Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0101910	07/14/2025
Name of Provider or Supplier	**Street Address, City, State**	
Ridgefield Pediatric Associates	38-B Grove St, Ridgefield, CT	

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 proficiency testing desk review of the Ridgefield Pediatrics Associates Laboratory was conducted pursuant to 42CFR Part 493 of the Clinical Laboratory Improvement Amendments (CLIA) of 1998.
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 record review of the proficiency testing (PT) data report (Casper 155) and graded results from College of American Pathologist (CAP), the laboratory failed to perform PT successfully for the regulated analytes: hematology, red blood cells and hematocrit for 2025. The laboratory had unsatisfactory scores for both Event 1 and Event 2. Refer to D2130 and D2131.

D2130	HEMATOLOGY CFR(s): 493.851(f) (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 record review and staff interview, the laboratory failed to achieve satisfactory performance for the hematology, red blood cells (RBC), and hematocrit (HCT) analytes for two consecutive Events 1 and 2 for 2025 in the specialty of Hematology. Findings include: 1. Record review on 7/11/2025 of the Proficiency Testing (PT) data report (Casper 155) revealed the laboratory failed to achieve successful scores for 2025 as follows: Analyte Event #1(score) Event # 2(score) 0760 Hematology 76 73 0775 RBC 60 20 0785 HCT 60 40 2. Record review on 7/11/2025 of the College of American Pathologist (CAP) "FH16-A 2025 Hematology Auto Differentials, FH16" Event #1, PT evaluation report revealed unsuccessful score for the following analytes: a. Hematology analyte: 76%. b. RBC analyte: 60%. c. HCT analyte: 60%. 3. Record review on 7/11/2025 of the CAP "FH16-B 2025 Hematology Auto Differentials, FH16" Event #2, PT evaluation report revealed unsuccessful score for the following analytes: a. Hematology analyte: 73%. b. RBC analyte: 20%. c. HCT analyte: 40%. 4. A telephone interview with the office manager on 7/14/2025 at 08:49 AM revealed the laboratory has still not received the PT "Original Evaluation Report" for Event 2 from CAP. He/she further commented that they are unaware of the unsuccessful scores for the Event 2 PT Survey.
D2131	HEMATOLOGY CFR(s): 493.851(g) (g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to achieve an overall satisfactory performance in hematology (0760) for two consecutive Events 1 and 2 for 2025 in the specialty of Hematology. Findings include: 1.Record review on 7/11/2025 of the Proficiency Testing (PT) data report (Casper 155) revealed the laboratory failed to achieve satisfactory PT scores for 2025 as follows: Analyte Event #1(score) Event # 2(score) 0760 Hematology 76 73 2. Record review on 7/14/2025 of the CAP "FH16-A 2025 Hematology Auto Differentials, FH16" Event #1 evaluation reports revealed unsuccessful score of 76% for "Hematology (0760)" analyte. 3. Record review on 7/14 /2025 of the CAP "FH16-B 2025 Hematology Auto Differentials, FH16" Event #2 evaluation reports revealed unsuccessful score of 73% for "Hematology (0760)" analyte. 4. A telephone interview with the office manager on 7/14/2025 at 08:49 AM revealed the laboratory has still not received the PT "Original Evaluation Report" for Event 2 from CAP. He/she further commented that they are unaware of the unsuccessful scores for the Event 2 PT.
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 record review of the 2025, Event 1 and Event 2 proficiency testing (PT) data report (Casper 155) and graded results from College of American Pathologist (CAP), the laboratory director failed to ensure effective remedial action was instituted in response to unsatisfactory PT score resulting in the second unsuccessful performance for the hematology, red blood cells and hematocrit analytes in 2025. Refer to D2130 and D2131.