

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2179740	(X3) Date Survey Completed 08/02/2022
Name of Provider or Supplier Mountaineer Wellness And Recovery, Llc	Street Address, City, State 310 George Street, Beckley, 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 Mountaineer Wellness and Recovery, LLC, on August 2, 2022, 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 are explained below.
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interviews, the laboratory failed to test proficiency testing (PT) specimens the same number of times that patient specimens are routinely tested in one of two PT events in 2021. Findings: 1. Review of the raw data for the American Proficiency Institute (API) 2nd event of 2021 identified samples UDS-04, UDS-05, and UDS-06 had 3 different results for all analytes tested, ran on different days (10/13/21 and 10/20/21). 2. An interview with laboratory testing personnel (TP1), on 8/2/22 at approximately 9:30 AM, confirmed that patient specimens are routinely ran only one time. TP1 stated the PT specimens for API 2021 2nd Event were ran 3 times over different days. 3. An exit interview with the laboratory director, on 8/2/22 at approximately 12:30 PM, confirmed the findings.</p>
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>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</p>

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, policies and procedures (P&P), lack of documentation, and interview the laboratory failed to verify the manufacturer ranges for quality control (QC) material for 9 of 9 analytes on the test menu in 2021 and 2022. Findings: 1. Review of QC records for 2021 and 2022 revealed no verification of new lots of QC material before being put into use. 2. Review of P&P revealed no process for the verification of manufacturer ranges for new lots of QC material before being put into use. 3. An interview with the laboratory testing personnel (TP1), on 8/2/22 at approximately 11:44 AM, confirmed that no verification of new lots of QC was being performed. 4. An exit interview with the laboratory director, 8/2/22 at approximately 12:30 PM, confirmed the findings.

D5481

CONTROL PROCEDURES
CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on record review and interview the laboratory failed to (f) verify that quality control was within the acceptable range before reporting patient results 4 of 7 times QC was out of range thru the period reviewed. Findings: 1. Review of QC data (March 2022 thru June 2022) identified 4 instances a level of QC was out of range, no corrective action documented, and patient results reported: 4/9/22, 5/16/22, 6/9/22, and 6/24/22. 2. Review of QC records and patient testing logs identified the following: 4/9/22 Amphetamine level 2 out, 44 patient results reported 5/16/22 Buprenorphine level 2 out, 37 patient results reported 6/9/22 Buprenorphine level 2 out, 70 patient results reported 6/24/22 Buprenorphine level 2 out, 45 patient results reported 3. An exit interview with the laboratory director, 8/2/22 at approximately 12:30 PM, confirmed the findings.