Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0920678	12/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Wv Office Of Laboratory Services	4710 Chimney Drive Suite G, 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
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 review of proficiency testing (PT) summary reports, corrective action (CA) reports and interview with the technical supervisor, the laboratory failed to ensure all non-regulated analytes it tests were evaluated for accuracy at least twice annually during 2018. Findings include: 1. The laboratory receives two or three sets of challenges from the Centers for Disease Control (CDC) Laboratory Response Network (LRN) each calendar year. CDC-LRN challenges are used by the facility to twice annually assess the accuracy of analytes not included in Subpart I. The surveyor reviewed all CDC-LRN challenges the laboratory participated in during 2018. 2. The laboratory did not participate in one (2018-2) of two challenges received during 2018 for the analyte cyanide (CN) in blood. 3. The laboratory did not participate in two (2018-2 & 2018-3) of three challenges received during 2018 for the analytes Abrine and Ricine in urine. 4. The laboratory received failing (less than 80%) scores in two challenges (2018-1 75.7% and 2018-3 0%) received during 2018 for the analytes of Lead, Cadmium and Mercury in urine. 5. Interview with the laboratory technical supervisor at approximately 4:00pm confirmed the findings.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.

	This STANDARD is not met as evidenced by: Based on review of the laboratory Quality Assurance Policy and Procedure manual and interview with staff, the laboratory failed to have defined, ongoing mechanisms and established monitors to periodically assess problem prone systems and processes in the general laboratory systems. Findings include: 1. The surveyor reviewed CDC-LRN challenge result reports from 2018 and noted for the analytes of Cynide in Blood, Abrine and Ricine and Urine Metals, the laboratory was only able to show evidence their methods were accurate only one time during the calendar year and the other times, the method was either not working correctly due to problems with instrumentation or staff transcription errors that caused their submitted results to not be scoreable by the CDC. 2. During interview with the technical supervisor at approximately 4:45pm, there was an admission to the surveyor the lab's methods for detection of agents of chemical terrorism, which is the only analytes they routinely test for, are only utilized when challenges from the CDC arrive for testing. 3. Cross-reference D5217 and D6118.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: A. Based on a tour of the facility, review of written method procedures and interview with staff, the laboratory failed to have a written procedure for all methods currently utilized by the facility for detection of agents of chemical terrorism. Findings include: 1. During a tour of the facility at approximately 3:10pm, the surveyor was informed the methodology for detection of Tetramine in urine was changed by the CDC during the summer of 2018. 2. The lab staff was unable to show the surveyor the updated standard operating procedure (SOP) for the detection of Tetramine in urine based on changes made by the CDC to the method from the summer of 2018. 3. During interview with the technical supervisor at approximately 5:15pm, there was an admission that a new (SOP) was not written based on the recent CDC methodology changes. B. Based on a review of testing methodologies and interview with staff, the laboratory failed to have a newly implemented methods of detection of agents of chemical terrorism reviewed, approved, signed and dated by the laboratory director before use in the facility. Findings include: 1. The surveyor reviewed documentation of new instrument installation, AT Model 7800 for detection of blood metals by ICP /MS that was dated September 8, 2017 and reviewed as approved by the lab director on September 22, 2017. 2. There was no evidence the technical supervisor had written a SOP corresponding to detection of blood metals by ICP/MS. 2. During interview with the technical supervisor and lab director at approximately 5:44pm, there was an admission that no SOP was available for this methology since the performance specifications were completed back in September 2017.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d)

	Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: A. Based on a tour of the facility, review of written method procedures and interview with staff, the laboratory failed to have newly implemented methods for detection of agents of chemcial terrorism reviewed, approved and signed, dated by the laboratory director before use in patient testing. Findings include: Cross-reference D5401. B. Based on a review of written quality assurance (QA) plan and interview with staff, the laboratory failed to ensure revisions made to the QAP were reviewed, approved, signed and dated by the laboratory director before use in the facility. Findings include: 1. The surveyor reviewed a version of the laboratory QA Plan identified as 'QAP1 Rev: 2.15' dated July 9, 2018. 2. During interview with the technical supervisor and lab director at approximately 5:44pm, there was an admission that revisions made to the lab's QAP during the summer of 2018 were not signed off as approved by the lab director.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: A. Based on a tour of the facility, review of written method procedures and interview with staff, the laboratory failed to ensure all requirements under this standard were addressed when new testing methods for detection of agents of chemical terrorism were obtained from the CDC. Findings include: 1. During a tour of the facility at approximately 3:05pm, the surveyor was informed of a revised methology for detection of Tetramine in urine. 2. When the surveyor asked for evidence of reestablishing method performance characteristics, the technical supervisor was only able to show evidence of successful evaluation of accuracy and precision. 3. There was no evidence the laboratory had considered and documented evaluation of other performance characteristics required in 2(iii) through (vii) of this subpart and the lab director had signed off as accepting the results of the method performance characteristics before patients were tested. 4. During interview with the technical supervisor and lab director at approximately 5:45pm, there was an admission that there was no consideration or evaluation of all performance characteristics when the method was changed by the CDC and the lab director also admitted to not signing off on the results of the performance spectifications to ensure all required characteristics were properly evaluated and performed statisfactory.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of CDC-LRN challenge results, PT Reporting Form documentation and interview with staff, the laboratory director failed to ensure whenever reviews of CDC-LRN challenge results indicated less than accetable performance (less than 80% scores), all appropriate staff were aware of the findings so that an evaluation of the laboratory's performance was conducted and to identify issues and/or problems with the lab's current method and/or process(es) that required corrective action is taken: Findings include: Cross-reference D5217 and D6118.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of CDC-LRN challenge results, PT Reporting Form documentation, laboratory SOPs, the QAP, documentation of re-establishment of performance specifications and interview with staff, the laboratory director failed to ensure the QAP had appropriate established monitoring activities of critical laboratory systems, to ensure: not only the quality of essential laboratory services was provided, to include the general lab, pre-analytic, analytic and post-analytic system and could identify failures in quality as they occurred, and ensured all laboratory instruments and testing methods were available when needed for public emergency situations. Findings include: Cross-reference D5217, D5291, D5401, D5407, D5423, D6115and D6118.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on review of CDC-LRN challenge results, PT Reporting Form documentation and interview with staff, the laboratory director failed to ensure all necessary and appropriate corrective actions were researched, taken and documented whenever major and significant deviations from the lab's established performance characteristics were detected in the laboratory testing methods: Findings include: Cross-reference D5217 and D6118.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2)

	The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of new instrument methods, CDC revised methods and interview with staff, the technical supervisor failed to ensure all performance specifications were adequately addressed and documented whenever new instrumentation was installed and/or revisions were made to existing testing methods prior to patient testing. Findings include: Cross-reference D5423.
D6118	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(5) The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on review of completed PT Reporting Forms and interview with staff, the technical supervisor failed to ensure any technical problems were resolved satisfactorily and appropriate corrective actions were taken when results of CDC-LRN challenges for detection of urinary metals failed to met minimum passing scores (80%) or greater in one of three events in 2018. Findings include: 1. The facility received a score of 75.7% in detection of urine metals; a corrective action was written, however the PT Reporting Form did not address/document: the cause of the failures, resolution of the problem(s) and a re-evaluation of samples tested to determine if the remedial action(s) taken by the lab actually corrected the problem. 2. During interview with the technical supervisor at approximately 4:55pm, there was an admission that the documentation could have been better for this event.