Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D0979344	11/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Office Of Forensic Toxicology Services	90 K Street Ne Suite 102, Washington, DC	

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
D3039	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(5) Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of proficiency testing documents and interview with staff, the laboratory has failed to retain all documented evidence of twice annual accuracy assessments performed for at least two years, as seven of seven testing events of College of American Pathologists (CAP) Urine Drug Confirmation (UDC) Proficiency Testing (PT) surveys, the facility participated in from January 2017 through October 2018, there was no records maintained by the facility that showed how analyte results were obtained. Findings include: 1. The surveyor noted the facility uses quarterly participation in the College of American Pathologists (CAP) Urine Drug Confirmation (UDC) Proficiency Testing (PT) surveys to periodically assess its' urine drug GCMS confirmation testing methology. 2. During 2017 in four of four events (2017 A-D) there was no record of retained CAP UDC PT runs, batch history, worksheet, and result forms, saved by the facility. 3. During 2018 in three of three events (2018 A-C) there was no record of retained CAP UDC PT runs, batch history, worksheet, and result forms, saved by the facility. 4. During an interview with the lab director and technical supervisor at approximately 1:45pm on Nov 27, 2018, there was an admission that records of CAP UDC PT event participation by the facility showing how the results were actually obtained in the same manner as patient specimens were not maintained by the facility.
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 review of proficiency testing (PT) policy, sample testing worksheets and interview with staff, the laboratory failed to establish policy and procedures that ensures positive identification and integrity of College of American Pathologists (CAP) PT specimens from the time of receipt of the survey through completion of testing and reporting of results for one of four CAP PT Urine Drug Confirmatory (UDC) testing events that contained ten (10) specimen testing bottles during 2017. Finding include: 1. The surveyor reviewed Management Instruction: CAP Forensic Urine Drug Testing (Confirmatory) PT dated March 25, 2013 and noted in the section titled 'Receipt of Survey' the following instructions were stated for testing personnel to follow "Upon receipt of the survey a file is created in DTMS using CAP as the Donor ID, CAP as the last name and the survey name (UDCA 2013 for example) as the first name. The specimen bottles can then be assigned specimen numbers (choose new specimen numbers to obtain a DTMS generated 9000 series ID number) and tests." 2. The batch review results worksheet created for CAP UDC 2017-B Event showed the printed labels (Specimen numbers) as 9000-1529 through 1538 created on May, 3, 2017 and each Donor ID was listed as 'CAP, UDCB 2017' for each of ten of ten specimen bottles. There was no further specimen ID delination as to which UDC 2017-B Bottle (identified as 1-10) corresponded to the Specimen numbers 9000-1529 through 1538. 3. During interview with the Technical Supervisor, General Supervisor and Lab Director at approximately 11:00am on November 27, 2018, there was an admission that testing personnel did not always record specific CAP bottle ID numbers along with specimen numbers generated by the LCMS to ensure positive identified and intregity of CAP PT samples testing.
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 review of CAP PT event summary reports, management instructions and interview with staff, the laboratory failed to ensure all results of CAP UDC event results reviewed in five of seven total events reviewed, including: four testing events during 2017 and one event during 2018, were properly evaluated; all analytes the laboratory reported as part of its urine confirmatory testing processes had there accuracy verified at least twice per year, and all results that were identified by CAP as either unsatisfactory and/or unsuccessful had corrective action(s) documented. Finding include: 1. The surveyor reviewed Management Instruction: CAP Forensic Urine Drug Testing (Confirmatory) PT dated March 25, 2013 and noted in the section titled 'Review of Evaluation Report' the following instructions were stated for laboratory staff to follow "The laboratory will review this report and prepare a response. Unacceptable performance on a specimen will be investigated and may include retesting." 2. UDC-A 2017 Event performance scored by CAP as 0/55 0% - Unacceptable; 3. UDC-B 2017 Event performance scored by CAP as 73/94 74% - Unacceptable; 4. UDC-C 2017 Event performance scored by CAP as 17/44 38% - Unacceptable; 5. UDC-D 2017 Event performance scored by CAP as 56/80 70% -

	Unacceptable; 6. UDC-B 2018 Event performance scored by CAP as 65/87 75% - Unacceptable; 7. During interview with the Technical Supervisor, General Supervisor and Lab Director at approximately 9:45am on November 28, 2018, there was an admission that testing personnel had no knowledge of how the CAP event scores were calculated, whether all analytes capable of being confirmed by the facility had their accuracy verified at least twice per year and corrective action was approproate and fully documented as required.
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 laboratory Quality Assurance program (QAP) and interview with staff, the laboratory failed to establish written policies and procedures for montitoring the accuracy of PT/patient specimen labelling and twice annual accuracy verification of UDC analytes not listed in Subpart H of the CLIA regulations to ensure there was an ongoing mechanism to monitor, assess and when indicated, correct problems identified with these non-regulatory reported analytes. Findings include: 1. The surveyor reviewed the facility Total Quality Management (Quality Assurance and Quality Control) program (listed as Chapter Three) identifed as 'FTDTL SOP 2010' and noted while the program on pg 38 lists it's Goals and Objectives, there was no mention of monitoring the accuracy of specimen labeling and patient identification. 2. The QAP failed to list/identify monitoring activities that included the QAP element #6. To provide results that are traceable and accurate while pertinent to the needs of PSA and CSOSA communities.; 3. The QAP failed to list/identify monitoring activities that included the QAP element #7. To provide for the monitoring of internal and external quality control (QC) and to assure the validity of analytic techniques...as a basis for validating data and for the projection of repair, maintenance, and replacement needs and establishment guidelines for the proper preparation, storage, handling...of standars, reagents and glassware.; 4. The QAP failed to list/identify monitoring activities that included the QAP element #8. To demonstrate through documentation that the QC procedures are, in fact, being conducted and ensured the accuracy of the methods, and; 5. The QAP failed to list/identify monitoring activities that included the QAP element #9. To establish quality standards for performance and corrective action (CA) contingencies when these standards are not met. 6. During interview with the Lab Director, Lab General Supervisor and Technical Supervisor at approximately 10:30am on Nov 28, 2018am, there was an admission by staff that the current QAP did not adequatel include monitoring activities to address these failures as they occurred and access failures in quality moving foward.
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 review of laboratory Quality Assurance program (QAP) and interview with staff, the laboratory failed to establish written policies and procedures for monitoring the accuracy of preanalytic system requirements to ensure there was an ongoing mechanism to monitor, assess and when indicated, correct problems identified within the system. Findings include: 1. The surveyor reviewed the facility Total Quality Management (Quality Assurance and Quality Control) program (listed as Chapter Three) identifed as 'FTDTL SOP 2010' and noted while the program on pg 38 lists it's Goals and Objectives, there was no mention of monitoring regulatory preanalytic requirements. 2. During interview with the Lab Director, Lab General Supervisor and Technical Supervisor at approximately 10:40am on Nov 28, 2018am, there was an admission by staff that the current QAP did not include monitoring of possible and/or problematic areas within the lab's preanalytic systems as they occurred and mitigate failures in quality moving foward.
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: Based on review of the QAP and interview with staff, the laboratory failed to have written procedures available for testing personnel to follow that included essential elements of the lab's testing system(s), to ensure all processes are performed uniformily by all staff. Finding include: 1. The surveyor reviewed the facility Total Quality Management (Quality Assurance and Quality Control) program (listed as Chapter Three) identifed as 'FTDTL SOP 2010' and noted there was no detailed step-wise procedures that stated exactly how testing personnel and other pertinent laboratory staff were to handle the following essential requirements within the regulations: a. The receipt, processing, labeling, treatment, analysis, confirmation and reporting of CAP UDC PT samples results; b. Policy, criteria and procedures, to include management reviews, for staff to take when failures in the lab system(s) occur and corrective action(s) are required; c. The laboratory 'Incident Reporting Procedure' date April 5, 2017 defines incidents as "An incident is any unexpected or unplanned occurrence which not normal or accepted operation of the OFTS that can affect the integrity of a test result." is to vague and issues related to the unexpected or unplanned results within CAP UDC PT sample testing and/or the performance of QC and assay calibrations are not included with the procedure; d. The laboratory QAP did not include policy and procedure on how facility pipettes would be verified for accuracy and how often this would be performed. e. The laboratory QAP did not include policy and procedures on how personnel competency would be performed and documented, to include how the laboratory would address the competency of the technical supervisor(s) and general supervisor(s). 2. During interview with the Lab Director, Lab General Supervisor and Technical Supervisor at approximately 1:30pm on Nov 27, 2018am, there was an admission the QAP did not include specific detailed policy /procedures for the regulatory requirements listed herein.
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 review of pipette calibration records and interview with staff, the laboratory failed to have a written procedure in place and criteria of acceptability defined for fourty-nine (49) pipettes used for test resulting reporting. Finding include: 1. The surveyor reviewed in-house pipette caliabration records during 2017 by the Artel PC Pipette Calibration System (PCS) and noted that for 48/49 pipettes in used during 2017 there was one record of pipette # U97010 being calibrated on March 23, 2017. No other records of calibration were available for the other 48 pipettes used in the laboratory during 2017. 2. During interview with the Lab Director, Technical Supervisor and General Supervisor at approximately 3:30pm on Nov 27, 2018, there was an admission to the absence of pipette calibration records in 2017 as well as the absence of a written policy and procedure on pipette calibration. 3. Cross-reference D5401.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on review of the QAP and interview with staff, the laboratory failed to have written procedures available for testing personnel to follow when failures in stated quality measures indicated corrective action were to be initiated to ensure accurate and reliable patient test results and reports. Finding include: 1. The surveyor reviewed the facility Total Quality Management (Quality Assurance and Quality Control) program (listed as Chapter Three) identifed as 'FTDTL SOP 2010' and noted there was section on 'Corrective Action' policy and procedure that must be followed by staff. 2. During interview with the Lab Director, Lab General Supervisor and Technical Supervisor at approximately 4:30pm on Nov 27, 2018am, there was an admission the QAP did not include specific detailed policy/procedures that included corrective action policy and procedures that staff must follow.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must

be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
A. Based on review of CAP UDC PT Evaluation Result sheets, PT corrective action memorandums and interview with staff, the laboratory failed to document appropriate corrective actions in fifteen (15) unacceptable PT results during four testing events (UDC-A through D) in 2017. Finding include: 1. Event UDC-A 2017: a. Specimen UDC-05: Morphine, total (ng/mL by GC-MS) Standard Deviation Index (SDI) result -2.2, graded as Unacceptable; b. Specimen UDC-02: Methylenedioxyamphetam (ng /mL by GC-MS) SDI result -2.3, graded as Unacceptable; c. Specimen UDC-08: Oxymorphone (ng/mL by GC-MS) SDI result -2.,6 graded as Unacceptable; d. Specimen UDC-02: Amphetamine: Reported result=Present; Intended result=Absent, graded as Unacceptable; e. Specimen UDC-02: Methamphetamine: Reported result=Present; Intended result=Absent, graded as Unacceptable; f. The surveyor noted on the written memorandum dated April 22, 2017, there were three corrective actions (CA) listed without statements of the results of CA taken and/or whether the specimens were rerun to determine if the CA was effective and the repeated specimens obtained expected results. 2. Event UDC-B 2017: a. Specimen UDC-11: Methamphetamine (ng/mL by GC-MS) (SDI) result +41.2, graded as Unacceptable; b. Specimen UDC-14: Oxycodone: Reported result=Absent; Intended result=Present, graded as Unacceptable; c. Specimen UDC-14: Oxymorphone: Reported result=Absent; Intended result=Present, graded as Unacceptable; d. Specimen UDC-18: 6-acetylmorphine (6-AM): Reported result=Absent; Intended result=Present, graded as Unacceptable; e. The surveyor noted on the written memorandum, dated July 30, 2017, there were four corrective actions (CA) listed without statements of the results of CA taken and/or whether the specimens were rerun to determine if the CA was effective and the repeated specimens obtained expected results. 3. Event UDC-C 2017: a. Specimen UDC-24: Codeine: Reported result=Present; Intended result=Absent, graded as Unacceptable; b. The surveyor noted on the written memorandum dated September 29, 2017, there was one corrective actions (CA) listed without statements of the results of CA taken and/or whether the specimens were rerun to determine if the CA was effective and the repeated specimens obtained expected results. 4. Event UDC-D 2017: a. Specimen UDC-33: Amphetamine, total (ng/mL by GC-MS) (SDI) result +2.0, graded as Unacceptable; b. Specimen UDC-33: Methamphetamine, total (ng/mL by GC-MS) (SDI) result +2.6, graded as Unacceptable; c. Specimen UDC-38: Methamphetamine: Reported result=Absent; Intended result=Present, graded as Unacceptable; d. Specimen UDC-31: Oxycodone: Reported result=Absent; Intended result=Present, graded as Unacceptable; e. Specimen UDC-34: Oxymorphone: Reported result=Absent; Intended result=Present, graded as Unacceptable; f. The surveyor noted on the written memorandum dated December 28, 2017, there was two corrective actions (CA) listed without statements of the results of CA taken and/or whether the specimens were rerun to determine if the CA was effective and the repeated specimens obtained expected results 5. During interview with the Lab Director and Technical Supervisor and at approximately 10: 00am on Nov 28, 2018, there was an admission from the staff that corrective actions taken for Unacceptable PT specimen results during 2017 were not well documented and no specimens were repeated to confirm CAs taken actually yielded the expected results. B. Based on review of laboratory incident reports and interview with staff, the laboratory failed to document appropriate corrective actions in fourty (40) incident reports written in 2017, that included: nine (9) incidents involving Instrument GCMS

	#6; twelve (12) involving Instrument GCMS #7; twelve (12) involving Instrument GCMS #10; seven (7) involving Instrument GCMS #11; and one (1) on involving Instrument GCMS #4; twenty-five (25) incident reports written in 2018 through the date of the survey, that included: three (3) incidents involving Instrument GCMS #6; seven (7) involving Instrument GCMS #7; twelve (12) involving Instrument GCMS #9; two (2) involving Instrument GCMS #11; and one (1) on involving Instrument GCMS #10, to ensure patient results to be reported were accurate and reliable. Findings include: 1. The sureyor noted the following incident reports from the laboratory Confirmation Unit written during 2017 were not adequately completed to ensure patient results from the batch listed were accurte and reliable before patient test results were released: a. Instrument Involved: GCMS #6: 9 batches affected including: 2165117, 2166617, 2166845, 2167407, 2167985, 2167912, 2168812, 2172974, and 2173946; b. Instrument Involved: GCMS #7: 12 batches affected including: 2168000, 2168699, 2168406, 2168869, 2170024, 2170623, 2170841, 2168319, 2168406, 2168699, 2168319, and 2168869; c. Instrument Involved: GCMS #10: 11 batches affected including: 216652, 2167831, 2165638, 2168778, 2168778 #2, 2170594, 2170815, 2171667, 2172336, 2172627, and 2174077; d. Instrument Involved: GCMS #11: 7 batches affected including: 2168853; 2169638, 2170804, 2171336, 2171643, 2171549, and 2172334; e. Instrument Involved: GCMS #4: 1 batch affected: 2165607. 2. The sureyor noted the following incident reports from the laboratory Confirmation Unit written during 2018 were not adequately completed to ensure patient results from the batch listed were accurte and reliable before patient test results were released: a. Instrument Involved: GCMS #6: 3 batches affected including: 2176238; 2177504, and 2178148; b. Instrument Involved: GCMS #7: 7 batches affected including: 2176029, 2148077, 2175752, 2175936, 2175586, 2175392, and 2175238; c. Instrument Involved: GCMS #9: 12 batches affected including: 2176325, 2179102, 2176571, 2176195, 2175796, 2175463, 2176082, 2176534, 2185259, 2185519, 2186409, and 2176534; d. Instrument Involved: GCMS #10: 1 batch affected: 2175150; e. Instrument Involved: GCMS #11: 2 batches affected including: 2176530 and 2176249. 3. During interview with the Lab Director and techical supervisor at approximately 4:30pm on November 28, 2018, there was an admission that written incident reports from 2017 and 2018 through the date of the survey were not fully completed to ensure corrective actions were appropriate and follow-up as necessary was conducted to ensure changes made did not reoccur and patient results were accurate and reliable.
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 laboratory Quality Assurance program (QAP) and interview with staff, the laboratory failed to establish written policies and procedures for monitoring the accuracy of analytic system requirements to ensure there was an ongoing mechanism to monitor, assess and when indicated, correct problems identified within the system. Findings include: 1. The surveyor reviewed the facility Total Quality Management (Quality Assurance and Quality Control) program (listed as Chapter Three) identifed as 'FTDTL SOP 2010' and noted while the program on pg 38 lists it's

	Goals and Objectives, there was no mention of monitoring regulatory analytic requirements. 2. During interview with the Lab Director, Lab General Supervisor and Technical Supervisor at approximately 10:50am on Nov 28, 2018am, there was an admission by staff that the current QAP did not include monitoring of possible and/or problematic areas within the lab's analytic systems as they occurred and mitigate failures in quality moving foward. 3. Cross-reference D5291 and D5783.
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 laboratory Quality Assurance program (QAP) and interview with staff, the laboratory failed to establish written policies and procedures for monitoring the accuracy of postanalytic system requirements to ensure there was an ongoing mechanism to monitor, assess and when indicated, correct problems identified within the system. Findings include: 1. The surveyor reviewed the facility Total Quality Management (Quality Assurance and Quality Control) program (listed as Chapter Three) identifed as 'FTDTL SOP 2010' and noted while the program on pg 38 lists it's Goals and Objectives, there was no mention of monitoring regulatory postanalytic requirements. 2. During interview with the Lab Director, Lab General Supervisor and Technical Supervisor at approximately 11:00am on Nov 28, 2018am, there was an admission by staff that the current QAP did not include monitoring of possible and/or problematic areas within the lab's postanalytic systems as they occurred and mitigate failures in quality moving foward.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedures, incident reports and PT summary reports, the laboratory director failed to have adequate policy and procedures written and established to ensure testing personnel were performing urine drug confiration testing methods as required for accurate and reliable patient results. Finding include: Cross-reference: D5401
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 laboratory policy and procedures, incident reports and PT summary reports, the laboratory director failed to have CAP UDC PT summary reports reviewed by all staff involved in the production of the results, when results of the event reports indicated unsatisfactory or unsuccessful PT performance. Finding include: Cross-reference: D5221 and D5779.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedures, incident reports and PT summary reports, the laboratory director failed to ensure approved corrective actions were initiated and followed for all unsatisfactory and/or unsuccessful identified PT results. Finding include: Cross-reference: D5779 and D5783.
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 laboratory procedures and the QAP, the laboratory director failed to have a written and established quality assessment program for urine drug screening assays and confirmatory methods to assure the quality of those services provided and to identify failures in quality as they occur. Finding include: Cross-reference: D5281, D5391, D5791 and D5891.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedures, the QAP and written incident reports, the laboratory director failed to specify in writing, the responsibility and duties of each technical and general supervisor, as well as all testing personnel and other pertinent staff engaged in the performance of preanalytic, analytic and/or postanalytic phases of testing for both urine drug screening assays and confirmations, that identified and listed which exmainations and procedures each individual is

	authorized and competent to perform and whether supervision is required in performance of the permitted tasks, to include all phases of patient testing. Finding: 1. The surveyor reviewed the procedure manual and QAP and noted there was no delegation of duties or assignment in writing of specific responsiblities of each supervisor and all testing personnel and other staff involved in the performance of patient urine drug screening and confirmations as required in this subpart. 2. This finding was admitted to by the lab director during an interview at approximately 3: 30pm on Nov 28, 2018.
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 laboratory policy and procedures, incident reports and PT summary reports, the technical supervisor failed to ensure technical problems when encountered in the performance of batch runs for both patient testing and/or PT samples, were adequately resolved, when testing instrumentation was found to have deviated from the laboratory's established performance spectifications. Finding include: Cross-reference: D5221 and D5783.
D6119	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(6) The technical supervisor is responsible for ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedures, incident reports and PT summary reports, the technical supervisor failed to ensure patient resultswere not released until all corrective actions were taken, approved and the testing instrumentation was determined to be functioning with established performance specifications. Finding include: Cross-reference: D5221 and D5783.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedures, annual employee competency

	assessments, incident reports and PT summary reports, the technical supervisor failed to ensure staff involved in recurring technical problems with urine drug confirmation testings were identified for additional and /or retraining, in-services and/or further education for the performance of testing on GCMS instruments. Finding include: 1. The surveyor reviewed testing personnel competency testing records for 2017 and noted there was none documented for ten of eleven testing personnel listed as performing drug toxicology confirmation testing by GCMS methods. 2. During interview with the lab director and technical supervisor at approximately 3:00pm on Nov 27, 2018, there was an admission that no staff competency testing was documented during 2017. 3. Cross-reference: D5221 and D5783.