Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1058095	05/31/2023
Name of Provider or Supplier	**Street Address, City, State**	
Dr Allen Sapadin	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on surveyor review of Competency Assessment (CA) records and interview with the Office Manager (OM), the laboratory failed to perform a CA on one out of one testing personnel for the calendar year 2022. The OM confirmed on 5/31/23 at 1: 30 pm that the CA was not performed as stated above.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on surveyor review of Biannual Assessment (BA) records and interview with the Office Manager (OM), the laboratory failed to verify the accuracy and reliability of Mohs Histopathology testing twice a year in the calendar year 2022. The finding includes: 1. The BA was documented once in 2022. 2. The OM confirmed on 5/31/23 at 1:05 pm that the laboratory did not verify the accuracy of Mohs Histopathology testing twice in the calendar year 2022.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

	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. This STANDARD is not met as evidenced by: Based on the lack of Temperature Logs (TL) and interview with the Office Manager (OM), the laboratory failed to monitor and document refrigerator temperature where Mart-1 reagents where being stored on the date of survey. The OM confirmed on 5/31 /23 at 1:35 pm that the aforementioned TL was not maintained.