

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 14D2058077	<b>(X3) Date Survey Completed</b> 05/27/2021
<b>Name of Provider or Supplier</b> Pinnacle Dermatology	<b>Street Address, City, State</b> 7123 W Archer Ave, Chicago, IL	
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>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and an interview with the testing personnel (TP3); the laboratory failed to retain the patient test records for the Mohs testing procedure performed for at least 2 years for 8 out of 8 patients. Findings include: 1. The laboratory's procedures manual, Mohs patients' logs, electronic medical records (EMR) were reviewed. 2. The Mohs test procedures and manual revealed the following: *The surgeon documented each tissue removal on Mohs Maps. *The Mohs map documents the patient's information, site of tissue excision, slide accession number, and prognosis. *The Mohs maps are later scanned into the patient's EMR and saved for 2 years. 3. The patients' test log and EMR revealed the following: *Eight (8) patients were selected from the Mohs logs who received Mohs surgery. *The paper Mohs maps of 8 out of 8 patients were not provided. *All 8 patients had scanned copies of Mohs maps in their respective EMR records. 4. Further review showed the Mohs maps had been discarded for at least the past 18 months. 5. The laboratory failed to follow policies and procedures to retain the original patients' Mohs maps for 8 out of 8 patients. 6. On a Recertification survey conducted on 05/27 /2021 at 11:20 AM, the TP3 confirmed the above findings.</p>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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>

This STANDARD is not met as evidenced by:

Based on records review, manual, and an interview with testing personnel (TP3), the laboratory failed to verify the accuracy of the Histopathology testing the laboratory performs for the years of 2019, 2020 and 2021. Findings include: 1. The laboratory quality assurance log book, Mohs patients' logs, and manual were reviewed. 2. The patients' test logs revealed the laboratory had been performing Mohs surgery procedures during the years of 2019, 2020, and 2021. 3. The documentation showed the laboratory had not verified the accuracy of its Mohs procedure during the years listed in Findings #2. 4. Further review revealed the laboratory has not performed biannual verification procedures since December 2018. 5. The laboratory failed to follow quality assurance procedures and verify the accuracy it's Mohs surgery procedure at least twice annually, for the years of 2019 through 2021. 6. On a Recertification survey conducted on 05/27/2021 at 11:20 AM, the TP3 confirmed the above findings.