Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2104729	10/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Shenandoah Dermatology, Pc	427 Lee Jackson Highway Suite 101, Staunton, 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 Shenandoah Dermatology, PC on October 13, 2022 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:
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 a review of procedures, proficiency testing (PT) logs, quality assurance (QA) reports, lack of documentation, and an interview, the laboratory failed to perform Mohs micrographic histopathology testing accuracy checks twice annually per their policy in calendar year 2021 and up to the date of the inspection on October 13, 2022. Findings include: 1. Review of the laboratory's procedure manual revealed a PT policy for Mohs micrographic surgery skin specimens (titled: "Quality Assurance: Proficiency Testing"). The written policy outlined, "Randomly selected cases to be peer reviewed by an outside party laboratory for compliance diagnosis twice per year". 2. Review of the laboratory's PT documentation for calendar year 2021 up to the date of the inspection on 10/14/22 revealed documentation of Mohs micrographic split sample testing were sent out for peer review on 8/31/21 and 10/3/22. 3. Review of the available QA reports revealed no documentation of additional accuracy checks for Mohs micrographic histopathology testing. The inspector requested to review additional PT record documentation. No additional PT documentation was available for review. 4. An exit interview with the lead histotechnologist and laboratory director on 10/13/22 at approximately 3:30 PM confirmed the above findings.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of procedures, proficiency testing (PT) records, Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, quality assurance (QA) reports, lack of documentation, and interviews, it was determined that the laboratory director's (LD) monthly and quarterly QA measures failed to: 1. identify lack of performance of Mohs micrographic histopathology accuracy checks twice annually per an approved QA proficiency testing policy in calendar year 2021 and up to the date of the inspection on October 13, 2022. Cross reference D5217. 2. identify the lack of training/semiannual competency evaluation documentation retention for one new histopathology testing personnel in calendar year 2021 and up the date of inspection on October 13, 2022. Cross reference D6127.
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 a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), laboratory personnel files, Quality Assurance (QA) reports, lack of documentation, and interviews, it was determined that the technical supervisor (TS) failed to retain documentation of semiannual competency evaluation for one new histopathology testing personnel ("TP A") in calendar year 2021 and up the date of inspection on October 13, 2022. (See Personnel Code Sheet.) Findings include: 1. Review of the CMS 209 form revealed that the laboratory director (LD) also performs the duties of TS and three testing personnel were identified as responsible for high complexity histopathology testing procedures during the review timeframe of January 2021 to 10/13/22. The lead histotechnologist identified "TP A" as having started employment in the laboratory as a new testing personnel processing/grossing/mapping patient tissue samples in June 2021. 2. Review of the laboratory personnel files revealed no training or competency assessments for TP A. The inspector requested to review training and competency assessments for TP A. The lead histotechnologist stated on 10/13/22 at approximately 2:00 PM, "The histotech worked here for a year but is no longer employed. A training check list and semiannual competency assessment were done but I do not have those records." 3. Review of the available QA reports revealed no mention/documentation of review of the training/competency assessments outlined above. 4. An exit interview with the lead histotechnologist and LD on 10/13/22 at approximately 3:30 PM confirmed the above findings.