

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D2104729	<b>(X3) Date Survey Completed</b>  06/04/2024
<b>Name of Provider or Supplier</b>  Shenandoah Dermatology, Pc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA Recertification survey was conducted at the Shenandoah Dermatology, PC on 06/04/24 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: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations:
<b>D5601</b>	<p><b>HISTOPATHOLOGY</b> CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&amp;P), patient testing logs, histological tissue slides, lack of documentation, and interviews, the laboratory failed to document a positive and negative quality control (QC) reactivity for the immunohistochemical (IHC) Pan-Cytokeratin (Pan-Ck) and Mart-1/Melon-A stains for 47 of 47 dates reviewed, resulting 47 patients. Findings include: 1. Review of the P&amp;P "Pan-Ck" and the "Mart-1/Melon-A" IHC stains" revealed the following statements, "one positive tissue control is needed for each set of tests. Known positive tissue controls should be utilized for monitoring correct performance of processed tissues and test reagents." "The same tissue used for positive control may be used for the negative control." 2. In interview with the general supervisor on 06/05/24 at 11:30 AM, they stated, "we process a positive and negative control slide with each use of the Pan-Ck and Mart-1 /Melon-A stains. The Mohs surgeon documents on the Mohs surgical map which stain was used, the result of the stain and that the case is negative or clear after the Mohs</p>

surgery." The inspector requested to review documentation of positive and negative reactivity for each date of use for the Pan-Ck and Mart-1/Melon-A IHC stains. The documentation was not available for review. 3. Review of patient test logs, to include the Mohs surgical maps, revealed the following dates and accession numbers that lacked documentation of a positive and negative QC reactivity: 01/18/23 M23- 0085, 01/25/23 M23- 0122, 02/08/23 M23- 0188, 02/08/23 M23- 0190, 02/15/23 M23- 0220, 02/15/23 M23- 0224, 02/21/23 M23- 0244, 02/23/23 M23- 0264, 03/02/23 M23- 0300, 03/07/23 M23- 0311, 03/07/23 M23- 0318, 07/11/23 M23- 0828, 07/20/23 M23- 0875, 08/22/23 M23- 1044, 09/07/23 M23-1116, 09/11/23 M23- 1133, 09/12/23 M23- 1144, 09/18/23 M23- 1172, 10/04/23 M23- 1262, 10/12/23 M23- 1311, 10/18/24 M23-1341, 10/23/23 M23- 1358, 10/25/23 M23- 1379, 10/30/23 M23- 1400, 11/02/23 M23- 1429, 11/09/23 M23- 1472, 11/09/23 M23- 1476, 11/21/23 M23- 1543, 11/22/23 M23- 1646, 12/13/23 M23- 1665, and 12/20/23 M23- 1701. 01/09/24 M24- 0046, 01/15/24 M24- 0079, 01/22/24 M24- 0112, 01/30/24 M24- 0162, 02/15/24 M24- 0262, 03/06/24 M24- 0378, 03/11/24 M24- 0397, 03/25/24 M24- 0488, 03/26/24 M24- 0499, 03/27/24 M24- 0510, 04/01/24 M24- 0532, 04/02/24 M24- 0549, 04/03/24 M24- 0559, 04/24/24 M24- 0680, 04/30/24 M24- 0717, and 05/08/24 M24- 0770. The surveyor randomly selected 13 of the 47 IHC cases and requested to review the histology slides and confirmed that each case had a positive and negative QC slide. 4. An exit interview with the laboratory director and general supervisor on 06/04/2024 at 12:50 confirmed the findings.

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control 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 the review of policy and procedures (P&P), patient testing logs, lack of documentation, and interviews, the laboratory director failed to document positive and negative quality control (QC) reactivity for the immunohistochemical (IHC) Pan-Cytokeratin (Pan-Ck) and Mart-1/Melon-A stains for 47 of 47 dates reviewed, resulting 47 patients. Findings include: 1. Refer to D5601 for access number and date details. 2. In an exit interview with the laboratory director, who is also the Mohs surgeon, on 06/04/24 at 12:50, they stated, "we cut and stain a positive and negative QC slide to check the reactivity of the IHC stains each time we do the stains. I check for reactivity, but I do not document the review/results of the QC slides. We can certainly add that log sheet."