

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2152458	<b>(X3) Date Survey Completed</b>  05/01/2024
<b>Name of Provider or Supplier</b>  Village Dermatology	<b>Street Address, City, State</b>  7575 San Felipe, Ste 300, Houston, TX	
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>	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended.
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's records, and staff interview, the laboratory failed to have documentation of following its policy by ensuring four of five personnel performing Mohs procedures reviewed the laboratory's policies and procedures in 2023. Findings include: 1. A review of the laboratory's policy titled 'Document Control Policy' revealed the following: "The policies and procedures will be reviewed by the Mohs physician annually to ensure that policies are current. Review of policy and procedure will be part of the lab personnel evaluation and competency assessment." 2. A review of the laboratory's records revealed the laboratory had five physicians performing Mohs procedures in 2023. 3. Further review of the laboratory's records revealed the following four testing personnel failed to have documentation of reviewing the laboratory's policies and procedures in 2023: - Testing person #4 - Testing person #5 - Testing person #6 - Testing person #7 4. In an interview on 5/1/24 at 2:45 p.m. in the conference room, after review of the records, the medical assistant confirmed the above findings.</p>
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p>

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policies, the laboratory's records, and staff interview, the laboratory failed to have a policy that included step-by-step instructions for performing quality control (QC) for one of one stain used in histopathology. Findings include: 1. A review of the laboratory's policies revealed the laboratory failed to have a policy that included step-by-step instructions for performing quality control for the H&E (Hematoxylin and Eosin) stain used for Mohs testing. 2. A review of the laboratory's records revealed the laboratory estimated performing 420 histopathology procedures annually. 3. In an interview on 5/1/24 at 2:45 p.m. in the conference room, after review of the records, the medical assistant confirmed the above findings.