

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2056626	(X3) Date Survey Completed 05/21/2025
Name of Provider or Supplier Pinnacle Dermatology	Street Address, City, State 1870 Silver Cross Blvd, Ste 250, New Lenox, 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
D5601	<p>HISTOPATHOLOGY 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with testing personnel (TP) #2; the laboratory failed to document the quality control (intended reactivity) of Hematoxylin and Eosin (H&E) staining material used for one of five Mohs surgical histopathology testing dates reviewed. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "Policy on Quality Control [QC] Slides", which stated, "The reviewing physician, examining patient tissue that day, will initial each Mohs day that a QC has been made and whether the staining if appropriate." 2. Review of laboratory records revealed one of five Mohs surgical histopathology testing dates reviewed lacked documentation of daily H&E quality control (intended reactivity). Date: Medical Record #: 07/20/2023 A731702 3. Interview with TP #2 on 05/21/2025, at 12:51 pm, confirmed the laboratory failed to document the QC of H&E staining material used for one of five Mohs surgical histopathology testing dates reviewed.</p>
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of</p>

specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, laboratory records, patient test reports, direct observation, and interview with testing personnel (TP) #2; the laboratory failed to accurately correlate pertinent information of patient specimen identification regarding the specimen source and number of Mohs histopathology surgical stages for one of five patients reviewed between the specimen tracking log, the surgical map, the provided surgical slides, and the final patient test report.

Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "Policy on Quality Assurance and Procedure - Mohs Surgery", which stated, under "Procedure", "ii. The specimen is given an accession number and logged into the Mohs logbook with patient name, date, site, diagnosis, stage or layer, and number of quadrants per stage." 2. Review of laboratory records revealed the specimen tracking log, which stated, for patient NL23-0113 (tested on 06/22/2023), under "Site", "LT [left] upper cutaneous lip", and under "# Sections [Stages]", "II [2]". 3. Review of laboratory records revealed Mohs histopathology surgical map document for patient NL23-0113, which indicated the location of Mohs surgical testing site as "left lower cutaneous lip" and illustrated only 1 Mohs surgical stage. 4. Direct observation of Mohs histopathology patient slides for patient NL23-0113, on 05/21/2025, at 01:01 pm, revealed 2 Mohs surgical stages. 5. Review of the patient test report for patient NL23-0113, from 06/22/2023, revealed, under "Impression/Plan: located on the left lower lip[and] Number of Stages: 2". 6. Interview with TP #2 on 05/14/2025, at 1:15 pm, confirmed the laboratory failed to have a reliable system in place to ensure test results, including the number of Mohs histopathology surgical sites and stages, were accurately transferred to the final report for one of five patients reviewed.