

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2155274	(X3) Date Survey Completed 09/26/2024
Name of Provider or Supplier Mountain State Health & Wellness	Street Address, City, State 400 South Ruffner Road, 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	A routine recertification survey was conducted at Mountaineer State Health and Wellness on September 26, 2024, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the Federal Clinical Laboratory Improvement Amendments (CLIA) regulations under 42 CFR 493. Specific deficiencies cited are explained below.
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of analyzer validation records, policies and procedures (P&P), patient test results, and interview the laboratory failed to ensure the reference intervals (cutoffs) provided to clients to interpret qualitative positive and negative results were accurate for two of four analytes tested on the Pentra 400 toxicology analyzer. Findings: 1. Review of the Pentra 400 toxicology analyzer validation records (put into use 12/5/2023) identified the following reference intervals(cutoffs) to determine a presumptive positive result: oxycodone as 100ng/ml, amphetamine as 1000 ng/ml, opiate as 300 ng/ml, benzodiazepam 200 ng/ml. 2. Review of current P&P for toxicology testing on the Pentra 400 analyzer revealed the reference intervals (cutoffs) for the 4 analytes to be consistent with the validated performance specifications. 3. Review of a LiteDM laboratory information system (LIS) final patient test report (9/26/24) identified two inaccurate reference intervals (cutoffs): oxycodone as 300 ng/ml and amphetamine as 500 ng/ml. 4. An interview with the laboratory director (LD) and testing personnel (TP1), 9/26/24 at 12:30 PM, confirmed the inaccurate cutoff values for the oxycodone and amphetamine analytes on patient test reports. 5. An exit interview with the LD, 9/26/24 at 1:00 PM, confirmed the findings.</p>