

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0671446	<b>(X3) Date Survey Completed</b>  03/15/2019
<b>Name of Provider or Supplier</b>  Childrens Medicine Pc	<b>Street Address, City, State</b>  3685 Lawrenceville Hwy Suite 100, Lawrenceville, GA	
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>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on March 15, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were was cited:
<b>D6019</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> 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 proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to ensure required corrective action was performed. Findings include: 1. American Proficiency Institute (API) document review revealed the LD failed to ensure corrective action was performed for a score of 80 percent for the 2018 third event for hematology. 2. An interview with Staff #4 (CMS 209) in an examination room on 3/15/19 at approximately 1:15 p.m. confirmed corrective action was not performed for the aforementioned PT event.</p>
<b>D6029</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(11)</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</p>

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on testing personnel (TP) competency document review and staff interview, the laboratory director (LD) failed to ensure TP had received proper training and were competent to perform test procedures as required. Findings include: 1. TP competency document review revealed an initial competency was not performed in 2017 for Staff #6 (CMS 209) and in 2018 for Staff #4 (CMS 209). 2. An interview with Staff #4 (CMS 209) in an examination room on 3/15/19 at approximately 1:15 p.m. confirmed the aforementioned initial competencies were not performed.