

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0131875	(X3) Date Survey Completed 11/13/2018
Name of Provider or Supplier Pediatric And Adolescent Medicine Llp	Street Address, City, State 390 West End Avenue, Suite 1 E, New York, NY	
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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the quality control (QC) records, assay range sheets, patient test reports and an interview with the practice manager and testing person, the laboratory failed to retain copies of manufacturers assay sheets for at least 2 years. Findings Include: It was confirmed by the practice manager and laboratory testing person on November 13, 2018 at approximately 2:30 pm that the laboratory failed to retain the manufacturer's assay sheets for the Coulter AcT Diff II analyzer for the following lot numbers: 069700, 069701, 068400, 068100, 068600, 088600, 069200 and 069600. This is a recitation from the August 10, 2017 survey.</p>
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>

This STANDARD is not met as evidenced by:
Based on a review of calibration records and confirmed in an interview with the laboratory testing person, the laboratory failed to calibrate the Coulter AcT Diff II hematology analyzer every six months. Findings Include: 1) It was confirmed with the laboratory testing person on November 13, 2018 at approximately 1:30 pm that the laboratory failed to follow the manufacturers and CLIA regulations to calibrate the Coulter AcT Diff II every six months. 2) Calibration was performed in October 2017, then in July 2018. 3) The Coulter AcT Diff II was due to be calibrated in April 2018. The laboratory was out of calibration for 3 months. 4) Approximately 345 patient specimens were tested and results released during that time.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on a review of calibration records, and confirmed in an interview with the laboratory testing person, the laboratory director failed to ensure that the QC program for hematology was maintained to assure the quality of laboratory services. Refer to: Refer to D3031 and D5437