Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D2076798	05/04/2022
Name of Provider or Supplier	**Street Address, City, State**	
Coplin Clinic Laboratory	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	An announced, on site, routine recertification survey was conducted at the Coplin Clinic Laboratory on May 4, 2022, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the laboratory failed to (b) assess and (c) document the completeness and effectiveness of the corrective actions taken to resolve quality control (QC) issues in Chemistry for 2 of 4 months reviewed and in Hematology for 1 of 4 months reviewed. Specifically: 1) Review of Chemistry QC records from November 2021 thru February 2022 revealed documentation for corrective actions to be taken for specific analytes in 2 of the 4 months. i) January 2022 QC monthly review document stated Creatinine was to be recalibrated. No documentation of the recalibration could be located in the laboratory records. ii) February 2022 QC monthly review document stated Creatinine, Magnesium, and Phosphorous were to be recalibrated. No documentation of the recalibration could be located in the laboratory records. 2) Review of Hematology QC and calibration records for November 2021 thru February 2022 revealed precision and accuracy issues across 5 parameters (lymphocytes, monocytes, hemoglobin, MCV, and MCHC) during three days of patient testing in December (12/8, 12/15, 12/28). No

	documentation of the corrective actions taken to resolve the issue could be located. 3. An interview with the technical consultant, on 5/4/22 at approximately 1:00 PM, confirmed the findings.