

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D0080289	<b>(X3) Date Survey Completed</b>  03/04/2022
<b>Name of Provider or Supplier</b>  Pediatric Associates Inc Of Brockton	<b>Street Address, City, State</b>  291 East Center St, West Bridgewater, MA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A CLIA paper desk review of proficiency testing was conducted on 3/4/22 for the Pediatric Associates of Brockton laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. Based on evidence of a second occurrence of unsuccessful proficiency testing performance for the White Blood Count (WBC) differential analyte, the following Condition level deficiencies were deemed to be not met: Condition 42 CFR 493.803 - Proficiency Testing - Successful Participation. Condition 42 CFR 493.1403 - Laboratory Director.
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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:</p>

	<p>Based on record review on 3/4/22 of calendar years 2020 and 2021 proficiency testing results (three testing events), the laboratory failed to successfully participate (achieve a score of 80 percent or more) in the American Proficiency Institute (API) proficiency testing program for the White Blood Count (WBC) differential analyte as evidenced by the following First Unsuccessful Occurrence: The laboratory achieved a testing event score for the WBC differential analyte of zero (0) percent for the third testing event of 2020 and the first testing event of 2021 resulting in the first instance of unsuccessful performance for the WBC differential analyte . Second Unsuccessful Occurrence: The laboratory achieved a testing event score for the WBC differential analyte of zero (0) percent for the first and third testing events of 2021 resulting in the second instance of unsuccessful performance for the WBC differential analyte. 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 WBC differential analyte. Refer to D2130.</p>
<p><b>D2130</b></p>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on record review of calendar year 2020 American Proficiency Institute (API) proficiency testing results, the laboratory failed to attain a testing event score of at least 80 percent for all hematology analytes as evidenced by the following testing event scores: White Blood Cell (WBC) differential analyte: 1. 2020 API testing event 3 - score of 0%. 2. 2021 API testing event 1 - score of 0%. 3. 2021 API testing event 3 - score of 0%. The WBC differential analyte scores were confirmed in a telephone interview with the office manager on 3/4/21 at 11:30 AM who stated that the erroneous results were due to data entry errors.</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on the deficiencies cited herein, the laboratory director failed to ensure that effective remedial action was instituted in response to unsatisfactory proficiency testing results resulting in repeated unsuccessful performance for WBC differential in the specialty of Hematology. Refer to D2016 and D2130.</p>