

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0883635	(X3) Date Survey Completed 09/10/2024
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
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 of the general supervisor (GS), technical supervisor (TS), technical consultant (TC) and clinical consultant (CC). Findings include: 1. Record review on 09/10/2024 of the laboratory's 'Personnel Training/ Employee Proficiency Evaluations/ Monthly Meetings' binder revealed lack of documentation of competency assessment for the regulatory positions of GS, TS, TC and CC. 2. Record review on 09/10/2024 of the laboratory's policies and procedure revealed lack of documentation of an established competency assessment policy and procedures to assess competency for the regulatory responsibilities of the GS, TS, TC and CC. 3. Staff interview on 09/10/2024 at 11:00 AM with testing personnel #1 confirmed the above findings. 4. The laboratory performs 413 tests annually in the subspecialty of mycology and 5,963 tests annually in the subspecialty histopathology.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review and staff interview the laboratory failed to follow their established policies and procedures to ensure that proficiency testing (PT) samples were performed twice annually in the subspecialty of histopathology. Findings Include: 1. Record review on 09/10/2024 of the laboratory's 'Monthly Quality Assurance/ Monthly Patient Quality Assurance/ Quality Control-Proficiency' binder revealed lack of documentation of PT samples being sent out for microscopic review /evaluations for 2023. 2. Record review on 09/10/2024 of the laboratory's 'Proficiency Testing: Mohs Micrographic Surgery Skin Specimen' procedure revealed 'Semi annually, the tech will send two cases containing the original slides and send it out for a microscopic examination by a Board Certified Dermatopathologist or Mohs surgeon'. 3. Staff interview on 09/10/2024 at 11:30AM with the testing personnel #1 confirmed the above findings. 4. The laboratory performs 5,963 samples annually in the subspecialty of histopathology.

D5779

CORRECTIVE ACTIONS
CFR(s): 493.1282(a)

Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to follow their established policies and procedures and document a corrective action when a discrepancy occurred for the same test performed on the same sample at multiple testing sites in the subspecialty of histopathology. Findings Include: 1) Record review on 09/10/2024 of a 'Random Pathology Review Quality Assurance' log for peer review cases revealed the following: a. A major disagreement with the final diagnosis of a pathology specimen between two pathologists b. Lack of documentation of a correction action for the resolution of the above disagreement. 2) Record review on 09/10/2024 of the 'Quality Assurance/Peer Review' policy and procedure manual revealed 'major discrepancy in the diagnosis will be referred to an outside consultant' for a third interpretation. 3) Staff interview on 09/10/2024 at 10:50 AM with the laboratory director confirmed the above findings. 4) The laboratory performs 5,963 tests annually in the subspecialty of histopathology.