

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D2031710	<b>(X3) Date Survey Completed</b>  04/27/2022
<b>Name of Provider or Supplier</b>  Pinnacle Dermatology	<b>Street Address, City, State</b>  1985 Emancipation Highway, Fredericksburg, VA	
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>	<p>An announced off-site CLIA recertification survey was conducted for Pinnacle Dermatology (formerly Virginia Dermatology and Skin Surgery Center) on April 27, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on April 8, 2022 and virtual record review conducted on April 22, 2022. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiency is as follows:</p>
<b>D5417</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's chemical log, policy and procedure manual, MOHS accession log and interview, the laboratory failed to ensure the eosin stain used for staining MOHS specimens was within manufacturer's expiration date while staining five-hundred seventy-seven (577) Mohs patient specimens from October 24, 2020 until December 29, 2020. Findings include: 1. A review of the laboratory's "Hematoxylin and Eosin Staining Maintenance Log" revealed eosin stain (lot number 1829205 exp 10/23/2020) documented as in use on October 24, 2020 until December 29, 2020. There were no other lots of eosin stain listed as in use on the laboratory's log. 2. A review of the laboratory's policy and procedure manual revealed a policy, "Materials and Reagents used", which stated "Reagents are never used after their expiration date." 3. A review of the laboratory's "MOHS Accession Log" revealed 577 Mohs patient specimens were stained from October 24, 2020 until December 29, 2020 while using the expired eosin stain (lot number 1829205 exp 10/23/2020). 4. In an exit interview with the Mohs Supervisor and Testing Personnel A on April 27, 2022 at approximately 12:30 PM, the findings were confirmed.</p>