Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2123331	06/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Orlando Foot And Ankle Clinic Inc	7148 Curry Ford Rd Ste 300, Orlando, FL	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory procedure manual did not include instructions for making the 50% reagent alcohol from 2/17 to 6/28/18. Findings: Review of the procedure manual for the laboratory showed that the procedure titled "Tissue Processing - VIP III Tissue Processor" failed to have instructions for making the 50% reagent alcohol from the "Adopted Date" of 2/17 through 6/28/18. The laboratory processes patient specimens using a Miles Scientific Tissue Tek VIP Tissue Processor. The tissue processing procedure "Tissue Processing - VIP III Tissue Processor" indicated that the instrument uses 50% reagents alcohol

	for the "Routine Overnight Processing for All Tissue Types" and for the "Same - Day Processing for Small Biopsy Specimens (0.5cm thick or less)". During an interview on 6/28/18 at 10:25 AM, Testing Personnel stated she makes the 50% reagent alcohol. During an interview on 6/28/18 at 10:40 AM, Quality Assurance Coordinator acknowledged the procedure did not contain instructions for making the 50% reagent alcohol.