

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2185277	(X3) Date Survey Completed 12/19/2022
Name of Provider or Supplier Derm Institute Of West Michigan, Plc The	Street Address, City, State 1661 Crystal Springs Blvd Se, Caledonia, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with the Chief Financial Officer (CFO) and the histotechnician, the laboratory failed to ensure reagents and tissue marking dyes used in histopathology testing did not exceed their expiration dates for 4 (blue, black, red, and yellow) of 4 marking dyes and 3 (Scott's Tap Water Substitute, Eosin Y stain Solution 1%, and Hematoxylin Stain Solution, Gill III) of 5 Hematoxylin & Eosin (H&E) staining reagents observed. Findings include: 1. During a tour of the laboratory on 12/19/2022 at 9:19 am, the surveyor observed 4 of 4 tissue marking dyes in the laboratory that had exceeded their expiration dates as follows: a. Tissue Marking Dyes 1. blue - lot 109673 expired 11/30/2022 2. black - lot 107324 expired 9/30/2022 b. Mercedes Scientific 1. red - lot 110105 expired 9/30/2022 c. Cancer Diagnostics 1. yellow - lot 20217 expired 8/31/2022 2. During a tour of the flammable cabinet on 12/19/2022 at 10:00 am, the surveyor observed 3 of 5 H&E staining reagents that had exceeded their expiration dates as follows: a. Scott's Tap Water Substitute 1. lot 2012125 (2 bottles) - expired on 5/05/2021 b. Eosin Y Stain Solution 1% 1. lot 2011812 - expired 4/30/2022 2. lot 2006626 - expired 3/13/2022 c. Hematoxylin Stain Solution, Gill III 1. lot 2008323 - expired 3/26/2022 3. An interview on 12/19/2022 at 9:25 and 10:00 am, the CFO and histotechnician confirmed the tissue marking dyes and the H&E staining reagents listed above had exceeded their expiration dates.</p>
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p>

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

. Based on lack of documentation and interview with the Chief Financial Officer (CFO), the laboratory failed to perform and document the function checks as required for the room temperature in the laboratory for 17 (August 2021 to December 2022) of 17 months of operation of the cryostat in the laboratory. Findings include: 1. A record review on 12/19/2022 at 11:34 am revealed a lack of documentation of the room temperature for 17 (August 2021 to December 2022) of 17 months of operation of the cryostat instrument in the laboratory. 2. When queried on 12/19/2022 at 11:34 am, the CFO was not able to provide the surveyor the documentation to show the room temperature had been performed and documented. 3. An interview on 12/19/2022 at 11:34 am, the CFO confirmed the laboratory failed to perform and document the room temperature function checks for the proper operation of the cryostat instrument.

D5787

TEST RECORDS

CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Chief Financial Officer (CFO), the laboratory director failed to ensure the final Mohs' map showed that the stage of testing was clear and/or negative of positive margins for 9 (M21-056, M21-073, M21-091, M21-132, M21-165, M22-016, M22-069, M22-118, and EM22-092) of 11 Mohs' maps reviewed. Findings include: 1. A record review for 9 of 11 final Mohs' maps in the patient's electronic medical record (EMR) revealed the final Mohs' map lacked the documentation to show that the stage of testing was clear and/or negative of positive margins to show the testing was complete as follows: a. M21-056 tested on 5/24/2021 b. M21-073 tested on 6/14/2021 c. M21-091 tested on 8/30/2021 d. M21-132 tested on 10/25/2021 e. M21-165 tested on 12/06/2021 f. M22-016 tested on 2/14/2022 g. M22-069 tested on 4/11/2022 h. M22-118 tested pm 6/13/2022 i. EM22-092 tested on 10/24/2022 2. When queried on 12/19/2022 at 10:15 am, the CFO was unable to provide the surveyor documentation to show the margins on the Mohs' map were negative. 3. An interview on 12/19/2022 at 10:15 am, the CFO confirmed the final Mohs' map do not show that the tumor margins were clear and/or negative.

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 record review and interview with the Chief Financial Officer (CFO), the laboratory failed to show corrective action for 4 (blue, black, red, and yellow) of 4 marking dyes and 3 (Scott's Tap Water Substitute, Eosin Y stain Solution 1%, and Hematoxylin Stain Solution, Gill III) of 5 Hematoxylin & Eosin (H&E) staining reagents that expired during the monthly quality assessment review. Findings include: 1. Record review of the "Monthly QA Checklist" revealed a lack of a correct response on the checklist under the "Our Analytic Systems were followed as written: All reagents, controls and calibrations are within the proper dating. (Check the Reagent Log, refrigerator, and freezer). Outdated materials were never used for testing patient specimens and were discarded." as follows: Tissue Marking Dyes a. Tissue Marking Dyes 1. blue - lot 109673 expired 11/30/2022 2. black - lot 107324 expired 9/30/2022 b. Mercedes Scientific 1. red - lot 110105 expired 9/30/2022 c. Cancer Diagnostics 1. yellow - lot 20217 expired 8/31/2022 Hematoxylin & Eosin staining reagents a. Scott's Tap Water Substitute 1. lot 2012125 (2 bottles) - expired on 5/05/2021 b. Eosin Y Stain Solution 1% 1. lot 2011812 - expired 4/30/2022 2. lot 2006626 - expired 3/13/2022 c. Hematoxylin Stain Solution, Gill III 1. lot 2008323 - expired 3/26/2022 2. A interview on 12/19/2022 at 9:25 am and 10:00 am the CFO confirmed the expired marking dyes and H&E stain reagents did not correlate with the responses recorded on the "Monthly QA Checklist".