

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 51D2160356	<b>(X3) Date Survey Completed</b> 05/13/2025
<b>Name of Provider or Supplier</b> Appalachian Labs Of Wv	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A routine recertification survey was conducted at Appalachian Labs of WV on May 13, 2025, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the CLIA regulations under 42 CFR 493, Requirements for Laboratories. Specific deficiencies cited are explained below.
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of policies and procedures, laboratory testing personnel records, lack of documentation, an interview with the general supervisor (GS), and an exit interview with the laboratory team, the laboratory failed to document the annual competency assessment (CA) for three of three testing personnel (TP) in LC/MS toxicology testing for 2023 and/or 2024. Findings: 1. Review of policies identified "Competency Evaluations" stating "testing personnel competencies are done every 6 months for the first year, thereafter on an annual basis." 2. Review of 2022, 2023, 2024, and 2025 TP records identified the following documented annual CA for the performance of LCMS testing: TP1 annual 4/8/2022, annual 5/19/2025 (no 2023 or 2024 CA) TP2 initial 7/17/2022, semi-annual 11/17/2022, 7/16/2023 (no 2024 CA) TP3 semi-annual 5/15/2022, annual 11/15/2022 (no 2023 or 2024 CA) 3. During an interview 5/13/2025 at approximately 8:30 AM, the GS stated the documentation for the missing competency assessments for 2023 and 2024 could not be located. 4. An exit interview with the laboratory team, 3/15/25 at 3:15 PM, confirmed the lack of documented competency assessments for the TP.</p>
<b>D5211</b>	<b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b>

CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on a review of College of American Pathologists (CAP) proficiency testing (PT) records, LCMS Sciex analyzer records, lack of documentation, and an exit interview with the technical supervisor (TS) and laboratory team, the laboratory failed to document the evaluation of ungraded PT results for one of one LCMS toxicology event of 2025. Findings: 1. Review of CAP 2025 UDC-A evaluation report revealed no results graded for analytes MDA and MDMA in toxicology confirmation testing. CAP coded the analytes as {42} no response received. 2. Review of raw data from the LCMS Sciex analyzer for 2025 UDC-A identified a result for both MDA and MDMA analytes on the PT specimens. 3. No corrective action or investigation could be located for the failure to report the MDA and MDMA results to CAP on the laboratory result submission for 2025 UDC-A. 4. An exit interview with the TS and laboratory team, 5/13/2025 at 3:15 PM, confirmed the lack of corrective action or investigation for the {42} no response received CAP code on the evaluation report.

**D5437**

**CALIBRATION AND CALIBRATION VERIFICATION**

CFR(s): 493.1255(a)

(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a) (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of policies and procedures, calibration records for CLC 720i analyzer, lack of documentation, and an exit interview with the technical supervisor (TS1) and laboratory team, the laboratory failed to (a)(2) perform calibrations every 7 days as established by the laboratory for the time period reviewed (February 24, 2025 thru date of survey). Findings: 1. Review of CLC 720i policies identified "Quality Control Drug Testing Calibration Requirements" stating "calibrations on the CLC-720 are done every seven days, with a new lot of reagent, quality control corrective action, and maintenance." A urine drug screen panel is performed on the CLC 720i analyzer consisting of 17 analytes (6-MAM, Alcohol, AMPH, BARB, BENZ, BUP, THC, COCM, EDDP, OPIATE, OXY, TCA, XTSY, Oxidants, pH, Specific gravity, Urine Creatinine). 2. Review of CLC 720i calibration records (February 24, 2025 thru date of survey) revealed the following calibrations: 2/24/25 17 of 17 analytes 3/3/25 no calibration records located 3/4/25 1 of 17 analytes (COCM) 3/10/25 15 of 17 analytes (missing BENZ, MDMA) 3/17/25 17 of 17 analytes 3/24/25 17 of 17 analytes 3/31/25 17 of 17 analytes 4/7/25 13 of 17 analytes (missing AMPH, COCM, BARB, BENZ) 4

/14/25 12 of 17 analytes (missing XTSY, COCM, BENZ, BARB, AMPH) 4/17/25 5 of 17 analytes (XTSY, COCM, BENZ, BARB, AMPH) 4/21/25 no calibration records located 4/28/25 17 of 17 analytes 5/5/25 16 of 17 (missing EDDP) 5/12/25 16 of 17 (missing EDDP) 3. An exit interview with TS1 and the laboratory team, 5/13/25 at 3: 15 PM, confirmed the findings.