

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2128423	(X3) Date Survey Completed 10/05/2020
Name of Provider or Supplier All Southbay Foot Care Podiatry Group Inc	Street Address, City, State 23365 Hawthorne Blvd Ste 101, Torrance, 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
D5217	<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 laboratory's policy & procedure, patient, quality control and proficiency testing records, and interview with the laboratory director and testing person #1 on October 5, 2020 at 12:45 pm, the laboratory failed to verify, at least twice annually, the accuracy of its fungal PCR test for the year of 2018 and 2019. The findings include: 1. The laboratory did not have any documentation showing that it had verified its fungal PCR test accuracy for the year of 2018 and 2019. Therefore, the accuracy of the laboratory's test results to the patients for fungal PCR test for the year of 2018 and 2019 can not be assured. The laboratory performs fungal PCR test by manual DNA preparation with a proprietary kit, gel electrophoresis and band detection methods which is a laboratory developed test. 2. The laboratory director and testing person #1 on October 5, 2020 at 12:45 pm, affirmed that the laboratory did not verify its fungal PCR test accuracy for the year of 2018 and 2019. 3. The laboratory's testing declaration form, signed by the laboratory director on 9/28/2020, stated that the laboratory performs 800 tests, annually.</p>
D6095	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6)</p> <p>The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on Surveyor review of laboratory's policy & procedure, patient, quality control and proficiency testing records, and interview with the laboratory director and testing person #1 on October 5, 2020 at 12:45 pm, it was determined that the laboratory director failed to ensure the maintenance of acceptable levels of analytical performance for its fungal PCR test. See D5217.