Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2170917	08/24/2021
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 Recertification survey was conducted at the Martinsville Dermatology and Skin Surgery Center on August 24, 2021 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:
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on the tour of the laboratory, review of policy and procedures (P&P), available microscope maintenance records, lack of documentation and interviews, the laboratory failed to retain the preventative maintenance (PM) documents for the two microscopes in the calendar year 2020. Findings include: 1. The entrance tour of the laboratory on 08/24/21 at approximately 9:15 AM revealed two microscopes (Olympus BX43 and Labomed) utilized to perform histological examination of Mohs tissue samples. 2. Review of the P&P, "Microscope Use Protocol" (approved by the lab director 11/01/19) revealed the following statement, "Preventative maintenance /grounding check is monitored yearly." 3. Review of available microscope maintenance documents revealed PM performed by an external company on 08/11/21. During an interview with on 08/24/21 at approximately 12:40 PM with Testing Personnel A (TP A), the inspector requested documentation to review of the PM performed for the two microscopes in the calendar year 2020. They stated that the sticker was removed from 2020 when the maintenance was performed on 08/11/21

	and that they did not have the documentation from the external company for review. 4. An exit interview with the laboratory director, office manager and TP A on 08/24 /21 at approximately 1 PM confirmed the findings.
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 the review of policy and procedures (P&P), lack of documentation, and interviews, the laboratory failed to follow the established policy for reviewing every thirtieth Mohs case for acceptable results by peer review for nineteen (19) of 19 months reviewed. Dates of record review 01/01/20 up to 07/31/21. Findings include: 1. Review of the P&P "Skin Surgery Center Quality Assessment Plan" (approved by the lab director 11/01/19) revealed the following statement, "Proficiency Testing" - "Every 30th Mohs case will be sent to dermatopathologist at the affiliated site for review and evaluation. The results will be recorded and reviewed by the laboratory director. The director will carefully evaluate any unacceptable, unsatisfactory, or unsuccessful result in an effort to identify the cause of failure." "Comparison of Test Results"- "Frozen section slides from every thirtieth Mohs case are reviewed by the dermatopathologist. If a discrepancy is discovered, the slides and map are returned to the appropriate surgeon who will then make a decision on how to proceed." 2. The inspector requested to review the documentation for peer review according to the established policy on 08/24/21 at approximately 11:15 AM. The documentation was not available for review. 3. An exit interview with the laboratory director, office manager and TP A on 08/24/21 at approximately 1 PM confirmed the findings.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on observation of testing procedures, policy and procedure (P&P), lack of documentation and interview, the laboratory failed to provide an established written protocol for identifying Mohs tissue sample transportation from the surgical room to the laboratory for the two (2) of 2 patients observed at the date of survey on 08/24/21. Findings include: 1. Observation of testing procedures for patient A and patient B on 08/24/21 at approximately 10:32 AM revealed transportation of the Mohs tissue samples from the surgical room to the laboratory on a surgical gauze, covered with a petri dish top. The tissue sample(s) placed on the grossing block and the Mohs surgical map(s) placed on the side of the grossing table. The tissue sample(s) for patient A and patient B lacked identification. 2. Review of the P&P for Mohs surgical testing revealed lack of documentation of a protocol for labeling/identifying the Mohs

	tissue sample from the time of collection and transportation to the laboratory. 3. An exit interview with the laboratory director, office manager and TP A on 08/24/21 at approximately 1 PM confirmed the findings.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, and interview, the technical supervisor (TS) failed to perform the semi-annual competency assessment for one (1) TP in 2020. Findings include: 1. Review of the CMS-209 Form revealed the laboratory director performs the duties of TS and TP A performs patient testing. 2. Review of TP A records revealed initial assessment performed in November 11, 2019 and lack of documentation of a semi-annual competency assessment in the calendar year 2020. (See attached list Personnel Code list.) 3. An exit interview with the laboratory director, office manager and TP A on 08/24/21 at approximately 1 PM confirmed the findings.