| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 21D2330830 | 06/12/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| University Of Maryland Dermatology | 6021 University Blvd Suite 390, Ellicott City, MD | |

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 |
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| **D3011** | FACILITIES<br>CFR(s): 493.1101(d)<br><br>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation and interview with the histotechnician (HT), the laboratory failed to ensure that a functional eye wash station was located in the laboratory area where testing occurred. Findings: 1. During a tour of the laboratory at 10:00 AM, it was observed that the laboratory did not have an eye wash station available where testing was performed. 2. During an interview at 10:00 AM, the HT stated that one of two bottles of eyewash had recently been used. The second bottle was stored behind a cabinet door under the sink, which was blocked by a cart and not easily accessible. 3. Upon inspection, it was observed that the remaining bottle of eye wash solution (lot number SK23142-11) had expired 4/2026. 4. During an interview on 05/15/2026 at 11:30 AM, the HT confirmed that the eye wash solution was expired and not located where testing personnel could access it quickly in an emergency. |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on proficiency testing (PT) record review, surveyor observation, and interview with the histotechnician (HT), the laboratory did not ensure that PT was performed at |

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| | least twice annually for the potassium hydroxide (KOH) slide test. Findings: 1. During a tour of the laboratory on 05/15/2026 at 9:45 AM, the surveyor observed one bottle of KOH 20% (lot number 002294, expiration date 06/27/2027) and one bottle of "Chlorazal Black E" (lot number 001489, expiration date 01/30/2027) sitting next to the microscope. 2. During an interview at 9:45 AM, the HT stated that some of the doctors in the office performed KOH testing on their patients. 3. The laboratory began testing on 08/27/2025. A review of PT records from 2025 and 2026 showed that there was no documentation that PT had been performed for KOH. 4. During an interview on 05/15/2026 at 9:45 AM, the HT confirmed that the laboratory was not performing PT for KOH. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation and interview with the histotechnician (HT), the laboratory failed to ensure that histopathology stains and reagents were not used after they exceeded their expiration date. Findings: 1. The laboratory performed Hematoxylin and Eosin (H&E) staining procedures to evaluate histopathology slides for Mohs surgery patients. The laboratory stored the staining reagents in a flammable cabinet. 2. During a tour of the laboratory at 10:00 AM, it was observed that the flammable cabinet contained one opened and in-use bottle of "Gill 3 Hematoxylin" (lot number 193125) which expired 09/30/2025. 3. The surveyor requested additional information on the number of patients tested using the expired reagent while onsite and again in emails on 05/20/2026, 05/29/2026, and 06/04/2026, however no information was provided. 4. During a phone call on 06/12/2026 at 9:45 AM, the HT stated that they had no way of determining how many patients had been testing using the expired reagent. 5. During an interview on 05/15/2026 at 11:30 AM, the HT confirmed that the laboratory performed testing on patients using expired reagents. |
| **D6016** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(i)<br><br>(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with the histotechnician, the laboratory director failed to perform proficiency testing for the potassium hydroxide slide test performed in the laboratory. Cross-refer to D5217. |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(11)<br><br>(e)(11) 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 |

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| | testing operations reliably to provide and report accurate results;<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with the histotechnician (HT), the laboratory director (LD) failed to ensure that prior to testing patient specimens, all testing personnel (TP) received the appropriate training for the type and complexity of the services offered, and had demonstrated that they could perform all testing operations reliably to provide and report accurate results for potassium hydroxide (KOH) testing. Findings: 1. The laboratory performed KOH testing on skin scraping specimens from dermatology patients. The laboratory began testing on 08/27/2025. 2. The laboratory listed five TP on the "Laboratory Personnel Report (CLIA)" (CMS-209). Two of five TP performed KOH testing. 3. A review of training and competency assessment records from 2025 and 2026 showed that there was no documentation of initial training or competency assessments for two of two TP who performed KOH testing. 4. The surveyor requested additional information on the number of patients tested for KOH by the two TP while onsite and again in emails on 05/20/2026, 05/29/2026, and 06/04/2026, however no information was provided. 5. During a phone call on 06/12 /2026 at 9:45 AM, the HT stated that they had no way of determining how many patients had been tested for KOH by the two TP. 6. During an interview 05/15/2026 at 11:30 AM, the HT confirmed that the LD failed to document training and competency assessments on all TP who perform KOH testing in the laboratory. |