Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2194997	07/08/2024
Name of Provider or Supplier	**Street Address, City, State**	
Integrated Dermatology	800 Falmouth Rd, Mashpee, MA	

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
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 surveyor observation, record reviewed and confirmed through an interview with the Practice Manager (PM) and MOHS Manager (MM), the laboratory failed to define and correctly document temperature conditions for the proper operation of the Advantik QS12 Cryostat as evidenced by the following: 1. Record review on 7/1/2024 at 10:00 AM of the laboratory's 'Hematoxylin and Eosin' maintenance logs which contain the day of use Cryostat temperatures revealed: a. The acceptable temperature range is -24 to -30 degrees Celsius. b. The recorded temperatures for March 2024 through June 2024 were out of range for 6 of 7 days when the Cryostat was in use. c. The temperature was not recorded for 1 of 7 days when the Cryostat was in use from March 2024 through June 2024. 2. Record review on 7/1/2024 of the laboratory's 'Cryostat Maintenance' procedure revealed: "The cryostat should be in the 24 to 30 degree Celsius range." The procedure does not contain the minus signs before the acceptable temperature range. 3. Record review on 7/1/2024 of the laboratory's 'Quarterly QA Checklist' signed by the laboratory Director on 6/20/2024 revealed:, the section that states, "When humidity or temperature checks were out of range, corrective action was taken and documented," was signed with a Y for Yes. 4. Staff interview with the laboratory PM and MM and surveyor observation on 7/1/2024 at 11:30 AM: a. Surveyor discussed the out of range temperatures noted in 1a above

	with the PM. As the surveyor was showing the PM the temperature charts, surveyor noticed the temperatures were now in range. A minus sign was placed in front of the temperatures where it had not been when reviewed at 10:00 AM. b. The MM revealed they had altered the document by adding the minus sign in front of the temperatures to correct them even though MM was not the person who took the temperatures in the first place. c. Confirmed temperature was not recorded for 1 of 7 days as indicated in #1c above. d. Confirmed the 'Quarterly QA Checklist' was signed with a Y for yes as indicated in #3 above, even though the temperatures recorded in #1b above were out of range. 5. The laboratory performs 300 tests annually in the specialty of Histopathology.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on record reviewed and confirmed through an interview with the Practice Manager (PM) and MOHS Manager (MM), the laboratory failed to have a maintenance procedure in place to check laboratory microscopes to ensure proper performance. Findings include: 1. Record review on 7/1/2024 of the laboratory's equipment maintenance records revealed the laboratory did not have preventative maintenance records for the microscope. 2. Staff interview with the laboratory PM and MM on 7/1/2024 at 11:00 AM confirmed the laboratory did not have maintenance records for the microscope and the PM was not sure when the last time preventative maintenance was performed. The PM stated, "I will try to locate the records." 3. Record review on 7/8/2024 of an email received from the PM on 7/8/2024 at 3:48 PM revealed: "I know it is supposed to be every two years. I will have that in writing and when the maintenance tech arrives, I will confirm with him what I have in writing. I will have all the identification information and all equipment maintenance spelled out going forward." 4. The laboratory performs 300 tests annually in the specialty of Histopathology.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and confirmed through an interview with the Practice Manager (PM) and MOHS Manager (MM), the laboratory director (LD) failed to ensure the laboratory's Quality Assurance program was followed to identify failures in quality in the specialty of Histopathology. Findings include: 1. Record review on 7/1 /2024 of the laboratory's "Quarterly QA Checklists(s)" revealed: a. The laboratory did not fill out the 'Quarterly QA Checklist' for 3 of 4 quarters in 2022. b. The laboratory did not fill out the 'Quarterly QA Checklist' for 4 of 4 quarters in 2023. c. The

	laboratory did not fill out the 'Quarterly QA Checklist' for 1 of 2 quarters to date in 2024. 2. Record review on 7/1/2024 of the laboratory's 'Quality Assurance' policy revealed. "The procedures and implementation of procedures will be evaluated on a quarterly basis. Laboratory inspections are performed quarterly and records are kept in the quality control manual." 3. Staff interview on 7/1/2024 at 11:30 AM with the PM and MM confirmed the above findings. 4. The laboratory performs 300 tests annually in the specialty of Histopathology.