

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2076798	(X3) Date Survey Completed 07/27/2022
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	An unannounced, off site, proficiency testing (PT) desk review was conducted for Coplin Clinic Laboratory on July 27, 2022, by the West Virginia Office of Laboratory Services. The laboratory PT evaluations from 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	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on review of American Proficiency Institute (API) evaluations and the CLIA 155D report for Coplin Clinic Laboratory, the laboratory failed to successfully</p>

participate in a program approved by CMS for the analyte #0435 LDH Total in two consecutive testing events. Findings: 1. LDH Total #0435 1st Event 2022- 0% 2nd Event 2022- 0%

D2096

ROUTINE CHEMISTRY
CFR(s): 493.841(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on review of the CLIA 155D report and the failures summary report from the American Proficiency Institute (API) proficiency testing (PT) evaluations, the laboratory failed to achieve satisfactory performance for the analyte #0435 LDH Total in two consecutive testing events of 2022. Findings: 1. Review of 155D revealed the following for #0435 LDH Total: 1st Event 2022- 0% 2nd Event 2022- 0% 2. Review of API failures summary report confirmed the unsuccessful performance and unsatisfactory analyte scores for #0435 LDH Total.