Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2299746	03/20/2025
Name of Provider or Supplier	**Street Address, City, State**	
Wellave Dermatology	198 Thomas Johnson Drive Suite 207, Frederick, MD	

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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 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. This STANDARD is not met as evidenced by: Based on procedure manual, laboratory patient log, and patient histopathology slide review, surveyor observation, and interview with the histotechnician (HT), the laboratory did not follow the established policies and procedures to ensure positive identification of histology specimens from the time of collection through completion and reporting of patient results. Findings: 1. The procedure manual shows an example of how to label the histopathology slides. The HT is required to include the last two digits of the current year followed by the next sequence number for that year, along with the patient's name, date of testing, specimen source (location), and stage number. 2. A random review of patient records showed that Patient A was listed as case # "25-96" in the patient log. Examination of Patient A's histopathology slides showed that there were three slides labeled "25-96," however two of the three slides were labeled with the name of a different patient (Patient B). 3. Patient log record review showed that the two mislabeled slides belonged to Patient B, who was logged as case # "25-95." Upon further investigation, it was observed that there were four slides labeled with the case # "25-95" and Patient B's name. 4. During an interview on 03/14/2025 at 11:20 AM, the HT confirmed that histopathology specimens were not correctly identified from the time of collection through completion and reporting of patient results.
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 procedure manual and temperature log record review, and interview with the histotechnician (HT), the laboratory failed to define the acceptable laboratory room temperature and humidity range for the QS12 Avantik cryostat to ensure reliable test system operation when performing histopathology testing. Findings: 1. The laboratory documents room temperature and humidity on the "Lab Maintenance" log each day that Mohs surgery is performed. The log lists the acceptable internal temperature range for the cryostat instrument, but does not list the laboratory's acceptable range for room temperature or humidity. 2. Procedure manual review showed that the laboratory did not have a procedure which instructed staff on how to take room temperature and humidity measurements, or which included any information on their acceptable ranges or what corrective actions to take when temperature and humidity readings are out of range. 3. A review of "Lab Maintenance" logs from February 2024 through February 2025 showed that room temperature and humidity was documented 51 times in 2024 and 10 times in 2025, however laboratory staff did not have a way to determine if the values were acceptable before performing histopathology testing. 4. During an interview on 03/14/2025 at 10:45 AM, the HT stated that they did not know what the proper operating temperature and humidity requirements were for the cryostat as dictated by the manufacturer, and confirmed that the laboratory failed to define and monitor room temperature and humidity to ensure accurate and reliable test system operation, and test reporting.