

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0673371	<b>(X3) Date Survey Completed</b>  02/15/2018
<b>Name of Provider or Supplier</b>  Reading Pediatrics Inc	<b>Street Address, City, State</b>  40 Berkshire Court, Suite 1, Wyomissing, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of American association Bioanalysis (AAB) Proficiency testing (PT) Records in 2017 and Interview of the Nursing manager, the laboratory Director failed to attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. Findings Include: 1. At the Time of the survey (02/15/2015), it was discovered that PT attestation forms of 2017 events #2 and #3 were not signed by the laboratory director. 2. The Nursing Manager confirmed the above finding on 02/15/2018 around 10:30 AM</p>
<b>D6030</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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>

This STANDARD is not met as evidenced by:  
Based on, the review of testing personnel competency assessment records, the review of the laboratory's procedure manual and interview with the Nursing Manager, the Laboratory Director failed to ensure that policies and procedure were established to assess the technical consultants regulatory responsibilities from 2016 to the date of survey. Findings: 1. On the date of survey 02/15/2018, the laboratory failed to provide competency assessment documentation for the technical consultant. 2. The Nursing manager was informed of the deficiency during the end of the survey on 02/15/2018 around 11:45 AM.

**D6051**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(v)

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.

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 Nursing Manager, the Technical Consultant failed to evaluate the assessment of 20 of 25 testing personnel from 2016 to the date of survey (02/15/2015) 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 25 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 20 of 25 testing personnel was not performed in 2016 and 2017. 3) The Nursing Manager confirmed the findings above on 02/15/2015 around 10:00 am.