

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D0673791	<b>(X3) Date Survey Completed</b> 04/13/2021
<b>Name of Provider or Supplier</b> Podiatry Assoc Of Englewood Pc	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<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 surveyor review of the Biannual Assessment (BA) records and interview with the Laboratory Director (LD), the laboratory failed to verify the accuracy of Mycology testing twice annually in the calendar year 2020. The LD confirmed on 4/13 /21 at 10:30 am that the laboratory did not verify the accuracy of the Mycology testing twice annually.</p>
<b>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Manufacturer Package Inserts (MPI), Patient Results (PR) and interview with Laboratory Director (LD), the laboratory failed to follow the MPI for the ACU-(Dermatophyte Test Medium) used for Mycology testing from 6/27 /18 to the date of the survey. The findings include: 1. The MPI stated "Color interpretation of test is questionable after 14 days due to the possibility of false positives" 2. A review of PR revealed that 22 out of 41 PR were read past 14 days 3. The LD confirmed on 4/13/21 at 10:20 am that the laboratory did not follow the MPI.</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 surveyor review of Quality Control (QC) records and interview with the Testing Personnel (TP), and Office Manager (OM) the laboratory failed to check QC on each batch of Dermatophyte Test Media (DTM) used for Mycology testing from 4 /13/19 to the date of the survey. The findings include: 1. The laboratory did not check DTM for: a. Ability to support growth. b. Ability to select or inhibit specific organisms c. Sterility 2. The TP # 1 listed on the CMS form 209 on 4/13/21 at 11:00 am that the laboratory did not perform the above-mentioned QC checks. Note: This was cited on the last survey 6/26/18

**D5803**

**TEST REPORT**

CFR(s): 493.1291(b)

Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.

This STANDARD is not met as evidenced by:

Based on the surveyor review of the Final Reports (FR), Test Results (TR) and interview with the Testing Personnel (TP), and Office Manager (OM) the laboratory failed to have TR on one out of ten FR reviewed from 1/31/20 to the date of the survey. The OM confirmed on 4/13/21 at 11:01 am that the TR was not on all the FR.