

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0877450	(X3) Date Survey Completed 02/18/2020
Name of Provider or Supplier Pediatric Affiliates, Pa	Street Address, City, State 400 Madison Ave, Lakewood, NJ	
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
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with Clinical Consultant (CC), the laboratory failed to take corrective action when controls were out of range for Hematology Testing on the Beckman Coulter Act diff 2 on 11/1/19. The findings include: 1. A review of QC records revealed on 11/1/19 White Blood Count (WBC), Red Blood Count (RBC), Hemoglobin (HGB), Hematocrit (HCT), and Platelet (PLT) were out of range on two out of three levels of controls. 2. There was no documented evidence that corrective action was performed. 3. Approximately 3 patients were run and reported. 4. The CC confirmed on 2/18/20 at 11:30 am that corrective action on failure of QC was not performed.</p>