| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 39D0673421 | 05/23/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Dermatology Physicians Inc | 2106 Harrisburg Pike Suite 314, Lancaster, 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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| **D3043** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(7)<br><br>The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of records and interview with the Hisotechnologist and a registered nurse (RN), the laboratory failed to retain histopathology slides for at least 10 years from the date of examination from 05/23/2009 to 05/23/2019. Findings Include: 1. On the day of survey, the laboratory could not provide histopathology slides read onsite from 05/23/2009 to 05/23/2019. 2. The Hisotechnologist and RN stated "all slides are kept at the main location located at 203 N. Lime Street, Lancaster PA, 17602 and or at Iron Mountain storage facility". 3. The laboratory was given till Wednesday 05/29 /2019 close of business day to send evidence of slide retention from 2018, 2017 and 2009. 4. On 5/30/2019 the surveyor did not receive any evidence, to show compliance. 5. On 05/30/2019 at 12:20 pm, the Hisotechnologist and RN were informed by email, that the laboratory would be cited for retention requirements. |
| **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) |

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| | 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 the review of histopathology patient test reports and interview with the Hisotechnologist and a registered nurse (RN), the laboratory failed to include on 2 of 2 test reports reviewed at the time of survey, the location where Tissue Pathology slides were read from 08/22/2017 to the date of survey. Finding Include: 1. On the day of survey, 05/23/2019, a review of some test reports (2 of 2) revealed the test reports did not include the correct address where the slides were being read. 2. The final reports states, "Slides prepared @ 2106 Harrisburg Pike, Lancaster PA 17604 and Slides read @ 203 N. Lime street, Lancaster, PA". 3. According to the histotechnologist and the RN, on 05/23/2019 around 09:15 am the test reports did not reflect that slides were read at 2106 Harrisburg Pike, Lancaster PA 17604 location. |
| **D8103** | BASIC INSPECTION REQUIREMENTS<br>CFR(s): 493.1773(b)(c)(d)<br><br>(b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of records and interview with the Hisotechnologist and registered nurse (RN), the laboratory failed to provide records, have data accessible and retrievable within a reasonable time frame during the inspection performed on 05/23/2019. Finding Include: 1. On the day of survey, 05/23/2019, the histotechnologist and RN could not provide the records below during the inspection: a. 2018 and 2019 KOH, Scabies and Histopathology peer review records. b. Patient reports for KOH and scabies from 01/2018 and 07/2018. c. Patient reports for histology from 10/2018 and 02/2019. 2. The Hisotechnologist and RN stated "all documents were kept at the main location located at 203 N. Lime Street, Lancaster PA, 17602", the laboratory was given till Wednesday 05/29/2019 by close of business day to send records to the surveyor for review. 3. On 5/24/2019 at 10:12 am, the survey received records for KOH peer reviews, but 5 of 7 peer reviews were not circled to indicate where the review was performed and 2 of 7 peer reviews were circled for the 203 N. Lime street, |

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| | Lancaster PA 17602, not the 2106 Harrisburg Pike, Suite 314, Lancaster PA 17604 location. 4. On 5/30/2019 the surveyor did not receive additional information from the laboratory, to show compliance. 5. On 05/30/2019 at 12:20 pm, the Hisotechnologist and RN were informed by email, that the laboratory would be cited for retention requirements. ***KOH= Potassium Hydroxide |