

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D2174031	<b>(X3) Date Survey Completed</b> 06/08/2022
<b>Name of Provider or Supplier</b> Foot And Ankle Clinic Of The Virginias	<b>Street Address, City, State</b> 2036 Leatherwood Lane, Bluefield, VA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA Recertification survey was conducted at the Foot and Ankle Clinic of the Virginias on 06/08/22 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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 the review of proficiency testing (PT) records, lack of documentation and interview, the lab failed to verify the accuracy twice a year for the nail fungus and wound culture panels in 2021. Findings include: 1. Review of available PT records revealed the lab receives at least five blind samples from Thermofisher Scientific to perform verification of accuracy for the nail fungus and wound culture panels assayed on the Biosystems QuantStudio 12 Flex real time PCR system, categorized as non-regulated analytes. In addition, the lab processed and submitted results for accuracy verification of the blind samples on 10/30/21 and 01/04/22. The inspector requested to review additional documentation of the verification of accuracy of the nail fungus and wound culture panels for the calendar year 2021. The documentation was not available for review. 2. An exit interview with the technical supervisor and primary testing personnel on 06/08/22 at noon confirmed the findings.</p>