Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2179740	(X3) Date Survey Completed 11/18/2020
Name of Provider or Supplier Mountaineer Wellness And Recovery, Llc	**Street Address, City, State** 310 George Street, Beckley, 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, initial survey was conducted at Mountaineer Wellness and Recovery LLC on November 18, 2020, by the West Virginia Office of Laboratory Services. The facility was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations 42 CFR 493. Specific deficiencies are explained below.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on a review of written laboratory policies and procedures (P&P), a tour of the laboratory, a review of assay specific manufacturer package inserts, a review of the laboratory test menu, and an interview with the general supervisor (GS), the laboratory failed to ensure the optimum integrity of urine specimens for analysis on the Biolis 50i. Findings: 1. A review of written P&P identified a "Toxicology Specimen Collection/Processing/Rejection" procedure that states "Labeling Specimens: Specimens must be properly labeled on the container, not the lid, with the following information: At a minimum: Patient first and last name, Second identifier-such as date of birth, accession number, medical record number. Additional optional information: date and time of collection" under the Labeling Specimens section. 2. A review of the Thermo Fisher DRI Buprenorphrine Assay package insert identified the following statement: " Testing of fresh urine specimens is suggested. Care should be taken to preserve the chemical integrity of the urine sample from the time it is collected until the time it is assayed." 3. A tour of the laboratory identified that patient specimens were being labeled with 2 patient identifiers and the date of collection.

	There was no time documented on the patient specimens upon collection. 4. During an interview with the GS, on 11/18/2020 at approximately 9:30 AM, the GS stated that the specimen collections will be documented with the time and date of collection to ensure the integrity of the urine specimen for testing. 5. A review of the Thermo Fisher DRI Methadone Assay package insert identified the following statement: "Samples within a PH range of 3 to 11 are suitable for testing with this assay." 6. A review of the laboratory test menu identified no PH assay being tested on patient specimens for the Biolis 50i and no other process or procedure to ensure specimen validity and integrity. 7. During an interview with the GS, on 11/18/2020 at approximately 10:00 AM, the GS stated that no PH testing was performed on patient specimens to ensure the integrity of the urine for analysis.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on a review of written laboratory policies and procedures (P&P) and an interview with the general supervisor (GS), the laboratory failed to establish a written P&P for (8) specimen referral. Findings: 1. A review of written P&P identified no policy or procedure for the criteria of the referral of patient urine specimens to AmmonLabs for confirmation testing. 2. During an interview with the GS, on 11/18 /2020 at approximately 10:30 AM, the GS stated that no written P&P for the criteria to send a urine specimen to AmmonLabs for confirmation testing could be located.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of laboratory maintenance logs, written policies and procedures (P&P), a tour of the laboratory, and an interview with the general supervisor (GS), the laboratory failed to define and monitor the criteria of (1) water quality for the Biolis 50i toxicology analyzer. Findings: 1. A review of maintenance logs for the laboratory identified no documented monitoring of the water system quality used by the Biolis 50i analyzer. 2. A review of P&P identified no defined criteria for the acceptability of the water quality for the Biolis 50i analyzer. 3.. A tour of the laboratory identified no defined criteria or documented monitoring of the water system quality used for the

	Biolis 50i analyzer. 4. During an interview with the GS, on 11/18/2020 at approximately 10:30 AM, the GS stated that the water system had no documentation of criteria being monitored. The GS located a log for the water system that defines the acceptable criteria and stated the laboratory will document the water system conditions daily.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records, manufacturer instructions for test assays, an interview with the specimen collection personnel and an interview with the general supervisor (GS), the laboratory failed to perform quality control procedures for the Discover Plus Fentanyl Drug Test Card at the required frequency of each day of patient testing. Findings: 1. Review of QC records identified no external quality control documented for the Discover Plus Fentanyl Drug Test Card. 2. Review of the manufacturer instructions identified that the Discover Plus Fentanyl Drug Test Card is for forensic use only and is classified as high complexity testing by the FDA. For high complexity testing a positive and negative external control are required to be ran each day of patient testing or an Individualized Quality Control Plan (IQCP) can be developed. 3. During an interview with the GS, on 11/18/2020 at approximately 8:30 AM, the GS stated that he was not sure how often the Discover Plus Fentanyl Drug Test Card was used for patient testing and that the specimen collection personnel in the specimen collection area (AmmonLabs employees) performed that specific test for patients. 4. During an interview with the specimen collection personnel, on 11/18 /2020 at approximately 8:30 AM, the specimen collection personnel stated that the Discover Plus Fentanyl Drug Test Card was a "waived test", "not performed on patient samples very often", and that there was no external QC performed.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) 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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records, manufacturer instructions for test assays, an interview with the specimen collection personnel and an interview with the general supervisor (GS), the laboratory failed to perform quality control procedures

	for the Discover Plus Fentanyl Drug Test Card at the required frequency of each day of patient testing. Findings: 1. Review of QC records identified no external quality control documented for the Discover Plus Fentanyl Drug Test Card. 2. Review of the manufacturer instructions identified that the Discover Plus Fentanyl Drug Test Card is for forensic use only and is classified as high complexity testing by the FDA. For high complexity testing a positive and negative external control are required to be ran each day of patient testing or an Individualized Quality Control Plan (IQCP) can be developed. 3. During an interview with the GS, on 11/18/2020 at approximately 8:30 AM, the GS stated that he was not sure how often the Discover Plus Fentanyl Drug Test Card was used for patient testing and that the specimen collection personnel in the specimen collection area (AmmonLabs employees) performed that specific test for patients. 4. During an interview with the specimen collection personnel, on 11/18 /2020 at approximately 8:30 AM, the specimen collection personnel stated that the Discover Plus Fentanyl Drug Test Card was a "waived test", "not performed on patient samples very often", and that there was no external QC performed.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of the laboratory written policies and procedures (P&P), quality control (QC) records, maintenance logs, and observation of the laboratory specimen collection processes, the laboratory director failed to ensure the overall quality of the laboratory testing. Findings: 1. A review of written P&P identified no policy or procedure for the referral of urine specimens for confirmation testing. See D5311. 2. A review of QC records identified no external quality control documented for the Discover Plus Fentanyl Drug Test Card. See D5449 and D5445. 3. A review of maintenance logs identified no documented monitoring of the water system quality for the Biolis 50i analyzer. See D5413. 4.. An observation of the urine specimen collection and testing procedure identified no process to ensure the validity and integrity of the specimens for testing on the Biolis 50i. See D5203.