Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2170917	11/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Martinsville Dermatology And Skin Surgery Center	312 Fairy St Extension, Suite 201, Martinsville, 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 Initial survey was conducted at the Martinsville Dermatology and Skin Surgery Center on November 5, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: A. Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, policy and procedures (P&P), lack of documentation, and interviews with the laboratory manager and TP, the lab director failed to ensure the laboratory maintained documentation of personnel education qualifications for one (1) of 2 TP at the date of survey on November 5, 2019 (Cross Reference D6171). B. Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, policy and procedures (P&P), patient testing records, and interviews with the laboratory manager and TP, the lab director failed to ensure the performance and documentation of initial training and competency assessment for one (1) of 2 TP and seventy-five (75) patients performed from August 19, 2019 up to October 14, 2019. Findings include: 1. Review of the CLIA CMS-209 Form and an interview with TP A at approximately 11:30 AM revealed that TP A was new and began inking and grossing Mohs histology tissue samples on August 19, 2019. (See attached TP code sheet). 2. Review of TP A records revealed an incomplete initial training and competency assessment prior to TP A

	inking and grossing histology tissue samples. The document lacked assessor information and the "Assessment of Problem Solving Skills" was blank. The laboratory director did not sign the document. 3. Review of Quality Assurance (QA) P&P (signed by lab director 11/01/19) revealed the following statements: "5. Personnel Competency Assessment"- "Policy"-Training and competency of all testing personnel will be ensured prior to testing patient specimens. "Procedure"- New personnel training will be provided by the clinical supervisor, technical consultant, and /or laboratory director." 4. Review of the patient testing records from August 19, 2019 up to October 14, 2019 revealed that TP A performed 75 patient samples. 5. An interview with the laboratory manager at approximately 12:45 PM confirmed the 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 the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, and interviews with the testing personnel (TP) and laboratory manager, the laboratory failed to maintain documentation of personnel education qualifications for one (1) of 2 TP at the date of survey on November 5, 2019 (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 the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, and interviews with the testing personnel (TP) and laboratory manager, the laboratory failed to maintain documentation of personnel education qualifications for one (1) of 2 TP at the date of survey on November 5, 2019. Findings include: 1. Review of the CLIA CMS-209 form revealed that there were 2 TP. An interview with the laboratory manager and TP A at approximately 11:30 AM revealed that TP A performed the grossing and inking of Mohs histological tissue samples from August 19, 2019 up to October 14, 2019. 2. Review of the laboratory's personnel records revealed a lack of education documentation for TP A (See attached TP code sheet). The inspector requested to review the education documentation for TP A. The documentation was not available at the date of survey. 3. An interview with the laboratory manager at approximately 12:45 PM confirmed the findings.