

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2076798	(X3) Date Survey Completed 04/09/2024
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
D0000	A routine recertification survey was performed at Coplin Clinic Laboratory on April 9, 2024 by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the Federal Clinical Laboratory Improvement Amendments (CLIA) regulations under 42 CFR 493. Specific deficiencies cited are explained below.
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to achieve satisfactory performance for Fecal Occult Blood and Urine Sediment testing in two out of three consecutive proficiency testing events of 2023. Findings: 1. Review of American Proficiency Institute (API) records identified the following unsatisfactory scores: Fecal Occult Blood:50% 2023 1st event, 50% 2023 3rd event Urine Sediment: 50% 2023 1st event, 50% 2023 3rd event 2. An interview with the technical consultant, 4/9 /24 at 9:30 AM, confirmed the unsatisfactory scores and unsuccessful performance of Fecal Occult Blood and Urine Sediment proficiency testing in two of three consecutive testing events.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic</p>

examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on review of policies and procedures (P&P), patient test records, and interview the laboratory failed to update the (10) reference ranges (RR) for Hematology to reflect the Sysmex XN-430 performance specifications. Findings: 1. Review of P&P identified a list of the reference ranges for the Sysmex XN-430 Hematology analyzer based on gender and age. 2. Review of a CBC test report for a 31 year old female identified reference ranges for MON%, EOS%, and BAS% that differed from the P&P. 3. Review of a CBC test report for a 3 year old female identified reference ranges for HCT, MCV, BAS%, and NEU# that differed from P&P. 4. An interview with the technical consultant, 4/9/24 at 10:00 AM, confirmed the reference ranges on the patient test report did not match the reference ranges in the P&P for the Sysmex XN-430.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on policies and procedures (P&P), record review, and interview the laboratory failed to perform and document the monitoring and assessment of the Individualized Quality Control Plan (IQCP) for Fisher SureVue serum hCG, Alere Determine HIV 1 /2 Combo, and I-Stat testing in 2022 and 2023. Findings: 1. Review of P&P identified that the " IQCP will be reviewed on a regular basis and if quality failures occur" for Fisher SureVue serum hCG, Alere Determine HIV 1/2 Combo, and I-Stat testing. 2. Review of IQCPs for serum hCG, HIV, and I-Stat testing revealed documented review on 12/30/2021. No documentation of reviews completed in 2022 or 2023 could be located. 3. An interview with the technical consultant, 4/9/24 at 11:00 AM, confirmed the findings.