

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D0884441	<b>(X3) Date Survey Completed</b>  09/17/2024
<b>Name of Provider or Supplier</b>  Adult & Pediatric Dermatology Specialists Pc	<b>Street Address, City, State</b>  162 Kings Highway North, Westport, CT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5471</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(1)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to document quality control (QC) checks on new lots and shipments of Dermatophyte Test Medium (DTM) for positive and negative reactivity in the subspecialty of mycology. Findings Include: 1. Record review on 09/17/2024 of the laboratory's QC binder revealed lack of documentation of positive and negative reactivity checks for the new lot numbers and shipments of DTM. 2. Record review on 09/17/2024 of the laboratory's 'Procedure of Obtaining Control Cultures' policy revealed that "Cultures for Westport are received in Trumbull, quality control done in Trumbull, then sent to Westport on a day that an employee is doing a split shift between Trumbull and Westport'. 3. Staff interview on 09/17/2024 at 9:50AM with the office supervisor confirmed the above findings. 4. The laboratory performs 59 DTM cultures annually in the subspecialty of mycology.</p>