

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D2032958	(X3) Date Survey Completed 09/25/2024
Name of Provider or Supplier Mountain West Derm Blackhart Pllc	Street Address, City, State 1700 W Riverstone Dr, Coeur D'Alene, ID	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of training and competency assessment records, laboratory procedures, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and an interview with testing personnel 1 (TP1) on 9/25/2024, the laboratory failed to follow written policies and procedures for initial training and assessing employee competency. The findings include: 1. The CMS 209 form identified seven (7) testing personnel performing potassium hydroxide (KOH) slide examinations of which three (3) were hired since the previous inspection on 8/22/2022. The CMS 209 form identified two (2) testing personnel performing histopathology grossing of which one (1) was hired since the previous inspection. 2. A lack of training records identified three (3) testing personnel listed on the CMS 209 form hired since the last inspection failed to have documentation of initial training for KOH examinations and one (1) failed to have initial training for histopathology grossing. 3. A lack of competency assessment records identified four (4) testing personnel listed on the CMS 209 form hired since the last inspection failed to have documentation of a six month competency assessment. 4. The laboratory reports performing 9,065 histopathology tests and KOH slide examinations annually.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p>

This STANDARD is not met as evidenced by:
Based on a lack of documentation and an interview with testing personnel 1 (TP1) on 9/25/2024, the laboratory failed to document, at least twice annually, the verification of accuracy for potassium hydroxide (KOH) slide examinations since the last inspection on 8/22/2022. The findings include: 1. A lack of documentation for bi-annual verification identified that the laboratory failed to document the verification of accuracy for KOH examinations at least twice annually in 2023 and 2024. 2. An interview with TP1 on 9/25/2024 at 3:34 pm confirmed that the laboratory failed to performed bi-annual verification of KOH examinations since the last inspection. 3. The laboratory reports performing 65 KOH slide examinations annually.

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 direct observations and an interview with testing personnel 1 (TP1) on 9/25/2024, the laboratory failed to discontinue the use of expired reagents used for potassium hydroxide (KOH) slide examinations and histopathology tests. The findings include: 1. A direct observation in the Mohs laboratory on 9/25/2025 identified that the laboratory failed to discontinue the use of three (3) bottles of Eprelia Eosin-Y lot 127640N expiration 2024-08-15 (2), lot 120759 expiration 2024-1-31 (1), one (1) EDM3 acetone bottle lot 6380 expiration 2024-03-08, and the following tissue marking inks: orange lot 9213 expiration 08/31/21, green lot 20266 expiration 09/30/22, blue lot 21293 expiration 10/31/23, red lot 21292 expiration 10/31/23, yellow lot 21288 expiration 10/31/23, green lot 21290 expiration 10/31/23, black lot 21291 expiration 10/31/23, orange lot 21292 expiration 10/31/23, blue lot 22196 expiration 07/31/24, and black lot 9228 expiration 08/31/24. 2. A direct observation in the KOH laboratory on 9/25/2025 identified that the laboratory failed to discontinue the use of Troy Biologics 10% KOH lot 40051492 expiration DEC 4 2021. 3. An interview with TP1 on 9/25/2024 at 4:09 pm confirmed the above findings. 4. The laboratory reports performing 9,065 tests annually.

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 a review of maintenance logs and an interview with testing personnel 1 (TP1) on 9/25/2025, the laboratory failed to perform and document maintenance with the frequency defined by the manufacturer for the Leica CV5030. The findings include: 1. A review of laboratory maintenance logs from 2023 and 2024 identified the laboratory failed to perform and document maintenance as required by the Leica

CV5030 robotic coverslipper manufacturer. No daily maintenance was performed in 2023 or 2024 which included: checking the loading chute for broken glass and adhesive residue, checking container of the dispenser needle cleaner, checking the level of the glass vial and fill as necessary, filling the loading bath, priming and checking the dispenser needle, inspecting the cover slip catch tray, checking the pick and place module, skids, suction cups and coverslip sensor for mountant residue and broken glass, checking the specimen slide for adhesive residue and cleaning if needed. 2. An interview with TP1 on 9/25/2024 at 2:58 pm confirmed the above findings. 3. The laboratory reports performing 9,000 histopathology tests annually.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, educational documents and an interview with testing personnel 1 on 9/25/2024, the laboratory failed to have two (2) of four (4) new testing personnel qualified with the minimum educational requirements. See D6065

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:
Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, educational documents and an interview with testing personnel 1 (TP1) on 9/25/2024, the laboratory failed to ensure that all testing personnel met the educational requirements for testing. The findings include: 1. A review of the CMS 209 form identified four (4) new testing personnel hired since the last survey on 8/22/2024. 2. A review of educational documents for the four (4) new testing personnel identified that the laboratory failed to have educational documentation for two (2) testing personnel to verify that they met the minimum educational requirements before performing potassium hydroxide (KOH) slide examinations. 3. An interview with TP1 on 9/25/2024 at 3:49 pm confirmed the above finding. 4. The laboratory reports performing 65 KOH slide examinations annually.