

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2076798	(X3) Date Survey Completed 05/27/2026
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 conducted at Coplin Clinic Laboratory on May 27, 2026, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the CLIA regulations under 42 CFR 493, Requirements for Laboratories. Specific deficient practices are cited and explained below.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory policies and procedures, current CMS 209, laboratory test menu, lack of documented direct observation in 2025 testing personnel competency assessment files, and an interview with the technical consultant (TC), the laboratory failed to document the direct observation of routine patient test performance on the Sysmex XN-430 and Vitros 3400 for 3 of 4 testing personnel (TP) annual competency assessments for 2025 in adherence to laboratory established policy. Findings: 1. A review of the "Personnel Assessment" policy revealed the established laboratory policy for assessing annual competency included all six required elements, including direct observation of routine patient testing for all methodologies. 2. Current CMS Form 209, signed by the laboratory director on April 24, 2026, included four, current laboratory testing personnel (TP1, TP2, TP3, TP4). 3. The laboratory test menu verified the analyzers used for patient testing in 2025 for chemistry as the Vitros 3400 and for hematology the Sysmex XN-430. 4. Review of the four 2025 TP competency assessment files, signed by the technical consultant in December 2025, revealed no documentation for direct observation of patient test performance using the Vitros 3400 and Sysmex XN-430 for 3 of 4 testing personnel (TP1, TP2, TP3). 5. An interview with the TC, 5/27/26 at 8:45 AM, verified the lack</p>

of documented direct observation for the Vitros 3400 and Sysmex XN-430 analyzers at the laboratory for the 3 of 4 TP in 2025.