

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0970227	(X3) Date Survey Completed 05/06/2022
Name of Provider or Supplier Pediatric Health Care Assoc Pc	Street Address, City, State 92 Montvale Avenue, Stoneham, MA	
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	Based on evidence of unsuccessful proficiency testing performance for the White Blood Cell Identification analyte (automated differential), the following Condition level deficiency was deemed to be not met: Condition 42 CFR 493.803 - Proficiency Testing - Successful Participation. .
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 proficiency testing performance review for calendar years 2020 and 2021 (three testing events), the laboratory failed to successfully participate (achieve a score of 80 percent or more) in a proficiency testing program for the white blood cell identification analyte (automated differential). The laboratory achieved a performance</p>

score of twenty four (24) percent for the second testing event of 2021 and a performance score of twenty eight (28) percent for the first testing event of 2022 for the white blood cell identification analyte (automated differential) . Based on this evidence the laboratory failed to undertake the appropriate training and/or technical assistance necessary to correct the problem of unsuccessful proficiency testing performance for the white blood cell identification analyte. Refer to D2130. .

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 proficiency testing performance review for calendar years 2020 and 2021 (three testing events), the laboratory failed to achieve satisfactory performance for the same analyte for two out of three proficiency testing events as evidenced by the following: The laboratory achieved a performance score of twenty four (24) percent for the second testing event of 2021 and a performance score of twenty eight (28) percent for the first testing event of 2022 for the white blood cell identification analyte (automated differential) resulting in unsuccessful performance for the analyte. The scores were confirmed via email correspondence with the Technical Consultant on 5/5/22 at 12:21 PM.