| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 24D2061348 | 01/11/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| North Metro Dermatology | 400 Village Center Dr #200, North Oaks, MN | |

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 document review and interview with laboratory personnel, the laboratory failed to perform and document activities used to verify the accuracy of Microbiology and Histopathology test procedures at least twice annually. Findings are as follows: The laboratory performed Microscopic Examinations for parasites and fungus under the specialty of Microbiology and Mohs Micrographic Surgery testing under the subspecialty of Histopathology as confirmed by the Practice Manager during a tour of the laboratory on 01/11/18 at 10:15 a.m. The laboratory began Histopathology testing in August 2017 and Microscopic Examinations in 2013. Microscopic Examinations 1. The Table of Contents for the laboratory's CLIA manual indicated verification of accuracy for non-waived tests (Microscopic Examinations) would be performed twice annually for each eligible physician. 2. Documentation of the 2017 Microscopic Examination verifications was not found in laboratory records. The laboratory was unable to provide verification documentation from 2017 upon request. 3. In an interview on 01/11/18 at 11:23 a.m., Office Personnel 1 confirmed Microscopic Examination accuracy had not been verified in 2017. Mohs Micrographic Surgery 1. A twice annual verification of accuracy requirement for the Mohs Micrographic Surgery testing was established in the laboratory's CLIA manual. 2. Documentation of the 2017 Mohs Micrographic Surgery verification was not found in laboratory records. The laboratory was unable to provide verification documentation from 2017 upon request. 3. In an interview on 01/11/18 at 11:00 a.m., the Mohs Technician confirmed Mohs Micrographic Surgery accuracy had not been verified in 2017. |
| **D5403** | PROCEDURE MANUAL |

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| | 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 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 document review and interview with laboratory personnel, the laboratory failed to include all required elements in the laboratory procedure manual. Findings are as follows: 1. The laboratory performed Microscopic Examinations for parasites and fungus and Mohs Micrographic Surgery testing as confirmed by the Practice Manager during a tour of the laboratory on 01/11/18 at 10:15 a.m. The laboratory began Histopathology testing in August 2017 and Microscopic Examinations in 2013. 2. The laboratory's CLIA manual did not include the following required items: a. Requirements for tissue labeling upon collection, documentation of receipt time, processing, and slide storage criteria; Mohs Log, Mohs Map, accession number criteria; and criteria for specimen acceptability and rejection (1) b. Microscopic examination procedures for parasites and fungus (2) c. Step-by-step performance of Mohs slide reading, including interpretation of results (3) d. Preparation of Mohs slides, slide labeling requirements, reagent lot numbers and expiration dates (4) e. Corrective action to take when control slide results fail to meet the laboratory's criteria for acceptability (8) f. Reference intervals (10) g. 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 (13) h. Description of the course of action to take if a test system becomes inoperable (14) The laboratory was unable to provide written policies or procedures for the above items upon request. 3. In an interview on 01/11/18 at 11:45 a.m., the Mohs Technician confirmed the above findings regarding the Mohs Micrographic Surgery. Office Personnel 1 confirmed the lack of Microscopic examination procedures on 01/11/18 at 11:23 a.m. |
| **D5407** | PROCEDURE MANUAL<br>CFR(s): 493.1251(d)<br><br>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. |

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| | This STANDARD is not met as evidenced by:<br>. Based on document review and interview with laboratory personnel, the laboratory failed to ensure all procedures were approved, signed and dated by the laboratory director prior to use. Findings are as follows: 1. The laboratory performed Microscopic Examinations for parasites and fungus and Mohs Micrographic Surgery testing as confirmed by the Practice Manager during a tour of the laboratory on 01/11 /18 at 10:15 a.m. The laboratory began Histopathology testing in August 2017 and Microscopic Examinations in 2013. 2. Laboratory procedures specific to Mohs Micrographic Surgery testing were found in the laboratory's CLIA manual and in equipment operation manuals provided by the manufacturers. Procedures were not found for Microscopic Examinations - see D5403. 3. The Laboratory Director did not approve, sign or date these procedures prior to the implementation of patient testing. 4. In an interview on 01/11/18 at 11:00 a.m., the Mohs Technician confirmed the laboratory director had not approved the procedures prior to testing implementation. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>. Based on observation, document review and interview with laboratory personnel, the laboratory failed to perform and/or document required maintenance on equipment used for Microbiology and Histopathology testing. Findings are as follows: 1. The laboratory performed Microscopic Examinations under the specialty of Microbiology and Mohs Micrographic Surgery testing under the subspecialty of Histopathology as confirmed by the Practice Manager during a tour of the laboratory on 01/11/18 at 10: 15 a.m. The laboratory began Histopathology testing in August 2017 and Microscopic Examinations in 2013. 2. A Luneon microscope for Microscopic Examinations and a Leica DM 1000 microscope for Mohs Micrographic Surgery were observed as present and available for use during the tour of the laboratory. 3. A requirement for cleaning after each use was established he Leica DM 1000 Instructions for Use manual provided by the manufacturer. A maintence procedure for the Luneon microscope was not found - See D5433. 4. Documentation of microscope cleaning was not found for either microscope during review of laboratory records. The laboratory was unable to provide documentation of this instrument maintenance upon request. 5. In an interview on 01/11/18 at 11:40 a.m., the Mohs Technician confirmed the above maintenance had not been documented as required. |
| **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. |

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| | This STANDARD is not met as evidenced by:<br>. Based on observation, document review and interview with laboratory personnel, the laboratory failed to establish a preventative maintenance protocol for all ancillary laboratory equipment. Findings are as follows: 1. The laboratory performed Microscopic Examinations under the specialty of Microbiology as confirmed by the Practice Manager during a tour of the laboratory on 01/11/18 at 10:15 a.m. The laboratory began performing Microscopic Examinations in 2013. 2. A Luneon microscope for Microscopic Examinations was observed as present and available for use during the tour of the laboratory. 3. An Luneon microscope equipment maintenance procedure was not found in the laboratory's procedure manual. The laboratory was unable to provide this procedure upon request. 4. In an interview on 01 /11/18 at 11:23 a.m., Office Personnel 1 confirmed the laboratory did not have a procedure defining maintenance activities for the Luneon microscope. |
| **D5609** | HISTOPATHOLOGY<br>CFR(s): 493.1273(e)(f)<br><br>(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>. Based on document review and interview with laboratory personnel, the laboratory failed to document all information required for Histopathology quality control records. Findings are as follows: 1. The laboratory performed Mohs Micrographic Surgery under the subspecialty Histopathology as confirmed by the Practice Manager during a tour of the laboratory on 01/11/18 at 10:15 a.m. The laboratory began Histopathology testing in August 2017. 2. Requirements for documentation of stain and reagent lot numbers and expiration dates were not found during review of the laboratory's procedure manual - See D5403. 3. A reagent receipt log was not found during review of laboratory records. The laboratory was unable to provide this log upon request. 4. In an interview on 01/11/18 at 11:45 a.m., the Mohs Technician confirmed reagent lot numbers and expiration dates had not been documented. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>. Based on document review and an interview with laboratory personnel, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems when identified. Findings are as follows:: 1. The laboratory performed Microscopic Examinations for parasites and fungus and Mohs Micrographic Surgery testing as confirmed by the Practice Manager during a tour of the laboratory on 01/11/18 at 10: 15 a.m. The laboratory began Histopathology testing in August 2017 and Microscopic |

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| | Examinations in 2013. 2. The laboratory failed to establish a Quality Assurance program to monitor, assess, and when indicated, correct problems identified in the pre-analytic, analytic, and post-analytic systems such as, but not limited to, the following: a. Twice annual verification of Microscopic Examinations and Mohs Micrographic Surgery test performance was not completed in 2017. See D5217 b The procedure manual did not include all elements required for test procedures. See D5403. c. The Laboratory Director failed to approve, sign, and date all procedures. See D5407. d. Microscope maintenance was not documented . See D5429 e. A maintenance procedure was not established for the Luneon microscope. See D5433 f. Documentation was not maintained to ensure reagents and stains were not used beyond their expiration dates. See D5609. 3. In an interview on 01/11/18 at 11:45 a. m., the Mohs Technician confirmed the above findings. |