

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0111810	(X3) Date Survey Completed 07/23/2018
Name of Provider or Supplier Pediatricare Associates	Street Address, City, State 90 Prospect Ave, Hackensack, 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
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual, Competency Assessment (CA) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to establish a Competency Assessment (CA) procedure with the required elements from 7/20/16 to the date of the survey. The TP # 2 listed on the CMS form 209 confirmed on 7/23/18 at 1:00 pm that a CA procedure was not established accurately.</p>