

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0100417	(X3) Date Survey Completed 07/24/2023
Name of Provider or Supplier Dermatology Assoc Of Western Ct Pc	Street Address, City, State 170 Mount Pleasant Rd, Suite 201, Newtown, 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 define and provide evidence of monitoring and documenting humidity requirements in the subspecialty of histopathology. Findings include: 1. Record review on 07/24/2023 of the laboratory maintenance records revealed lack of documentation of humidity levels in the laboratory area. 2. Record review on 07/24/2023 of the 'Tissue-Tek V.I.P. Vacuum Infiltration Processor' manual revealed a relative humidity of 0% to 85% (non-condensing). 3. Record review on 07/24/2023 of the 'Leica EG1160 Paraffin Embedding Center' manual revealed a relative humidity of 0% to 60% (non-condensing). 4. Record review on 07/24/2023 of the 'Leica CM 1510S' manual revealed a relative humidity of 0% to 60% (non-condensing). 5. Staff interview on 07/24/2023 at 9:45 AM with the laboratory supervisor (LS) confirmed the above findings. The LS further commented that he/she was unaware of the humidity requirements. 6. The laboratory performs 8,809 tests annually in the subspecialty of histopathology.</p>
D5893	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c)</p>

(b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to ensure policies and procedures were in place to prevent reporting errors and when errors were identified, implement appropriate corrective action to prevent reoccurrence in the subspecialty of histopathology. Findings include: 1. Record review on 07/24/2023 of the "Corrected Reports Log" for 2022 and 2023 revealed the following corrected reports: a. 2022: 14 of 16 corrected reports for 'incorrect anatomic location'. b. 2022: 2 of 16 corrected reports for 'specimen switched in bottle'. c. 2023: 4 of 4 corrected reports for 'incorrect anatomic location'. d. Lack of documentation of staff retraining to prevent the reoccurrence. 2. Staff interview on 07/24/2023 at 11:45 AM with the laboratory supervisor confirmed the above findings. 3. The laboratory performs 8,809 tests annually in the subspecialty of histopathology.