

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D2054711	<b>(X3) Date Survey Completed</b>  12/18/2018
<b>Name of Provider or Supplier</b>  Reading Pediatrics, Inc	<b>Street Address, City, State</b>  541 W Penn Ave, Robesonia, 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>D6018</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iii)</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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p> <p>This STANDARD is not met as evidenced by: Based on review of American Association Bioanalysts (AAB) proficiency testing records and interview with testing personnel (TP) #6, the Laboratory Director failed to ensure that all proficiency testing reports received, identified problems that require corrective action in 2017. Findings include: 1. On the day of survey, 12/18/2018, review of AAB Proficiency testing records, revealed the laboratory did not document corrective action for AAB 2017 Event #1, 80% for Platelets. 2. TP#6 confirmed the findings above on 12/18/2018 around 08:30 am</p>
<b>D6046</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) competency assessment records and</p>

interview with the technical consultant (TC) #1, the technical consultant failed to evaluate the competency of all testing personnel as required in 2017 and 2018. Findings include: 1. On the day of survey, 12/18/2018, review of competency record revealed 2 out of 9 TP were not assessed for competency in 2017 (TP#1 and #2). 2. Also on the day of survey, it was revealed, when the laboratory director is unavailable or out of the office, other physicians will sign reports in their place. The laboratory failed to perform yearly regulatory competency assessment on these personnel and they were not listed on the CMS 209 Laboratory Personnel Report. 3. TC#1 confirmed the findings above on 12/18/2018 around 08:00 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 review of testing personnel competency assessment records, proficiency records and interview with Testing personnel (TP) #6 the technical consultant failed to assess the test performance through previously analyzed specimens, internal blind testing samples or external proficiency testing samples for testing personnel who perform hematology tests from 2016 to the date of survey. Findings Include: 1. On the day of survey, 12/18/2018, review of TP competency assessments records revealed, 8 out of 9 TP were not assessed through external proficiency testing samples or internal blind testing samples in 2017 and 2018 for centrifugal hematology. 2. TP#6 confirmed the findings above on 12/18/2018 around 8:45 am.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
Based on review of competency assessment record and interview with the Technical Consultant, the Technical Consultant (TC) #1 failed to evaluate and document the performance of 1 out of 9 testing personnel (TP) responsible for the hematology tests for their semi-annually competency during the first year. Findings include: 1. On the day of survey, 12/18/2018, the laboratory was unable to produce documentation for TP #5's semi-annually competency during the first year of hematology testing in 2017 to 2018. 2. During the interview on 12/18/2018, around 08:00 am, TC#1 confirmed that testing personnel #5 was hired on 06/05/2017 and their semi-annual competency assessments was not assessed during the first year performing hematology testing, and they were not assessed for competency again until 03/27/2018.