

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0898048	(X3) Date Survey Completed 11/02/2022
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 announced, on site, routine recertification survey was conducted at Central Labs Inc. on November 2, 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.
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to achieve satisfactory performance for the analyte #0775 RBC in one of two proficiency testing (PT) events of 2022. Findings: 1. Review of American Proficiency Institute (API) PT records identified an unsatisfactory score of 40% for the analyte #0775 RBC in the 2nd testing event of 2022. 2. An interview with the laboratory director, 11/2/22 at approximately 9:30 AM, confirmed the unsatisfactory performance of the analyte.</p>
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the</p>

reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on written policies and procedures (P&P), record review, lack of documentation, and interview the laboratory failed to (b)(1)(ii) document the action taken for patient results outside of established reportable range for 3 of 5 GGT critical results released in 2022. Findings: 1. Review of P&P identified the established reportable range of GGT as 0-800 U/L. 2. Review of the 2022 critical value log identified 3 of 5 patient results for GGT with values released outside the reportable range of 0-800 U/L (962 U/L, 1384 U/L, and 835 U/L). No corrective action could be located for the 3 patient test values released outside the reportable range for the analyte GGT. 3. An interview with the laboratory director, 11/2/22 at approximately 10:30 AM, confirmed the findings.