Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
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# Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 36D0689722	**(X3) Date Survey Completed** 12/12/2022
Name of Provider or Supplier North Coast Dermatology Associates, Inc	**Street Address, City, State** 4807 Rockside Rd, Ste 100, Independence, OH	
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
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interviews with the Laboratory Director (LD) and Histopathology processor (HP), the LD failed to provide overall management and direction in accordance with 493.1445 of this subpart for the MOHS tissue biopsy testing procedures performed in the specialty of Histopathology. This deficient practice had the potential to affect all patient MOHS cases from 04/27/2021 to 12/12/2022. Findings Include: 1. The LD failed to ensure that performance verification activities were conducted, documented and acceptable to determine accuracy, precision and other pertinent performance characteristics when the laboratory equipment (cryostat, manual stain station and microscope) utilized for the MOHS testing was moved on 05/02/2022. (Refer to D6086) 2. The LD failed to ensure that the HP was processing MOHS tissue biopsy specimens as required for accurate and reliable results. (Refer to D6087) 3. The LD failed to ensure that the quality assessment program was maintained to assure the quality of laboratory services provided. (Refer to D6094) 4. The LD failed to ensure that patient MOHS tissue biopsy test results were only reported when the test system was functioning properly and when the room humidity was monitored and documented according to the manufacturer's operating specifications. (Refer to D6097, Item 1) 5. The LD failed to ensure that patient MOHS tissue biopsy test results were only reported when the system was functioning properly and Histopathology reagents, solutions and stains were not used beyond their expiration dates. (Refer to D6097, Item 2)
D6086	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Director (LD) and Histopathology processor (HP), the LD failed to ensure performance verification activities were conducted and documented to determine accuracy, precision and other pertinent performance characteristics when the laboratory equipment (cryostat, manual stain station and microscope) utilized for the MOHS testing were moved on 05 /02/2022. This deficient practice had the potential to affect all patient MOHS testing procedures from 05/02/2022 to 12/12/2022. Findings Include: 1. Review of the laboratory's "Performance Verification of Cryostat Leica CM1860 after office relocation" procedure provided for inspection review found the performance verification activities included the following: *instrument positioning with appropriate wall clearance *the cryostat was not turned on for a minimum of 4 hours after delivery *the cryostat was connected to a dedicated electrical circuit without an extension cable *an electrician verified the electrical circuit met the manufacturers requirements for operation *operating temperature of 0 to -35 degrees of Celsius was obtained *the temperature was maintained for 5 days prior to putting cryostat in use Accuracy and precision studies were not performed and documented, as required. 2. Review of the laboratory's "Performance Verification of Cryostat Leica CM1860" also provided for inspection review found the optimal room temperature and humidity conditions specified and instructions that they would be documented on the day of use. Accuracy and precision studies were not performed and documented, as required. 3. The Inspector requested all of the laboratory's performance specification documentation for the cryostat, manual stain station and microscope after it was moved to the current laboratory location on 05/02/2022 from the LD and HP. The LD and HP confirmed the laboratory only documented the items listed above for the cryostat, did not perform and document accuracy and precision studies as required prior to patient MOHS testing and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 12/12/2022 at 10:25 AM.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Director (LD) and Histopathology processor (HP), the LD failed to ensure that the HP was processing MOHS tissue biopsy specimens as required for accurate and reliable results. Between 04/27/2021 and 12/12/2022, 64 patient MOHS specimens required a re-cut due to no epidermis or the lack of a complete epidermis. This deficient practice had the potential to affect all patient MOHS specimens between 04/27/2021 and 12/12/2022. Findings Include: 1. Review of the laboratory's "Part 3: Laboratory Procedures Mohs Micrographic Surgery Specimen Processing" policy and procedure revealed the

	following statements: "A detailed map is made to correlate with the tissue removed. The cut edge of the tissue is inked with blue (broken lines on map) and red dye (solid lines on map) to demonstrate margins. ...6. Check under microscope for the red ink, blue ink, and complete half circle of skin. All three need to be present for a proper section." 2. Review of the laboratory's "MOHS Histology QA/QC Log" from 04/27 /2021 to 12/12/2022 found documentation of 64 patient MOHS tissue biopsy specimens indicating "re-cut" due to no epidermis or the lack of a complete epidermis. 3. The Inspector requested the laboratory's documentation of the sole HP's re-training and/or remedial corrective action from the HP. The HP stated there was no retraining or remedial corrective action due to no epidermis or the lack of a complete epidermis from MOHS tissue biopsy specimens they processed. There was only a request for a re-cut and therefore the HP was unable to provide the requested re-training and/or remedial corrective action documentation on the date of the inspection. The interview occurred on 12/12/2022 at 9:52 AM. 4. The Inspector requested the laboratory's documentation of the sole HP's re-training and/or remedial corrective action for the MOHS tissue biopsy recuts from the LD. The LD confirmed that the laboratory did not document any corrective action other than "recut" and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 12 /12/2022 at 11:09 AM.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: **This is a repeat deficiency from the 11/21/2016 CLIA Inspection** Based on record review and an interview with the Laboratory Director (LD), the LD failed to ensure that the preanalytic quality assessment program was maintained to assure the quality of laboratory services provided. This deficient practice had the potential to affect all patient MOHS procedures performed from 04/27/2021 to 12/12/2022. Findings Include: 1. Review of the laboratory's "Part 1: Quality Control Programs and Forms" policy and procedure found the following statement: "Corrective Action: *When QC analysis indicates a test system failure remedial action will be documented on the corrective action form." 2. Review of the laboratory's "Policy and Procedure for Quality Assessment of the MOHS Procedure" revealed the following instructions: "1. The laboratory director will maintain and document ongoing assessment activities, monitor assess and correct identified problems in the laboratory [s] they occur; a. Review effectiveness of corrective action taken b. review and update policy and procedures to prevent recurrence of the problems" 3. Review of the laboratory's 2021 and 2022 "CLIA Quality Assurance for Moh's Surgery" running worksheets provided for inspection review revealed 64 patient MOHS tissue biopsy procedures since the last CLIA inspection to current date indicated "re-cut" due to no epidermis or the lack of a complete epidermis. 4. On 12/12/2022 at 9:52 AM, the Inspector requested the corrective action documentation for the tissue biopsy recuts from the HP. The HP stated they did not receive and document any retraining or remedial action and was unable to provide the requested documentation on the date of the inspection. 5. The Inspector requested the laboratory's 2021 and 2022 quality assessment documentation to include the review of corrective action effectiveness from the LD. The LD stated that the laboratory included and documented the review of corrective action

	effectiveness as "problem resolved - yes" and believed that to be sufficient for that specific cut of tissue, however was unable to provide the requested documentation on the date of the inspection for the ongoing occurrences. The interview occurred on 12 /12/2022 at 11:09 AM and via a telephone conference call on 01/18/2023 at 12:04 PM.
D6097	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Item 1 Based on record review and interviews with the Laboratory Director (LD) and Histopathology processor (HP), the LD failed to ensure that patient MOHS tissue biopsy test results were only reported when the room humidity was monitored and documented according to the manufacturer's operating specifications. This deficient practice had the potential to affect all patient MOHS cases conducted between 04/27 /2021 to 12/12/2022. Findings Include: 1. Review of the "Leica 1860 Cryostat" manufacturer's operating specifications found the following instructions: "Relative humidity, maximum 60 % (non-condensing)" %; percent 2. Review of the laboratory's "Performance Verification of Cryostat Leica CM 1860" policy and procedure provided for inspection review found the following instructions to monitor and document humidity conditions. "...2) Room humidity, maximum 60% (non-condensing) 3) The room temperature and humidity will be documented on the day of usage to confirm optimum performance during use." 3. The Inspector requested the laboratory's humidity documentation each day of MOHS testing procedures from 04 /27/2021 through 12/12/2022 from the HP. The HP confirmed the laboratory did not monitor and document humidity conditions from 04/27/2021 through 12/12/2022 and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 12/12/2022 at 9:55 AM. Item 2 Based on record review and interviews with the Laboratory Director (LD) and Histopathology processor (HP), the LD failed to ensure that patient MOHS tissue biopsy test results were only reported when the system was functioning properly and Histopathology reagents, solutions and stains were not used beyond their expiration dates. This deficient practice had the potential to affect 477 out of 477 patient MOHS cases conducted between 04/27/2021 to 12/12/2022. Findings Include: 1. Review of the laboratory's "Reagent Labeling, Preparation, and Storage:" section in the "Part 3: Laboratory Procedures" policy and procedure, provided for inspection review, revealed the following statement: "4. Reagents will not be used after expiration date." 2. Review of the laboratory's "Form 22: Reagent and Culture Medium Receipt Log" provided on the date of the inspection, revealed the following records: Reagent Lot # Opened Expired Eosin 453753 10/30 /19 11/19 Eosin 492062 03/02/20 10/20 Eosin 103656 04/19/21 07/22 as of 12/12 /2022, still in use Hematoxylin 491085 03/02/20 10/20 Hematoxylin 104142 04/19/21 08/22 as of 12/12/2022, still in use Bluing 546522 08/18/20 07/22 Blue Cryo 530983 08/18/20 09/22 Pink Cryo 535350 08/18/20 01/22 Yellow Cryo 530062 08/18/20 08 /22 as of 12/12/2022, still in use Cryo; Cryochrome 3. The HP stated the reagent order had not arrived, the emptied Eosin and Hematoxylin bottles were discarded and confirmed the last lot number of each reagent indicated above were expired and still in use. The LD was unaware of the use of expired reagents. The interviews occurred on 12/12/2022 at 10:25 AM.