Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D2085573	06/05/2019
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing records and CASPER 153D and 155D reports, the laboratory failed to successfully participate in an approved proficiency testing program. Findings: 1. CASPER report 153D, run 6 /3/2019, demonstrated a failure for the laboratory under analyte 0765. 2. CASPER report 155D, run 6/3/2019, demonstrated the following unsatisfactory proficiency testing (PT) scores: a. Hematology Event 3 of 2018 i. 73% for analyte 0765, Cell ID or WBC diff b. Hematology Event 1 of 2019 i. 62% for analyte 0760, hematology overall ii. 73% for analyte 0765, Cell ID or WBC diff iii. 60% for each of the following analytes A. 0775, RBC B. 0785, HCT C. 0795, HGB D. 0805, WBC E.

	0815, PLATELETS 3. The API Comparative Evaluations for 2018 event 3 and 2019 event 1 confirm the findings on the CASPER reports.
D2128	HEMATOLOGY CFR(s): 493.851(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing records and CASPER 153D and 155D reports, the laboratory failed to successfully participate in an approved proficiency testing program. Findings: 1. CASPER report 153D, run 6 /3/2019, demonstrated a failure for the laboratory under analyte 0765. 2. CASPER report 155D, run 6/3/2019, demonstrated the following unsatisfactory proficiency testing (PT) scores: a. Hematology Event 3 of 2018 i. 73% for analyte 0765, Cell ID or WBC diff b. Hematology Event 1 of 2019 i. 62% for analyte 0760, hematology overall ii. 73% for analyte 0765, Cell ID or WBC diff iii. 60% for each of the following analytes A. 0775, RBC B. 0785, HCT C. 0795, HGB D. 0805, WBC E. 0815, PLATELETS 3. The API Comparative Evaluations for 2018 event 3 and 2019 event 1 confirm the findings on the CASPER reports.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing records and CASPER 153D and 155D reports, the laboratory failed to successfully participate in an approved proficiency testing program. Findings: 1. CASPER report 153D, run 6 /3/2019, demonstrated a failure for the laboratory under analyte 0765. 2. CASPER report 155D, run 6/3/2019, demonstrated the following unsatisfactory proficiency testing (PT) scores: a. Hematology Event 3 of 2018 i. 73% for analyte 0765, Cell ID or WBC diff b. Hematology Event 1 of 2019 i. 62% for analyte 0760, hematology overall ii. 73% for analyte 0765, Cell ID or WBC diff iii. 60% for each of the following analytes A. 0775, RBC B. 0785, HCT C. 0795, HGB D. 0805, WBC E. 0815, PLATELETS 3. The API Comparative Evaluations for 2018 event 3 and 2019 event 1 confirm the findings on the CASPER reports.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance

	with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing records and CASPER 153D and 155D reports, the laboratory director failed to ensure successful participation in an approved proficiency testing program. Findings: 1. CASPER report 153D, run 6/3/2019, demonstrated a failure for the laboratory under analyte 0765. 2. CASPER report 155D, run 6/3/2019, demonstrated the following unsatisfactory proficiency testing (PT) scores: a. Hematology Event 3 of 2018 i. 73% for analyte 0765, Cell ID or WBC diff b. Hematology Event 1 of 2019 i. 62% for analyte 0760, hematology overall ii. 73% for analyte 0765, Cell ID or WBC diff iii. 60% for each of the following analytes A. 0775, RBC B. 0785, HCT C. 0795, HGB D. 0805, WBC E. 0815, PLATELETS 3. The API Comparative Evaluations for 2018 event 3 and 2019 event 1 confirm the findings on the CASPER reports.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing records and CASPER 153D and 155D reports, the laboratory director failed to ensure successful participation in an approved proficiency testing program. Findings: 1. CASPER report 153D, run 6/3/2019, demonstrated a failure for the laboratory under analyte 0765. 2. CASPER report 155D, run 6/3/2019, demonstrated the following unsatisfactory proficiency testing (PT) scores: a. Hematology Event 3 of 2018 i. 73% for analyte 0765, Cell ID or WBC diff b. Hematology Event 1 of 2019 i. 62% for analyte 0760, hematology overall ii. 73% for analyte 0765, Cell ID or WBC diff iii. 60% for each of the following analytes A. 0775, RBC B. 0785, HCT C. 0795, HGB D. 0805, WBC E. 0815, PLATELETS 3. The API Comparative Evaluations for 2018 event 3 and 2019 event 1 confirm the findings on the CASPER reports.