

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2049329	(X3) Date Survey Completed 09/23/2026
Name of Provider or Supplier Primary And Urgent Care	Street Address, City, State 10009 Southpoint Parkway, Fredericksburg, VA	
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 announced CLIA recertification survey was conducted at Primary and Urgent Care, LLC on September 23, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Primary and Urgent Care, LLC is in compliance with the applicable Conditions and Standards under 42 CFR part 493 CLIA Regulations.
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 a laboratory tour, review of the laboratory's policy and procedure manual,

instrument verification records, patient records and interviews, the laboratory's failed to establish a procedure for their new Sysmex XQ-320 Hematology analyzer prior to utilizing the instrument for patient Complete Blood Cell counts and automated differentials (CBC/autodiff) testing on October 7, 2025. The findings include: 1. During a laboratory tour and entrance interview with the Nurse Manager at 9:30 AM on September 23, 2026, it was revealed the laboratory began utilizing the Sysmex XQ-320 (serial # 15159) analyzer for patient CBC and auto diff testing on October 7, 2025. 2. A review of the laboratory's policy and procedure manual revealed a lack of test procedure for the Sysmex XQ-320. The surveyor requested to review the laboratory's Sysmex XQ-320's procedure. The laboratory provided an instrument "Quick Guide" and "XQ-320 Instruction Manual". Neither document was signed as approved by the Laboratory Director (LD). No documentation of the laboratory's LD approved Sysmex XQ-320 procedure was provided. 3. A review of the laboratory's Sysmex XQ-320's records revealed an installation date of July 17, 2025. Further review of the instrument's records revealed the LD reviewed and signed as acceptable the Sysmex XQ-320's verification documents in October 2025. 4. A review of patient records revealed the laboratory began utilizing the instrument for patient testing on October 7, 2025. 5. In an exit interview with the Laboratory Director and Nurse Manager on September 23, 2026 at 1:00 PM, the above findings were confirmed.