

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2160356	(X3) Date Survey Completed 08/26/2024
Name of Provider or Supplier Appalachian Labs Of Wv	Street Address, City, State 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 off site, proficiency testing (PT) desk review was conducted for Appalachian Labs of WV on August 26, 2024, by the West Virginia Office of Laboratory Services. The laboratory PT evaluations were reviewed for successful participation and compliance with the Federal Clinical Laboratory Improvement Amendments (CLIA) under 42 CFR 493. The identified unsuccessful participation in PT is an initial occurrence and explained below.
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 review of CASPER 155D proficiency testing (PT) report, laboratory evaluations from the College of American Pathologists (CAP), and interview, the</p>

	<p>laboratory failed to achieve satisfactory performance for the analyte #0635 Carbamazepine in two consecutive testing events resulting in unsuccessful participation for the specialty of #0605 Toxicology for the first two PT events in 2024. Refer to D2110 and D2111.</p>
<p>D2110</p>	<p>TOXICOLOGY CFR(s): 493.845(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of CASPER 155D proficiency testing (PT) report, laboratory PT evaluations from the College of American Pathologists (CAP), and interview, the laboratory failed to achieve satisfactory performance for the specialty of #0605 Toxicology in two consecutive testing events in 2024. Findings: 1. Review of CASPER 155D Report revealed the following unsatisfactory performance for the #0605 Toxicology specialty: 66% 2024 event 1 66% 2024 event 2 2. CAP laboratory evaluations confirmed the unsatisfactory performance for #0605 Toxicology due to 0% failure to participate scores for the analyte #0635 Carbamazepine in two consecutive PT events. 3. The technical supervisor, via telephone interview 8/23/24 at 9:30 AM, confirmed the unsatisfactory performance for #0605 Toxicology and stated the #0635 Carbamazepine 0% scores was due to not removing the analyte from the CAP menu.</p>
<p>D2111</p>	<p>TOXICOLOGY CFR(s): 493.845(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on review of CASPER 155D proficiency testing (PT) report, laboratory PT evaluations from the College of American Pathologists (CAP), and interview, the laboratory failed to successfully participate in two consecutive testing events for the analyte #0635 Carbamazepine in 2024. Findings: 1. Review of CASPER 155D Report revealed the following unsatisfactory scores for the analyte #0635 Carbamazepine: 0% 2024 event 1 0% 2024 event 2 2. CAP laboratory evaluations confirmed the 0% failure to participate scores for the analyte #0635 Carbamazepine in two consecutive PT events. 3. The technical supervisor, via telephone interview 8/23/24 at 9:30 AM, confirmed the failure to participate and stated that the #0635 Carbamazepine 0% scores was due to not removing the analyte from the CAP menu when the laboratory ceased testing.</p>