

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2131053	(X3) Date Survey Completed 03/24/2021
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
D0000	An announced, on site, recertification survey was conducted at CAMC Respiratory on March 24, 2021, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policies and procedures (P&P), quality assessment (QA) documents, and an interview with the technical consultant (TC), the laboratory failed to perform and document the evaluation of the established procedure for reporting critical (alert) values from the ABL90 analyzers. Findings: 1. Review of P&P identified a "CAMC Respiratory Performance Improvement Plan" that stated alert values were monitored as part of the post-analytical QA. 2. No documentation of the alert value assessment could be located. 3. During an interview with the TC, on 3 /24/21 at approximately 10:45 AM, the TC confirmed the lack of documentation for the monitoring of the alert values process and procedure.</p>