| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 03D2102434 | 06/05/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Hamblin Dermatology Pllc | 5300 S Sutter Dr Ste 1, Show Low, AZ | |

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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| **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 lack of accuracy verification documentation for review for Mohs testing and interview with the facility personnel, the laboratory failed to verify the accuracy of testing performed under the subspecialty of Histopathology at least twice annually during 2021 and 2022. Findings include: 1. No documentation was presented for review during the survey conducted on June 5, 2023 to indicate the laboratory verified the accuracy of the microscopic interpretation (reading/diagnosis) at least twice annually during 2021 and 2022 for histopathology specimens which are read during the Mohs procedure. 2. The facility personnel interviewed on June 5, 2023 at 1:45 PM confirmed the laboratory failed to verify the accuracy of histopathology testing at least twice annually during 2021 and 2022. 3. The laboratory performs patient testing under the subspecialty of Histopathology, with an annual test volume of 1,200. |
| **D5291** | GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1239(a)<br><br>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of established Quality Assessment (QA) policies and procedures for |

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| | review and interview with the facility personnel, the laboratory failed to establish QA policies and procedures for the general laboratory systems, including but not limited to, policies and procedures related to the accuracy verification process for dermatopathology testing performed by the laboratory. Findings include: 1. The laboratory performs the microscopic interpretation (reading/diagnosis) of dermatopathology specimens which are read during the Mohs procedure. 2. No documenation was presented for review during the survey to indicate the laboratory established QA policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. 3. No documentation was presented for review during the survey to indicate the laboratory established policies and procedures related to the verification of accuracy process for Mohs testing, including but not limited to, information specific to the frequency of the review, number of cases reviewed, individual or laboratory performing the review and a remedial action plan in the event of a noted discrepancy. 4. The facilty personnel interviewed during the survey on June 5, 2023 at approximately 1:55 PM confirmed that the laboratory failed establish a written policy and procedure specific to the verification of accuracy process for the microscopic interpretation of Mohs specimens, and failed to establish QA policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. 5. The laboratory's annual test volume is 1,200. |
| **D5891** | POSTANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1299(a)<br><br>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of postanalytic Quality Assessment (QA) policies and procedures, review of patient test reports and interview with the facility personnel, the laboratory failed to establish policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291, including but not limited to, policies for signing off on pathology test reports in a timely manner. Findings include: 1. The laboratory performs Mohs testing on patient specimens under the subspecialty of histopathology, with an annual test volume of 1,200. The laboratory utilizes an electronic medical record (EMR) system to maintain patient records, including Mohs operative (test) reports which are electronically signed by the individual who performed the examination and made the diagnosis. 2. No documentation was presented for review during the survey to indicate the laboratory established QA policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291, including but not limited to, signing off on test reports maintained in the electronic record in a timely manner. 3. Review of the Mohs test reports maintained in the EMR indicated the individual who performed the examination and made the diagnosis electronically signed the pathology test reports as follows: Case# 105-23 - Date of Service (DOS) 2/28/23- electronically signed on 3/21/23; Case# 355-22 - DOS 6/08/22 - electronically signed on 7/14/22; and Case# 201-21 - DOS 4/06/21 - electronically signed on 5/02/21. 4. The facility personnel interviewed on June 5, 2023 at 2:05 PM confirmed the |

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| | laboratory failed to provide evidence of QA policies and procedures for the postanalytic systems, and confirmed the Mohs test reports indicated above were not signed in a timely manner by the individual who performed the examination and made the diagnosis. |