

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2106871	(X3) Date Survey Completed 09/26/2023
Name of Provider or Supplier New Dermatology Group Ltd	Street Address, City, State 2360 Duck Creek Pkwy, Green Bay, WI	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures, competency assessments, and interview with testing personnel, staff A, the laboratory did not follow their written policies for training and competency evaluation for two of two current testing personnel. Findings include: 1. Review of the "Mohs Competency Assessment and Review" procedure stated "Policy: All Mohs technicians are re-evaluated twice a year for competency." Further review stated "Individual technical competency of laboratory personnel is reassessed on a biannual basis by the Technical Supervisor". 2. Review of competency assessment records showed documentation of competency assessment for staff A and staff B January-June in 2021 and 2022 and July -December in 2021 and 2022. Further review showed no documentation of competency assessment for the first half of 2023. 4. Interview with staff A on September 26, 2023, at 9:25 AM confirmed the laboratory did not follow their written policies for competency assessment.</p>
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p>

This STANDARD is not met as evidenced by:
 Based on surveyor review of testing personnel records and interview with staff A, the laboratory director did not ensure one of one testing personnel newly qualified to perform high complexity grossing of tissue specimens received the appropriate training for Mohs surgical grossing prior to performing on patient specimens. Findings include: 1. Review of personnel records for staff C showed documentation of additional university credits to qualify staff C as high complexity testing personnel as of June 27, 2023. 2. Review of competency assessment records for staff C showed competency assessment did not include grossing for 2021 and 2022. Further review showed the laboratory director did not document staff C had demonstrated the ability to perform tissue grossing procedures. 3. Interview with staff A and staff C on September 26, 2023, at 9:25 AM, confirmed staff C performed high complexity testing as of June 27, 2023. Further interview confirmed the laboratory director did not ensure documentation of appropriate training for staff C was performed prior to the high complexity testing being performed.

D6175

TESTING PERSONNEL RESPONSIBILITIES
 CFR(s): 493.1495(b)(1)

Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:
 Based on surveyor review of laboratory procedures, laboratory records, and interview with testing personnel, staff A, testing personnel did not follow the procedure when documenting stain quality control for the hemotoxylin and eosin (H&E) stain for twelve of twelve patient testing days reviewed. Findings include: 1. Review of the "Mohs Staining Quality Control" procedure stated "The stain quality and specimen preparation is documented on the Mohs H&E Staining Quality Control Log." "The Mohs H&E staining Quality Control Log includes the following information: A. Surgery date B. Patient number C. Case number D. Stain acceptance- Y or N E. Slide /specimen preparation acceptable-Y or N F. Comments or corrections G. Technician initials H. Mohs surgeon signature" Further review stated "The Mohs surgeon signs the log each Mohs day". 2. Review of the "Mohs H&E Staining Quality Control Log" showed no documentation of the Mohs surgeon's signature for twelve patient testing days between January 2, 2023 and March 16, 2023. 3. Interview with staff A on September 26, 2023, at 9:50 AM confirmed testing personnel did not follow their procedure to document stain quality control by the Mohs surgeon.