Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0898048	10/02/2024
Name of Provider or Supplier	**Street Address, City, State**	
Central Labs Inc	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	A routine recertification survey was conducted at Central Labs, Inc., on October 2, 2024, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the Federal Clinical Laboratories Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies cited are explained below.
D2093	ROUTINE CHEMISTRY CFR(s): 493.841(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on review of CASPER 155D report, proficiency testing (PT) records, and interview, the laboratory failed to successfully submit test results to the American Proficiency Institute (API) for one of three PT events in 2024 (Chemistry Core 2024 2nd Event). Findings: 1. Review of CASPER 155D report revealed an unsatisfactory score of 0% for the specialty of Chemistry in the 2024 2nd testing event. 2. Review of API evaluation records confirmed the 0% score (failure to participate) for the 34 Chemistry analytes in the 2024 2nd testing event. 3. An interview with the laboratory director, on 10/2/24 at 9:45 AM, confirmed the failure of the laboratory to submit the results to API before the deadline for the 2nd testing event in Chemistry, resulting in a 0% score.
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 record review and interview the laboratory failed to achieve satisfactory scores for the analyte TIBC (measured) for two consecutive proficiency testing (PT) events in 2024, resulting in an unsuccessful performance. Findings: 1. Review of American Proficiency Institute (API) evaluation records revealed the following unsatisfactory PT scores for TIBC(measured): 60% 1st event 2024 0% 2nd event 2024 2. An interview with the laboratory director, 10/2/24 at 9:45 AM, confirmed the unsuccessful scores for the analyte TIBC (measured) in the two consecutive testing events, resulting in an unsuccessful PT performance for the unregulated analyte.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the laboratory failed to evaluate the appropriateness of the reference intervals (normal values) for 16 of 16 complete blood count (CBC) parameters during the verification of the Medonic hematology analyzer performance specifications in February of 2023. Findings: 1. Review of the verification of the performance specifications for the Medonic hematology analyzer (put in use 2/15/2023) revealed no evaluation of the CBC reference intervals (normal ranges) for the patient population served by the laboratory. 2. No documentation the laboratory evaluated specimens to verify the manufacturer established reference intervals (normal ranges) or published reference intervals (normal ranges) for 16 of 16 CBC parameters. 3. An interview with the laboratory director, 10/2/24 at 10:40 AM, confirmed that no documentation could be located and the CBC reference intervals (normal ranges) had not been evaluated by the laboratory for the patient population served.