

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2160356	(X3) Date Survey Completed 07/20/2021
Name of Provider or Supplier Appalachian Labs Of Wv	Street Address, City, State 708 Bigley Ave, 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	An announced, on site, recertification survey was conducted at Appalachian Labs of WV on July 20, 2021, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of records and interview the laboratory failed to evaluate the unsuccessful results of 1 of 3 College of American Pathologists (CAP) 2020 proficiency testing (PT) events and 1 of 2 CAP 2021 PT events. Findings: 1. Review of CAP records for 2020 UDC-D revealed no evaluation of the unacceptable results for the following analytes: hydromorphone, EDDP, oxycodone. 2. Review of CAP records for 2021 UDC-A revealed no evaluation of the unacceptable results for the following analytes: morphine, amphetamines, buprenorphine, norbuprenorphine, THC, phenobarbital, benzoylecgonine, hydromorphone. 3. An interview with the technical supervisor, on 7/20/21 at approximately 12:00 PM, confirmed the findings.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p>

This STANDARD is not met as evidenced by:
Based on review of policies and procedures (P&P) and interview the laboratory failed to establish a written P&P for the quality assessment (QA) of the general laboratory systems for LCMS/MS testing, which includes the monitoring and assessment of confidentiality, specimen identification and integrity, complaint investigations, communications, personnel competency, and proficiency testing evaluation. Findings: 1. No written P&P for QA of general laboratory systems for LCMS/MS testing could be located. 2. An interview with the technical supervisor, 7/20/21 at approximately 9:15 AM, confirmed the findings.

D5391

PREANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1249(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:
Based on a review of policies and procedures (P&P),and interview the laboratory failed to establish a written P&P for the quality assessment (QA) of the preanalytic system for the LCMS/MS testing, which includes test request and specimen submission, handling, and referral. Findings: 1. No written P&P could be located for the QA of the LCMS/MS preanalytic systems. 2. An interview with the technical supervisor, on 7/20/21 at approximately 9:15 AM, confirmed the findings.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on record review, review of policies and Procedures (P&P), and interview the laboratory failed to establish a written policy & procedure for (7) quality control (QC)

procedures during the extraction phase of specimen preparation (hydrolysis) with the LCMS/MS test systems. Findings: 1. A review of QC records identified a UTAK hydrolysis quality control (morphine-glucuronide) for the extraction phase of hydrolysis being performed and evaluated. 2. A review of P&P revealed a lack of the procedure for the UTAK hydrolysis QC in the "LCMS/MS Analytical Procedure for App Labs of WV." 3. An interview with the technical supervisor, 7/20/21 at approximately 10:30 AM, confirmed the findings.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on review of written policies and procedures (P&P) and interview the laboratory failed to establish a written P&P for the quality assessment (QA) of the analytic systems involved in LCMS/MS testing, which includes procedure manuals, test systems/equipment/supplies, establishment and verification of performance specifications, maintenance and function checks, calibration and calibration verification procedures, control procedures, comparison of test results, corrective actions, and test results. Findings: 1. No written P&P for the QA of analytic systems for LCMS/MS testing could be located. 2. An interview with the technical supervisor, on 7/20/21 at approximately 9:15 AM, confirmed the findings.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on review of policies and procedures (P&P) and interview the laboratory failed to establish a P&P for the quality assessment (QA) of postanalytic systems for LCMS/MS testing, which includes test reports, established reporting time frames, notification of test results, routine tests, STATS, abnormal or panic values, and verification of the accuracy of the LIS. Findings: 1. No written P&P for the QA of the postanalytic system for LCMS/MS testing could be located. 2. An interview with the technical supervisor, on 7/20/21 at approximately 9:15 AM, confirmed the findings.