

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0101910	(X3) Date Survey Completed 05/29/2020
Name of Provider or Supplier Ridgefield Pediatric Associates	Street Address, City, State 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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on an offsite desk review of the laboratory's 2019 and 2020 College of American Pathologists (CAP) proficiency testing (PT) records and an email communication with the practice manager on 5/22/20, the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for the regulated analyte of hemoglobin (HGB) in two (2) out of three (3) events resulting in unsuccessful PT performance. See tags D2121 and D2130.</p>
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p>

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 of the College of American Pathologists (CAP) proficiency testing (PT) results on 5/22/20, the laboratory failed to obtain a score of at least 80% for the specialty of hematology leading to an unsatisfactory performance as evidenced below. Findings include: 1. Review of PT records from CAP on 5/22/20 revealed test scores below 80% was obtained by the laboratory for the following analytes in the specialty of hematology: 2019-Event 2: Hemoglobin 0% 2020-Event 1: Hemoglobin 0% 2020-Event 1: White Blood Cell (WBC) 20% 2020-Event 1: WBC Differential 0% 2. Review of the laboratory's PT documentation received via email communication with the practice manager from 5/22/20 through 5/28/20 confirmed the above scores. 3. The laboratory performs 358 complete blood count tests annually.

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 an offsite desk review of the laboratory's 2019 and 2020 College of American Pathologists (CAP) proficiency testing (PT) records and an email communication with the practice manager on 5/22/20, the laboratory failed to attain a score of at least eighty (80) percent of acceptable responses for the regulated analyte of hemoglobin (HGB) in two (2) out of three (3) consecutive events resulting in unsuccessful performance. Findings includes: 1. Review of the CAP proficiency testing records on 5/22/20 revealed the laboratory failed to obtain a score of at least 80% leading to unsatisfactory performance in 2 out of 3 consecutive PT events as follows. Year/Event # Score 2019 Event-2: Hemoglobin 0% 2020 Event-1: Hemoglobin 0% 2. Review of the laboratory's PT documentation received via email communication with the practice manager from 5/22/20 through 5/28/20 confirmed the above scores. 3. This is the first unsuccessful performance for the regulated analyte of hemoglobin. 4. The laboratory performs 358 complete blood count tests annually.