Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D2085573	10/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Rainbow Pediatrics Inc	354 Commerce Drive, Beaver, 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, recertification survey was conducted at Rainbow Pediatrics on October 21, 2021, 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.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to attain a satisfactory performance score for platelets in 1 of 2 American Proficiency Institute (API) proficiency testing (PT) events in 2021. Findings: 1. Pre-Survey review of CASPER 155D Report for the laboratory identified an unsatisfactory score of 60% for analyte 0815 Platelets in Hematology PT 1st event 2021. 2. Review of API records confirmed the unsatisfactory performance score; Hematology event 1 2021 0815 Platelets- 60% 3. An interview with the laboratory manager, 10/21/21 at approximately 9:00 AM, confirmed the findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number

	and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform and document 3 levels of daily quality control (QC) for the Horibas hematology analyzer for 10 of 61 days of patient testing. Findings: 1. Review of three random, daily task report logs identified 61 days of patient testing in January 2021, February 2021, and September 2021. 2. Review of daily QC logs for January 2021, February 2021, and September 2021 identified 10 days no daily QC was documented. 3. An interview with the laboratory manager, 10/21/21 at approximately 9:45 AM, confirmed the findings.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of written policies and procedures (P&P), lack of documentation, and interview the laboratory failed to (g) document the verification of new lots of quality control materials for the Horibas hematology analyzer in 2020 and 2021. Findings: 1. Review of P&P identified a "Procedure for Change in Lot of Assayed Control Materials" which states "Each level of the new control material must be evaluated five times, with alternating personnel and on multiple days when possible, to verify that control results fall within manufacturer stated 2SD ranges" 2. No documentation of the verification of new lots could be located for 2020 or 2021. 3. An interview with he laboratory manager, 10/21/21 at approximately 10:15 AM, confirmed the findings.