Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1074211	04/18/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pathology Laboratories	822 Perkins St, Leesburg, 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	A recertification survey was conducted on April 18, 2022. Pathology Laboratories clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
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's procedure manual failed to include step by step instructions on the use of the Miles Scientific Tissue Tek Vacuum Infiltration Processor (VIP) from 04/06/2022 to 04/18/2022. Findings: Review of the laboratory's procedure manual showed the manual was last signed and dated by the

	Laboratory Director on 04/06/2022. Review of the procedure manual showed there was no procedure on the operation of the Tissue Tek VIP. On 04/18/2022 at 11:20 AM, the Laboratory Director said the procedure for operating the Tissue Tek VIP may have been removed when the manual was reorganized.