Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2181230	04/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
Foot And Ankle Concepts, Inc.	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
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's sample handling, processing, and testing areas, and interview with the laboratory general supervisor on April 28, 2022, at 12:30 pm, the laboratory failed to use separate areas for specimen processing and reagent preparation for the molecular amplification procedure. The findings include: 1. The laboratory used a laboratory developed test (LDT) which utilized molecular amplification by polymerase chain reaction (PCR) to detect various bacteria and fungus in the patient sample. The laboratory processed the sample in a biosafety cabinet, then extracted the nucleic acid using a semiautomated Kingfisher instrument. The laboratory used the extracted nucleic acid to prepare the PCR plate manually with the amplification reagents on an open bench which then amplified and detected by Quantstudio instrument. Although, the laboratory said that it used a unidirectional workflow, but the sample and reagent preparation were done in a very close proximity on the open bench. All the processes were done in a very small room. Unidirectional workflow refers to the manner in which testing personnel and patient specimens move through the molecular testing process to prevent cross-contamination and consists of separate areas for reagent preparation, pre-amplification area for specimen preparation and amplification reaction set up, and post-amplification area for specimen amplification, product detection, and storage or disposal of amplified products. Therefore, the accuracy of the reported result cannot be assured due to the possible cross contamination and might have affected patient care adversely. 2. The laboratory general supervisor on April 28, 2022, at 12:30 pm, affirmed that the laboratory did not use separate areas for the sample and reagent preparation. 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.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the severity of the deficiencies cited herein, the Condition: Analytic System was not met. The findings include: 1. The laboratory failed to maintain quality testing and provide accurate test result to the patients as it reported the patient test result when the quality control failed (D5401). 2. Testing personnel failed to follow the laboratory's established policies and procedures (D5481 and D6175).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's quality control (QC) records, and interview with the laboratory general supervisor on April 28, 2022, at 1:20 pm, the laboratory testing person failed to follow laboratory's written procedure in adding extraction control in 1 run out of 5 runs, reviewed. The findings include: 1. The laboratory performed a run on 4/12/2022, batch # 101342 which included a no template control (NTC). According to the laboratory's procedure, the testing person must add an extraction control into the NTC. However, the testing person failed to add the extraction control into the NTC. Therefore, the validity of the test run cannot be assured due to the possible cross contamination since, it cannot be confirmed that the NTC went through the same process as the sample and may have affected patient care adversely. 2. The laboratory general supervisor on April 28, 2022, at 1:20 pm, confirmed that the testing person failed to add the extraction control during the process. 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.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's quality control (QC) and patients test records, and interview with the laboratory general supervisor on April 28, 2022, at 1: 20 pm, the laboratory failed to obtain an acceptable control result before reporting patients test result for 1 batch run out of 5, reviewed. The findings include: 1. The laboratory ran a batch containing 1 negative control, 1 positive control and 6 patients sample on 03/17/2021. Although, the positive control did not produce results within the laboratory's acceptable quality control limits, but the laboratory reported all 6 patients test results from that run. Therefore, the accuracy of the reported test results cannot be assured and might had affected patient care adversely. 2. The laboratory general supervisor on April 28, 2022, at 1:20 pm, affirmed that the laboratory reported the patients test result even though the positive control did not meet the acceptable criteria. 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.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on the deficiencies found during an onsite survey on April 28, 2022, and the severity of the cited deficiencies, it was determined that the laboratory director failed to provide direction on administration and analytical phase of testing and fulfill the director's responsibilities causing minimalized quality testing which might had adversely affected patient care. Findings include: 1. The laboratory director failed to ensure that the physical plant and environmental conditions of the laboratory are appropriate in order to prevent cross-contamination of patient specimens. See D6083. 2. The laboratory director failed to ensure that the laboratory personnel are performing the test methods as required for accurate and reliable results. See D6087. 3. The laboratory director failed to ensure that the patient test results are reported only when the system is functioning properly. See D6097.
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's sample handling, processing, and testing areas, and interview with the laboratory general supervisor on April 28, 2022, at 12:30 pm, the laboratory failed to use separate areas for specimen and reagent preparation for the molecular amplification procedure. The findings include: See D3005.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii)

	The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's quality control (QC) records, and interview with the laboratory general supervisor on April 28, 2022, at 1:20 pm, the laboratory testing person failed to follow laboratory's written procedure. The findings include: See D5401.
D6097	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's quality control (QC) and patients test records, and interview with the laboratory general supervisor on April 28, 2022, at 1: 20 pm, the laboratory failed to obtain an acceptable control result before reporting patient test results. The findings include: See D5481.
D6175	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(1) Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's quality control (QC) and patients test records, and interview with the laboratory testing person #1 on April 28, 2022, at 1:20 pm, the laboratory testing person #1 failed to follow laboratory's procedures for specimen processing, test analyses, and reporting. The findings include: See D5401 and D5481.