Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D1075780	03/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Mountaineer Family Medicine Lab	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	A routine recertification survey was conducted at Mountaineer Family Medicine Lab on March 18, 2025, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the CLIA regulations under 42 CFR 493, Requirements for Laboratories. Specific deficiencies cited are explained below.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of written policies and procedures, lack of documentation, and interview with the technical supervisor (TS1), the laboratory failed to establish and follow a process to assess the competency of clinical consultant (CC), technical supervisor (TS), and general supervisor (GS) positions based on the position responsibilities listed in Subpart M. Findings: 1. Review of "Laboratory Quality Management Plan" identified "Personnel, New Employee Orientation, Training, and Competency Assessment" stating the requirements and frequency of competency assessment for testing personnel. 2. No written policy or procedure to assess the competency of the clinical consultant, technical supervisor, and general supervisor based on the position responsibilities could be located. 3. During an interview with the TS1, 3/18/25 at 9:45 AM, the TS1 stated that no competency of the CC, TS, and GS based on position responsibilities had been documented and no written policy or procedure could be located. 4. An exit interview with TS1 and GS, 3/18/25 at 5:35 PM, confirmed the findings.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)

	At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of College of American Pathologists (CAP) proficiency testing (PT) records, current laboratory test menu, lack of documentation, and interview with the technical supervisor (TS2), the laboratory failed to verify the accuracy of 9 of the 35 analytes tested in a toxicology confirmation panel on the AB Sciex 3200 toxicology analyzer twice in 2024. Findings: 1. Review of CAP PT records for 2024 revealed 9 analytes that are on the current laboratory test menu for the AB Sciex 3200 confirmation panel and not enrolled in commercial PT (7-aminoclonzepam, Amitriptyline, Gabapentin, Lorazepam, MDMA, Meperidine, PCP, Tapentadol, Venlafaxine). All 9 are unregulated analytes and not included in Subpart I. 2. No documentation that the laboratory performed an alternate accuracy verification twice in 2024 could be located for the 9 analytes. 3. A phone interview with TS2, 3/18/25 at approximately 4:05 PM, confirmed the lack of alternative verification for the 9 analytes in 2024. TS2 stated the commercial PT program did not cover the whole test menu and an alternative verification will happen. 4. An exit interview with TS1 and GS, 3/18/25 at 5:35 PM, confirmed the findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on review of written policies and procedures, AB Sciex 3200 LCMS toxicology analyzer external quality control (QC) records, interview with the technical supervisor (TS1) and interview with the general supervisor (GS), the laboratory failed to perform and document three levels of external quality control (QC) with each run of patient specimens as established by the laboratory. Findings: 1. Review of "3200 Confirmation Procedure" revealed "Quality Control Protocol" stating "for the assay run to be deemed acceptable, the following criteria must be met: Negative QC level within range and One of two Positive QC levels within range". Reference charts for quality control materials used and the expected concentrations state "QC-1 Low QC-75% of cutoff, QC-2 2x cutoff, QC-3 7x cutoff". 2. Review of 2025 AB Sciex 3200 QC records (November 2024 thru date of survey) identified two levels of QC evaluated for acceptability with each run of patient samples: QC-1-Low QC 75% of cutoff and QC-2 2x cutoff for 35 of 35 analytes. No documentation that the QC-3 7x cutoff level of QC was performed could be located. 3. During an interview with the GS, 3/18/25 at approximately 12:25 PM, GS stated that only two levels of QC are evaluated and documented as acceptable for the toxicology testing in the Stratus

	laboratory information system (LIS) for each patient run. 4. An exit interview with TS1 and GS, 3/18/25 at 5:35 PM, confirmed the findings.
D5801	TEST REPORT CFR(s): 493.1291(a) (a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on a review of Stratus laboratory information system (LIS) patient results, chromatograms from the AB Sciex 3200 LCMS toxicology analyzer, direct observation of test setup in the Stratus LIS, interview with the technical supervisor (TS1), and general supervisor (GS), the laboratory failed to ensure the cutoff values programmed into the Stratus LIS were correct for one of 11 analytes in the drug screening panel and one of 35 analytes in the drug confirmation testing panel. Findings: 1. Review of 5 final patient toxicology reports from the Stratus LIS system and the corresponding chromatograms from the AB Sciex 3200 LCMS analyzer identified the following: a. Patients 76331 and 78401 were both reported in the Stratus LIS as POSITIVE for benzodiazepine screening with a stated cutoff of 300 ng/mL. Review of chromatograms revealed both patient results were below 300 ng/mL (228.5 and 184.7, respectively). b. Patients 79076 and 86325 were both reported in the Stratus LIS as POSITIVE for buprenorphine confirmation with a stated cutoff of 50 ng /mL. Review of chromatograms revealed both patient results were below 50 ng/mL (34 and 33, respectively). 2. On a tour of the laboratory, 3/18/2025 at approximately 3: 00 PM, the GS accessed and reviewed the Stratus LIS test setup for benzodiazepine screen and buprenorphine confirmation. The cutoff for benzodiazepine on the drug screening panel was programmed at 100 ng/mL. Subsequently, patients 76331 and 78401 were reported as POSITIVE when the results obtained were negative according to the lab's established cutoff of 300 ng/mL. The cutoff for buprenorphine on the drug confirmation panel was programmed at 25 ng/mL. Subsequently, patients 79076 and 86325 were reported as POSITIVE when the results obtained were negative according to the lab's established cutoff of 50 ng/mL. 3. During an interview with TS1, 3/18/25 at 3:15 PM, TS1 stated the cutoffs programmed into the Stratus LIS were inaccurate according to the established cutoffs for the two analytes. 4. An exit interview with TS1 and GS, 3/18/25 at 5:35 PM, confirmed the findings.
D5807	TEST REPORT CFR(s): 493.1291(d) (d) 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. This STANDARD is not met as evidenced by:

	Based on review of written policies and procedures, Stratus laboratory information system (LIS) final report, and interview with the technical supervisor (TS1) and the general supervisor (GS), the laboratory failed to ensure the reference intervals (cutoffs) provided to clients for interpretation of drug screen results were accurate for two of 35 confirmation analytes on the final report. Findings: 1. Review of the "Reference Ranges" in the "3200 Confirmation Test Procedure" stated cutoffs established during instrument validation for all 35 analytes tested in a confirmation toxicology panel on the AB Sciex 3200 analyzer. 2. Review of one Stratus LIS patient report (69876) identified a PCP cutoff of 50 ng/mL and 6-MAM cutoff as 20 ng/mL. The "3200 Confirmation Test Procedure" stated that both the PCP and 6-MAM cutoffs were 100 ng/mL. 3. During an interview with the TS1, 3/18/25 at approximately 11:00 AM, TS1 agreed the cutoffs for PCP and 6-MAM on the LIS final report differed from the cutoffs for PCP and 6-MAM in the written test procedure. 4. An exit interview with TS1 and GS, 3/18/25 at 5:35 PM, confirmed the findings.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of written policies and procedures, lack of documentation, and interview with the technical supervisor (TS1) and general supervisor (GS), the laboratory failed to document the performance of the post analytic systems quality assessment (QA) for the Stratus laboratory information systems (LIS) information verification from September 2023 thru date of survey. Findings: 1. Review of the "Laboratory Quality Management Plan" identified the laboratory manager performs "monthly/quarterly audits" including "Result Verification Audit (verification that the raw data generated from the Sciex LCMS 3200 analyzer is consistent with the data that is entered into the Laboratory Information System- Stratus)". 2. Review of QA documents (September 2023 thru date of survey) revealed no documentation that the laboratory directly compared raw data (chromatograms) from the AB Sciex 3200 analyzer with final patient reports from the Stratus LIS to verify the accuracy of transmitted data. 3. During an interview with TS1, 3/18/25 at approximately 4:30, TS1 agreed no documentation of the Result Verification Audit for QA could be located since September 2023. 4. An exit interview with TS1 and GS, 3/18/25 at 5:35 PM, confirmed the findings.