

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2160358	(X3) Date Survey Completed 09/04/2019
Name of Provider or Supplier Fort Payne Care Plus Llc	Street Address, City, State 3000 Gault Ave, Fort Payne, AL	
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
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the CMS form (#209), Laboratory Personnel Report for CLIA, a review of the personnel records, and an interview with the laboratory supervisor, the laboratory failed to ensure the position of Technical Consultant was filled with someone who met the required clinical qualifications. This deficient practice began on December 17, 2018, when patient testing started. The findings include: 1. On the initial of the laboratory, on September 4, 2019 at 11:30 AM, the laboratory supervisor stated CBC (Complete Blood Count) testing was included in the test menu. On the CMS Laboratory Personnel Report for CLIA, the laboratory staff listed the Laboratory Director, who is a licensed physician, as also serving as the Technical Consultant. 2. The personnel record for the physician revealed no evidence of laboratory training and experience necessary to qualify the individual as a Technical Consultant. Please refer to Interpretative Guidelines 493.1411: "The type of experience required under this regulation is clinical in nature. This means, examination and test performance on human specimens for purposes of obtaining information for the diagnosis, treatment, and monitoring of patients..." 3. In an interview on September 4, 2019 at 2:15 PM, the surveyor inquired of the physician's clinical and technical qualifications, and laboratory experience. The laboratory supervisor stated the staff thought the physician's resume would serve as evidence he has clinical laboratory experience. The surveyor discussed the CLIA regulations at 493.1411 with the laboratory supervisor, who made a copy of the interpretative guidelines pertaining to the technical consultant qualifications.</p>