Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D2085573	03/05/2018
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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, testing personnel training/competency records and interview with Testing Personnel #1 (TP1), the laboratory failed to follow their established policy for the initial training assessment of 4 of 4 testing personnel. Record review was from 11/13/17 until present. The findings include: 1. Review of the laboratory's policy and procedure manual identified a policy, "Staff Orientation, Training, and Competency", which states "Initial Training: Initial training on individual analyzers, equipment, test methods, and kits must be documented. Document initial training competency at the completion of each training activities. Document all initial instrument orientation the Personnel Training Checklist and the New Employee Checklist." 2. Review of the laboratory's training/competency records identified the lack of completed "Initial Personnel Training Checklist" for 4 of 4 testing personnel. 3. On 3/5/18 at approximately 1:00 PM, TP1 confirmed the findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii)

	Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the Horiba Micros 60 (serial #702CS96673) validation /verification records and interview with Testing Personnel #1 (TP1), the laboratory failed to verify the normal range for Complete Blood Cell (CBC) counts performed on the Horiba Micro 60 prior to analyzing patient specimens. The findings include: 1. Review of the Horiba Micros 60 validation/verification records identified a lack of documentation of the verification of the normal ranges for Complete Blood Cell counts (CBCs) performed on Horiba Micros 60. 2. On 3/5/18 at approximately 3:20 PM, TP #1 stated they did not know they had to verify the normal ranges.
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 review of Horiba Micros 60 analyzer's patient test printouts and interview with Testing Personnel #1 (TP1), the laboratory did not maintain a record system that included the identity of the personnel who performed the Complete Blood Cell (CBC) counts on the Horiba Micros 60 for 6 of 6 patient reports reviewed. Record review was from 11/13/18 to the present. The findings include: 1. Review of 6 of 6 Horiba Micros 60 analyzer's instrument printouts revealed the laboratory was not identifying the personnel who performed the CBC counts on the Horiba Micros 60 analyzer. 2. On 3/8/18 at approximately 4:05 PM, TP1 confirmed the findings.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of the laboratory's instrument validation/verification records and interview with Testing Personnel #1 (TP1), the technical consultant failed to verify the normal ranges for Complete Blood Cell counts performed on the Horiba Micros prior to beginning patient testing (see D5421).