

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D0881525	(X3) Date Survey Completed 10/20/2020
Name of Provider or Supplier Owensboro Dermatology Associates	Street Address, City, State 2821 New Hartford Road, Owensboro, KY	
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
D5517	<p>MYCOLOGY CFR(s): 493.1263(a)(c)</p> <p>The laboratory must check each batch (prepared in-house), lot number (commercially prepared), and shipment of lactophenol cotton blue when prepared or opened for intended reactivity with a control organism(s). (c) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview on 10/20/2020, the laboratory failed to perform a positive quality control organism on new lot numbers of Dermatophyte Testing Media (DTM) received 02/03/2020 and 09/29/2020. The findings include: Findings include: Review of the Policy and Procedure Manual revealed the Media and Stain Quality Control Record included "Must Do QC Positive Growth Test Per Lot #". 1. Record review revealed DTM lot number 453461 was received 02/03/2020. However, there was no documentation of quality control performed to confirm positive growth. 2. Record review revealed DTM lot number 467199 was received 09/29/2020. However, there was no documentation of quality control performed to confirm positive growth. Interview with testing personnel at 10:45 AM on 10/20/2020, revealed the laboratory failed to have a system in place to ensure policy was followed and a positive control was performed on new lot numbers of Dermatophyte Testing Media.</p>