

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0902738	(X3) Date Survey Completed 06/22/2023
Name of Provider or Supplier Dermatopathology Lab Of New England Pc	Street Address, City, State 140 Green Road, Meriden, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish competency assessment policy and procedures to assess competency for the regulatory responsibilities for the general supervisor (GS), technical supervisor (TS) and clinical consultant (CC). Findings include: 1. Record review on 06/22/2023 of the staff training and competency files revealed lack of competency assessment documentation for the regulatory positions of GS, TS, and CC. 2. Staff interview on 06/22/2023 at 10:00 AM with the laboratory manager (LM) confirmed the above findings. The LM further commented that he/she was unaware that a GS, TS, and CC competency assessment is a regulatory requirement. 3. The laboratory performs 26,674 tests annually in the subspecialty of histopathology.</p>
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>

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 and room temperature in the subspecialty of histopathology. Findings include: 1. Record review on 06/22/2023 of the laboratory maintenance records revealed lack of documentation of humidity levels and room temperature for all laboratory areas. 2. Record review on 06/22/2023 of the 'Temperature Quality Control' standard operating procedure revealed lack of documentation of humidity and room temperature requirements. 3. Record review on 06/22/2023 of the 'Leica CV5030 Robotic Coverslipper' manual revealed the following site requirements: a. Relative humidity: Maximum 85% (non-condensing). b. Operating temperature range: 15 to 35 degrees Celsius. 4. Record review on 06/22/2023 of the 'Tissue-Tek DRS 2000 Automatic Slide Stainer' manual revealed the following site requirements: a. Relative humidity: 30% to 85% (non-condensing). b. Operating temperature range: 10 to 40 degrees Celsius. 5. Record review on 06/22/2023 of the 'Tissue-Tek V.I.P. Vacuum Infiltration Processor E150 /E300 Series' manual revealed the following site requirements: a. Relative humidity: 0% to 85% (non-condensing). b. Operating temperature range: 10 to 40 degrees Celsius. 6. Record review on 06/22/2023 of the 'Tissue-Tek Tissue Embedding Console System' manual revealed the following site requirements: a. Relative humidity: 0% to 85% (non-condensing). b. Operating temperature range: 15 to 35 degrees Celsius. 7. Record review on 06/22/2023 of the 'Leica BOND-MAX Automated Immunohistochemistry (IHC) Stainer' manual revealed the following site requirements: a. Relative humidity: 10% to 85% (non-condensing). b. Operating temperature range: 18 to 26 degrees Celsius. 8. Record review on 06/22/2023 of the 'Leica RM2235 Microtome' manual revealed the following site requirements: a. Relative humidity: Maximum 80% (non-condensing). b. Operating temperature range: 10 to 35 degrees Celsius. 9. Staff interview on 06/22/2023 at 11:00 AM with the laboratory manager (LM) confirmed the above findings. The LM further commented that he/she was unaware of the humidity and room temperature requirements. 10. The laboratory performs 26,674 tests annually in the subspecialty of histopathology.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES
 CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
 Based on record review and staff interview, the technical supervisor (TS) failed to ensure 5 of 5 testing personnel (TP) that perform macroscopic gross examination of histological specimens were assessed for competency by a qualified individual for the period of 2022 and 2023 in the subspecialty of histopathology. Findings include: 1. Record review on 06/22/2023 of the laboratory's testing personnel competency records for 2022 and 2023 revealed 5 of 5 competency assessments for TP 'specimen grossing' have documented signature by the laboratory manager (LM) and lack of documentation of review and approval by a TS; lacked the six required elements of competency assessments. 2. Record review on 06/22/2023 of the LM credentials

revealed the highest level of educational qualification was a bachelor's degree and does not meet the histopathology requirement of a medical degree to perform competency assessments. 3. Staff interview on 06/22/2023 at 10:30 AM with the LM confirmed the above findings. The LM further commented that he/she was unaware that in histopathology the TS is required to perform competency assessments for TP performing macroscopic gross examination of histological specimens. 4. The laboratory performs 26,674 tests annually in the subspecialty of histopathology.