Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D2085573	11/18/2025
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	A routine recertification survey was completed at Rainbow Pediatrics Inc. on November 18, 2025, 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.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of two 2025 American Proficiency Institute (API) proficiency testing (PT) records, lack of documentation, and interview with laboratory testing personnel (TP1), the laboratory failed to document the evaluation of a less than 100% performance for erythrocyte count (#0775 RBC) in the second PT event of 2025 in hematology. Findings: 1. Review of two API PT evaluation reports for 2025 revealed an 80% performance for erythrocyte count (#0775 RBC) in hematology event 2 of 2025. PT Specimen HEM-07 had a reported result outside the acceptable range and scored by API as unacceptable. 2. No documented evaluation of the less than 100% performance for erythrocyte count (#0775 RBC) could be located. 3. During an interview 11/18/25 at 9:30 AM, TP1 verified that no documented evaluation of the 80% performance for erythrocyte count (#0775 RBC) could be located.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on review of the hematology instrument operator's manual, eleven 2025 monthly maintenance logs for the analyzer, lack of documentation, current CMS-209 form, and interview with two laboratory testing personnel (TP1 and TP2), the laboratory testing personnel (TP1 and TP2) failed to document whether a weekly maintenance procedure required by the manufacturer of the Horiba Micros 60 hematology analyzer was performed from January 2025 through the date of the survey. Findings: 1. Review of the Horiba Micros 60 operator manual identified a required maintenance protocol stating "weekly maintenance is to perform a concentrated cleaning with Minoclair". 2. Review of the Horiba Micros 60 analyzer monthly maintenance logs (January 2025 thru date of survey) revealed a specific area for recording the performance of a concentrated cleaning on a weekly basis. The weekly performance of a concentrated cleaning with Minoclair was not documented on 11 of 11 monthly maintenance logs reviewed. No other documentation indicating that the weekly concentrated cleaning had been performed could be located. 3. Review of the current laboratory CMS-209 form identified TP1 and TP2 as current testing personnel. 4. During an interview 11/18/2025 at 10:30 AM, TP1 and TP2 verified that the performance of the weekly concentrated cleaning had not been documented on the monthly maintenance logs for the Horiba Micros 60 analyzer.