

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0509370	(X3) Date Survey Completed 07/23/2018
Name of Provider or Supplier Laboratory Of Michael H Simpson,Md,Pa	Street Address, City, State 1700 Murchison Drive Site 215, El Paso, TX	
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 surveyor observations, review of Troy Biologicals Dermatophyte media instructions for use, and interview with facility personnel, the laboratory failed to check each batch of media for sterility, check each batch of media for its ability to support growth and select or inhibit specific organisms or produce a biochemical reaction, and document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer for 1 of 1 lots of media. The findings included: 1. At 09:50 hours on 7/23/2018 in the laboratory, the surveyor observed the following media in use: Troy Biologicals, Inc. Catalog Number 7051 DTM - (Dermatophyte Test Medium) "For cultivation of fastidious microorganisms" Lot: 1810013 Expiration date: 2019 -04 - 10 2. Based on review of the Troy Biologicals Dermatophyte Test Medium instructions for use, under II. Quality Control, the document states: "The following incoming inspection procedures must be performed for each batch (batch equals same lot, same shipment) of culture media received in the laboratory: 1. Inspect plates according to instructions in Section VI Storage/Shelf Life 2. Write in the lot number and expiration date of the product being accepted into the laboratory on a log sheet. 3. Initial and date the log sheet. Note: Notify Technical Service immediately if media does not meet the inspection criteria." And; Under Section X. Procedure, the document states the following: "Inoculate the</p>

specimen as soon as possible after it is received in the laboratory. Place the specimen onto the center of the agar with sterile forceps. Press carefully to ensure firm contact with the agar surface. Replace the cap but do not tighten completely. Incubate the inoculated media at 22 to 30 Celsius for up to 14 days. (Do not incubate cultures at 35 - 37 Celsius). Examine the culture daily for a change in the color of the medium and evidence of fungal growth." And; Under Section XI. Expected Results: "NCCLS Control organisms (ATCC Strains). Expected cultured response on Dermatophyte Test Medium at 30 Celsius after 2 - 7 days. Trichophyton mentagrophytes White cotton-like growth, pink to red. Medium ATCC 9533 Aspergillus niger Inhibition, partial to complete ATCC 16405 Candida albicans White/off-white growth ATCC 10231 Escherichia coli Inhibition, partial to complete ATCC 25922." 3. In an interview at 10:15 hours on 7/23/2018 in the laboratory, Testing Person 2 stated the laboratory had been performing patient testing with the Dermatophyte media for about one (1) year but had not documented each batch of media for sterility, check each batch of media for its ability to support growth and select or inhibit specific organisms or produce a biochemical reaction, and document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. Testing Person 2 went on to say the laboratory had previously performed this end-user quality control in the past, but had not performed this quality control since restarting patient testing with this media.