

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0235474	(X3) Date Survey Completed 09/18/2020
Name of Provider or Supplier Rainelle Medical Center	Street Address, City, State 176 Medical Center Drive, Rainelle, 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 Rainelle Medical Center on September 18, 2020, 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.
D2127	<p>HEMATOLOGY CFR(s): 493.851(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory American Proficiency Institute (API) proficiency testing (PT) records, CASPER Report 155D, and an interview with the laboratory manager, the laboratory failed to return PT results to API within the specified time frame for the 2020 Hematology/Coagulation 2nd event and received an unsatisfactory performance score of 0. Findings: 1. A review of laboratory 2019 and 2020 API PT records identified unsatisfactory scores of 0 for Cell ID or WBC Diff, RBC, HCT, HGB, WBC, and Platelets for the API 2020 Hematology/Coagulation 2nd testing event. A documented corrective action and a self evaluation for the testing event were located by the state surveyor. 2. A review of the laboratory CASPER Report 155D identified unsatisfactory scores of 0 for Cell ID or WBC Diff, RBC, HCT, HGB, WBC, and Platelets for the API 2020 Hematology/Coagulation 2nd testing event. 3. During an interview with the laboratory manager, on 9/18/2020 at approximately 9:11 AM, the laboratory manager stated the unsatisfactory performance for the API 2020 Hematology/Coagulation 2nd testing event was due to not being able to return the PT results to API within the specified timeframe due to technical issues.</p>