

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 51D2100196	<b>(X3) Date Survey Completed</b> 09/25/2019
<b>Name of Provider or Supplier</b> Mon Health Wedgewood Primary Care	<b>Street Address, City, State</b> 1300 Fort Pierpont Dr Suite 101, Morgantown, 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>D2081</b>	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(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 laboratory American Proficiency Institute (API) proficiency testing (PT) records and an interview with Technical Consultant 1 (TC1), the laboratory failed to submit PT results to API for the 2019 Immunology 2nd testing event within the timeframe specified. Findings: 1. A review of PT records for 2019 identified an unsatisfactory performance with a result of 0% for the API 2019 Immunology 2nd testing event. 2. An interview with TC1, on 9/25/19 at approximately 12:30 PM, confirmed that the laboratory failed to return the PT results to API before the deadline for the 2019 Immunology 2nd testing event.</p>
<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 a review of laboratory Proficiency Testing (PT) records and an interview with Technical Consultant 1 (TC1), the laboratory received unsatisfactory analyte performance scores from American Proficiency Institute (API) for PT results submitted for the API 2018 Hematology 2nd testing event and the API 2019 Hematology 1st testing event Findings: A. 1. A review of 2018 API PT records</p>

identified an unsatisfactory performance of 0% for Vaginal Wet Preparation in the 2018 Hematology 2nd testing event. For sample VA-02 the laboratory reported "clue cells seen", when the correct answer was "no yeast, Trich, or clue cells". This resulted in an unsatisfactory score of 0%. 2. An interview with TC1, on 9/25/19 at approximately 12:30 PM, confirmed the findings. 3. The laboratory took remedial action and documented the remedial action taken. B. 1. A review of 2019 API PT records identified unsatisfactory analyte performance scores of 60% for Erythrocyte Count and 33% for White Blood Cell Differential in the automated hematology of the API 2019 Hematology 1st testing event. 2. An interview with TC1, on 9/25/19 at approximately 12:30 PM, confirmed the findings. 3. The laboratory took remedial action and documented the remedial action taken.

**D2122**

**HEMATOLOGY**  
CFR(s): 493.851(b)

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:  
Based on a review of the laboratory American Proficiency Institute (API) proficiency testing (PT) records and an interview with Technical Consultant 1 (TC1), the laboratory received an unsuccessful overall testing event score of 67% for the automated Hematology in the API 2019 Hematology/Coagulation 2019 1st event. Findings: 1. A review of PT records for 2019 identified unsuccessful analyte scores of 60% for Erythrocyte Count and 33% for White Blood Cell Differential in the API 2019 Hematology/Coagulation 1st testing event. The other analytes in the automated Hematology (HCT, HGB, WBC count, and Platelet count) had successful scores. 2. An interview with TC1, on 9/25/19 at approximately 12:15 PM, confirmed the findings. 3. The laboratory took remedial action and documented the remedial action taken.