

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0856782	(X3) Date Survey Completed 02/28/2022
Name of Provider or Supplier Glendale Foot & Ankle Podiatry Ctr	Street Address, City, State 110 S Adams St, Glendale, CA	
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
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's quality control records, five (5) randomly chosen patient records, and interview with the laboratory director (LD) and testing personnel (TP); it was determined that the laboratory failed to perform control procedures using the number and frequency specified by the manufacturer to support control procedures for the Dermatophyte Testing Media (DTM) used in the laboratory. Findings included: 1. The laboratory used DTM to check for the presence of dermatophytes on patients' samples. 2. At the time on the survey on 2/28/2022 at approximately 11:00 a.m. the LD submitted for review a quality control log for the DTM media used in the laboratory; however, when asked about the organisms' quality controls (QC) listed on the log, no QC organisms were available or have been used for the years 2020, 2021 and in the past two months of 2022. 3. The LD and TP affirmed that the laboratory had not used QC organisms to check the DTM capability to support growth as recommended by the manufacturer. 4. Based on the laboratory testing declaration submitted at the time of the survey, the laboratory cultured and reported approximately 96 DTM mycology testing samples annually.</p>
D6020	LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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.

This STANDARD is not met as evidenced by:

The Laboratory Director is herein cited for deficient practice in overall administration to ensure testing of Quality Control materials is established and maintained for each lot number of Dermatophyte Test Media used in the laboratory. See D5445. .