Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D2213939	05/29/2024
Name of Provider or Supplier	**Street Address, City, State**	
Clearline Dermatology	776 Daniel Ellis Dr Ste 1a, Charleston, SC	

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
D0000	An announced CLIA initial survey was conducted at Clearline Dermatology on 05/29 /2024 by the South Carolina Department of Environmental Control (SCDHEC). The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. The facility was found to be out of compliance with the standards of the CLIA program. The following CONDITION LEVEL DEFICIENCES were found to be out of compliance:
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on direct observation, manufacturer's instructions, lack of documentation, and staff interview, the laboratory failed to follow manufacturer's instructions to monitor and ensure specified room temperature ranges for the second laboratory area. 2 of 2 boxes Findings included: 1. A direct observation during the laboratory tour on 05/29 /2024 at 1:04 pm, revealed: a. Manufacturer instructions for One Step hCG Urine cassette stored in cabinet. 2. Review of manufacturer's instructions for One Step hCG Urne cassette label Lot #0000776145 exp 8-29-2025 2 C -30 C (36 F-86 F) 3. Review of records revealed a lack of environmental logs monitoring room temperature for specified range. 4. In an interview with the practice manager on 05/29/2024 at 1:05 pm in the second laboratory, the above findings were confirmed. There was no thermometer observed in the laboratory on 05/29/2024 at 1:04 pm, the day of the survey to monitor the temperature. Key Celsius= C Fahrenheit= F
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)

	At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on policy and procedures, records review CMS 209, lack of documentation, and staff interview, the laboratory failed to verify the accuracy of Histopathology (Moh's testing) results. Findings included: 1. Review of policy and procedures titled "KOH Protocol" revealed a "quality control accuracy verification is performed on a bi-annual basis completed in the months of January and June. This is logged in the notebook labeled KOH LOG, by initialing in RED. 2. Review of CMS 209 revealed two clinical consultants (CC) for Histopathology, and Dermatopathology. 3. Review of QC & QA verification log on 05/29/2024 reveal patient results for KOH with initials, some with two initials with one written in red. No documentation available on the day of survey for accuracy checks for reading Mohs slides. 4. In an interview with staff in the breakroom on 05/29/2024 at 1:30 pm the above findings were confirmed.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on policy and procedures review and staff interview, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems requirements. Findings included: 1. Review of policy and procedures reveal the laboratory lacks a written plan to monitor quality assessment for Moh's procedures. 2. In an interview with staff on 05/29/2024 at 1:30 pm the above findings were confirmed.
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 policy and procedures, records review CMS 209, and staff interview, the laboratory failed to have individuals who meet the qualification requirements for high complexity testing performed. Refer to D6171 Findings included: 1. Review of policy and procedure titled "Mohs Laboratory Procedures Staining Protocol", Policy #L1.10, 3rd page, 5. Tissue processing in the laboratory a. The Mohs technician will perform the necessary tissue sectioning and inks the specimen for microscopic margin evaluation b. The Mohs technician uses a clean scalpel blade to make relaxing cuts inside the specimen in order to assist in laying the specimen flat and facilitate complete sectioning of the epidermis and deep margin. 2. Review of CMS 209

	Laboratory personnel report reveal one testing personnel for Histopathology. 3. Review of personnel files reveal no documentation of qualifications for testing personnel available on of survey 05/29/2024. 4. In an interview with staff and Dermpath Solutions on 05/29/2024 at 1:30 pm in the breakroom, the above findings were confirmed.
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 policy and procedures, record review CMS 209, and staff interview, the laboratory failed to document testing personnel's qualifications for high complexity testing. Refer to D6168 Findings included: 1. Review CMS 209 laboratory personnel report form listed one person as testing personnel (TP) for high complexity testing. 2. A review of personnel files reveal no documentation of qualifications, no training records available on 05/29/2024, day of survey for TP. 3. In an interview with staff and Dermpath Solutions representative on 05/29/2024 at 1:30 pm the above findings confirmed.