

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0898048	(X3) Date Survey Completed 03/25/2025
Name of Provider or Supplier Central Labs Inc	Street Address, City, State 97 Main Avenue, Pineville, 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 offsite proficiency testing (PT) desk review was conducted for Central Labs Inc., on March 25, 2025, by the West Virginia Office of Laboratory Services. The laboratory PT evaluations were reviewed for successful participation and compliance with the CLIA regulations under 42 CFR 493, Requirements for Laboratories. The identified unsuccessful participation is an initial occurrence and 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 CASPER 155D proficiency testing (PT) report, laboratory PT evaluations from American Proficiency Institute (API), and confirming phone interview with testing personnel (TP1), the laboratory failed to achieve satisfactory</p>

performance for #0345 total calcium and 0505 BUN in two of three consecutive testing events in 2024 and 2025, resulting in an occurrence of unsuccessful participation in PT. Refer to D2096.

D2096

ROUTINE CHEMISTRY
CFR(s): 493.841(f)

(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 CASPER 155D proficiency testing (PT) report, laboratory PT evaluations from American Proficiency Institute (API), and phone interview with testing personnel (TP1), the laboratory failed to achieve satisfactory performance for the analytes #0345 total calcium and #0505 BUN in two of three consecutive events in 2024 and 2025, resulting in an occurrence of unsuccessful participation in PT.
Findings: 1. Review of CASPER 155D PT report revealed the following unsatisfactory scores for analyte #0345 total calcium: 0% 2024 event 2 60% 2025 event 1 2. Review of CASPER 155D PT report revealed the following unsatisfactory scores for analyte #0505 BUN: 0% 2024 event 2 60% 2025 event 1 3. Review of API evaluation reports confirmed the unsatisfactory scores for analytes #0345 total calcium and #0505 BUN in two of three consecutive PT events. 4. A phone interview with TP1, 3/25/25 at 10:35 AM, verified the occurrence of unsuccessful participation in PT for analytes #0345 total calcium and #0505 BUN.