| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 03D0912335 | 10/15/2020 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Associated Dermatologists Pc | 1055 N La Canada, Ste 125, Green Valley, AZ | |

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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| **D5203** | SPECIMEN IDENTIFICATION AND INTEGRITY<br>CFR(s): 493.1232<br><br>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of frozen biopsy test reports, review of patient slides and interview with the facility personnel, the laboratory failed to ensure positive identification of the patient's dermatopathology specimens. Findings include: 1. The laboratory performs dermatopathology testing under the sub-specialty of histopathology, with an approximate annual test volume of 300. It is the practice of the laboratory to indicate the frozen biopsy test results on the Mohs map. 2. Review of the frozen biopsy slide for patient C.B. from 8/14/20 revealed the slide was labeled with the Mohs accession number, "20-147" and the site was listed as "R Central Eyebrow". The correct site of the frozen biopsy was "L Nasal Ala", as indicated in the test result listed on the Mohs map. 3. The facility personnel interviewed during the survey conducted on 10/15/20 stated that it is the practice of the laboratory to label frozen biopsy slides with the patient name, date of service and specimen location. No accession number is assigned to the frozen biopsy cases. 4. The facility personnel confirmed that the frozen biopsy slide from the patient indicated above was erroneously labeled with the Mohs accession number and the incorrect specimen location. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's established policies and procedures and interview with the facility personnel, the laboratory failed to establish a policy and procedure for Frozen Biopsy testing performed under the sub-specialty of histopathology. Findings include: 1. The laboratory performs Frozen Biopsy interpretations under the sub-specialty of histopathology, with an approximate annual test volume of 300. 2. No policy or procedure was presented for review during the survey conducted on October 15, 2020 to indicate the laboratory established policies and procedures for Frozen Biopsy interpretations, including but not limited to, specimen labeling and identification, specimen processing, step-by-step performance of the procedure, microscopic examination, control procedures, and test reporting processes. 3. The facility personnel confirmed that the laboratory failed to establish policies and procedures for Frozen Biopsy interpretations. |
| **D5433** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(b)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory maintenance policies, microscope maintenance documentation and interview with the facility personnel, the laboratory failed to perform and document the annual microscope maintenance as defined by policy during 2018 and 2019. Findings include: 1. The laboratory's established microscope maintenance policy states the microscope is "inspected and cleaned annually". 2. No documentation was presented for review to indicate the laboratory performed the maintenance as indicated above on the microscope during 2018 and 2019. 3. The facility personnel confirmed that the laboratory failed to perform yearly maintenance on the microscope as indicated in policy. |