Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0884441	03/29/2022
Name of Provider or Supplier	**Street Address, City, State**	
Adult & Pediatric Dermatology Specialists Pc	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure changes to the fungal culture procedure were updated, approved and signed by the laboratory director in the subspecialty of mycology prior to patient testing. Findings include: 1. Record review on 3/29/2022 of the laboratory's 'Obtaining/entering/reading /documenting results overview' procedure revealed: a. The procedure for 'taking /obtaining a fungal culture' was to inoculate the fungal culture media Sabouraud Dextrose Agar. b. After 2 weeks the provider does a visual reading of the Sabouraud Dextrose agar vial and results a positive or negative culture. c. Approval date of the procedure was 7/31/2018. 2. Surveyor observation on 3/29/2022 at 10:10 AM of the laboratory's fungal culture media revealed 2 boxes of Remel Dermatube Dermatophyte Test Medium (DTM), Lot #: 367893 exp 9/22/2022 in use. 3. Record review on 3/29/2022 of the Remel DTM manufacturer product insert revealed to examine the media at regular intervals for a red color development. 4. Record review on 3/29/2022 of the laboratory's 'Form 21: Laboratory Test Requisition and Report Log' revealed: a. 2 shipments of Sabouraud Dextrose Agar with date received 6/20/18 and 1/24/2019. b. 4 shipments of DTM with date received 1/17/2020, 9/4/2020, 10/21 /2021 and 2/16/2022 (Lot #367893). 5. Staff interview with the laboratory director (LD) on 3/29/2022 at 10:30 AM confirmed the above findings. The LD disclosed he /she was aware the laboratory switched to DTM at some point and a positive result on DTM is the color change to red but did not update the procedure. 6 The laboratory performs 212 fungal cultures annually in the subspecialty of mycology.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory failed to follow the manufacturer instructions for proper storage of dermatophyte test medium (DTM) used for fungal cultures in the subspecialty of mycology. Findings include: 1. Surveyor observation on 3/29/2022 at 10:10 AM revealed the following: a. 2 boxes of uninoculated Remel DTM located on a shelf in a storage closet at room temperature. b. DTM package label identified a storage condition of 2 to 8 degrees Celsius until ready to use. 2. Staff interview with the laboratory director on 3/29/2022 at 10:30 AM confirmed the above findings. 3. The laboratory performs 212 fungal cultures annually in the subspecialty of mycology.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (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. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to follow manufacturer instructions to monitor and document temperatures for proper testing performance of fungal cultures in the subspecialty of mycology. Findings include: 1. Record review on 3/29/2022 of the Remel Dermatophyte Test Media (DTM) product insert revealed to incubate DTM in ambient air at 25-30 degrees Celsius for up to 14 days. 2. Record review on 3/29/2022 of laboratory maintenance records revealed the lack of documentation of room temperature readings where inoculated DTM are stored during the 14 day testing period. 3. Staff interview with the laboratory director on 3/29/2022 at 10:30 AM confirmed the above findings. 4. The laboratory performs 212 fungal cultures annually in the subspecialty of mycology.