

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0928417	(X3) Date Survey Completed 08/18/2026
Name of Provider or Supplier Prine Health Medical Group Pllc	Street Address, City, State 3003 New Hyde Park Road Suite 201, New Hyde Park, NY	
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 lack of Quality Control (QC) documentation, review of the Standard Operating Procedures (SOPs), as well as interview with the Laboratory Director (LD), the laboratory failed to draft and approve control procedures. FINDINGS: 1. There was no documentation of lot-to-lot QC validation performance for the Roche Cobas Pro e801, Roche Cobas Pro ISE U411, Roche Cobas Pro c503, and Horiba Yumizen H2500 analyzers. 2. The Prine Health Medical Group SOPs did not include

instructions for lot-to-lot validation of new QC materials. 3. The LD confirmed the findings on August 18, 2026, at approximately 12:30 P.M.