

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2155274	(X3) Date Survey Completed 12/02/2020
Name of Provider or Supplier Mountain State Health & Wellness	Street Address, City, State 400 South Ruffner Road, 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 Mountain State Health & Wellness on December 2, 2020, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory test menu, manufacturer package inserts for specific assays, and an interview with the laboratory director (LD), the laboratory failed to ensure the optimum integrity of a patient urine specimen by not assuring that patient urine specimens had a PH within a 3 to 11 range as specified for the test methodology of the Indiko Plus analyzer. Findings: 1. A review of the laboratory test menu on the Indiko Plus analyzer, identified the analytes 6AM, Amphetamine, Barbituates, Benzodiazepine, Buprenorphine, Cocaine, MDMA, ETOH, Oxycodone, PCP, THC, and Opiates as tests performed by the laboratory. 2. A review of the 12 assay specific manufacturer package inserts identified a statement "Samples within a PH range of 3 to 11 are suitable for testing with this assay" for 5 of the 12 analytes: ETOH, THC, Barbiturates, Opiates, and PCP. No documentation of this PH range being verified for patient urine specimens being analyzed for ETOH, THC, Barbiturates, Opiates, or PCP on the Indiko Plus could be located. 3. During an</p>

interview with the LD, on 12/2/2020 at approximately 10:45 AM, the LD stated that no PH testing, either pre analytical or analytical, was currently being performed by the laboratory.

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 a review of the laboratory test menu, proficiency testing (PT) documents from the College of American Pathologists (CAP), blind split sample testing documents, and an interview with the laboratory director (LD), the laboratory failed to verify the accuracy of the analyte MDMA at least twice annually in 2019. Findings: 1. A review of the laboratory test menu and CAP PT enrollment identified 11 analytes, not included in Subpart I, that are tested during the CAP UDS events to meet the requirement of verifying the accuracy of each test at least twice a year. 6AM is the only analyte not enrolled in CAP PT, due to not being available with the UDS program. 2. A review of 2019 and 2020 CAP PT documents identified no submission or evaluation of the test data for MDMA in 2 of 3 2019 testing events. a. CAP UDS-A 2019 had no data or evaluation for MDMA b. CAP UDS-C 2019 had no data or evaluation for MDMA c. CAP UDS-B 2019 had data for MDMA submitted to CAP and evaluated by the laboratory to verify the accuracy of the test. 3. A review of the blind split sample testing documents identified a verification of the accuracy of 6AM twice a year for 2019 (5/19 and 11/19). There was no documentation of blind split sample testing of MDMA in 2019. 4. During an interview with the LD, on 12/2/2020 at approximately 11:00 AM, the LD stated that the analyte MDMA data had not been submitted to CAP or evaluated by the laboratory to verify the accuracy in 2 of 3 testing events for 2019. The LD stated that no blind split sample testing had been performed for MDMA in 2019.