

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2076798	(X3) Date Survey Completed 02/12/2020
Name of Provider or Supplier Coplin Clinic Laboratory	Street Address, City, State 483 Court St, Elizabeth, 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
D2020	<p>BACTERIOLOGY CFR(s): 493.823(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</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 and an interview with the general supervisor (GS), the laboratory received an unsatisfactory performance score of 60 percent in Microbiology 1st event of 2018. Findings: 1. A review of API PT records identified an unsatisfactory performance of 60 percent in Bacteriology for the 1st Microbiology event of 2018. 2 of the 5 samples for Group A Strep Antigen had unacceptable answers by the laboratory. a. Sample ST-04 was reported by the laboratory as Negative for Group A Strep Antigen. The expected result was Positive. This was an unacceptable performance for Sample ST-04. b. Sample ST-05 was reported by the laboratory as Negative for Group A Strep Antigen. The expected result was Positive. This was an unacceptable performance for sample ST-05. 2. A review of API PT records identified an investigation into the 60 percent unsatisfactory performance for Group A Strep Antigen in the 1st API Microbiology 2018 testing event. 3. An interview with GS, on 2/18/2020 at approximately 10:50 AM, confirmed the findings.</p>
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(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:</p>

Based on a review of laboratory American Proficiency Institute (API) proficiency testing (PT) records and an interview with the general supervisor (GS), the laboratory failed to attain a score of at least 80 percent for each analyte in the 2019 API Routine Chemistry 1st testing event. Findings: 1. A review of the 2019 API PT records identified an overall successful score of 96 percent for the 2019 API 1st testing event in Routine Chemistry. 2. A review of the 2019 API PT records identified an unsatisfactory performance score of 40 percent for the analyte Total Cholesterol. 3 of 5 specimens had unacceptable responses for Total Cholesterol. a. Specimen CH-01 was reported as 176. The expected value was 253-310. b. Specimen CH-05 was reported as 208. The expected value was 92-114. c. Specimen CH-04 was reported as 59. The expected value was 42-52. 3. A review of the 2019 API 1st testing event in Routine Chemistry identified an investigation into the unsatisfactory analyte performance of Total Cholesterol. 4. An interview with GS, on 2/12/2020 at approximately 10:50 AM, confirmed the findings.