

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2131053	(X3) Date Survey Completed 02/04/2019
Name of Provider or Supplier Camc Respiratory W&C	Street Address, City, State 800 Pennsylvania Ave, Charleston, WV	
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
D6013	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's records and interview with the lab supervisor and quality management coordinator, the laboratory director failed to sign off on the verification data for accuracy and precision for the new instruments in July of 2017. Findings: 1. Review of the document provided with precision and accuracy data for ABL90 #1 and ABL90 #2, dated July 2017, determined there was no signature of acceptance by the laboratory director. 2. On 2/4/2019 at approximately 12:00 PM, the supervisor was unable to find the original, signed copy of the performance characteristics of accuracy and precision for the new instruments, ABL90 #1 and ABL90 #2, performed in July of 2017.</p>