

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2104729	(X3) Date Survey Completed 01/14/2021
Name of Provider or Supplier Shenandoah Dermatology, Pc	Street Address, City, State 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	<p>An announced CLIA Initial on-site survey was conducted at Shenandoah Dermatology on January 14, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The initial contact and entrance interview with laboratory was conducted on December 14, 2020 with virtual record review of documentation on January 12, 2021. Specific deficiencies cited are as follows:</p>
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's policy and procedures (P&P), daily patient testing log sheets, patient MOHS dermatologic maps and corresponding slides, and interview, the laboratory failed to follow the established P&P for patient labeling of MOHS histopathology tissue slides for eight (8) of 12 random samples selected for review. Dates of record review include June 15, 2020 up to date of survey on January 1, 2021. Findings include: 1. Review of the P&P "Laboratory Procedure Manual Histopathology- Central Virginia Skin Surgery Center Clinic MOHs Surgery" (signed by the lab director 06/08/20) revealed "3.4 Specimen Handling, Storage, Preservation and Identification" "3.4.6- Patient name, site, date, Mohs surgeon and laboratory technician is written on Mohs log, along with total number of slides processed." "3.4.9- Laboratory technician will label slides with Mohs number, layers and patient last name. Slides will be labeled permanently with Mohs number, patient last name, date, facility and Mohs layers." 2. Review of 12 random histology tissue slides, corresponding MOHS maps and daily patient testing log sheets revealed that on</p>

October 16, 2020, 8 patient slides improperly labeled with the date of October 15, 2020 as the date of MOHS testing. In addition, the corresponding MOHS maps lacked the documentation of the laboratory technician that performed the processing of the samples (M20-393 to M20-400). 3. An interview with the histotechnologist on January 14, 2021 at approximately 11:00 AM confirmed the findings.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's policy and procedures (P&P), daily patient testing log sheets, patient MOHS dermatologic maps and corresponding slides, and interview, the established P&P for reading results failed to identify the improperly dated slides and lack of laboratory technician identification on the MOHS maps for eight (8) of 12 random samples selected for review. Dates of record review include June 15, 2020 up to date of survey on January 1, 2021. Findings include: 1. Review of the P&P "Laboratory Procedure Manual Histopathology- Central Virginia Skin Surgery Center Clinic MOHs Surgery" (signed by the lab director 06/08/20) revealed "9.1 Reading Results- 4. When the case is completed, the Mohs map will be scanned or photographed and the laboratory technician will cross check and verify that all information is correct and completed on the operative/repair notes, Mohs map, patient photographs and Mohs patient log. When the QA is complete, the laboratory technician will sign the log sheet. 5. The preliminary report is reviewed by the Mohs surgeon and is verified that all the information is correct and the report is electronically signed and finalized." 2. Review of M20-393 to M20-400 histology tissue slides, corresponding MOHS maps, daily patient testing log sheets and reports revealed discrepancies. Refer to D5203. 3. An interview with the histotechnologist on January 14, 2021 at approximately 11:00 AM confirmed the findings.