

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0427406	(X3) Date Survey Completed 05/14/2025
Name of Provider or Supplier Danilo V Del Campo Md Sc	Street Address, City, State 5440 W Belmont Ave, Chicago, IL	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the CMS-209 (Laboratory Personnel Form), laboratory policies and procedures, lack of documentation, and interview with the laboratory representative; the laboratory failed to establish written policies and procedures to assess testing personnel (TP) competency for three of three TP performing high complexity grossing of Mohs tissue specimens in the subspecialty of histopathology. Findings include: 1. Review of the CMS-209 (Laboratory Personnel Form) revealed three TP (TP 2, 3, and 4) performing high complexity grossing of Mohs tissue specimens. 2. Review of the laboratory policies and procedures revealed the lack of a competency assessment policy/procedure in place for three of three TP performing high complexity grossing of Mohs tissue specimens. 3. Interview with the laboratory representative on 05/14/2025, at 11:55 am, confirmed the laboratory failed to have a competency policy/procedure in place to assess employee competency for three of three TP performing high complexity grossing of Mohs tissue specimens in the subspecialty of histopathology.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of laboratory records, lack of documentation, and interview with the laboratory representative; the laboratory failed to evaluate results of bi-annual method accuracy (proficiency testing/peer reviewed Mohs histopathology interpretations) for two of two events from the beginning of testing in June 2024 through the date of survey, 05/14/2025. Findings include: 1. Review of laboratory records revealed the laboratory lacked documentation of evaluations for peer reviewed Mohs histopathology interpretations for two of two reviewed bi-annual method accuracy events. 2. Interview with the laboratory representative on 05/14/2025, at 11:54 am, confirmed the laboratory failed to document evaluation of results of peer reviewed Mohs histopathology interpretations from the beginning of testing in June 2024 through the date of survey, 05/14/2025.

D5801

TEST REPORT
CFR(s): 493.1291(a)

(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:
Based on direct observation, laboratory records, patient test reports, and interview with testing personnel (TP) #3; the laboratory failed to have a reliable system in place to ensure test results, including the number of Mohs histopathology surgical stages, were accurately transferred to the final report for one of four patients reviewed. Findings include: 1. Review of laboratory records revealed the document titled, "Mohs Case Log Sheet", which indicated, for patient 25-009 (tested on 04/30/2025), under "Diagnosis": "II [2 stages]". 2. Review of laboratory records revealed the Mohs histopathology map document for patient 25-009, which indicated: "II [2 stages]". 3. Direct observation of Mohs histopathology patient slides for patient 25-009 on 05/4 /2025, at 11:15 am, revealed 2 Mohs surgical stages. 4. Review of the patient test report for patient 25-009, from 04/30/2025, revealed, under "Physical Exam:"Total # of Mohs Stages: 1". 5. Interview with TP #5 on 05/14/2025, at 11:21 am, confirmed the laboratory failed to have a reliable system in place to ensure test results, including the number of Mohs histopathology surgical stages, were accurately transferred to the final report for one of four patients reviewed.