

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0895833	(X3) Date Survey Completed 06/28/2023
Name of Provider or Supplier Ada West Dermatology	Street Address, City, State 1618 S Millennium Way Ste #200, Meridian, 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
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 a record review of the Staining Quality Control (QC) log and an interview with the testing personnel (TP), the laboratory failed to ensure that the TP did not use expired stains. Findings include: 1. Record review of the Staining QC log revealed that the laboratory failed to document any reagents in use, replaced, and/or expired for 01/04/2022 through 06/28/2023. 2. Interview with the TP on 06/28/2023 at 03:30 PM stated, "I was told that I did not have to log that information anymore." 3. The laboratory reports performing approximately 1600 histopathology tests annually.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory tour, record review, and interview with the laboratory manager, the laboratory failed to perform annual preventative maintenance (PM) service for 1 of 1 Avantik cryostat in 2022 and 2023. Findings include: 1. Laboratory tour revealed that 1 of 1 Avantik cryostat had an annual PM service due date of 08/2022. 2. Record review revealed that the laboratory failed perform annual PM service for 2022 and</p>

2023. 3. Interview with the laboratory manager on 06/28/2023 at 04:00 PM confirmed that the laboratory did not perform annual PM on Avantik cryostat for 2022 and 2023. 4. The laboratory reports performing approximately 1600 histopathology samples annually.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of competency assessment and interview with laboratory manager, the technical supervisor (TS) failed to include the 6 competency assessment (CA) criteria found in CLIA regulation 42 CFR 493.1451(b)(8) for testing personnel (TP) Findings include: 1. Review of 1 of 1 TP CA for dates 7/21/21, 9/9/2022, and 1/9/2023, revealed that the TS failed to perform CA in accordance with CLIA regulations. 2. Interview with the laboratory manager on 6/28/2023 at 02:05 PM confirmed that the TS failed to include the 6 CA criteria found in CLIA regulations for TP-1 CA.