Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0236331	03/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Upc - Bridgeport Pediatrics	900 Lodgeville Road, Bridgeport, WV	

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	A routine recertification survey was conducted on March 5, 2025, for UPC-Bridgeport Pediatrics by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the CLIA regulations under 42 CFR 493, Requirements for Laboratories. Specific deficiencies cited are explained below.
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 hematology policies and procedures, lack of documentation, and interview with the laboratory director (LD) and testing personnel (TP1), the laboratory

	failed to establish (b)(11) the complete blood count (CBC) critical values for patients over the age of 12 months. Findings: 1. Review of policies and procedures revealed a "Critical Value Procedure" stating the critical values for CBC parameters in patients 12 months of age and younger. No established critical values in patients over the age of 12 months could be located. 2. During an interview with the LD, 3/5/25 at approximately 11:00 AM, the LD agreed a policy or procedure with critical values for patients over the age of 12 months could not be located. 3. An exit interview, 3/5/25 at 11:55, with the LD and TP1 confirmed the findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of written policies and procedures, complete blood count (CBC) patient reports, lack of documentation, and interview with the laboratory director (LD) and testing personnel (TP1), the laboratory failed to document the resolution of hematology parameters flagged for review by the Horibas Micro 60 analyzer for 19 of 35 patient CBCs in January 2025. Findings: 1. Review of Hematology "Postanalytic Policies and Procedures" for interpreting results states to "review all morphology flags for the presence of pathological elements" and "if any patient test results appear inconsistent with clinically relevant criteria or previous test results, confer with the laboratory director to see if the specimen should be sent to an outside laboratory for confirmation." 2. Review of 35 January 2025 patient CBC results revealed 19 patient results released with a morphology flag (M2, G1, G2, or L1) and no documentation of review for consistency with clinical presentation of the patient or review with the laboratory director could be located. 3. During an interview with the laboratory director (LD), 3/5/2025 at approximately 11:30 AM, the LD agreed the 19 patient CBC results lacked the complete documentation. 4. An exit interview with the LD and TP1, 3/5/2025 at 11:55 AM, confirmed the findings.