

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2152108	<b>(X3) Date Survey Completed</b>  09/20/2021
<b>Name of Provider or Supplier</b>  Macinnis Dermatology	<b>Street Address, City, State</b>  1950 Laurel Manor Dr Ste 124, The Villages, FL	
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>	An initial certification survey was conducted on September 20, 2021. MacInnis Dermatology clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT 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 observation, record review and interview, the laboratory failed to ensure the Scott's Tap Water Substitute (Bluing Reagent) was not expired prior to patient testing from 05/06/2021 to 09/20/2021. Findings: Observations made during a tour of the laboratory on 09/20/2021 at 8:40 AM, showed the bottle of Scott's Tap Water Substitute lot #2012125 expired on 05/05/2021. Review of the reagent log showed there was no "End of Use Date" recorded for the Bluing reagent. Review of the laboratory's procedure on reagents noted "Reagents are not used after expiration." According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 09/14/2021, the laboratory had an estimated annual test volume of 600 histopathology tests per year. On 09/20/2021 at 8:40 AM, Testing Personnel B acknowledged the Scott's Tap Water Substitute was expired.</p>