Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0236407	05/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Upc-Pediatrics Associates	7 Chenoweth Drive Ste A, 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	An announced, on site, routine recertification survey was conducted at UPC-Pediatrics Associates on May 25, 2023, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the FederaL Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies cited are explained below.
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 written policy and procedure (P&P), record review, and interview the laboratory failed to document the resolution of analyzer flags according to established P&P before releasing patient results in 11 of 69 patient CBC results reviewed for March 2023. Findings: 1. Review of P&P identified a process to handle error codes on the AcTDiff analyzer: thoroughly mix and rerun sample, if error code is resolved the results can be released. If the error code is not resolved, the laboratory director will review. 2. Review of 69 March 2023 patient CBC results revealed 11 patient results released with an error code (X Flag) and no documentation of review by the laboratory director (3336829, 3752312, 3310554, 3320913, 3248451, 3748548, 3748782, 3336602, 3319317, 2638892, and 3750076) 3. An interview with the

	laboratory manager, 5/25/23 at approximately 11:00 AM, confirmed the lack of corrective action documentation for the 11 CBC patient results released.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to ensure a positive patient identifier was utilized throughout the analytic system for 16 of 69 patient CBC specimens ran in March 2023 and 7 of 44 patient CBC specimens ran in May 2023. Findings: 1. Review of the 69 CBC specimens released in March 2023 identified 16 patient specimens that were manually entered into the CBC test system without the positive patient identifier used by the laboratory (7 digit MRN). 2. Review of the 44 CBC specimens released in May 2023 identified 7 patient specimens that were manually entered into the CBC test system without the positive patient identifier used by the laboratory (7 digit MRN). 3. An interview with the laboratory manager, 5/25 /23 at approximately 10:00 AM, confirmed the findings.