

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D2104539	<b>(X3) Date Survey Completed</b>  06/13/2022
<b>Name of Provider or Supplier</b>  Dermio Dermatology	<b>Street Address, City, State</b>  9200 Calumet Ave Suite N203, Munster, IN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D6168</b>	<p>TESTING PERSONNEL CFR(s): 493.1487</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on personnel record review and interview, the laboratory failed to ensure two of two (SP1 and SP2) Mohs surgery (Mohs) technicians performing the duties of a testing personnel (TP) were qualified for high complexity testing (refer to D6171).</p>
<b>D6171</b>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b)</p> <p>(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</p>

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 record review, lack of documentation, and interview, the laboratory failed to ensure two of two (SP1 and SP2) Mohs surgery (Mohs) technicians performing the duties of a testing personnel (TP) meet qualification requirements for high complexity testing. Findings include: 1. Review of "Quality Control Employee Evaluation[s]" for SP1 (Mohs technician) from 3/31/2021, 1/27/2022, 2/24/2022, and 3/31/2022, and for SP2 (Mohs technician) from 4/25/2022 and 5/23/22 (all signed by SP3 (laboratory director), state that SP1's and SP2's performance is "Satisfactory" regarding "Proper dye markings of tissue", "Proper Mohs mapping, size, orientation, and proper placement on [the] slide", and "proper cover-slipping, avoiding air bubbles[,] and tissue dying". 2. Review of "Forefront Dermatology Certificate of Training" for SP2 signed by SP3 on 10/22/2019, states that SP2 had received training for processes specific to Mohs histology, which included "Inking and Mapping of Mohs skin specimens." 3. Two "Monthly Quality Assurance Checklist[s]" for SP1 from 2/24/22 and 3/31/22 (both signed by SP3) state that "Quality Control Policies were performed

as specified". The list of quality control policies performed includes that "all quality control/calibrations were performed and were within acceptable limits before test results were reported." 4. On 06/08/2022 at 12:37 pm, SP1 indicated that they and SP2 perform quality control for Mohs. 5. On 06/08/2022 at 12:45 pm, SP1 indicated that they have earned an associate degree in Medical Laboratory Technology, but they did not have a copy of their diploma nor transcripts available during the survey. 6. On 06/08/2022 at 1:12 pm, SP3 indicated that SP1 performs Mohs grossing. 7. On 06/08/2022 at 1:45 pm, SP2 indicated that they had received training certificates for Mohs histology. SP2 then acknowledged that they had not received any formal college education in biology, chemistry, and/or medical laboratory technology. 8. On 06/13/2022 at 4:19 pm, SP1 indicated via email that they could not provide documentation of their associate's degree in Medical Laboratory Technology. 9 The annual test volume for Mohs surgery is approximately 550.