

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 51D0976783	<b>(X3) Date Survey Completed</b> 12/13/2022
<b>Name of Provider or Supplier</b> Upc Family Medical Clinic Of Jane Lew	<b>Street Address, City, State</b> 134 Industrial Park Road Ste 200, Jane Lew, WV	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced, on site, routine recertification survey was conducted at UPC Family Medical Clinic of Jane Lew on December 13, 2022, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on written policies and procedures (P&amp;P), lack of documentation, and interview the laboratory failed to (1) establish criteria for specimen referral of an</p>

analyzed complete blood count (CBC) for a peripheral smear or pathologist review. Findings: 1. Review of P&P revealed no written policy or procedure for the referral of a CBC specimen for further testing based on the analyzer automated results. 2. An interview with the laboratory manager, 12/12/22 at approximately 11:00 AM, confirmed that no written P&P could be located for the referral of CBC specimens for a peripheral smear or pathologist review.