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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 21D2132684 | (X3) Date Survey Completed 05/02/2018 |
| Name of Provider or Supplier Advanced Dermatology Of Maryland | Street Address, City, State 174 Waterfront Street Suite 200, Oxon Hill, MD | |
| 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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| D5403 | <p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on standard operating procedure manual (SOPM) review and interview with the laboratory staff, the laboratory did not ensure that there was an approved policy for processing and sending out patient specimens to their referral laboratory. Findings: 1. During an interview at 9 AM, laboratory staff stated that patient dermatological specimens are collected and sent out to a referral laboratory which makes and reads histological slides and then sends the final report back to the office. 2. A review of the SOPM showed that there was not an approved policy (signed and dated by the laboratory director) for the processing and send out of specimens to the referral</p> |

laboratory at the time of the survey. 3. During an interview on 5/2/18 at 10:45 AM, the laboratory staff confirmed that there was no approved policy for the processing and send out of specimens to the referral laboratory at the time of the survey.

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

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.

This STANDARD is not met as evidenced by:
Based on record review and interview with laboratory staff, the laboratory did not ensure that routine maintenance was performed and recorded on the laboratory microscope. Findings: 1. The laboratory's "Quality Assurance Manual" was reviewed. The section, "III. Post-Analytical" states, "the equipment for performing any testing is maintained in accordance with the manufacture instructions and all maintenance is logged on the appropriate sheet for that instrument. The microscope must be cleaned after each day of use." 2. A review of laboratory records showed that a microscope maintenance log was not available at the time of the survey; and 3. During an interview on 5/2/18 at 10:45 AM, laboratory staff stated that the microscope was cleaned, and confirmed that it had not been recorded on a maintenance log.