

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D1075780	(X3) Date Survey Completed 04/19/2023
Name of Provider or Supplier Mountaineer Family Medicine Lab	Street Address, City, State 4114 1st Avenue, Nitro, 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 for Mountaineer Family Medicine Lab on April 19, 2023, 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.
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to (b)(1)(i) document the corrective action taken when the external quality control (QC) for the SCIEX API 3200 analyzer failed to meet the established acceptable range 3 of 5 times in April 2023. Findings: 1. Review of April 2023 QC records for the SCIEX API 3200 analyzer identified 5 testing days the low fentanyl QC data was not within the acceptable range. 3 of the 5 days had no corrective action documented for the out of range result: 4/5/23, 4/11/23, 4/18/23. 2. An interview with the general supervisor and technical supervisor, 4/19/23 at approximately 12:00 PM, confirmed the lack of corrective action documentation for the low fentanyl QC out of range results on 4/5/23, 4/11/23, and 4/18/23.</p>