

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D2120820	(X3) Date Survey Completed 08/15/2023
Name of Provider or Supplier Appalachian Wellness, Llc	Street Address, City, State 592 Ky 15 South, Campton, KY	
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 Recertification Survey was initiated and concluded on 08/15/2023. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
D6045	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7)</p> <p>(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory documentation, proficiency testing records, personnel records, and staff interview, the technical consultant failed to ensure the laboratory completed training for the moderate complexity hematology testing prior to patient testing for one (1) of two (2) Testing Personnel (TP) #1 employed by the laboratory. The Findings include: Review of the "CMS-209", completed by the Laboratory Director, dated 08/09/2023, revealed two (2) employees held the title of TP. According to the Laboratory Personnel Report, TP #1 performed moderate complexity testing. Review of Proficiency testing records from American Proficiency Institute for 2022 hematology Event #3, revealed "For all [Proficiency Testing] results, an attestation statement must be signed by testing personnel and the laboratory director and retained for a minimum of two (2) years." The Attestation Statement for the hematology sample tested was signed by TP #1 on 12/15/2022, and by the Laboratory Director on 12/20/2022. Review of TP #1's "Personnel File Checklist" revealed TP #1's initial training was not completed until 02/03/2023. During an interview, on 08/15/2023 at 12:29 PM, TP #1 stated she was hired at the laboratory on 09/05/2022. TP #1 stated she did not receive training until February 2023 and acknowledged she performed proficiency testing for Event 3 in December 2022. During an interview, on</p>

08/15/2023 at 1:02 PM, the Technical Supervisor (TS) stated he was responsible for the training and competency of all employees. Further, the TS acknowledged the laboratory failed to ensure TP #1 completed an initial training to ensure she knew how to perform the job before she used the instruments.