

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0883635	(X3) Date Survey Completed 08/13/2026
Name of Provider or Supplier Adult & Pediatric Dermatology Specialists, Pc	Street Address, City, State 160 Hawley Lane, Trumbull, 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	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 review and staff interview, the laboratory failed to define and provide evidence of monitoring and documenting ambient room temperature and humidity requirements in the subspecialty of histopathology. Findings include: 1. Surveyor observation on 08/13/2026 at 10:45 AM of the laboratory's histopathology slide reading room revealed one of one 'Olympus BX45 Microscope' in use. 2. Record review on 08/13/2026 of the laboratory's equipment maintenance records for 2024 and 2025 revealed the lack of documentation of ambient room temperature and humidity levels for the histopathology slide reading room. 3. Record review on 08/13/2026 of the 'Olympus BX45 Microscope' operator's manual revealed the following operating environmental conditions: a. 'Ambient temperature: 5 to 40 degrees Celsius' b. 'Maximum relative humidity: 80%' 4. Staff interview on 08/13/2026 at 11:00 AM with the laboratory's practice manager confirmed the above findings. 5. The laboratory performs 4,635 tests annually in the subspecialty of histopathology.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)

(e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to document daily quality assessment of hematoxylin and eosin (H&E) stains, special stains, and immunohistochemistry (IHC) stains in the subspecialty of histopathology. Findings include: 1. Record review on 08/13/2026 of the laboratory's specimen transport logs for 2026 and 2025 revealed lack of documentation of daily quality assessment of hematoxylin and eosin (H&E) stains, special stains, and immunohistochemistry (IHC) stains. 2. Record review on 08/13/2026 of the laboratory's 'Quality Control Assurance' standard operating procedure revealed the following: a. 'Quality Control Procedure' i. 'Upon receipt and prior to interpretation, the dermatopathologist shall assess each slide for adequate staining quality and contrast'. b. Lack of documentation that the assessment of stain quality and contrast is required to be documented. 3. Staff interview on 08/13/2026 at 10:30 AM with the laboratory's practice manager confirmed the above findings. 4. The laboratory performs 4,635 tests annually in the subspecialty of histopathology.