Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D2134666	05/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
New Dermatology Group Ltd	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
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of temperature logs and interview with testing personnel, staff A, the laboratory did not document corrective action when temperature readings were outside the defined acceptable range for the Thermofisher Excelsior ES processor retort for seventy-nine of eighty-five days for processor 1 and sixty-four of eighty-two days for processor 2 in 2023. Findings include: 1. Review of temperature logs revealed no documentation of corrective action on temperature readings outside the defined acceptable range of 55-63 degrees Celsius (C) for the following in 2023: Processor 1: January: 20 of 22 days February: 19 of 20 days March: 21 of 23 days April: 19 of 20 days Processor 2: January: 18 of 19 days February: 15 of 20 days March: 17 of 23 days April: 14 of 20 days 2. Interview with staff A on May 25, 2023, at 11:45 AM confirmed the laboratory did not document corrective action when the temperature readings were outside the defined acceptable range on the Thermofisher Excelsior ES processor in 2023.
D6168	TESTING PERSONNEL CFR(s): 493.1487

	The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on surveyor review of the Centers for Medicare and Medicaid Services (CMS) Form 209 Laboratory Personnel Report, laboratory records, Food and Drug Administration (FDA) test complexity assignment database, and staff credentials, and interview with testing personnel, staff A, the laboratory did not have documentation to show one of three histology testing personnel, who operate the high complexity immunohistochemical (IHC)l stainer, met the qualification requirements to perform high complexity testing. Findings include: 1. One of three new testing personnel did not have documented education and training that met the qualification requirements of 493.1489. See D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and

	storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on surveyor review of the Centers for Medicare and Medicaid Services (CMS) Form 209 Laboratory Personnel Report, laboratory reports, Food and Drug Administration (FDA) test complexity assignment database, and staff credentials and interview with testing personnel, staff A, the laboratory did not have documentation to show one of three histology testing personnel, who operate the high complexity immunohistochemical(IHC) stainer, met the qualification requirements to perform high complexity testing. Findings include: 1. Review of Form CMS-209 "Laboratory Personnel Report" signed by the laboratory director on May 4, 2023, showed three of four staff listed were not shown as personnel at the time of the previous survey. Further review showed staff A and B listed as high complexity testing personnel and staff C listed as 'processing only' personnel. 2. Review of the "IHC/Special Stain QC Log" showed staff C performed IHC staining on the Leica Bond Max automated IHC slide stainer the following dates: Date/Case number/Number of IHC stains November 23, 2022/D22-12856/3 January 4, 2023/D22-14463/3 March 21, 2023/D23-2856/3 March 22, 2023/D23-2878/2 March 28, 2023/D23-2878/2 April 4, 2023/D23-3424/3 3. Review of the FDA database for test complexity showed the Leica Bond Max was categorized as a high complexity analyzer. 4. Review of academic qualifications for staff C did not show staff C had acceptable degree or education to meet the qualification requirements for high complexity testing. 5. Interview with staff A on May 25, 2023, at 12:30 PM confirmed staff C performed high complexity testing on the Leica Bond Max IHC automated slide stainer and did not meet the qualification requirements for high complexity testing.