

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1055603	(X3) Date Survey Completed 03/14/2018
Name of Provider or Supplier Reading Pediatrics Inc	Street Address, City, State 25 Lorane Road, Reading, PA	
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, the review of testing personnel competency assessment records, review of the laboratory's procedure manual and interview with the Testing Personnel (TP) #1, the Laboratory Director failed to ensure that policies and procedure were established to assess the Technical Consultants (TC) regulatory responsibilities from 2016 to the date of survey. Findings: 1. On the date of survey 03/14/2018, the laboratory failed to provide a policy and competency assessment documentation for 7 of 7 technical consultant listed on the CMS 209. 2. TC #2 signed off on American Association of Bioanalytics (AAB) Proficiency testing records for hematology in 2016 and 2017. 3. TP #1 confirmed the findings above on 3/14/2018 around 9:30 AM.</p>