

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2181230	(X3) Date Survey Completed 07/20/2022
Name of Provider or Supplier Foot And Ankle Concepts, Inc.	Street Address, City, State 2100 Solar Dr Ste 102, Oxnard, 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
D5453	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iv)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: No deficiency details available.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: No deficiency details available.</p>
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated</p>

that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
No deficiency details available.

D6170

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1489(a)

Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's patients test records, and interview with the laboratory general supervisor on July 20, 2022, at 1:20 pm, the laboratory failed to use testing person who is licensed in the State of California. The findings include: 1. The laboratory used PCR test to detect microorganisms present in the patients' sample. A California licensed testing person ran the PCR test on 7/12/2022. However, the licensed person did not analyze the test data. A different person who is not licensed in California and resides in another location, analyzed the test data and reported the results. Therefore, the accuracy of the reported test results cannot be assured and might had affected patient care adversely. 2. The laboratory general supervisor on July 20, 2022, at 1:20 pm, affirmed that the laboratory used an unlicensed person to analyze and report the sample test results. 3. The laboratory's testing declaration form, signed by the laboratory director on 4/28/2022, stated that the laboratory performed 88,000 tests, annually.