Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2189573	03/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Hamzavi Dermatology Suite 1	43151 Dalcoma Drive Suite 1, Clinton Township, 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
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) (a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. In addition, retain the following: (a)(6)(i) Immunohematology reports as specified in 21 CFR 606.160(d). (a)(6)(ii) Pathology test reports for at least 10 years after the date of reporting This STANDARD is not met as evidenced by: . Based on record review and interview with the office manager, the laboratory failed to retain Mohs histopathology test reports for 2 (#1 & #2) of 8 patient test reports reviewed. Findings include: 1. The surveyor requested test reports on 3/5/2025 at 1:00 pm for patients receiving Mohs histopathology testing from April 2023 to January 2025; however, reports for two patients were not made available: a. Patient #1, date of service 04/10/2023 b. Patient #2, date of service 06/26/2023 2. A review of the laboratory's policy titled "Histopathology CLIA Level of Complexity: HIGH", page 2, paragraph 4, states " Retain all slides and copies of the reported test that are associated with the slides for ten years." 3. An interview on 3/5/2025 at 3:00 pm with the office manager confirmed the test reports were not available.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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, record review and interview with the office manager, the laboratory failed to ensure 14 reagents were not used after expiration date for patient testing. Findings include: 1. During the tour of the laboratory, the surveyor observed 14 bottles of expired reagents available for patient testing on 03/05/2025 at 12:15 pm: a. 4 of 4 bottles of Colorbond Marking Dye Mordant, expired 1/31/2025 b. 2 of 2 bottles of CDI Yellow Tissue Marking Dye expired 8/31/2024 c. 2 of 2 bottles of CDI Blue Tissue Marking Dye expired 4/30/2024 and 6/30/2024 d. 2 of 2 bottles of CDI Red Tissue Marking Dye expired 6/30/2024 e. 1 of 1 bottles of CDI Green Tissue Marking Dye expired 2/29/2024 f. 1 of 3 bottles of Polarstat Frozen Embedding Media expired 1/31/2025 g. 1 of 9 bottles of Acromount Plus expired 1/31/2024 h. 1 of 1 100% Alcohol expired 1/31/2025 2. A review of the laboratory's policy titled "HISTOPATHOLOGY, CLIA LEVEL OF COMPLEXITY: HIGH", page 3, section named "REAGENT STORAGE, USE AND HANDLING", paragraph 3 states, "Do not use reagents after expiration date." 3. An interview with the office manager on 03/05/2025 at 12:30 pm confirmed reagents were expired and available for patient testing.
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. This STANDARD is not met as evidenced by: . Based on record review and interview with the office manager, the laboratory failed to follow established policy and procedures for an ongoing mechanism to monitor, assess and correct problems in the analytic laboratory systems for 2 (06/14/2024 and 11/22/2024) of 4 twice a year assessments reviewed for 2023 to 2025. Findings include: 1. A tour of the laboratory by the surveyor on 03/05/2025 at 12:15 pm revealed 14 expired reagents available for patient testing: a. 4 of 4 bottles of Colorbond Marking Dye Mordant, expired 1/31/2025 b. 2 of 2 bottles of CDI Yellow Tissue Marking Dye expired 8/31/2024 c. 2 of 2 bottles of CDI Blue Tissue Marking Dye expired 4/30/2024 and 6/30/2024 d. 2 of 2 bottles of CDI Red Tissue Marking Dye expired 6/30/2024 e. 1 of 1 bottles of CDI Green Tissue Marking Dye expired 2/29/2024 f. 1 of 3 bottles of Polarstat Frozen Embedding Media expired 1/31/2025 g. 1 of 9 bottles of Acromount Plus expired 1/31/2024 h. 1 of 1 100% Alcohol expired 1/31/2025 2. A review of the laboratory's Quality Assurance checklists revealed the following: a. Quality Assurance Checklist dated 06/14/2024 documented a checkmark on the line item "___All reagents, control, kits, media, ect [sic] that exceeded their expiration date were properly disposed." The checklist was signed by the Laboratory Director. b. Quality Assurance Checklist dated 11/22/2024 documented a checkmark on the line item "___All reagents, control, kits, media, ect [sic] that exceeded their expiration date were properly disposed." The checklist was signed by the Laboratory Director. 3. An interview with the laboratory office manager on 03/05/2025 at 3:15 pm confirmed the Quality Assurance Checklist on 06/14/2024 and 11/22/2024 did not identify the expired reagents. 4. A review of the laboratory Policy titled Part 1" Quality Assessment Procedures, number 3 states "Ongoing Assessment: Each laboratory's quality systems will undergo assessment on a regular basis to maintain and improve laboratory performance and services...".