

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D2120820	(X3) Date Survey Completed 09/06/2024
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	The following deficiencies are a result of a desk review of proficiency testing (PT) scores obtained from the national database and verified with the PT company. The laboratory was found to be out of compliance with the conditions of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on a proficiency testing (PT) desk review of the Certification and Survey</p>

	<p>Provider Enhanced Reporting-0155 and American Proficiency Institute 2024 records (1st and 2nd events), the laboratory failed to successfully participate in a PT program. The laboratory failed to successfully participate in the specialty of Hematology for Red Blood Cell, Hemoglobin, and White Blood Cell Count for 2 of 2 testing events. Refer to D2130 and D2131.</p>
<p>D2130</p>	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) desk review of the Certification and Survey Provider Enhanced Reporting (Casper)-0155 and American Proficiency Institute (API) 2024 records (1st and 2nd events), the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in 2 of 2 consecutive testing events in Hematology for Red Blood Cell (RBC), Hemoglobin (HGB), and White Blood Cell Count (WBC Count). The findings include: 1. Review of the CASPER -0155 report revealed the following: Hematology 2024- 1st Event Laboratory received an unsatisfactory score of 40% for RBC. Hematology 2024- 2nd Event Laboratory received an unsatisfactory score of 0% for RBC. Hematology 2024- 1st Event Laboratory received an unsatisfactory score of 60% for HGB. Hematology 2024- 2nd Event Laboratory received an unsatisfactory score of 0% for HGB. Hematology 2024- 1st Event Laboratory received an unsatisfactory score of 60% for WBC Count. Hematology 2024- 2nd Event Laboratory received an unsatisfactory score of 0% for WBC Count. 2. A PT desk review from API 2024 PT records confirmed the above findings.</p>
<p>D2131</p>	<p>HEMATOLOGY CFR(s): 493.851(g)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) desk review of the Certification and Survey Provider Enhanced Reporting (CASPER)-0155 and American Proficiency Institute (API) 2021 records (1st and 2nd events), the laboratory failed to achieve overall satisfactory performance (80% or greater) for 2 of 2 consecutive events in the specialty of Hematology. The findings include: 1. Review of the Casper-0155 report revealed the following: Hematology 2024- 1st Event Laboratory received an unsatisfactory score of 73% for the Hematology. Hematology 2024- 2nd Event Laboratory received an unsatisfactory score of 0% for the Hematology. 2. A PT desk review from API 2024 PT records confirmed the above findings.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.</p>

1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on a proficiency testing (PT) desk review of the Certification and Survey Provider Enhanced Reporting-0155 and American Proficiency Institute 2024 records (1st and 2nd events), it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services to ensure successful PT participation of the specialty of Hematology, Red Blood Cell, Hemoglobin, and White Blood Cell Count during 2 of 2 testing events. Refer to D6016.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on a proficiency testing (PT) desk review of the Certification and Survey Provider Enhanced Reporting-0155 and American Proficiency Institute 2024 records (1st and 2nd events), the laboratory director failed to ensure that the PT samples were tested as required under Subpart H during 2 of 2 testing events. Refer to D2130 and D2131.