

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  09D2131870	<b>(X3) Date Survey Completed</b>  02/18/2022
<b>Name of Provider or Supplier</b>  Integrated Dermatology Of I Street	<b>Street Address, City, State</b>  900 17th Street Suite 300, Washington, DC	
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>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review laboratory logs, interview with the testing person (TP), and the medical assistant (MA) at 1:00 PM, The lab did not perform maintenance procedures on all lab equipment to ensure accurate and reliable patient testing. Findings: 1. The lab performs MOHS surgery. The lab prepares slides with patient tissue collected during the surgery procedures for review by the pathologist. 2. The autoclave is used to sterilizes tools used during surgery procedures. 3. The lab did not perform spore checks on the autoclave to ensure contamination was not present. 4. The MA stated that she was unaware that spore checks needed to be performed on the autoclave. 5. The TP confirmed that spore checks were not performed on the autoclave to ensure contamination was not present.</p>
<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 review of the written procedure manual, review of Histopathology reagents,</p>

and interview with the testing person at 11:30 AM, the lab failed to ensure that reagents were not used beyond the expiration date. Findings: 1. The lab performs MOHS surgery. The lab prepares slides with patient tissue collected during surgery procedures for review by the pathologist. 2. The Eosin stain used for slide preparation had expired in December 2021. The bottle was opened in the year 2022 and used for testing. 3 The testing person (TP) did not realize the stain had expired. The TP stated that the stain was ordered from a different vendor and the expiration date was shorter. He was unsure of the exact date the stain was opened. 4. The written procedure manual QA procedure states that reagents must not be used when expired. 5. The TP confirmed that the Histopathology Eosin stain used for patent testing expired in December 2021.