Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D1086270	09/02/2020
Name of Provider or Supplier	**Street Address, City, State**	
Wv Drug Testing Laboratories Inc	1422 East Main Street, Princeton, 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 WV Drug Testing Laboratories- Mercer on September 2, 2020, by the West Virginia Office of Laboratories 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.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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 a review of the laboratory written policies and procedures (P&P),quality control (QC) records, calibration records, the "Reagent/QC/Calibration Log Book", a tour of the laboratory, and an interview with the laboratory manager and laboratory director (LD), the laboratory failed to document and retain all analytic systems activities regarding the qualitative urine drug screen testing performed on the AU 400 as specified in CFR 493.1252 (d). Findings: 1. A review of the laboratory P&P identified a "Quality Control Policy" that states "Purpose: To ensure proper handling, storage, and use of all quality control materials. To provide precise and accurate results.." by incorporating the following processes: a. "Upon receiving Quality Control material into the laboratory the lot numbers and expiration dates will be documented in the Reagent/QC/Calibration Log Book with the date received." b. "Anytime reagent, quality control, or calibrators need to be replenished for use on the analyzer documentation in the Log Book will occur." 2. A review of the QC and calibration records identified that QC and calibrations were being performed at the appropriate and required times. 3. A review of the "Reagent/QC/Calibration Log Book" identified a lack of documentation of lot numbers and expiration dates for

	reagents, quality control, and calibration material used in the AU 400 analytic system. a. No documentation of lot numbers and expiration dates for the reagents cocaine, propoxyphene, barbiturate, amphetamine, tetracannabinoids, and alcohol could be located in the log book. 1. The log book had the last entry for the reagent benzodiazepine as lot number 73312172 with an expiration date of 2/2020. b. No documentation of lot numbers and expiration dates for the calibrator Multi Drug Cal I could be located in the log book. 1. The log book had the last entry for the calibrator Multi Drug II as lot number 73552649 with an expiration date of 5/2020. 2. The log book had the last entry for the calibrator Multi Drug III as lot number 72394545 with an expiration date of 9/2019. c. No documentation of lot numbers and expiration dates for the QC materials for cocaine, methadone, opiates, oxycodone, propoxyphene, and specific gravity could be located. 4. A tour of the laboratory identified that (1) there were no expired reagents, QC, and calibration materials being utilized by the laboratory for testing on the AU 400 analytic system and (2) there was not an electronic record of lot numbers and expiration dates stored on the AU 400 analyzer. 5. An interview with the laboratory manager was conducted on 9/02/2020 at approximately 10:15 AM. The laboratory manager stated the "Reagent/QC /Calibration Log Book" reviewed by the state surveyor was the current log book being used by the testing personnel. 6. During an interview with the laboratory director (LD), on 9/2/2020 at approximately 11:00, the LD stated that the lack of documentation for the lot numbers and expiration dates for reagents, quality control, and calibration materials was an issue that will addressed immediately.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the laboratory College of American Pathologists (CAP) proficiency testing (PT) records and an interview with the laboratory director (LD), the laboratory failed to investigate and document the corrective action taken regarding an unacceptable score of the analyte creatinine in the CAP DAI-A 2019 testing event. Findings: 1. A review of 2018 and 2019 CAP PT records identified an unacceptable result for creatinine in the CAP DAI-A 2019 testing event. a. Specimen DAI-02 had a result of 20.8. The CAP acceptable result range was 23.1-40.4. 2. A review of the PT documents for the CAP DAI-A 2019 testing event identified a LD review of the result evaluation of the testing event. No documentation of the corrective action taken regarding the unacceptable result for specimen DAI-02 creatinine could be located. 3. An interview with the LD, on 9/2/2020 at approximately 11:30 AM, confirmed there was no documentation of corrective action taken for the unacceptable creatinine result for the CAP DAI-A 2019 testing event. The LD stated that the results of the PT event were reviewed and that no documentation of corrective action could be located.
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 a review of the laboratory written policies and procedures (P&P), and an interview with the laboratory manager and the laboratory director (LD), the laboratory failed to have a written process to delineate when a urine specimen would be (b)(1) referred for confirmatory testing by a quantitative methodology. Findings: 1. A review of the P&P identified a "Positive Drug Screen Repeat Testing" policy that states a procedure for the repeat testing of a presumptive positive result from the AU 400 chemistry/toxicology analyzer. This P&P applies to repeat testing of a positive result on the same methodology. The AU 400 toxicology testing performed by this lab is a qualitative screening of urine for the presence or absence of illicit substances and the quantitative testing of urine for specific gravity and creatinine. 2. No P&P for the criteria of specimen referral for confirmatory testing at a reference laboratory with a different quantitative methodology could be located. 3. During an interview with the laboratory manager and the laboratory director, on 9/2/2020 at approximately 12:00 PM, they both stated that a P&P for specimen referral for confirmatory testing could not be located.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of the laboratory written policies and procedures (P&P),quality control (QC) records, calibration records, the "Reagent/QC/Calibration Log Book", a tour of the laboratory, and an interview with the laboratory manager and laboratory director (LD), the laboratory failed to document all lot numbers and expiration dates for reagents, quality control, and calibration materials utilized in the AU 400 test system for qualitative urine drug screens. Findings: 1. A review of the laboratory P&P identified a "Quality Control Policy" that states "Purpose: To ensure proper handling, storage, and use of all quality control materials. To provide precise and accurate results.." by incorporating the following processes: a. "Upon receiving Quality Control material into the laboratory the lot numbers and expiration dates will be documented in the Reagent/QC/Calibration Log Book with the date received." b. "Anytime reagent, quality control, or calibrators need to be replenished for use on the analyzer documentation in the Log Book will occur." 2. A review of the QC and

	calibration records identified that QC and calibrations were being performed at the appropriate and required times. 3. A review of the "Reagent/QC/Calibration Log Book" identified a lack of documentation of lot numbers and expiration dates for reagents, quality control, and calibration material used in the AU 400 analytic system. a. No documentation of lot numbers and expiration dates for the reagents cocaine, propoxyphene, barbiturate, amphetamine, cannabinoids, and alcohol could be located in the log book. 1. The log book had the last entry for the reagent benzodiazepine as lot number 73312172 with an expiration date of 2/2020. b. No documentation of lot numbers and expiration dates for the calibrator Multi Drug Cal I could be located in the log book. 1. The log book had the last entry for the calibrator Multi Drug II as lot number 73552649 with an expiration date of 5/2020. 2. The log book had the last entry for the calibrator Multi Drug III as lot number 72394545 with an expiration date of 9/2019. c. No documentation of lot numbers and expiration dates for the QC of cocaine, methadone, opiates, oxycodone, propoxyphene, and specific gravity could be located. 4. A tour of the laboratory identified that (1) there were no expired reagents, QC, and calibration materials being utilized by the laboratory for testing on the AU 400 analytic system and (2) there was not an electronic record of lot numbers and expiration dates stored on the AU 400 analyzer. 5. An interview with the laboratory manager was conducted on 9/02/2020 at approximately 10:15 AM. The laboratory manager stated the "Reagent/QC/Calibration Log Book" reviewed by the state surveyor was the current log book being used by the testing personnel. 6. During an interview with the laboratory director (LD), on 9/2/2020 at approximately 11:00, the LD stated that the lack of documentation for the lot numbers and expiration dates for reagents, quality control, and calibration materials was an issue that will addressed immediately.