

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D2147067	(X3) Date Survey Completed 01/12/2023
Name of Provider or Supplier Connecticut Dermatology Group	Street Address, City, State 600 West Putnam Ave, Greenwich, CT	
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	<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 record review and staff interview, the laboratory failed to ensure proper monitoring and documentation of room temperature in the subspecialty of histopathology. Findings include: 1. Record review on 01/12/2023 of the 'MOHS Daily Log Binder' for the year of 2022 revealed lack of documentation of room temperature monitoring. 2. Record review on 01/12/2023 of the 'Avantik Cryostat QS11/QS11UV Instructions Manual' revealed a room temperature operation condition of '+5 degrees Celsius up to +35 degrees Celsius'. 3. Staff interview on 01/12/2023 at 10:15 AM with the Operations Manager (OM) confirmed the above findings and further stated that he/she was unaware of the requirement to monitor for and document room temperature for proper function of the cryostat. 4. The laboratory performs 143 MOHS surgeries annually in the subspecialty of histopathology.</p>
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p>

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to follow its written procedure of an ongoing audit mechanism to confirm manual entries versus the final electronic result in the subspecialty of mycology. Findings include: 1. Record review on 01/12/2023 of the 'Quality Assurance Program' procedure revealed 'once a month, lab manager will perform audits on the patient logs to confirm that the information provided on the log sheet corresponds accurately to the information in the system'. 2. Record review on 01/12/2023 of the potassium hydroxide (KOH) log revealed the following: a. Audit verification dates of 06/28/2022 and 01/05/2023. b. Lack of documentation of audit verification dates for the month of January, February, March, April, May, July, August, September, October, November, and December of 2022. 3. Record review on 01/12/2023 of the KOH log, patient A test result versus the final electronic result revealed the following: a. A positive KOH result for patient A on the KOH log. b. A negative KOH result for patient A in the final electronic result. c. A provider note on the final electronic result stating 'KOH, negative, however clinically looks like tinea corporis'. 4. Staff interview on 01/12/2023 at 11:45 AM with the OM confirmed the above findings and further commented that the medical assistant transcribed the results into the KOH log incorrectly, but the provider indicated the correct results in the final electronic report. 5. The laboratory performs 13 KOH tests annually in the subspecialty of mycology.