Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D2160356	07/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Appalachian Labs Of Wv	708 Bigley Ave, Charleston, 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 Appalachian Labs of WV on July 25, 2023, 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 cited are explained below.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the laboratory failed to verify the accuracy of 46 of the 88 analytes tested on the Sciex toxicology analyzers (two 4500 analyzers and two 5500 analyzers) in 2022 and 2023. Findings: 1. Review of proficiency testing (PT) documents (January thru December 2022 and January thru date of survey 2023) revealed 46 analytes that are not included in Subpart I and not enrolled in commercial PT. 2. No documentation of the verification of accuracy for the 46 analytes on the Sciex analyzers could be located for the timeframe reviewed. 3. An exit interview with the technical supervisor and laboratory administration, 7/25/23 at approximately 5:00 PM, confirmed the lack of accuracy verification for the 46 analytes.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When

	control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the laboratory failed to document the verification of new lots of external quality control (QC) for the Abacus-5 hematology analyzer and the validation of the established statistical parameters for new lots of external QC on the Sciex 4500 and 5500 analyzers before being put into use for patient testing. Findings; 1. No policy or procedure could be located for the following: a) verifying manufacturer's established values for assayed hematology QC b) validating statistical parameters for unassayed, in house prepared toxicology QC 2. No documentation of the verification of the manufacturer established limits for new lots of assayed QC for the Abacus-5 hematology analyzer could be located. 3. No documentation could be located that new lots of in house prepared toxicology QC for the Sciex analyzers recovered the established statistical parameters for each analyte before being put into use. 4. An exit interview with the technical supervisors and laboratory management, 7/25/23 at approximately 5:00 PM, confirmed no policy or procedure for the validation and verification of new lots of QC and no documentation of the processes could be located.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. 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 establish a system to evaluate the comparison of test results between instruments. Findings: 1. Review of P&P revealed a lack of an established process to compare test results derived from the same methodology but performed on different analyzers. 2. Review of analyzer records identified testing performed between 2 of 4 Sciex analyzers in 2022 and 2023. No documentation of the evaluation of the data and the acceptability criteria for the comparison could be located. 3. No documentation of the comparison of test results and criteria for acceptability between the two CLC 720i analyzers for 2023 could be located. 4. An exit interview with technical supervisor 1 and technical supervisor 2, 7 /25/23 at approximately 5:00 PM, confirmed the laboratory had no P&P in place for performing and evaluating comparison testing among analyzers performing the same methodology of testing.