Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0687229	04/08/2024
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Associates Of West Michigan	1740 E Paris Avenue Se, Grand Rapids, MI	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: . Based on record review and interviews with Testing Personnel #17 and the Clinical Manager, the laboratory failed to enroll in a proficiency testing program for its gram stain testing for 2 (April 2022 to April 2024) of 2 years reviewed. Findings include: 1. A review of the laboratory's procedure manual revealed a procedure for performing gram stains to identify gram positive and gram negative organisms. 2. An interview on 4/8/24 at 3:45 pm with Testing Personnel #17 revealed the laboratory had not enrolled in proficiency testing for gram staining for 2022, 2023, and 2024. 3. An interview on 4/8/24 at 3:58 pm with the Clinical Manager revealed a total of 270 patient gram stains had been performed between April 8, 2022 and April 8, 2024.
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: . Based on record review and interview with the Clinical Manager, the laboratory failed to follow its competency assessment policies for 3 (Testing Personnel #3, #6, and #8) of 19 testing personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's "Quality Control/Quality Assurance Policy" revealed a section stating, "Quality assurance for the reading of KOH slides, Tzank Preps, and histopathology will be validated twice yearly via online with the Michigan Dermatology Society, by completing educational materials and/or by participating in peer review of slides." 2. A review of the laboratory's testing personnel competency assessments revealed a lack of documentation for the following personnel: a. Testing Personnel #3 completed Michigan Dermatological Society educational materials only once in 2023. b. Testing Personnel #6 completed Michigan Dermatological Society educational materials only once in 2022. c. Testing Personnel #8 completed Michigan Dermatological Society educational materials only once in 2023. 3. An interview on 4 /8/24 at 4:20 pm with the Clinical Manager confirmed documentation of twice annual performance of Michigan Dermatological Society educational materials, used to assess testing personnel competency, was not available for the testing personnel listed above. **This is a repeated deficiency from the 6/21/22 recertification survey.**
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: . Based on observation and interview with Testing Personnel #17, the laboratory failed to label its xylene and acetone containers to include the expiration dates for 2 jars observed. Findings include: 1. The surveyor observed two glass coplin jars labeled "xylene" and "acetone" without expiration dates. 2. An interview on 4/8/24 at 12:42 pm with Testing Personnel #17 confirmed the laboratory had not labeled the two glass coplin jars with the expiration dates.
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 and interview with the Clinical Manager and Testing Personnel #17, the laboratory failed to ensure its Potassium Hydroxide preparation testing reagents were not used when they exceeded expiration dates for 2 (one Potassium Hydroxide 10% and one Chlorazol Black E) bottles observed. Findings include: 1. The surveyor observed two expired reagent bottles during a tour of the laboratory's testing areas on 4/8/24 at 1:02 pm: a. One Chlorazol Black E dropper

	bottle lot 6505 with the expiration date of 3/23/24. b. One Potassium Hydroxide 10% dropper bottle lot 1342 with the expiration date of 12/8/23. 2. An interview on 4/8/24 at 4:20 pm with the Clinical Manager and Testing Personnel #17 confirmed the reagents were expired and had been used to test four patients since 12/8/23.
D5475	CONTROL PROCEDURES CFR(s): 493.1256(e)(3)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (3) Check fluorescent and immunohistochemical stains for positive and negative reactivity each time of use. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with the Clinical Manager and Testing Personnel #17, the laboratory failed to perform and document immunohistochemical stain controls for positive and negative reactivity each time of use for 3 (Patients 9-11) of 3 patients reviewed. Findings include: 1. A review of 3 patient test reports for patients receiving testing using immunohistochemical stains revealed a lack of documentation of control positive and negative reactivity: a. Patient #9 received testing on 01/08/2024 for PRAME/MART1, SOX10 red, and p16. b. Patient #10 received testing on 06/19/2023 for BAP1, BRAF, Ki-67/MART1, PRAME/MART1, and p16. c. Patient #11 received testing on 07/21/2022 for BRAF, CD10, CD31, Ki-67MART1, S100, p16, and p63. 2. The surveyor requested documentation of immunohistochemical stain controls for positive and negative reactivity on 4/8/24 at 3: 38 pm and it was not made available. 3. An interview on 4/8/24 at 4:20 pm with the Clinical Manager and Testing Personnel #17 confirmed documentation of immunohistochemical stain controls for positive and negative reactivity each time of use was not available.