

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D0872860	<b>(X3) Date Survey Completed</b>  10/08/2019
<b>Name of Provider or Supplier</b>  Frank C Taliercio Md	<b>Street Address, City, State</b>  811 North Broadway, Suite 101, North White Plains, NY	
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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the twice annual verification records and an interview with the Moh's processor, the laboratory failed to verify the accuracy of the skin biopsies slides at least twice annually. Findings Include: On October 8, 2019, at approximately 12:15 PM the laboratory director confirmed that the laboratory failed to perform twice annual verification for skin biopsy slide interpretation from October 2017 through the date of this survey. Approximately 860 patient slides were read and results reported for skin biopsies.</p>
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <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</p>

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 procedure manual and an interview with the Moh's processor, the laboratory failed to have a complete procedure manual for histopathology. Findings Include: On October 8, 2019, at approximately 10:45 AM, it was confirmed by the Moh's processor that the laboratory failed to have procedures for the following: 1) Designation of the pathologist to be in charge of the pathology section. 2) Intervals in which equipment maintenance is performed.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on a lack of humidity records and an interview with the Moh's processor, the laboratory failed to follow the manufacturer's instructions for the Leica cryostat to monitor and document the room humidity where testing is performed. Findings Include: It was confirmed by the Moh's processor on October 8, 2019, approximately 12:00 PM that the laboratory has not followed the manufacturer's direction to monitor and document the humidity of the room where Moh's testing is performed.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on surveyor review of maintenance records and an interview with the Moh's processor, the laboratory failed to follow the manufacturer's requirements for instrument maintenance. Findings include: The Moh's processor confirmed on October 8, 2019, at approximately 10:15 AM that the laboratory failed to perform maintenance for the fume hood used to process patient tissue for Moh's slides and the microscope used for read skin biopsy slides. Maintenance for the fume hood was last performed in 2017 and no documentation was available for the microscope used to read skin biopsies.

**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 QA procedures and an interview with the Moh's processor, the director failed to ensure that the laboratory's QA program for histopathology testing was maintained for all phases of laboratory testing. Refer to D5217, D5403, D5413 and D5429