

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0287532	<b>(X3) Date Survey Completed</b>  02/15/2023
<b>Name of Provider or Supplier</b>  Levine Podiatry Group Llc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Levine Podiatry Group LLC on 02/15/2023. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
<b>D5413</b>	<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 observation, and interview with the Laboratory Director, the laboratory failed to document refrigerator (where the Dermatophyte Test Medium (DTM) vials were stored) temperatures from 01/01/22 to 02/16/23 for the refrigerator in use. Findings Included: Observation during the tour of the laboratory, on 02/15/23 at 09:20 a.m., revealed the DTM vials were being stored in a refrigerator. Record review of the laboratory's policy "Quality Assurance Procedures and Regulations [undated]" revealed "6. Refrigerator temperature will monitored on a daily basis and record kept of the findings. Temperatures below 36 F [sic - Fahrenheit] and above 46 F will be reported to the physician. . ." Record review of the DTM manufacturer's instructions revealed, "STORAGE For maximum shelf life, ACU-DTM should be stored at 2 [degrees] C [Celsius] - 8 [degrees] C (36 F - 46 F). DO NOT FREEZE." On 02/15/23 at 09:40 a.m., during an interview, the Laboratory Director confirmed that refrigerator temperatures had not been documented since 12/31/21.</p>

**D5471**

**CONTROL PROCEDURES**

CFR(s): 493.1256(e)(1)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review, and interview with the Laboratory Director, the laboratory failed to check the positivity and negativity reactivity for new lots of Dermatophyte test medium (DTM) for two out of two years (2021 - 2023). Findings included: Record review of the laboratory's policy "Equipment Usage and Storage" (undated) revealed "2. All DTM medium to be logged in at the time of receipt with log # [sic - number], expiration date, opened date. . . 3. Visual Inspection of medium will be done." Record review of the laboratory's policy "Quality Control Monitor" (undated) revealed "Upon opening a batch of DTM vials, a random selection of a media vial will be taken and inoculated [sic] with a positive specimen. . . Negative specimens will also be done at random. The laboratory personnel will anticipate the need for opening a new batch, and assure that the pre-test will be done prior to the need for the batch." Record review of the laboratory's "DTM Inspection and Acceptance" logs revealed the laboratory had performed quality control visual checks on lot number D087 - 0818 that was opened on lot number 09/10/20, X15 - 469 - 463 that was opened on 10/20/20, and lot number D - 451 - 0122 that was opened on 11/1/22. No documentation was provided for checking the positivity and negativity reactivity for lot numbers, D087 - 0818, X15 - 469 - 463, and D - 451 - 0122. On 02/15/2023 at 09:50 a.m., during an interview, the Laboratory Director stated the previous Office Manager had not informed him of the previous survey deficiency of not checking the positivity and negativity reactivity of new lots of the DTM. This is a repeat deficiency. .