214125 Date of Service: June 16, 2020: Account 155715 Date of Service: July 28, 2020: Account 89695 Date of Service: December 29, 2020: Account 148047 2. In interview on February 9, 2021 at 1:29 pm, the Laboratory Director confirmed the laboratory did not include the address on patient final reports. 3. Review of the laboratory's test menu revealed the laboratory performs 72 Mohs (Histopathology) tests annually.
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 record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Refer to D5417.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 control program was maintained to assure the quality of laboratory testing. Refer to D5609.

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 observation, 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.
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.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure final reports included required pertinent information. Refer to D5805.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D5209.

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 policy and procedure manual and interview with laboratory 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. Findings: 1. The laboratory failed to have a complete policy and procedure manual. Refer to D5401 I. 2. The laboratory failed to follow their established policy for labeling of slides. Refer to D5401 II. 3. The laboratory failed to have complete policies and procedures for quality control (QC). Refer to D5403. 4. The laboratory failed to have the policy and procedure manual approved and signed by the Laboratory Director. Refer to D5407.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 form, personnel records, policies and procedures, and interview with personnel, the Laboratory Director failed to delegate responsibilities of the Technical Supervisor to one (1) of one (1) Technical Supervisor. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed one (1) Technical Supervisor. 2. Review of personnel records for the Technical Supervisor revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks of Technical Supervisor to her. 3. Further review of personnel records and laboratory's policy and procedure manual revealed the laboratory did not include written responsibilities for the Technical Supervisor. 4. In interview on February 9, 2021 at 3:00 pm, the Laboratory Director confirmed he did not have documentation of delegating the Technical Supervisor responsibilities to the personnel serving as the Technical Supervisor.
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 have a complete policy and procedure manual. Refer to D5401 I. 2. The laboratory failed to follow their established policy for labeling of slides. Refer to D5401 II. 3. The laboratory failed to have complete policies and procedures for quality control (QC). Refer to D5403. 4. The laboratory failed to ensure solutions did not exceed their expiration date. Refer to D5417.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Supervisor failed to ensure that quality control programs are maintained to assure the quality of laboratory testing. Refer to D5609.
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 direct observation, record review, and interview with personnel, the Technical Supervisor failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5781.