

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0287532	(X3) Date Survey Completed 10/22/2020
Name of Provider or Supplier Levine Podiatry Group Llc	Street Address, City, State 5210 Linton Blvd Ste 206, Delray Beach, 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 10/22/20 at Levine Podiatry Group, a clinical laboratory in Delray Beach, Florida. The laboratory was not in compliance with Code of Federal Regulations (CFR), Part 493, requirements for clinical laboratories.
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 laboratory personnel, there was no documentation to indicate that control organisms were used to check each batch of fungal culture media for its ability to support growth and to demonstrate the correct biochemical response. The findings included: Review of fungal culture quality control records for the past two years on 10/22/20 revealed that there was no documentation to show that positive and negative controls were performed on each batch of media. Physical characteristics were documented for each batch, there were package inserts for an Accuderm quality control kit, and the laboratory had a quality control form to document the reaction of positive and negative organisms, but there were none filled out for the batches of media used over the past two years. During an interview with the laboratory assistant at 10:45 a.m. on 10/22/20 she said she must have forgotten to do the quality control.</p>