

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2152724	(X3) Date Survey Completed 07/07/2025
Name of Provider or Supplier Stockdale Podiatry Group, Inc	Street Address, City, State 110 New Stine Rd, Bakersfield, 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>(d)(3)(iv) Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; and</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's specimen processing and test records, and interview with the laboratory director on July 7, 2025, at 2:20 p.m., the laboratory failed to include control materials for DNA extraction. The findings include: 1. The laboratory used patients' specimens to extract DNA and performed PCR. However, it did not include any extraction control. Therefore, the accuracy of the patients' test results rendered by the laboratory cannot be assured and may have potential to harm patient. 2. The laboratory director on July 7, 2025, at 2:20 p.m., confirmed that the laboratory did not include control at the DNA extraction phase. 3. The laboratory's testing declaration form, signed by the laboratory director on July 7, 2025, stated that the laboratory performed approximately 9,957 tests in microbiology, annually.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>(e)(5) Ensure that the quality control and quality assessment 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: Based on Surveyor review of laboratory's testing process and interview with the</p>

laboratory director on July 7, 2025, at 2:20 p.m., the laboratory director failed to ensure that the quality control programs are established for the DNA extraction and PCR tests. The findings include: See D5453.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

(e)(12) 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 that they can perform all testing operations reliably to provide and report accurate results;

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's testing personnel qualifications and interview with the laboratory director on July 7, 2025, at 1:25 p.m., the laboratory director failed to ensure that all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered. The findings include: See D6170.

D6170

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

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

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's testing personnel qualifications and interview with the laboratory director on July 7, 2025, at 1:25 p.m., the laboratory failed to use the California State licensed testing personnel who performed high complexity testing. The findings include: 1. The laboratory performed high complexity testing such as DNA extraction and PCR. The laboratory had only 1 testing person and the testing person did not have the State license. Therefore, the accuracy of the laboratory test results obtained by unqualified testing person cannot be assured and may have potential to harm patients. 2. The laboratory director on July 7, 2025, at 1:25 p.m., affirmed that the testing person did not have California State license. 3. The laboratory's testing declaration form signed by the laboratory director on July 7, 2025, stated that the laboratory performed approximately 9,957 tests in microbiology, annually.