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| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>10D0936067   | <b>(X3) Date Survey Completed</b><br><br>06/15/2023 |
| <b>Name of Provider or Supplier</b><br><br>Associates In Dermatology Inc                                                   | <b>Street Address, City, State</b><br><br>530 Ocoee Commerce Pkwy, Ocoee, FL |                                                     |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |                                                                              |                                                     |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
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| <b>D0000</b>              | A recertification survey was conducted on June 15, 2023. Associates in Dermatology Inc clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>D5433</b>              | <p><b>MAINTENANCE AND FUNCTION CHECKS</b><br/>CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on observation, review of quality control and quality assurance (QA) records, and interview, the laboratory failed to document all maintenance activities and QA for 2 (October 2022, December 2022) of 5 months (October 2021, June 2022, October 2022, December 2022, March 2023) reviewed, and failed to have separate temperature and maintenance logs for each cryostat or indicate which cryostat was used each day of patient testing in 2022 and 2023. Findings: 1. Review of the "Staining Daily Maintenance", "Cryostat Maintenance Log", "Cryostat Temperature Log" and "Quality Assurance of Daily Controls Checks" showed not all days in which testing was performed were documented. Review of the "Mohs Accession Log" listed the dates and the patients who had Mohs surgical procedure. Documentation on the "Staining Daily Maintenance" log was missing for the following dates when patient testing was performed: 10/12/2022 - 6 patients 10/25/2022 - 3 patients 12/12/2022 - 2 patients 12/14/2022 - 2 patients 12/21/2022 - 3 patients Documentation on the "Cryostat Maintenance Log" log was missing for the following dates when patient</p> |

testing was performed: 10/03/2022 - 4 patients 10/26/2022 - 4 patients Documentation on the "Cryostat Temperature Log" and "Quality Assurance of Daily Controls Checks" was missing for the following dates when patient testing was performed: 10/12/2022 - 6 patients 10/25/2022 - 3 patients 10/26/2022 - 4 patients 12/12/2022 - 2 patients 12/14/2022 - 2 patients 12/21/2022 - 3 patients On 06/15/2023 at 11:08 AM, the Operations Manager acknowledged some of the documentation was not recorded.

2. A tour of the laboratory on 06/15/2023 at 10:05 AM noted the laboratory had 2 cryostats. Review of the "Cryostat Maintenance Log" and the "Cryostat Temperature Log" showed the laboratory had only one log for both cryostats and did not indicate which cryostat was used on each day of testing. On 06/15/2023 at 11:08 AM, the Operations Manager stated they only had one cryostat maintenance log and one cryostat temperature log, and that she did not know which instrument was used for each day of patient testing.