

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0673791	(X3) Date Survey Completed 06/27/2018
Name of Provider or Supplier Podiatry Assoc Of Englewood Pc	Street Address, City, State 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
D5006	<p>MYCOLOGY CFR(s): 493.1203</p> <p>If the laboratory provides services in the subspecialty of Mycology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1263, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on lack of the Laboratory Records and interview with the Testing Personnel (TP) the laboratory failed to meet the general laboratory and analytic system requirements for Mycology testing from 6/28/16 to the date of survey. The findings include: 1. The laboratory did not have the manufacturer's Package Insert for DTM. Cross refer to D 5411 2. The laboratory did not monitor and document the temperature where Dermatophyte Test Media (DTM) were stored. Cross Refer to D 5413. 3. The laboratory used expired DTM for fungal testing. Cross Refer 5417 4. The laboratory failed to check each batch of DTM for sterility and its ability to support and inhibit growth . Cross Refer to D 5477.</p>
D5411	<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 Quality Control (QC) records, Procedure Manual and interview with the Laboratory Director (LD), the laboratory failed to retain the</p>

Manufacturer's Package Inserts (MPI) for Troy Biologicals Dermatophyte Test Media used for fungal cultures from 6/28/16 to the date of survey. The LD confirmed on 6/26/18 at 10:00 am that the MPI were not retained.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

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.

This STANDARD is not met as evidenced by:
Based on surveyor review of Temperature Records (TR) and interview with the Testing Personnel (TP), the laboratory failed to monitor and record the temperature of the room where Dermatophyte Test Media was stored from 6/28/16 to the date of the survey. The TP # 2 listed on the CMS form 209 confirmed on 6/26/18 at 11:00 am that room temperature was not monitored and recorded in the storage area.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on surveyor observation of Dermatophyte Test Medium (DTM) with active cultures, and interview with the Testing Personnel (TP), the laboratory used expired DTM for Mycology testing from 6/11/18 to the date of survey. The findings include:
1. Troy Biologicals DTM lot # 1715020 expired 5/30/18. 2. Seven patients were cultured with DTM lot # 1715020 two on 6/11/18, one on 6/12/18, two on 6/18/18, one on 6/22/18 and one on 6/26/18 3. The TP # 2 listed on the CMS form 209 confirmed on 6/26/18 at 11:01 am that the laboratory used expired DTM.

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:

	<p>Based on surveyor review of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to check QC on each batch of Dermatophyte Test Media (DTM) used for Mycology testing from 7/24/17 to the date of the survey. The findings include: 1. The laboratory did not check SSA for: a. Ability to support growth. b. Ability to select or inhibit specific organisms c. Sterility 2. The TP # 2 listed on the CMS form 209 on 6/26/18 at 11:00 am that the laboratory did not perform the above-mentioned QC checks.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of the Laboratory Work Records and interview with the Testing Personnel (TP), the Laboratory Director failed to provide overall management and direction to the laboratory for performing Mycology tests from 6/28/16 to the date of survey. The findings include: 1. The LD failed to ensure that Quality Control programs were maintained. Cross refer to D 6020. 2. The LD failed to establish a competency assessment procedure. Cross refer to D 6030.</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that the established QC program was maintained for laboratory services provided from 7/24/17 to the date of the survey. The TP #2 listed on CMS form 209 confirmed confirmed 6/26/18 at 10:50 am the LD did not ensure the QC plan was maintained.</p>
<p>D6030</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>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</p>

proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on surveyor review of the Procedure Manual and interview with the Testing Personnel (TP), the Laboratory Director failed to establish a Competency Assessment (CA) procedure with the required elements from 6/28/16 to the date of the survey. The TP # 2 listed on the CMS form 209 confirmed on 5/23/18 at 2:00 pm that a CA procedure was not established.