

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1047729	(X3) Date Survey Completed 09/26/2019
Name of Provider or Supplier Pediatricare Associates	Street Address, City, State 901 Route 23, Pompton Plains, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Competency Assessment (CA) records and interview with the Testing Personnel (TP), the laboratory failed to perform a CA on nine out of nine TP in the calendar year 2018. The TP # 2 listed on CMS form 209 confirmed on 9/26/19 at 10:00 am that CA was not performed on TP in 2018.</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Quality Assurance (QA) policy and interview with the Testing Personnel (TP), the Laboratory Director failed to ensure that a QA program was maintained from 11/21/17 to the date of survey. The finding includes: 1. The QA procedure stated the Laboratory Director will complete a monthly QA review but there was no documented evidence a QA review was done. 2.</p>

The TP #2 listed on CMS form 209 confirmed on 9/26/19 at 11:20 am that the laboratory did not maintain the QA program.