Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0380094	08/01/2024
Name of Provider or Supplier	**Street Address, City, State**	
West Michigan Dermatology	6150 Northland Drive Ne, Rockford, 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 interview with the team lead, the laboratory failed to enroll in a proficiency testing program for its gram stain testing for one (July 2024) of one month since the laboratory started performing gram stain testing. Findings include: 1. A review of the laboratory's patient test records revealed testing personnel #9 had performed gram stain testing on 7/26/24 for one patient. 2. An interview on 8/1 /24 at 6:14 pm with the team lead revealed testing personnel #9 had started performing gram stain testing at the laboratory on 7/3/24 and the laboratory had not enrolled in proficiency testing.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.

	This STANDARD is not met as evidenced by: . Based on record review and interview with the team lead, the laboratory failed to observe safety procedures to ensure protection from biohazardous and chemical hazards for one observation of the laboratory. Findings include: 1. The surveyor observed a tumbler of clear fluid on the counter next to the cryostat on 8/1/24 at 2:58 pm. 2. A review of the laboratory's "Safety" policy revealed a section stating, "Safety precautions will be addressed in the following written plans, which may be maintenance within the overall safety manual for the practice: a. A written Hazard Communication Plan with applicable material safety data sheets for products used within the laboratory. b. A written Exposure Plan. c. A written Medical Waste Management Plan. d. A written Chemical Hygiene Plan. e. A written TB Control Plan." 3. An interview on 8/1/24 at 2:58 pm with the team lead confirmed the tumbler with clear fluid was present in the laboratory and was there against laboratory policies and procedures.
D5028	HISTOPATHOLOGY CFR(s): 493.1219 If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1273, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on record review and interview, the laboratory failed to establish test procedures for its histopathology microscopic tissue examinations using gram staining, immunohistochemical staining, colloidal iron, Periodic Acid-Schiff, and hematoxylin and eosin stains (refer to D5401) and failed to perform and document cryostat maintenance (refer to D5433).
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: . Based on record review and interview with the team lead, the laboratory failed to establish test procedures for its histopathology microscopic tissue examinations using gram staining, immunohistochemical staining, colloidal iron, Periodic Acid-Schiff, and hematoxylin and eosin stains for one (July 2024) of one month since the laboratory started performing testing. Findings include: 1. An interview on 8/1/24 at 5: 07 pm with the team lead revealed the laboratory hired testing personnel #9 to start on 7/3/24 and had performed histopathology micrscopic tissue examinations using gram staining, immunohistochemical staining, colloidal iron, periodic acid-Schiff, and hematoxylin and eosin stains on 59 patients in July 2024. 2. A review of the laboratory's test procedures revealed a lack of policies and procedures for the performance of histopathology micrscopic tissue examinations using gram staining, immunohistochemical staining, colloidal iron, periodic acid-Schiff, and hematoxylin and eosin stains. 3. An interview on 8/1/24 at 6:15 pm with the team lead confirmed

	test procedures were not established for histopathology micrscopic tissue examinations using gram staining, immunohistochemical staining, colloidal iron, periodic acid-Schiff, and hematoxylin and eosin stains.
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 the team lead, the laboratory failed to label its aliquots of tissue marking dyes with the expiration dates for three of three containers observed. Findings include: 1. The surveyor observed the specimen grossing station with three aliquots of tissue marking dates with the preparation date of 6/17/24 written on the bottom. No expiration dates were present. 2. An interview on 8/1/24 at 3:03 pm with the team lead confirmed the tissue marking dye aliquots did not include the expiration dates.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: . Based on record review and interview with the team lead, the laboratory failed to perform and document cryostat maintenance for four (August 2022 to November 2022) of 24 months reviewed. Findings include: 1. A review of nine histopathology Mohs surgery patient testing dates and the laboratory's "2022 Maintenace Record- Cryostat" revealed a lack of cryostat maintenance and temperature function checks for the following: a. Patient #7 with testing performed on 8/18/22. b. Patient #10 with testing performed on 11/22/22. c. Patient #11 with testing performed on 10/7/22. 2. A review of the laboratory's "2022 Maintenance Record- Cryostat" revealed the following statement, "Each day of use, clean debris, wipe with 100% alcohol. Weekly or as needed, sanitize with 95% or 100% alcohol, drain, air dry. Each day of use, sanitize with disinfecting wipe. Blades: Permanent- sanitize with 100% alcohol. Moving components are oiled monthly or as needed. Air filter: Cleaned every 6 months (once being at the annual preventative maintenance.) Temperature: Recorded daily on temperature sheet (normal range is -32 to -10 degrees Fahrenheit.) Calibration of thermometer: done during annual preventative maintenance." 3. An interview on 8/1/24 at 6:15 pm with the team lead confirmed cryostat maintenance documentation was not available for August 2022 to November 2022.

D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure the laboratory was enrolled in a proficiency testing program for its gram stain testing (refer to D6088), failed to ensure testing personnel #9 had demonstrated they could perform histopathology testing reliably prior to testing patient specimens (refer to D6102), and failed to ensure test procedures were established for its histopathology microscopic tissue examinations using gram staining, immunohistochemical staining, colloidal iron, periodic acid-Schiff, and hematoxylin and eosin stains (refer to D6106).
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on record review and interview with the team lead, the Laboratory Director failed to ensure the laboratory was enrolled in a proficiency testing program for its gram stain testing. Refer to D2000.
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 record review and interview with the team lead, the Laboratory Director failed to ensure testing personnel #9 had demonstrated they could perform histopathology testing reliably prior to testing patient specimens for 59 patient specimens tested testing personnel #9 since they started testing on 7/3/24. Findings include: 1. The surveyor requested testing personnel #9's competency assessment documentation on 8/1/24 at 5:03 pm and it was not made available. 2. An interview on 8/1/24 at 5:07 pm with the team lead revealed testing personnel #9 had started their employment at the laboratory on 7/3/24 and was performing histopathology microscopic tissue exams stained with hematoxylin and eosin, immunohistochemical stains, colloidal iron stain, Periodic Acid-Schiff, and gram stains. They confirmed no documentation of training or competency assessments were available. A total of 59 patient cases had been performed by testing personnel #9 since 7/3/24.

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 record review and interview with the team lead, the Laboratory Director failed to ensure test procedures were established for its histopathology microscopic tissue examinations using gram staining, immunohistochemical staining, colloidal iron, periodic acid-Schiff, and hematoxylin and eosin stains. Refer to D5401.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: . Based on record review and interview, the technical supervisor failed to perform direct observations of routine patient testing as part of testing personnel competency assessments (refer to D6121) and failed to perform direct observations of instrument maintenance and function checks as part of testing personnel competency assessments (refer to D6124).
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: . Based on record review and interview with the team lead, the technical supervisor failed to perform direct observations of routine patient testing as part of testing personnel competency assessments for two (August 2022 to August 2024) of two years reviewed. Findings include: 1. A review of competency assessments for the laboratory's tissue processing staff revealed they had been incorrectly documented as performing gross tissue examinations. 2. An interview on 8/1/24 at 6:15 pm with the team lead revealed the technical supervisor had not performed observations of patient testing directly as part of testing personnel competency assessments.
D6124	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.

	This STANDARD is not met as evidenced by: . Based on record review and interview with the team lead, the technical supervisor failed to perform direct observations of instrument maintenance and function checks as part of testing personnel competency assessments for two (August 2022 to August 2024) of two years reviewed. Findings include: 1. A review of competency assessments for the laboratory's tissue processing staff revealed they had been incorrectly documented as performing gross tissue examinations. 2. An interview on 8 /1/24 at 6:15 pm with the team lead revealed the technical supervisor had not performed observations of instrument maintenance and function checks for testing personnel competency assessments.