| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 45D0672772 | 11/08/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Dallas Associated Dermatologists, Pllc | 12700 Park Central Drive Ste B-150, Dallas, TX | |

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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| **D0000** | Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiency, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately. |
| **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>I. Based on review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment in 2016 and 2017 for the grossing of the histology specimens. The findings were: 1. The laboratory was asked to provide documentation of assessing the accuracy of specimen grossing for Histology twice in 2016 and 2017. No documentation was provided. 2. An interview with the laboratory representative on 11 /08/2018 at 1000 hours in the conference room revealed the laboratory did not perform twice annual accuracy assessments for grossing in 2016 and 2017. This confirmed the findings. II. Based on review of the laboratory's records and staff interview, it was revealed that the laboratory failed to submit histology microscopic |

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| | slides for twice annual accuracy assessment without the laboratory's results known to the reviewer for 2017 and 2018. Findings included: 1. Review of the laboratory record titled "Quality Assurance Proficiency Program" revealed the following options for evaluation of the histology microscopic slides submitted for twice annual accuracy assessment: a. Agree with diagnosis b. Agree with diagnosis with Mild Discrepancy and No Clinical Significance c. Disagree with No Clinical Significance d. Disagree with Mild Clinical Significance e. Disagree with Severe Clinical Significance 2. A random review of the 2018 laboratory records titled "Quality Assurance Proficiency Program" revealed the following 5 of 5 cases in which the "Agree with diagnosis" option was selected by the reviewer: a. Case Number: S18-0290 b. Case Number: S18-0736 c. Case Number: S18-3734 d. Case Number: S18-4918 e. Case Number: S18-3077 The laboratory failed to ensure that the histology microscopic slides for twice annual accuracy assessment were submitted without the laboratory's final diagnosis known to the reviewer. 3. Further review of laboratory records revealed the laboratory failed to have documentation of a written policy for the submission of histology microscopic slides for twice annual accuracy assessment. 4. During an interview with the laboratory representative on 11/08/2018 at 1000 in the conference room, the laboratory representative stated, "The slides were submitted for review along with the patient history and diagnosis. The reviewer then indicates agreement or not with the diagnosis." This confirmed the above findings. |
| **D6121** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(8)(i)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.<br><br>This STANDARD is not met as evidenced by:<br>Review of form CMS-209, competency assessment records and laboratory representative interview revealed the laboratory's technical supervisor failed to evaluate the competency assessment for testing personnel for 2017 and 2018. Findings included: 1. Review of form CMS-109 revealed 3 testing personnel performing high complexity testing. (Testing Person #2, Testing Person #3, and Testing Person #4) and 1 Technical Supervisor. 2. Review of the laboratory forms titled "Laboratory Grossing Competency Assessment" and "Laboratory Competency Assessment" revealed that the laboratory testing personnel (Testing Person #2, Testing Person #3, and Testing Person #4) were assessed by an individual other than the Technical Supervisor listed on the CMS-209 for 2017 and 2018. 3. The individual who assessed the testing personnel did not quality as a Technical Supervisor. 4. The above findings were confirmed in an interview with laboratory representatives on 11/08/2018 at 1000 in the conference room. |