Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2202867	11/01/2022
Name of Provider or Supplier	**Street Address, City, State**	
Applied Pathology Systems, Llc	222 Maple Ave, Rose Gordon Bldg, Suite 224, Shrewsbury, MA	

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 initial CLIA certification survey was conducted for the Applied Pathology Systems, LLC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Please refer to Conditions of Participation for Clinical Laboratories 42 CFR Part 493.
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 procedure manual review und interview it was determined that the laboratory failed to establish a written policy and procedure for one laboratory

	process. a) A review of the laboratory's main policy for receiving and processing tissue specimens revealed that the lab's slide labeling policy applied to slides received by the laboratory. There was no policy available outlining the labeling requirements for slides prepared in the laboratory. b) The laboratory director confirmed in an interview on 11/1/22 at 12:42 PM that there was no written policy or procedure to describe the laboratory's current protocol for labeling slides prepared in the laboratory. The laboratory processes approximately 1,000 specimens annually. .
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation procedure review and interview the laboratory failed to define a function check protocol for all equipment used in the laboratory as evidenced by the following: a) It was observed during a walkthrough of the laboratory on 11/1/22 that the pipette used in tissue slide preparation had a calibration date of 4/12/21. b) The laboratory director stated in an interview on 11/1/22 at 1:44 PM that the laboratory policy for pipette calibration checks would be ever two years. However there was no written pipette function check protocol available. .