

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0080475	(X3) Date Survey Completed 09/04/2019
Name of Provider or Supplier Pediatric Associates Inc Of Brockton	Street Address, City, State 370 Oak Street, Brockton, 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	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.
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION 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 7/5/17, 4/4/18, and 4/16/19. Testing Person One interviewed on 9/4/19 at 10:45 AM confirmed that calibrations were not performed every 6 months per the test system's instructions.</p>