

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0710944	(X3) Date Survey Completed 09/06/2018
Name of Provider or Supplier Kevin H Lapoff Dpm	Street Address, City, State 6422 Lake Worth Rd, Lake Worth, FL	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory did not verify the accuracy of fungal cultures twice annually. Findings include: Review of proficiency testing records on 09/06/18 revealed that split samples were sent to a reference laboratory for fungal cultures in May, 2018 and before that in July of 2016. During an interview with the laboratory director at 10:10 a.m. on 09/06/18, he confirmed that accuracy had not been verified twice annually.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with laboratory personnel, the laboratory used culture media that had expired. Findings include: The surveyor observed at 10:05 a.m. on 09/06/18 that two of twenty fungal cultures were on media, lot # 1715020, that expired on 05/30/18. One of the cultures was dated 08/21/18 and the other was 08/22/18. During an interview with the laboratory director at 10:10 a.m. on 09/06/18, he confirmed that the two cultures were on expired media.</p>

D5477

CONTROL PROCEDURES

CFR(s): 493.1256(e)(4)(g)

(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.

This STANDARD is not met as evidenced by:

Based on record review and interview with laboratory personnel, the laboratory did not perform negative controls for each batch of media used for fungal cultures.

Findings include: Review of quality control records for fungal cultures on 09/6/18 revealed that the laboratory did a positive control but no negative control to check for the correct biochemical response for each batch of media. During an interview with the laboratory director at 10:15 a.m. on 09/06/18, he confirmed that they did not do negative controls.