Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2062017	03/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Associates Of Sw La, Llc	2000 Tybee Lane, Lake Charles, 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 March 21, 2022 at Dermatology Associates of SWLA, LLC, CLIA ID # 19D2062017. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 observation by surveyor and interview with personnel, the laboratory failed to ensure supplies did not exceed expiration date. Findings: 1. Observation by surveyor during the laboratory tour on March 21, 2022 at 1:29 pm revealed the following expired items: Cancer Diagnostic, INC Red Tissue Marking Dye, Lot 9203, Expiration Date: 2021-07-01, Quantity: one (1) bottle (located on counter, in-use) Cancer Diagnostic, INC Blue Tissue Marking Dye, Lot 9252, Expiration Date: 2021-09-30, Quantity: one (1) bottle (located on counter, in-use) Cancer Diagnostic, INC Black Tissue Marking Dye, Lot 9253, Expiration Date: 2021-09-30, Quantity: one (1) bottle (located on counter, in-use) Cancer Diagnostic, INC Green Tissue Marking Dye, Lot 9254, Expiration Date: 2021-09-30, Quantity: one (1) bottle (located on counter, in-use) Cancer Diagnostic INC Yellow Tissue Marking Dye, Lot 9252, Expiration Date: 2021-09-30, Quantity: two (2) bottles (located in drawer) Cancer Diagnostic INC Violet Tissue Marking Dye, Lot 9246, Expiration Date: 2021-09-30, Quantity: two (2) bottles (located in drawer) Cancer Diagnostic INC Orange Tissue Marking Dye, Lot 9255, Expiration Date: 2021-09-30, Quantity: one (1) bottle (located on counter, in-use) Cancer Diagnostic INC Red Tissue Marking Dye, Lot 9249, Expiration Date: 2021-09-30, Quantity: one (1) bottle (located in drawer)

	Cancer Diagnostic INC Green Tissue Marking Dye, Lot 9360, Expiration Date: 2021-12-31, Quantity: one (1) bottle (located in drawer) Formalin, Prep date: 5/15/18, Expiration Date: 2/2022, Quantity: one (1) gallon bottle Leica Surgipath Clearium Mounting Medium, Lot 042219, Expiration Date: 2021-04-22, Quantity: seven (7) bottles 2. In interview on March 21, 2022 at 1:35 pm, Testing Personnel 1 confirmed the identified marking dyes were expired. Testing Personnel 1 further stated she fills the in -use bottles with marking dyes located in the drawer. Surveyor did not observe secondary labeling on the expired marking dyes. 3. In further interview on March 21, 2022 at 1:45 pm, Testing Personnel 1 stated the formalin is received from from Pathology department. Testing Personnel 1 stated the laboratory does not use the Clearium mounting medium. Testing Personnel 1 confirmed the items identified 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 maintenance logs and interview with personnel, the laboratory failed to ensure monthly maintenance for the air vent was performed as required for twenty four (24) of twenty six (26) months reviewed. Findings: 1. Review of the laboratory's "Fume Hood/Air Vent Log" revealed the following instructions: a) "The air vent of fume hood shall be turned on as soon as the lab is open for operation, shall remain on during operating hours. At all times the stains are to remain under the hood (if applicable)." b)" Dust air vent monthly, document by using the letter D" c) "Replace filter as required by manufacture [sic], document" d) "Grounding to be checked and documented annually" 2. Review of the laboratory's "Fume Hood/Air Vent Log" for 2020, 2021, and 2022 revealed the laboratory did not document the air vent monthly maintenance for the following months: 2020: January through June and September through December 2021:January through December 2022: January and February 3. In interview on March 21, 2022 at 2:45 pm, Testing Personnel 1 stated she had not been documenting the monthly air vent maintenance.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic 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 analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Findings: 1. Review of the laboratory's"Monthly Quality Assurance Checklist" revealed the following monitors: a) Patient Test Management System b) Quality Control Policies which included a check of "all reagents, controls, kits, etc.

	that exceeded their expiration date were discarded and all instrument maintenance was performed and documented" c) Laboratory Safety Policies d) Proficiency Testing Policies e) Personnel Policies f) Quality Assurance Program 2. Observation by surveyor, review of records, and interview with personnel revealed the laboratory did not identify the following issues with the analytic system: a) The laboratory failed to ensure supplies did not exceed expiration dates. Refer to D5417. b) The laboratory failed to ensure monthly maintenance for the air vent was performed as required for twenty four (24) of twenty six (26) months reviewed. Refer to D5429.
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 and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Refer to D5417.
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 by surveyor, 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 D5793.
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 maintenance logs and interview with personnel, the Laboratory Director failed to ensure maintenance procedures were performed to ensure acceptable levels of test performance. Refer to D5429.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate

	results. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the Laboratory Director failed to ensure two (2) of five (5) Testing Personnel reviewed were approved to perform grossing of Mohs (Histopathology) samples. Findings: 1. In interview on March 21, 2022 at 3:42 pm Testing Personnel 1 stated Testing Personnel 3 was hired May 13, 2021 and Testing Personnel 4 on June 11, 2021. 2. Review of personnel records for Testing Personnel 3 and Testing Personnel 4 revealed an initial training was performed October 6, 2021 by an outside consulting group. The laboratory did not have documentation of the Laboratory Director's approval/signature for patient testing. 3. In interview on March 21, 2022 at 3:42 pm Testing Personnel 1 stated new staff receive a hands-on training from an outside consulting group and then she performs an in-house training. Testing Personnel 1 confirmed the Laboratory Director did not approve/sign-off the identified personnel for testing after their initial training.