

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2051558	(X3) Date Survey Completed 09/07/2021
Name of Provider or Supplier Dermatology At Midtowne, Pc	Street Address, City, State 555 Midtowne St Ne, Suite 301, Grand Rapids, MI	
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
D5477	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (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. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the office manager, the laboratory failed to check each lot of Dermatophyte Test Media (DTM) for sterility for 2 (September 2019 to September 2021) of 2 years. Findings include: 1. A review of the laboratory's "Media or Stin Receipt Log" revealed a lack of documentation of a sterility check on the following lots used between September 2019 to September 2021: a. D12941018 received on 10/8/18 b. D13770820 received on 5/13/20 2. An interview on 9/7/21 at 12:47 pm with the office manager confirmed the laboratory did not perform sterility checks for the DTM media lots listed above.</p>