

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D0694243	(X3) Date Survey Completed 06/28/2018
Name of Provider or Supplier Michael R Pincus Dpm Llc	Street Address, City, State 2207 A Golf Course Rd Se, Rio Rancho, NM	
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
D0000	The following deficiency was cited as the result of a recertification survey on 0628 /2018 for 42 CFR part 493 Laboratory Requirements.
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 the review of 2017-2018 quality control records, invoices and interview with the laboratory director, the laboratory failed to test a positive and negative organism for 1 lot of Dermatophyte Test Medium (DTM) received un November 2017. 148 vials were potentially used for patient testing. Findings are: A. Review of the Certificates of Analysis and DTM quality control log revealed a gap in time between lots of DTM media. Troy Biologicals DTM lot 1632207 expiration date 11/17 /2017 6 boxes of 20 vials were received on 07/31/2017. Troy Biologicals DTM lot 1810003 expiration date 04/10/2019 6 boxes of 20 vials were received on 05/02/2018. B. Review of an invoice from the distributor indicated receipt of another lot of DTM media in November 2017 but the lot number and expiration date were not printed on the invoice. There was no documentation in the quality control log of the performance of quality control materials. C. During interview on 06/28/2018 at 1:45 pm, the laboratory director stated that the employee responsible for documentation of the</p>

DTM media was no longer with the laboratory. He also stated he wasn't sure what happened; perhaps he wasn't working the day the DTM shipment arrived in the laboratory.