

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D1055601	(X3) Date Survey Completed 02/15/2018
Name of Provider or Supplier Reading Pediatrics	Street Address, City, State 5101 Allentown Pike, Temple, 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
D6019	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of American Association of Bioanalysts (AAB) Proficiency Testing (PT) records and interview with testing personnel #1 (TP#1) at the time of survey, the laboratory director did not ensure that an approved, effective corrective action plan was followed for the unsatisfactory AAB 2016 and 2017 (2nd events) hematology PT results. Findings include: I. The CAP Hematology 2016 and 2017 PT record reviewed on 02/15/2018, at the time of survey revealed there was documentation of corrective action followed for the following unsatisfactory PT scores: White Blood Cell count 2016 2nd event : 80%. Platelets count 2017 2nd event : 80%. 2. Interview with TP #1 on 02/15/2018 around 1:15 PM confirmed that there was no documented plan of correction for the unsatisfactory PT scores.</p>
D6051	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.</p>

This STANDARD is not met as evidenced by:

Based on, the review of testing personnel competency assessment records, American Association of Bioanalysts (AAB) proficiency records and interview with the Testing personnel #1 (TP#1), the Technical Consultant failed to evaluate the assessment of 3 of 8 testing personnel from 2016 to the date of survey for external proficiency testing samples or internal blind testing samples. Findings Include: 1) During review of the laboratory's attestation statements it was discovered that 5 of 8 testing personnel performed in the 2016 and 2017 AAB, Complete Blood Count (CBC) proficiency testing events. 2) Review of testing personnel competency assessments revealed, evaluation of test performance through external proficiency testing samples or internal blind testing samples of non-waived tests for 3 of 8 testing personnel was not performed in 2016 and 2017. 3) TP #1 confirmed the findings above on 02/15/2015 around 01:00 PM.