Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2310132	05/23/2025
Name of Provider or Supplier	**Street Address, City, State**	
Path Reads Llc	3600 Quaker Mill Ct, Ellicott City, MD	

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) (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 review of the standard operating procedure manual (SOPM) and interview with the laboratory director (LD), the laboratory's SOPM did not include instructions for accessing and entering results into the third party information management software. Findings: 1. The pathologists entered their final interpretations into an information management software program called IntelliPath Pro. 2. The SOPM did

	not include instructions for accessing and using IntelliPath Pro. 3. During the exit interview on 05/15/2025 at 12:00 PM, the LD confirmed that the SOPM did not include instructions to access and enter results into IntelliPath Pro.
D5821	TEST REPORT CFR(s): 493.1291(k) (k)When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on review of test reports and email communication with the laboratory director (LD), the laboratory failed to maintain a duplicate of the original report when a corrected report was issued. Findings: 1. The final patient reports were entered and issued from a third party information management software called IntelliPath Pro. 2. The laboratory issued a corrected report for accession number MA25-182. 3. In an email received on 05/23/2025 at 4:28 PM, the LD confirmed that the IntelliPath Pro system did not retain a copy of the original report when results were corrected or amended and a duplicate of the original report was not maintained.