

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D1086599	(X3) Date Survey Completed 08/08/2018
Name of Provider or Supplier Childrens Medicine Pc	Street Address, City, State 1500 Peachtree Industrial Boulevard Suite 250, Suwanee, GA	
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
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on August 8, 2018. 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 cited:
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.</p> <p>This STANDARD is not met as evidenced by: Based on testing personnel (TP) competency and staff interview, the laboratory director failed to delegate employee competency responsibilities to qualified personnel as required. Findings include: 1. TP competency document review revealed the initial competency for Staff #4 (CMS 209) was performed by unqualified TP. 2. TP competency document review revealed the annual competencies for 2017 and 2018 were performed by unqualified TP for the following TP on CMS 209: Staff #3, Staff #5, Staff #6, and Staff #7. 3. An interview with the clinic manager on 8/8/18 in the breakroom at approximately 1 p.m. confirmed the aforementioned TP competencies were performed by unqualified TP.</p>

D6029

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(11)

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)(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 competency document review and staff interview, the laboratory director (LD) failed to ensure all personnel receive appropriate training for the type and complexity of the services offered. Findings include: 1. Laboratory personnel document review revealed an initial training competency has not been performed for the technical consultant (TC) in the specialty of hematology in 2018 thus far . 2. An interview with the clinic manager on 8/8/2018 in the breakroom at approximately 1:00 p.m. confirmed an initial training competency has not been performed for the TC in 2018 thus far.