

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 51D0661665	<b>(X3) Date Survey Completed</b> 02/26/2020
<b>Name of Provider or Supplier</b> Monroe Health Center - Union	<b>Street Address, City, State</b> 200 Health Center Drive, Union, WV	
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>	An announced CLIA recertification survey was conducted at Monroe County Health Center on February 26, 2020 by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with regulations implementing the Federal Clinical Laboratory Improvement Amendments (CLIA) 42 CFR 493. Specific deficiencies cited are as follow:
<b>D2121</b>	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory American Proficiency Institute (API) proficiency testing (PT) records and an interview with the laboratory director (LD), the laboratory failed to attain a satisfactory score for the analyte 0765 CELL ID OR WBC DIFF in the API 2018 Hematology/Coagulation 3rd testing event. Findings: 1. A review of API PT records for 2018 and 2019 Hematology/Coagulation testing events identified an unsatisfactory score for the analyte 0765 CELL ID OR WBC DIFF in 1 of 6 events. The 2018 API 3rd event unsuccessful score of 60 percent for 0765 CELL ID OR WBC DIFF was identified thru review of the following data: a. The laboratory had 2 of 5 results scored as unacceptable for granulocytes. b. The laboratory had 1 of 5 results scored as unacceptable for lymphocytes. c. The laboratory had 3 of 5 results scored as unacceptable for monocytes. 2. A review of API PT records for the 3rd event of 2018 identified an investigation into the unsatisfactory score of 60 percent for analyte 0765 CELL ID OR WBC DIFF was performed and documented. 3. During an interview with the LD, on 02/26/2020 at approximately 11:00 AM, the LD stated she was aware of the unsatisfactory score of 60 percent for 0765 CELL ID OR WBC DIFF and that an investigation was conducted regarding the unacceptable results for the analytes.</p>