

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2311158	<b>(X3) Date Survey Completed</b>  02/05/2025
<b>Name of Provider or Supplier</b>  Visage Dermatology	<b>Street Address, City, State</b>  5013 96th St E, Palmetto, FL	
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 initial survey was conducted at Visage Dermatology on 02/05/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
<b>D5473</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(2)(g)</p> <p>(e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.</p> <p>This STANDARD is not met as evidenced by: Based on review of records and interview, the laboratory failed to ensure documentation of test staining materials for the intended reactivity for four (11/05/24, 11/25/24, 1/7/25 and 1/14/25) of six test days (11/05/24, 11/25/25, 12/16/24, 1/7/25, 1/14/25, and 2/4/25) of patient Hematoxylin and Eosin (H&amp;E) Histopathology testing. Findings include: The MOHS Daily Quality Control Worksheet for November 2024, December 2024, January 2025, and February 2025 include a column titled "Doctor". There was no documentation by the doctor for 11/05/24, 11/25/24, 1/7/25 and 1/14/25, for expected reactivity of patient H&amp;E Histopathology testing. The Procedure Manual approved by the Lab Director 02/05/2025 included instructions for "Monitoring of Quality Control Testing." The instructions showed "Quality Control [QC] Testing is performed for all types of staining procedures. Prior to patient specimen testing, a slide is prepared (stained) and reviewed by the laboratory Director." The Clinic Manager and Histology Tech both confirmed on 02/05/25 at 11:35 AM there was no documentation of expected reactivity of H&amp;E staining performed on 11/05/24, 11/25/24, 1/7/25 and 1/14/25.</p>
<b>D5805</b>	<p><b>TEST REPORT</b> CFR(s): 493.1291(c)</p>

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on record review and interview, the test report failed to indicate the address for patient Hematoxylin and Eosin (H&E) Histopathology testing for one of one patient report (Patient #1). Findings include: Review of Patient #1's test report failed to document the correct laboratory address where the H&E was performed. The Histology Tech confirmed, on 02/05/2025 at 11:30 AM, the listed name was not the correct laboratory name for the testing performed at this laboratory.

**D6120**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(7)(8)

(b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's personnel records and confirmed in staff interview, the Technical supervisor failed to evaluate the competency for one out of two Testing Persons (TP B) from 11/05/2024 to 02/05/2025. Findings include: Review of the CMS 209 Laboratory Personnel Report signed by the Laboratory Director on 01/04/2025, showed two Testing Personnel A and B. Testing Personnel A was listed as Laboratory Director, Technical Supervisor, and General Supervisor. Review of TP B's personnel record revealed no documentation of initial evaluation of competency. 11/05/2024 was the first day of patient testing. On 02/05/25 at 11:15 AM, the Clinic Manager and Histology Tech confirmed the lack of documentation of competency for TP B from 11/5/2024 to 2/05/2025.