

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D0080289	<b>(X3) Date Survey Completed</b>  09/04/2019
<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 recertification survey was conducted for the Pediatric Associates of Brockton laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
<b>D5437</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to provide documentation to verify that calibrations were performed following the manufacturer's test system instructions as evidenced by the following: The manufacturer's instructions for calibration of the CELL-DYN Emerald Hematology analyzer indicated that calibrations must be performed every six months according to the policy "Emerald User Guide and Policy and Procedure for Obtaining Hemoglobin and CBC." A review of calibration records from calendar years 2017, 2018, and 2019 revealed that calibrations were performed on 8/22/17, 3/23/18, 2/13/19, 3/12/19, and 4/1/19. Testing Person One interviewed on 9/4/19 at 1:00 PM confirmed that calibrations were not performed every 6 months per the test system's instructions.</p>