| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 31D0694951 | 05/13/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Dermatology & Laser Center Pa | 145 Wyckoff Road Suite 200, Eatontown, NJ | |

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 surveyor review of the Biannual Assessment (BA) records and interview with the Office Manager (OM), the laboratory failed to verify the accuracy of Histopathology testing twice annually in the Calendar years 2019 and 2020. The OM confirmed on 5/13/21 at 1:30 pm that the laboratory did not verify the accuracy of Histopathology testing. |
| **D5601** | HISTOPATHOLOGY<br>CFR(s): 493.1273(a)(f)<br><br>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of Quality Control (QC) records and interview with the Office Manager (OM), the laboratory failed to document Hematoxylin and Eosin (H&E) control slide reaction from 11/29/18 to the date of survey. The findings include: 1. The laboratory did not document H&E stain QC reaction for reading of biopsy slides. 2. The laboratory read and reported approximately 400 patient slides. 4. |

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| | The OM confirmed on 5/14/21 at 1:40 pm that the laboratory did not document H&E QC stain reaction. |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Final Report (FR) and interview with the Office Manager (OM) the laboratory failed to ensure that the FR included the correct address of the laboratory where testing was performed from April 2021 to the date of survey. The finding includes: 1. The laboratory moved and did not change the address on the FR to the new location 2. The OM confirmed on 5/13/21 at 2:00 pm that the FR did not have the correct address where testing was performed. |