| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 10D0692984 | 07/19/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Umdc Dermatology Mohs Chemosurgery | 1150 Nw 14th St Suite 503j, Miami, FL | |

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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| **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>Based on record review and staff interview, the laboratory failed to verify the accuracy of the reading and interpretation of the Hematoxylin and Eosin (H&E) stain from 8/29/17 to 7/19/18 for 1 out of 2 testing personnel who perform the reading and interpretation of the H&E slides. Findings: Review of the laboratory's records failed to show documentation of the peer review for testing personnel B from 8/29/17 to 7/19 /18. The laboratory uses peer review to evaluate the accuracy of the reading and interpretation of the H&E stain. During an interview on 7/19/18 at 9:50 AM, Testing Personnel C stated she did not know they needed to do peer review on all personnel who read and interpret the H&E stains. |
| **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, 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 |

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| | 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 record review and interview, the laboratory's written procedure manual was incomplete. Findings: Review of the procedure titled "Tissue Processing Procedure" showed the procedure failed to included step by step instructions for making the 95% alcohol solution used for the Hematoxylin and Eosin (H&E) stain and for changing the reagents used for the H&E stain. During an interview on 7/19/18 at 11:00 AM, Testing Personnel C acknowledged that there were no written instructions for making the 95% alcohol solution. During an interview on 7/19/18 at 11:39 AM, Testing Personnel C acknowledged that there were no written instructions for changing the reagents for the H&E stain. Review of the procedure titled "Quality Assurance /Performance Improvement Plan" section titled "Participation In Proficiency Testing" showed the procedure states "The results are compared with ours and ensure that they are similar in case there are differences between both diagnostics investigation and remedial action will be taken." The procedure fails to include what the laboratory would do if there is a difference between both diagnostics investigation and what would be done if the patients Mohs report needed to be amended. During an interview on 7/19/18 at 11:05 AM, Testing Personnel C acknowledged the procedure does not include what the laboratory would do if there is a difference between both diagnostics investigation. During an interview on 7/19/18 at 11:40 AM, Testing Personnel C acknowledged the procedure does not include what would be done if the patients Mohs report needed to be amended. |