

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D2113855	<b>(X3) Date Survey Completed</b>  03/30/2023
<b>Name of Provider or Supplier</b>  Sanjiv K Saini, Md Llc	<b>Street Address, City, State</b>  3168 Braverton Street, Suite 340, Edgewater, MD	
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>D3011</b>	<p><b>FACILITIES</b> CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation and interview with the histotechnician, the laboratory did not ensure that an eye wash station was located in the laboratory area where testing occurs. Findings: 1. During a tour of the laboratory at 9:15 AM, it was observed that there was no eye wash station available in the laboratory where laboratory testing is performed. 2. During an interview on 03/30/2023 at 9:15 AM, the histotechnician stated that there was an eyewash station in another room in the office, however laboratory testing is not performed in that room. They confirmed that the eye wash station was not located in the room where laboratory testing is performed.</p>
<b>D5203</b>	<p><b>SPECIMEN IDENTIFICATION AND INTEGRITY</b> CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual, laboratory patient log, and patient electronic medical record (EMR) review and interview with the histotechnician, the laboratory did not follow the established policies and procedures to ensure positive identification of a</p>

patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. Findings: 1. The laboratory performs histopathology testing on patient specimens from Mohs surgery. The patients are entered on a patient log, where they are assigned a "Mohs Case Number." The procedure manual states that the case number must include the doctor's initial and the last two digits of the current year followed by the next sequence number for that year. 2. A random review of patient records showed that Patient A was listed as "Case # C22-153" in the patient log. Examination of Patient A's histology slides showed that they were labeled correctly with "C22-153," however a review of the patient final report in the EMR showed that the case number in the "visit note" was documented as "C22-152." 3. During an interview on 03/30/2023 at 11:00 AM, the histotechnician confirmed that written policies and procedures that ensure positive identification of histology specimens from the time of collection or receipt of the specimen through completion of testing and reporting of results were not followed.

**D5415**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:  
Based on observation and interview with the histotechnician, the laboratory did not ensure that the in-use histology stain reagents were labeled with the date that they were opened. Findings: 1. During a tour of the laboratory at 10:00 AM, it was observed that the opened and in-use histology stain reagents in the laboratory flammable cabinet were not labeled with the date that they were opened and put in to use. These include Methyl Alcohol, Absolute (lot# 2492-00, expiration date 08/31/2024); Eosin-Y Alcoholic 0.25% (lot# 15527, expiration date 08/31/2024); 100% Reagent Alcohol (lot# 143775, expiration date 02/29/2024 and lot# 127751, expiration date 08/31/2023); and XS-3 Xylene Substitute (lot# 124488, expiration date 05/31/2023). 2. During an interview on 03/30/2023 at 11:00 AM, the histotechnician confirmed that the histology stain reagents in-use were not labeled with the date that they were opened.