

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0689244	(X3) Date Survey Completed 07/22/2026
Name of Provider or Supplier Wnc Dermatological Associates, Pa	Street Address, City, State 281 Mcdowell Street, Asheville, NC	
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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, observation, and interview with the laboratory director 7/22/26, the laboratory failed to discard Dermatophyte Test Medium (DTM) slants that exceeded their expiration date. Findings: Review of the Hardy Diagnostics Dermatophyte Test Medium (DTM) Instructions for Use revealed "...STORAGE AND SHELF LIFE ... The product may be used and tested up to the expiration date on the product label and incubated for the recommended incubation times ..." During a tour of the laboratory at approximately 10:40 a.m., the surveyor observed 5 Hardy Diagnostics DTM slants (lot number 662353, expiration date 12/16 /25) in the refrigerator, available for use. During interview at approximately 10:40 a. m., the laboratory director confirmed the DTM slants were expired and discarded them.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer.

This STANDARD is not met as evidenced by:

Based on review of manufacturer's instructions, review of 2025 and 2026 patient fungal culture logs, and interview with the laboratory director 7/22/26, the laboratory failed to check each lot number of DTM for growth and appropriate biochemical response. Approximately 17 patients were tested 11/3/25 - 7/22/26 using DTM that was not checked for growth and appropriate biochemical response. Findings: Review of the Hardy Diagnostics Dermatophyte Test Medium (DTM) Instructions for Use revealed "USER QUALITY CONTROL End users of commercially prepared culture media should perform QC testing in accordance with applicable government regulatory agencies, and in compliance with accreditation requirements. Hardy Diagnostics recommends end users check for signs of contamination and deterioration and, if dictated by laboratory quality control procedures or regulation, perform quality control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or a negative reaction, if applicable. ..." Review of 2025 and 2026 patient fungal culture logs revealed the laboratory had used two lot numbers of DTM since the previous survey on 10/7/25: 1. Lot number 658018, expiration 11/2/25 - the laboratory documented the performance of a check for media quality and acceptability on receipt, but had not performed any checks for growth and appropriate biochemical response. 2. Lot number 662353, expiration 12/16/25 - the laboratory had not performed a check for media quality and acceptability on receipt and had not performed any checks for growth and appropriate biochemical response. During interview at approximately 10:50 a.m., the laboratory director confirmed that the laboratory had not checked each lot number of DTM for growth and appropriate response. He stated the DTM manufacturer stopped providing a quality control kit with each shipment of media and they had not been able to find another source for the quality control kit.