Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0688909	06/27/2024
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Consultants Inc	1330 Oak Lane - Suite 101, Lynchburg, VA	

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 recertification survey was conducted at Dermatology Consultants, Inc. on June 27, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and includes the Condition under 42 CFR part 493 CLIA Regulation: D6168 -42 C.F.R. 493. 1487 Condition: Testing Personnel
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on a review of microscope maintenance records, procedures, lack of documentation, and interview, the laboratory failed to follow their established policy of annual service/maintenance for two (2) of 2 microscopes utilized for Mohs histopathology and Potassium Hydroxide (KOH) microscopy test results in calendar year 2023. Findings include: 1. A review of equipment maintenance records for the review timeframe of August 26, 2022 to the date of the inspection on June 27, 2024 revealed microscope service was performed by Laboratory Optical Service, INC vendor on 10/26/22 and 5/2/24 for the laboratory's two Olympus microscopes: BX46 (serial number 5M42410 -Mohs lab) and BH-2 (serial number 211956-Microscopy General Lab). 2. Review of the laboratory procedure manual revealed a quality assurance policy under "Equipment" section that outlined: "The microscope will be

	cleaned, aligned, and serviced annually". The inspector requested to review annual maintenance service documentation for the 2 microscopes outlined above performed in calendar year 2023. No documentation was available. 3. An interview with the lead histotech on 6/27/24 at 2:00 PM confirmed the above findings.
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 a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), review of testing personnel (TP) training /education records, lack of documentation, and interview, the laboratory failed to ensure that one of three TP met qualifications to perform high complexity grossing procedures of Mohs surgical tissue samples processed from May 2023 through the date of the survey on June 27, 2024. (Cross reference 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 review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), Mohs Dermatology testing personnel (TP) training /education records, lack of documentation, and interview, the laboratory failed to ensure that one (1) of three (3) TP met education qualifications to perform high complexity Mohs surgical tissue grossing from May 2023 through the date of the survey on June 27, 2024. Findings include: 1. Review of the laboratory's CMS 209 form revealed 3 TP were identified by the lab director (LD) as responsible for high complexity Mohs laboratory duties to include grossing/inking. 2. Review of TP A's training/education records revealed a technical college transcript that lacked the required educational credit/elements to qualify for histopathology high complexity procedures. The inspector noted that TP A's file indicated training checklist was completed 5/3/23 for start of histopathology procedures. *See Personnel Code Sheet. 3. The inspector requested to review additional education records for TP A. No additional records were available for review. 4. An interview with the lead histotech on 6/27/24 at 2:00 PM confirmed the above findings.