

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D1058095	<b>(X3) Date Survey Completed</b>  09/28/2021
<b>Name of Provider or Supplier</b>  Dr Allen Sapadin	<b>Street Address, City, State</b>  370 Summit Avenue, Hackensack, NJ	
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>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of temperature records and interview with the Office Manager (OM) the laboratory failed to record the Room Temperature (RT) and Cryostat Temperature (CT) that was used for Mohs testing from 12/16/20 to 1/13/21. The findings include: 1. There was no RT recorded where Mohs testing was performed and reagents were stored. 2. There was no CT recorded for the Avantik QS 12. 3. The OM confirmed on 9/28/21 at 10:00 am that the RT and CT were not recorded.</p>
<b>D5429</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Preventive Maintenance (PM) records and interview</p>

with the Office Manager (OM), the laboratory failed document PM for the Avantik QS 12 Cryostat used in Mohs patient testing from 12/16/21 to 1/13/21. The OM confirmed on 9/28/21 at 10:00 am that the PM was not documented.

**D5601**

**HISTOPATHOLOGY**  
CFR(s): 493.1273(a)(f)

(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. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:  
Based on surveyor review of Quality Control (QC) records and interview with the Office Manager (OM), the laboratory failed to document Hematoxylin and Eosin (H&E) control slide reaction from 12/16/20 to 1/13/21. The findings include: 1. The laboratory did not document H&E stain QC reaction for reading of biopsy slides. 2. The laboratory read and reported approximately 25 patient slides. 3. The OM confirmed on 9/28/21 at 10:00 am that the laboratory did not document H&E QC stain reaction.