Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D2076798	04/10/2024
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 off site, proficiency testing (PT) desk review was conducted for Coplin Clinic Laboratory on April 10, 2024, by the West Virginia Office of Laboratory Services. The laboratory PT evaluations were reviewed for successful participation and compliance with the Federal Clinical Laboratory Improvement Amendments (CLIA) under 42 CFR 493. The identified unsuccessful participation is the second occurrence involving three of three laboratory testing personnel and is 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 review of CASPER 155D proficiency testing (PT) report, laboratory PT evaluations from American Proficiency Institute (API), signed API PT attestation

	records, and the current personnel roster (CMS-209), the laboratory failed to achieve satisfactory performance for the analyte #0765 Blood Cell ID in three of 5 consecutive testing events and has sustained a subsequent occurrence of unsuccessful participation in PT involving three of three laboratory testing personnel. Refer to D2130.
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 review of CASPER 155D proficiency testing (PT) report, laboratory PT evaluations from American Proficiency Institute (API), signed API PT attestation records, and the current personnel roster (CMS-209), the laboratory failed to achieve satisfactory performance for the analyte #0765 Blood Cell ID in three of 5 consecutive testing events and has sustained a subsequent occurrence of unsuccessful participation in PT involving three of three laboratory testing personnel. Findings: 1. Review of CASPER 155D Report revealed the following unsatisfactory scores for #0765 Blood Cell ID. Signed API PT attestation records identified three of three testing personnel (TP) responsible for the testing events. 60% 2022 event 2 (performed by TP2) 60% 2023 event 1 (performed by TP3) 40% 2023 event 3 (performed by TP1) 2. Review of API PT evaluation reports confirmed the unsatisfactory scores and the second unsuccessful performance for analyte #0765 Blood Cell ID in three of 5 consecutive testing events. 3. Review of laboratory personnel roster (CMS-209), from recertification survey performed 4/9/2024, identified TP1, TP2, and TP3 as current testing personnel.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of CASPER 155D proficiency testing (PT) report, laboratory PT evaluations from American Proficiency Institute (API), signed API PT attestation records, and the current personnel roster (CMS-209), the laboratory director failed to ensure deficient practices leading to the initial unsuccessful participation in PT for the analyte #0765 Blood Cell ID were corrected, resulting in a subsequent occurrence of unsuccessful participation in three of 5 consecutive testing events involving three of three laboratory testing personnel. Refer to D6019.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

	and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of CASPER 155D proficiency testing (PT) report, laboratory PT evaluations from American Proficiency Institute (API), signed API PT attestation records, and the current personnel roster (CMS-209), the laboratory director failed to ensure deficient practices leading to the initial unsuccessful participation in PT for the analyte #0765 Blood Cell ID were corrected, resulting in a subsequent occurrence of unsuccessful participation in three of 5 consecutive testing events involving three of three laboratory testing personnel. Findings: 1. Review of CASPER 155D Report revealed the following unsatisfactory scores for #0765 Blood Cell ID. Signed API PT attestation records identified three of three testing personnel (TP) responsible for the testing events. 60% 2022 event 2 (performed by TP2) 60% 2023 event 1 (performed by TP3) 40% 2023 event 3 (performed by TP1) 2. Review of API PT evaluation reports confirmed the unsatisfactory scores and the second unsuccessful performance for analyte #0765 Blood Cell ID in three of 5 consecutive testing events. 3. Review of laboratory personnel roster (CMS-209), from recertification survey performed 4/9 /2024, identified TP1, TP2, and TP3 as current testing personnel. 4. The unsatisfactory performance scores for analyte #0765 Blood Cell ID in 2023 Event 3 is a repeated occurrence of unsuccessful participation in three of 5 testing events involving three of three laboratory TP (TP1, TP2, TP3).