| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 31D2035208 | 04/12/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Haddonfield Dermatology Associates | 24 West Kings Highway, Haddonfield, 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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| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>a)Based on surveyor review of the Procedure Manual (PM), observation of the Automated Staining Station (ASS) and interview with the Office Manager (OM), the laboratory failed to follow Mohs Staining Procedure from June 2017 to the date of the survey. The findings include: 1. The ASS in the laboratory did not correspond with the staining procedure in the PM. a) The PM stated Staining Container (SC) # 2 was for 95% Alcohol but ASS had water. b) The ASS had SC # 3 for Hematoxylin but it was water in the PM. c) The ASS had SC # 4 for water but it was Hematoxylin in the PM. d) The ASS had SC # 5 for 95% Alcohol but it was Hematoxylin in the PM. e) The ASS had SC # 6 for Eosin but it was Water in the PM. f) The ASS had SC # 7 for 95% Alcohol but it was water in the PM. g) The ASS had SC # 8 for 100% Alcohol but it was Scott's Bluing in the PM. h) The ASS had SC # 9 for 100% Alcohol but it was water in the PM. i) The ASS had SC # 10 for Xylene Substitute but it was Eosin in the PM. j) The ASS had SC # 11 for Xylene Substitute but it was 95% Alcohol in the PM. k) The ASS had SC # 12 for 100% Alcohol but it was 95% Alcohol in the PM. l) The PM has steps 13-15 but the ASS ends at 12. 2. The OM confirmed on 4/12 /18 at 12:45 pm that PM procedure did not match with ASS. b) Based on surveyor review of the Biannual Assessment (BA) procedure, Procedure Manual (PM) and interview with the Office Manager (OM), the laboratory failed follow the BA procedure for the Calendar year 2016 and 2017. The finding includes: 1.The PM stated that the BA will be submitted for review at a CMS-approved Laboratory. a) There was no evidence that the BA was submitted to a CMS-approved Laboratory. b) |

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| | There was no evidence of physician review of slides c)The BA does not identify the reviewing physician. 2. The PM stated that Mohs Surgeon will "review five categories" a) There was no evidence the five categories were reviewed. 3. The PM stated that 4-10 Mohs cases will be submitted for review. a) Two cases were submitted in BA event 01/10/17 b) Three cases were submitted in BA event 8/9/17 4) The PM stated the BA "will be conducted twice a year"but the laboratory did only once in 2016. 3. The OM confirmed on 4/12/18 at 11:01 am that the BA procedure was not followed. |
| **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 surveyor review of the Temperature Logs (TL) and interview with the Office Manager (OM), the laboratory did not document corrective action taken when the Room Temperature (RT) and Cryostat was out of range from 5/31/2017 to date of survey. The findings include: 1. A review of the TL where testing is performed revealed that RT was outside the established range 8 out of 12 days from 1/3/18 to 4/11/18. 2. A review of the TL where testing is performed revealed the temperature was outside the established range for Cryostat 5/13/17 3. There was no documented evidence of corrective action taken. 3. The OM confirmed on 4/12/18 at 10:00 am the laboratory did not document corrective action. |
| **D5787** | TEST RECORDS<br>CFR(s): 493.1283(a)<br><br>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Mohs Log (ML), Patient Slide Review (PSR), and interview with the Office Manager (OM), the laboratory failed to maintain accurate ML for Mohs test from January 2017 to the date of survey. The finding includes: 1. Review of ten PSR reviled that three out of ten did not have the correct stage and slide count documented in the ML. 2. The OM confirmed on 4/12/18 at 10:30 am that the laboratory did not maintain accurate ML. |
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| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Procedure Manual (PM), Monthly Patient Quality Assurance Checklist (MPQAC), and interview with the Office Manager (OM), the Laboratory Director failed to ensure that the MPQAC was maintained from 4/14/16 to the date of survey. The OM confirmed on 4/12/18 at 11:00 am that the QA program was not maintained. |