

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0710944	(X3) Date Survey Completed 11/04/2020
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
D0000	An announced recertification survey was conducted on 11/4/20 at Kevin H. Lapoff DPM, a clinical laboratory in Lake Worth, Florida. Kevin H. Lapoff DPM is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview with laboratory personnel, the temperature of the refrigerator used to store media for fungal cultures was not recorded. The findings included: Review of quality control records on 11/4/20 revealed there were no temperature charts for the refrigerator. The manufacturer specified that the media was to be stored at 2 to 8 degrees centigrade. During an interview with the laboratory director at 10:55 a.m., on 11/4/20, he confirmed that they did not record the refrigerator temperature.</p>
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</p>

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 staff interview with laboratory personnel, the laboratory did not do a positive and a negative control with each batch of fungal culture media to check that it produced the correct biochemical response. The findings included: On 11/4/20, review of quality control records for the past two years revealed that the laboratory tested each batch of media with a known positive or negative organism, not with both. During an interview with the laboratory director at 10:55 a.m., on 11/4/20, he confirmed that they had not done a positive and a negative organism with each new batch of media.