

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D2143283	<b>(X3) Date Survey Completed</b>  10/03/2022
<b>Name of Provider or Supplier</b>  Eagle Dermatology	<b>Street Address, City, State</b>  74 N Fisher Parkway, Eagle, ID	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<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> <p>This STANDARD is not met as evidenced by: Based on a lack of documents and an interview with the laboratory manager on 10/03/2022, the laboratory failed to document, at least twice annually, the verification of accuracy for Mohs in 2021 . The findings include: 1. A lack of documentation for bi-annual verification identified that the laboratory failed to document verification of accuracy for Mohs twice annually in 2021. 2. An interview with the laboratory manager on 10/03/2022 at 12:42 PM confirmed that the laboratory had not performed verification of accuracy for Mohs twice in 2021. 3. The laboratory reports performing 220 Mohs surgery procedures annually.</p>
<b>D5417</b>	<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 direct observation and an interview with the laboratory manger on 10/03/2022, the laboratory failed to discontinue the use of expired tissue marking dyes. The findings include: 1. During the laboratory tour on 10/03/2022 a direct observation identified that the laboratory failed to discontinue the use of expired tissue marking dye used in the Mohs surgery procedure. Blue dye lot 92210 expiration 12-31-2021</p>

	<p>Green dye lot 91588 expiration 12-31-2021 Red dye lot 92021 expiration 12-31-2021 Yellow dye 91795 expiration 12-31-2021 Violet dye 82181 expiration 7-01-2020 2. An interview with the laboratory manager on 10/03/2022 at 2:18 pm confirmed the above findings. 3. The laboratory reports performing 220 Mohs surgery procedures annually.</p>
<p><b>D5429</b></p>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> 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 record review and interview with the laboratory manager on 10/03/2022, the laboratory failed to perform maintenance on the Leica CM1520 cryostat as defined by the manufacturer. The findings include: 1. The Leica CM1520 cryostat manual states that the instrument must have the plastic coupling oiled and the specimen cylinder lubricated weekly. 2. A record review of the laboratory logs identified that the laboratory failed to document weekly maintenance required by the manufacturer on the Leica cryostat CM1520. 3. An interview with the laboratory manager on 10/03/2022 at 2:18 pm confirmed that the laboratory had not document performance of weekly maintenance on the Leica cryostat CM1520. 4. The laboratory reports performing 220 Mohs surgery procedures annually.</p>
<p><b>D5473</b></p>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory quality control (QC) log and an interview with the laboratory manager on 10/03/2021, the laboratory failed to have a qualified testing person document the quality of Hematoxylin and Eosin (H&amp;E) stain daily. The findings include: 1. A review of the laboratory's H&amp;E QC log identified that the laboratory failed to have a qualified testing person review and document the quality of the H&amp;E stain daily for Mohs surgery procedures. 2. An interview with the laboratory manager on 10/03/2021 at 1:24 pm confirmed the above finding. 3. The laboratory reports performing 220 Mohs surgery procedures annually.</p>