

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2174031	(X3) Date Survey Completed 10/29/2020
Name of Provider or Supplier Foot And Ankle Clinic Of The Virginias	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA Initial on-site survey was conducted at the Foot and Ankle Clinic of the Virginias on October 29, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The initial contact with laboratory was on September 28, 2020 with off-site record review of documentation beginning on October 15, 2020 and a follow-up phone conference on October 23, 2020. Specific deficiencies cited are as follows:
D6120	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)</p> <p>(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the Laboratory Personnel Report (CLIA) (CMS 209) Form, verification of performance specification records, testing personnel (TP) records, lack of documentation, and interview with the technical supervisor (TS), the TS failed to provide documentation of the initial training and competency assessment for one (1) of 1 TP at the date of survey on October 29, 2020. Findings include: 1. Review of the CLIA CMS 209 Form revealed there was one TP performing patient testing (TP A). See attached TP code sheet. 2. Review of the verification of performance specification records for the QuantStuio 12k Flex Wound and Foot Fungus Polymerase Chain Reaction (PCR) test method revealed the laboratory performed initial verification studies beginning December 17, 2019. The site began testing patients on January 13, 2020. 3. Review of TP A personnel records revealed the lack of documentation of</p>

initial training and competency assessment. The inspector requested to review the initial training and competency records. The records were not available for review. 4. The TS stated, "The documents are not available for review. It was accidentally deleted from the Dropbox file when we switched lab director" during the exit interview at approximately 10:35 AM on October 29, 2020.