| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 39D0196404 | 10/19/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Pa Dermatology Partners Ov | 385 Oxford Valley Road Suite 312, Yardley, PA | |

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 documentation and interview with the Director of training and compliance (DTC), the laboratory failed to perform twice annually the verification of accuracy of Mohs microscopic examinations from 01/05/2022 to the date of survey. Findings include: 1. On the day of survey, 10/19/2023 at 10:48 am, the laboratory could not provide the biannual documentation for the verification of accuracy of Mohs microscopic examinations from 01/15/2022 to the date of survey. 2. According to the laboratory's proficiency testing policy, "Semi-annually, the tech or risk manager will send five cases containing the original slide, and send out for a microscopic examination by a board certified Dermatopathologyst". 3. The laboratory reported an annual volume of 1222 microscopic examinations/tests performed in Histopathology (CMS 116). 4. The DTC confirmed the above findings on 10/19/2023 at 12:10am. |
| **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. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's quality control (QC) records and interview with the Director of training and compliance (DTC), the laboratory failed to document Hematoxylin and Eosin (H&E) QC monitoring activities for intended reactivity each day of patient testing for MOHS micrographic examinations performed from 01/04 /2023 to 10/19/2023. Findings Include: 1. On the day of the survey, 10/19/2023 at 09: 54 am, review of the staining QC records revealed the laboratory did not document QC monitoring activities for intended reactivity each day of patient testing for MOHS micrographic surgery slide examinations stained using H&E for 50 of 50 days from 01 /04/2023 to 10/19/2023. 2. The DTC confirmed the finding above on 10/19/2023 around 12:10 pm. |
| **D5781** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(1)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's temperature records and interview with the Director of training and compliance (DTC), the laboratory failed to provide documentation of the corrective actions taken when Cryostat (CT) temperatures were outside of the laboratory's established acceptable ranges of -21 to -26 Celsius (C) for 32 of 47 days in 2023 when Histopathology testing was performed. Findings include: 1. On the day of survey 10/19/23 at 10:05 am, review of the laboratory's temperature records revealed the following 32 of 47 days in 2023 were outside of the laboratory's established acceptable range (-21 to -26C): - January: 2 of 2 days CT temperature: -35 C - February: 2 of 2 days Ct temperatures: -36C and -38C - March: 4 of 4 days CT temperatures: -28C, -35C (2 days) and -33C - May: 8 of 9 days CT temperatures: -35 C (4 days), -36C (2 days), -31C and -30C. - June: 6 of 6 days CT temperatures: -31C (2 days), -30C (3 days), and -28C - July: 3 of 5 days CT temperatures: -30C (2 days) and -31C - August: 4 of 7 days CT temperatures: -31C (2 days), -30C, and -28C - September: 3 of 8 days CT temperatures:-31C (2 days) and -33C 2. The laboratory could not provide documentation for corrective actions taken when temperatures were out of range. 3. The DTC confirmed the findings above on 10/19/2023 at 12:10 pm. |