Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2255421	03/13/2024
Name of Provider or Supplier	**Street Address, City, State**	
New Dermatology Group Ltd	1606 S Stephenson Avenue, Iron Mountain, MI	

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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . Based on record review and interview, the laboratory failed to follow policies and procedures to assess and correct problems when identified during verification of accuracy testing. Refer to D5791.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by: . Based on observation, record review, and interview with Testing Personnel #3, the laboratory failed to perform preventative cryostat maintenance as required by the manufacturer for 2 of 2 cryostats observed. Findings include: 1. The surveyor observed two Avantik QS12 cryostats with manufacturer stickers indicating when preventative maintenance was last performed on 1/13/22 and the next service was due January 2023. 2. An interview on 3/13/24 at 9:13 am with Testing Personnel #3

	confirmed the laboratory did not have the cryostats serviced according to the manufacturer maintenance stickers.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #3, the laboratory failed to follow its policy to assess and correct problems when identified during verification of accuracy testing for 1 (February 2024 testing event) of 2 events reviewed. Findings include: 1. A review of the laboratory's "Mohs Surgeon Quality Assurance Plan" revealed a section stating, "Every six months for quality assurance purposes, the Mohs technician pulls slides of three random Mohs cases" and "The material is sent to a Mohs College peer member for outside quality assurance. The peer member is required to complete the remaining sections of the Mohs Surgeon Quality Assurance Log and sign the log showing that they agree with the diagnosis and clearing of the patient tissue tested at our facility. The peer member is asked to complete the review and return the material in a timely manner. In the case of discrepancy, a third-party Mohs surgeon is consulted. When received, the date returned is recorded on the Slide & Block Check-Out Log. The slides and Mohs Surgeon Quality Assurance Log are given to the Mohs surgeon for review. If needed, the Mohs surgeon will respond to any comments from the peer member on the log." 2. A review of the laboratory's "Mohs Surgeon Quality Assurance" log for the review term of August-December 2023 revealed 2 of 3 patients with additional comments: 1. Patient #1 with testing performed on 8/9/23 for the site "Right Mid Forehead" had the comment "Suspicious spot on one cut." 2. Patient #2 with testing performed on 12/6 /23 for the site "Right Zygoma" had the comment "AK vs SK o/w clear." 3. The surveyor requested documentation of comments from the Mohs surgeon or the consultation from the third-party Mohs surgeon or corrective action performed because of the quality assurance review on 3/13/24 at 9:33 am and it was not provided. 4. An interview on 3/13/24 at 11:29 am with Testing Personnel #3 confirmed the laboratory did not have documentation showing it corrected problems identified during the quality assurance review listed above.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: . Based on record review and interview, the Laboratory Director failed to ensure quality assessment programs established identified and corrected failures in quality as they occurred. Refer to D6094.

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: . Based on record review and interview with Testing Personnel #3, the Laboratory Director failed to ensure quality assessment programs established identified and corrected failures in quality as they occurred. Refer to D5791.