| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 31D0673791 | 06/27/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Podiatry Assoc Of Englewood Pc | 363 Grand Ave, Englewood, NJ | |

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 |
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| **D3009** | FACILITIES<br>CFR(s): 493.1101(c)<br><br>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.<br><br>This STANDARD is not met as evidenced by:<br>Based on an in-office review of the laboratory's requirements for a New Jersey State Clinical Laboratory License (NJCLL) under New Jersey Statutes Annotated: N.J.S.A. 45:9-42.28. License; necessity; categories, the laboratory failed to maintain NJCLL for 2023. A Surveyor for the Clinical Laboratory Improvement Services (CLIS) confirmed on 6/28/23 that the laboratory did not have a NJCLL license for 2023. |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation of Acuderm ACU-DTM Dermatrophyte Test Medium (DTM), review of Acuderm ACU-DTM Manufacturers Package Insert (MPI), Room Temperature (RT) Logs and interview with the Laboratory Director (LD), the laboratory failed to follow the MPI for Storage at the time of survey. The findings include: 1. The IFU stated under Storage "For maximum shelf life, Acu-DTM should |

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| | be stored at 2-8 degrees Celsius (36-46 degrees Fahrenheit). 2. The above mentioned media was being stored at RT of 70 degrees Fahrenheit. 3. The LD confirmed on at 1: 50 pm that the laboratory failed to follow the Acuderm Acu-DTM MPI. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Daily Room Temperature Log (DRTL) and interview with the Laboratory Director (LD) and Procedure Manual (PM), the laboratory failed to monitor and document the room temperature where mycology tests were performed on 7/25/22, 7/26/22, 7/27/22, 7/28/22, 7/29/22. The findings include; 1. No documented evidence for the room temperatures not being documented on the above mentioned dates. 2. The LD confirmed on 6/27/23 at 1:35 pm that the laboratory failed to document the room temperature on the above mentioned dates. |
| **D6030** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(12)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of the Procedure Manual and interview with the Laboratory Director (LD), the LD failed to establish a Competency Assessment (CA) procedure with the required elements from 6/27/18 to the date of the survey. The LD confirmed on 6/27/23 at 2:00 pm that a CA procedure was not established. Note: This is a repeat deficiency which was cited on 6/27/18. |