Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D2076798	05/04/2023
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 unannounced, off site, proficiency testing (PT) desk review was conducted for Coplin Clinic Laboratory on May 4, 2023, by the West Virginia Office of Laboratory Services. The laboratory PT evaluations with the American Proficiency Institute (API) were reviewed for compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on record rveiew, the laboratory failed to successfully participate in proficiency testing (PT) for the analyte #0765 Cell ID for two of the last 3 American Proficiency

	Institute (API) testing events. Findings: 1. Review of CASPER 155D Individual Laboratory Profile Report identified the following unsatisfactory scores for analyte #0765 Cell ID: 60% event 2 2022 60% event 1 2023 2. Review of PT evaluation reports from API confirmed the unsuccessful participation for analyte #0765 Cell ID in two of the last 3 PT events.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to perform successfully in proficiency testing (PT) for the analyte #0765 Cell ID for two of the last 3 American Proficiency Institute (API) testing events in 2022 and 2023. Findings: 1. Review of CASPER 155D Individual Laboratory Profile Report identified the following unsatisfactory scores for analyte #0765 Cell ID: 60% event 2 2022 60% event 1 2023 2. Review of PT evaluation reports from API confirmed the unsatisfactory performance scores for analyte #0765 Cell ID in 2nd event 2022 and 1st event 2023. 3. An interview with the clinical laboratory director, 5/5/23 at approximately 8:00 AM, confirmed the unsuccessful performance for analyte #0765 Cell ID in two of the last 3 PT events.