

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 51D1075780	<b>(X3) Date Survey Completed</b> 04/27/2021
<b>Name of Provider or Supplier</b> Mountaineer Family Medicine Lab	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced, on site, recertification survey was conducted at Mountaineer Family Medicine Lab on April 27, 2021, by the West Virginia Office of Laboratory Services. The laboratory was surveyed for compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
<b>D2094</b>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the laboratory failed to (2) retain the documentation of proficiency testing (PT) remedial actions taken for an unsatisfactory score in 1 of 2 College of American Pathologists (CAP) testing events in 2020 for the API 3200 ABSCIEX LCMS toxicology confirmation testing. Findings: 1. Review of CAP PT 2020 evaluation scores identified an unsatisfactory score for DMPM-B 2020. 2. No documentation could be located for the remedial actions taken by the laboratory for the DMPM-B 2020 unsatisfactory score. 3. The technical supervisor confirmed the findings on 4/27/2021 at 12:15 PM.</p>
<b>D3031</b>	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p>

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:

Based on record review, lack of documentation, and interview the laboratory failed to retain the API 3200 ABSCIEX LCMS analyzer quality control (QC), calibrations, maintenance, function checks, reagent storage, and environmental monitoring documentation records for 17 of 18 months reviewed. Findings: 1. Record review from September 2019 thru April 2021 identified no API 3200 ABSCIEX LCMS analytic systems records for 4 of 4 months in 2019, 12 of 12 months in 2020, and 1 of 2 months in 2021. Lack of documentation included: no QC data and review from patient testing days, calibration data and review from patient testing days, maintenance, function checks, temperature and humidity logs, and reagent use and storage monitoring. 2. The technical supervisor confirmed the findings on 4/27/2021 at 1:00 PM.

**D3037**

**RETENTION REQUIREMENTS**

CFR(s): 493.1105(a)(4)

Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:

Based on record review, lack of documentation, and interview the laboratory failed to retain all College of American Pathologists (CAP) proficiency testing (PT) records for 4 of 4 testing events in 2019 and 2020 for the API 3200 ABSCIEX LCMS toxicology analyzer. Findings: 1. Record review of CAP PT documentation for 2019 and 2020 revealed a lack of records for 2 of 2 events in 2019 and 2 of 2 events in 2020. Lack of documentation included: no original data results from the analyzer, signed attestation statements, laboratory review of submitted results, and corrective actions for unsuccessful performance. 2. Review of CAP evaluation reports revealed the laboratory submitted results for the 2 testing events in 2019 and the 2 testing events for 2020. 3. An interview with the technical supervisor 4/27/2021 at 12:15 PM confirmed the findings.

**D3039**

**RETENTION REQUIREMENTS**

CFR(s): 493.1105(a)(5)

Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.

This STANDARD is not met as evidenced by:

Based on record review, lack of documentation, and interview the laboratory failed to retain quality assessment (QA) records of the general laboratory, pre analytic, analytic, and post analytic systems for 17 of 18 months reviewed. Findings: 1. Record review from September 2019 thru April 2021 identified no QA records for 4 of 4 months in 2019, 12 of 12 months in 2020, and 1 of 2 months in 2021. Lack of documentation included: no QA of patient confidentiality, specimen ID, specimen integrity, complaint investigations, communications, personnel competencies, proficiency test performance for General Laboratory Systems; no QA of test requests,

specimen submission, specimen handling and referral for Pre Analytic Systems; no QA for test procedures, environmental conditions, maintenance and function checks, calibrations, quality control procedures, corrective actions, test records for Analytic Systems; no QA for test reports and critical values for Post Analytic Systems. 2. An interview with the technical supervisor 4/27/2021 at 1:00 PM confirmed the findings.

**D5433**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:  
Based on record review, lack of documentation, and interview the laboratory failed to provide documentation of the performance of unscheduled and scheduled maintenance for the API 3200 ABSCIEX LCMS analyzer, a method developed in-house, for 17 of 18 months reviewed. Findings: 1. Maintenance record log review from September 2019 to April 2021 revealed no documentation of unscheduled or scheduled maintenance on the API 3200 ABSCIEX LCMS analyzer. The lack of documentation included: no service call invoices, no daily, weekly, monthly, or preventive maintenance logs, and no required function checks. 2. An interview with the technical supervisor 4/27/2021 at 1:00 PM confirmed the findings.

**D5437**

**CALIBRATION AND CALIBRATION VERIFICATION**  
CFR(s): 493.1255(a)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:  
Based on record review, lack of documentation, and interview the laboratory failed to document the calibration procedures established by the laboratory for the API 3200 ABSCIEX LCMS analyzer for 17 of 18 months reviewed. Findings: 1. Review of calibration records from September 2019 thru April 2021 revealed no documentation of calibrations for 4 of 4 months in 2019, 12 of 12 months in 2020, and 1 of 2 months in 2021 on days of patient testing. Lack of documentation included: no calibration

	<p>records for the 36-analyte toxicology confirmation panel on the API 3200 ABSCIEX LCMS analyzer. 2. An interview with the technical supervisor on 4/27/2021 at 1:00 PM confirmed the findings.</p>
<p><b>D5481</b></p>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(f)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the laboratory failed to document the quality control (QC) procedures for the API 3200 ABSCIEX LCMS analyzer for 17 of 18 months reviewed. Findings: 1. Review of QC records from September 2019 thru April 2021 revealed no documentation of QC data for 4 of 4 months in 2019, 12 of 12 months in 2020, and 1 of 2 months in 2021 on days of patient testing. Lack of documentation included: no QC records for the 36-analyte toxicology confirmation panel on the API 3200 ABSCIEX LCMS analyzer. 2. An interview with the technical supervisor on 4/27/2021 at 1:00 PM confirmed the findings.</p>
<p><b>D6095</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(6)</p> <p>The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview the laboratory director (LD) failed to ensure the laboratory documented and maintained: Evaluation of and corrective action plan for unacceptable proficiency testing scores (see D2094) Proficiency testing records from 2019 and 2020 testing events (see D3037) Quality assurance policies from September 2019 thru January 2021 (see D3039) Quality control procedures from September 2019 thru January 2021 (see D3031 and D5481) Maintenance and function checks from September 2019 thru January 2021 (see D5433) Analyzer calibrations from September 2019 thru January 2021 (see D5437)</p>