

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2227594	(X3) Date Survey Completed 06/30/2025
Name of Provider or Supplier Woodruff Institute, The	Street Address, City, State 1333 3rd Ave South Suite 201, Naples, 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
D0000	An announced CLIA recertification survey was conducted at WOODRUFF INSTITUTE, THE from 06/24/2025 to 06/30/2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory records review and staff interview, the laboratory failed to have a personnel policy in the Procedure Manual and failed to do Initial competency evaluation for one out of six Testing Personnel (TP) Findings included: 1-Review of FORM CMS 209 signed by the Laboratory Director (LD) on 06/12/2025 revealed that the LD was Clinical Consultant (CC), Technical Supervisor (TS) for Histopathology and TP#1, the laboratory had also 5 more TP (TP#2, TP#3, TP#4, TP#5 and TP#6). 2- Review of Procedure Manual signed by the LD on 06/12/2025, revealed that the Procedure Manual failed to have a policy that described all the personnel, the job descriptions and the frequency of the competencies. 2- Review of personnel records revealed that TP#3 that is a pathologist who started testing since 03/25/2025 failed to have a Job description and the Initial Competency Evaluation. 3-During an interview on 06/24/2025 at 12:30 PM, with General Supervisor, he confirmed that TP#6 failed to have the Initial Competency evaluation.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p>

(b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 observation, record review and staff interview, the laboratory procedure manual failed to include the instruction for making the solution for Alcohol 50%, 70%, 80% and 95% used for the Sakura VIP Tissue Tek Processor. Findings included: -During the tour of the laboratory on 06/24/2025 at 10:30 AM, in the flammable cabinet the laboratory had 100 % Reagent Alcohol. Review of Sakura VIP Processor stations revealed that the laboratory used alcohol as follows: station 2 (Alcohol 50%), station 3 (Alcohol 70%), station 4 (Alcohol 80%), station 5 (Alcohol 95%) and stations 6, 7 and 8 (Alcohol 100%). -Review of the procedure manual signed by the laboratory director on 06/12/2025, in the policy "Specimen Policy SOP 1.8, on page 4 had a table with the alcohol solutions used in the process: Alcohol 50%, 70%, 80% 95% and 100%. The policy failed to include the instructions of the preparation of the alcohol solutions used. During an interview on 06/24/2025 at 11:30 AM, the General Supervisor confirmed that the procedure manual failed to include the procedure for preparation of the Alcohol 50%, 70%, 80% and 95% used in the VIP Tissue Processor.