Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D1101784	10/24/2023
Name of Provider or Supplier	**Street Address, City, State**	
Quest Diagnostics Llc	130 Warren Street, Bldg C, Beaver Dam, WI	

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 surveyor review of procedures and interview with a QA (quality assurance) data analyst, the laboratory did not have a procedure for pathologist evaluation of wright-stained peripheral blood smears. Findings include: 1. Review of procedures showed no evidence of a procedure that included criteria for the evaluation of sample acceptability, instructions for microscopic evaluation, control procedures, corrective actions to take when slides are not acceptable, reporting process and documentation including retention of original result forms, and identification of panic or alert values. 2. Interview with the QA data analyst (staff A) on October 24, 2023, at 12:15 PM

	confirmed the laboratory had not developed a procedure for pathologist evaluation and reporting of wright-stained peripheral blood smears.