Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2117278	02/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Toxicology Center	3705 W Memorial Rd Suite 305, Oklahoma City, OK	

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	The survey was performed on 2/12,13,14/18 The findings were reveiwed with the technical supervisor and testing person #1 at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 493.1213; D5022: Toxicology 493.1441; D6076: Laboratory Director 493.1447; D6108: Technical Supervisor
D5022	TOXICOLOGY CFR(s): 493.1213 If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records, procedure manuals, manufacturer's instructions, and interview with the general supervisor, technical supervisor, and testing person #1, the laboratory failed to ensure the requirements were met for the subspecialty of Toxicology. Findings include: (1) The laboratory failed to verify the accuracy of testing at least twice annually. Refer to D5217; (2) The laboratory failed to have a written procedure for specimen submission, handling and processing. Refer to D5311; (3) The laboratory failed to provide written instructions to clients collecting and referring urine drug specimens. Refer to D5317; (4) The laboratory failed to have written procedures for the analytical phase of testing. Refer to D5403; (5) The laboratory failed to ensure an analyzer was stored as required by the manufacturer. Refer to D5413; (6) The laboratory failed to verify the acceptable performance of the laboratory computer system. Refer to D5421; (7) The laboratory failed to establish analytical specificity and validate specimen integrity for urine and saliva drug testing. Refer to D5423; (8) The laboratory failed to define a function check protocol to ensure the centrifuge was functioning properly. Refer to D5435; (9) The laboratory

	failed have an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
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 records and interview with the technical supervisor and testing person #1, the laboratory failed to ensure the accuracy of testing was verified at least twice annually. Findings include: (1) On the first day of the survey, testing person #1 stated to surveyor #2 the laboratory began performing urine drug testing using the AB Sciex Triple Quad 4500 LCMS (liquid chromatography-mass spectrometry) analyzer (see below for drugs tested) on 10/04/16; (2) On the second day of the survey, the surveyors reviewed records for testing performed in 2016 and 2017 and identified the accuracy of the testing had not been verified twice annually between 10/19/16 and 10 /26/17; (3) The surveyors reviewed the records with the technical supervisor and testing person #1, who stated the accuracy of urine drug testing had not been verified twice in 2017. LCMS testing includes the following drugs: 6MAM (Monoacetylmorphine), 7-Aminoclonazepam, Acetaminophen, Alpha Hydroxyalprazolam, Alprazolam, Amitriptyline, Amphetamine, Benzyolecgonine, Buprenorphine, Carisoprodol, Clonazepam, Codeine, Cotinine, Dextromethorphan, Dextrorphan, Duloxetine, EDDP (Methadone Metabolite), Ethyl-glucuronideuornide, Fentanyl, Gabapentin, Hydrocodone, Hydromorphone, Hydromorphone-Glucuronide, Lorazepam Glucuronideuronide, MDA(3,4-ethylenedioxyamphetamine), MDEA (3,4-methylenedioxy-N-ethylamphetamine), MDMA(methylenedioxymethamphetamine), Meperidine, Meprobamate, Methadone, Methamphetamine, Methylphenidate, Morphine, Morphine-Glucuronide, Naloxone-Glucuronideuronide, Norbuprenorphine, Norbuprenorphine-Glucuronide, Nordiazepam, Norfentanyl, Norhydrocodone, Norketamine, Normeperidine, Noroxycodone, Nortriptyline, O-desmethylvenlafaxine, Oxazepam-Glucuronide, Oxycodone, Oxymorphone, Oxymorphone-Glucuronide, PCP (Phencyclidine), Pentazocine, Phentermine, Pregabalin, Propoxyphene, Ritalinic Acide, Tapentadol, Tapentadol-glucuronide, Temazepam, Temazepam-Glucuronide, THC-COOH (Tetrahydrocannabinol-9-carboxylic acid), THC-COOH-Glucuronide, Tramadol, Venlafaxine, Zolpidem, and Zolpidem P4CA
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 the procedure manual, and interview with the general supervisor, technical supervisor and testing person #1 the laboratory failed to have a

	written procedure for specimen submission, handling and processing. Findings include: (1) On the first day of the survey, surveyor #2 reviewed the procedure manual. A specimen submission, handling and processing procedure could not be located for urine or saliva samples received in the laboratory for testing; (2) Surveyor #2 explained to the general supervisor, technical supervisor and testing person #1 that a specimen submission, handling and processing procedure could not be located. The general supervisor, technical supervisor and testing person #1 stated that a procedure had not been written.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on an interview with the technical supervisor and testing person #1, the laboratory failed to provide written instructions to clients collecting and referring urine drug specimens. Findings include: (1) On the first day of the survey, testing person #1 stated the following to surveyor #2: (a) The laboratory began performing urine drug testing using the AB Siex Triple Quad 4500 LCMS (liquid chromatography-mass spectrometry) analyzer on 10/04/16 (see below for drugs tested); (b) The urine specimens were transported to the laboratory from two outside clinics. (2) Surveyor #2 asked testing person #1 if instructions (e.g., client service manual) had been written and provided to the two clients which would explain the laboratory's specimen handling policies (e.g., collection, preservation, storage, transport, testing schedule times, and how to obtain additional assistance for unusual circumstances). Testing person #1 stated specimen handling instructions had not been written and provided to the clients. LCMS testing includes the following drugs: 6MAM (Monoacetylmorphine), 7-Aminoclonazepam, Acetaminophen, Alpha Hydroxyalprazolam, Alprazolam, Amitriptyline, Amphetamine, Benzyolecgonine, Buprenorphine, Carisoprodol, Clonazepam, Codeine, Cotinine, Dextromethorphan, Dextrorphan, Duloxetine, EDDP (Methadone Metabolite), Ethyl-glucuronideuornide, Fentanyl, Gabapentin, Hydrocodone, Hydromorphone, Hydromorphone-Glucuronide, Lorazepam Glucuronideuronide, MDA(3,4-ethylenedioxyamphetamine), MDEA (3,4-methylenedioxy-N-ethylamphetamine), MDMA(methylenedioxymethamphetamine), Meperidine, Meprobamate, Methadone, Methamphetamine, Methylphenidate, Morphine, Morphine-Glucuronide, Naloxone-Glucuronideuronide, Norbuprenorphine, Norbuprenorphine-Glucuronide, Nordiazepam, Norfentanyl, Norhydrocodone, Norketamine, Normeperidine, Noroxycodone, Nortriptyline, O-desmethylvenlafaxine, Oxazepam-Glucuronide, Oxycodone, Oxymorphone, Oxymorphone-Glucuronide, PCP (Phencyclidine), Pentazocine, Phentermine, Pregabalin, Propoxyphene, Ritalinic Acide, Tapentadol, Tapentadol-glucuronide, Temazepam, Temazepam-Glucuronide, THC-COOH (Tetrahydrocannabinol-9-carboxylic acid), THC-COOH-Glucuronide, Tramadol, Venlafaxine, Zolpidem, and Zolpidem P4CA
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 policy and procedure manual and interview with the technical supervisor and testing person #1, the laboratory failed to have written procedures for the analytical phase of testing. Findings include: (1) On the first day of the survey, surveyor #2 reviewed the laboratory policy and procedure manual. The following could not be located: (a) The reportable range for toxicology analytes; (b) Control procedures for testing performed on the AB Sciex Triple Quad 4500 analyzer (i.e., explanation of levels used, frequency of testing, how control results are evaluated for acceptability); (c) The corrective action policy for unacceptable toxicology control results; (d) Reference intervals for toxicology analytes; (e) Imminently life-threatening test results, or panic values for toxicology analytes; (f) The system for entering results in the patient record and reporting results for all test systems; (g) Column change validation. (2) On the second day of the survey, the surveyors reviewed the findings with the technical supervisor and testing person #1, and asked if the above policies and procedures were available. The technical supervisor and testing person #1 stated the policies and procedures had not been written.
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 records, manufacturer's instructions, and interview with testing person #1, the laboratory failed to ensure an analyzer was stored as required by the manufacturer. Findings include: (1) On the first day of the survey, testing person #1 stated to surveyor #2 urine drug testing testing was performed on the AB Sciex Triple Quad 4500 LCMS (Liquid Chromatography-Mass Spectrometry) analyzer; (2) On the

	second day of the survey, surveyor #2 reviewed the manufacturer's environmental requirements for the analyzer. The manufacturer required the relative humidity be maintained within the range of 20-80% (3) Surveyor #2 reviewed laboratory humidity records from November 2016 through February 2018 which verified the humidity readings were less than 20% for 10 of 15 months as follows: (a) November 2016 - 1 of 30 humidity readings were documented as less than 20% (day 29); (b) December 2016 - 4 of 31 humidity readings were documented as less than 20% (days 13,19,20,21); (c) January 2017 - 14 of 31 humidity readings were documented as less than 20% (days 5,9,11,12,13,16,17,18,23,24,25,27,30,31); (d) February 2017 - 12 of 28 humidity readings were documented as less than 20% (days 1,2,3,6,7,8,9,13,14,15,16,17); (e) March 2017 - 4 of 31 days humidity ranges were documented as less than 20% (days 3,7,8,15); (f) October 2017 - 2 of 31 days humidity ranges were documented as less than 20% (days 9,11); (g) November 2017 - 1 of 30 days humidity ranges were documented as less than 20% (day 8); (h) December 2017 - 2 of 31 days humidity ranges were documented as less than 20% (days 13,14); (i) January 2018 - 3 of 31 days humidity ranges were documented as less than 20% (days 8,9,15); (j) February 2018- 3 of 28 days humidity ranges were documented as less than 20% (days 2,7,12); (4) The surveyors reviewed the records with testing person #1 who stated the humidity of the laboratory had been maintained below 20% as indicated above; (5) Refer to D5423 for examples of patient testing performed when the humidity had not been maintained as required.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical supervisor and testing person #1, the laboratory failed to verify the acceptable performance of the laboratory computer system. Findings include: (1) On the first day of the survey, testing person #1 verified to surveyor #2 the laboratory began patient urine drug testing on 10/04/16, which included installing the Lab Daq laboratory information system (LIS); (2) On the third day of the survey, the surveyors asked the technical supervisor and testing person #1 for documentation to prove the laboratory ensured the LIS performed acceptably before it was put into use; (3) The technical supervisor and testing person #1 were not able to locate records and stated to the surveyors there was no documentation to substantiate the laboratory had determined the acceptable performance of the new LIS when it was installed.
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:
Based on a review of records and interview with the technical supervisor and testing person #1, the laboratory failed to establish analytical specificity and validate specimen integrity for urine and saliva drug testing. Findings include: (1) On the first day of the survey, testing person #1 stated to the following to surveyor #2: (a) The laboratory began performing drug testing using the AB Sciex Triple Quad 4500 LCMS (liquid chromatography-mass spectrometry) analyzer on 05/16/17 (saliva testing) and 10/04/16 (urine testing) (see below for drugs tested); (b) The urine specimens were brought (in an ice-chest) to the laboratory in a Sarsdedt 5 ml pour off tube from two outside clinics, transported in a vehicle by courier at room temperature; (c) The saliva specimens were brought to the laboratory in a collection kit (Quantisal Oral Fluid Collection) from two outside clinics, transported in a vehicle by courier at room temperature; (d) On the day a specimen(s) was received in the laboratory, it was tested on the analyzer if time allowed. If testing could not be performed on the day of receipt, a specimen(s) would be tested following storage in the laboratory refrigerator. The specimen would be stored for up to 1 week prior to testing. (2) The surveyors asked the technical supervisor and testing person #1 if a validation had been performed to ensure urine and saliva specimens tested on the AB Sciex Triple Quad 4500 LCMS analyzer maintained their integrity from the point of collection through the day of testing. The technical supervisor and testing person #1 stated a specimen integrity validation had not been performed on site; (3) The following are examples of patient urine drug testing performed: (a) Patient #1 - testing performed on 11/14/16 (b) Patient #2 - testing performed on 11/29/16 (c) Patient #3 - testing performed on 12 /05/16 (d) Patient #4 - testing performed on 12/13/16 (e) Patient #5- testing performed on 01/17/17 (f) Patient #6 - testing performed on 01/20/17 (g) Patient #7 - testing performed on 01/25/17 (h) Patient #8 - testing performed on 01/30/17 (i) Patient #9 - testing performed on 02/01/17 (j) Patient #10 - testing performed on 02/08/17 (k) Patient #11 - testing performed on 02/13/17 (l) Patient #12 - testing performed on 02 /20/17 (m) Patient #13 - testing performed on 03/01/17 (n) Patient #14 - testing performed on 03/08/17 (o) Patient #15 - testing performed on 03/15/17 (p) Patient #16 - testing performed on 03/22/17 (q) Patient #17 - testing performed on 03/31/17 (r) Patient #18 - testing performed on 04/05/17 (s) Patient #19 - testing performed on 04 /12/17 (t) Patient #20 - testing performed on 04/26/17 (u) Patient #21 - testing performed on 05/10/17 (v) Patient #22 - testing performed on 05/24/17 (w) Patient #23 - testing performed on 06/05/17 (x) Patient #24 - testing performed on 06/14/17 (y) Patient #25 - testing performed on 06/21/17 (z) Patient #26 - testing performed on 07/06/17 (aa) Patient #27 - testing performed on 07/18/17 (bb) Patient #28 - testing performed on 08/07/17 (cc) Patient #29 - testing performed on 08/21/17 (dd) Patient #30 - testing performed on 09/11/17 (ee) Patient #31 - testing performed on 09/19/17 (ff) Patient #32 - testing performed on 10/09/17 (gg) Patient #33 - testing performed on 10/17/17 (hh) Patient #34 - testing performed on 12/06/17 (ii) Patient #35 - testing performed on 12/14/17 (jj) Patient #36 - testing performed on 01/01/18 (kk) Patient #37 - testing performed on 01/30/18 (ll) Patient #38 - testing performed on 02/05/18 (4) The following is an example of a patient saliva drug test performed: (a) Patient

	#39 - testing performed on 05/16/17 LCMS testing includes the following drugs: 6MAM (Monoacetylmorphine), 7-Aminoclonazepam, Acetaminophen, Alpha Hydroxyalprazolam, Alprazolam, Amitriptyline, Amphetamine, Benzyolecgonine, Buprenorphine, Carisoprodol, Clonazepam, Codeine, Cotinine, Dextromethorphan, Dextrorphan, Duloxetine, EDDP (Methadone Metabolite), Ethyl-glucuronideuornide, Fentanyl, Gabapentin, Hydrocodone, Hydromorphone, Hydromorphone-Glucuronide, Lorazepam Glucuronideuronide, MDA(3,4-ethylenedioxyamphetamine), MDEA (3,4-methylenedioxy-N-ethylamphetamine), MDMA(methylenedioxymethamphetamine), Meperidine, Meprobamate, Methadone, Methamphetamine, Methylphenidate, Morphine, Morphine-Glucuronide, Naloxone-Glucuronideuronide, Norbuprenorphine, Norbuprenorphine-Glucuronide, Nordiazepam, Norfentanyl, Norhydrocodone, Norketamine, Normeperidine, Noroxycodone, Nortriptyline, O-desmethylvenlafaxine, Oxazepam-Glucuronide, Oxycodone, Oxymorphone, Oxymorphone-Glucuronide, PCP (Phencyclidine), Pentazocine, Phentermine, Pregabalin, Propoxyphene, Ritalinic Acide, Tapentadol, Tapentadol-glucuronide, Temazepam, Temazepam-Glucuronide, THC-COOH (Tetrahydrocannabinol-9-carboxylic acid), THC-COOH-Glucuronide, Tramadol, Venlafaxine, Zolpidem, and Zolpidem P4CA
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, policy and procedure manual, and interview with the technical supervisor and testing person #1, the laboratory failed to define a function check protocol to ensure the centrifuge was functioning properly. Findings include: (1) On the first day of the survey, testing person #1 verified the Thermo Legend Micro 21r centrifuge was used to process urine specimens for urine drug testing at a speed of 2100 rpm (Revolutions Per Minute) and a time of 10 minutes; (2) On the second day of the survey, the surveyors asked testing person #1 to explain how often function checks (speed and timer checks) were performed and documented on the centrifuge. Testing person #1 stated the laboratory did not have a policy to check the speed and timer of the centrifuge and function checks had not been performed on the urine centrifuge; (3) Refer to D5423 for examples of patient urine drug testing performed when function checks had not been performed on the centrifuge. .
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 a review of records, procedure manuals, manufacturer's instructions, and interview with the general supervisor, technical supervisor, and testing person #1 the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to have written procedures for the analytical phase of testing. Refer to D5403; (b) The laboratory failed to ensure an analyzer was stored as required by the manufacturer. Refer to D5413; (c) The laboratory failed to verify the acceptable performance of the laboratory computer system. Refer to D5421; (d) The laboratory failed to establish analytical specificity and validate specimen integrity for urine and saliva drug testing. Refer to D5423; (e) The laboratory failed to define a function check protocol to ensure the centrifuge was functioning properly. Refer to D5435.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, procedure manuals, manufacturer's instructions, and interview with the general supervisor, technical supervisor and testing person #1, the laboratory director failed to provide overall management and direction for high complexity testing. Findings include: (1) The laboratory director failed to ensure that testing systems developed and performed in the laboratory provided quality laboratory services for all aspects of test performance to include the preanalytic and analytic phases of testing. Refer to D6082; (2) The laboratory director failed to ensure verification procedures were adequate to determine the performance characteristics. Refer to D6086; (3) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6093; (4) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6094; (5) The laboratory director failed to ensure policies and procedures had been written. Refer to D6106.
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 a review of records, manufacturer's instructions, and interview with the technical supervisor and testing person #1, the laboratory director failed to ensure that testing systems developed and performed in the laboratory provided quality laboratory services for all aspects of test performance to include the preanalytic and analytic

	phases of testing. Findings include: (1) The laboratory director failed to ensure the laboratory provided written instructions to clients collecting and referring urine drug specimens. Refer to D5317; (2) The laboratory director failed to ensure an analyzer was stored as required by the manufacturer. Refer to D5413.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical supervisor and testing person #1, the laboratory director failed to ensure verification procedures were adequate to determine the performance characteristics. Findings include: (1) The laboratory director failed to ensure the acceptable performance of the laboratory computer system was verified. Refer to D5421; (2) The laboratory director failed to ensure analytical specificity and specimen integrity were validated for urine and saliva drug testing. Refer to D5423.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 a review of records, policy and procedure manual, and interview with the technical supervisor and testing person #1, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Findings include: (1) The laboratory director failed to ensure the accuracy of testing was verified at least twice annually. Refer to D5217; (2) The laboratory director failed to define a function check protocol to ensure the centrifuge was functioning properly. Refer to D5435.
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 a review of records, procedure manuals, manufacturer's instructions, and interview with general supervisor, technical supervisor, and testing person #1, the laboratory director failed to ensure a quality assessment program had been established

	and maintained. Findings include: (1) The laboratory director failed to ensure there was an effective mechanism for performing quality assessment due to the issues identified during the survey. Refer to D5791.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on a review of the procedure manual, and interview with the general supervisor, technical supervisor and testing person #1, the laboratory director failed to ensure policies and procedures had been written. Findings include: (1) The laboratory director failed to ensure a procedure had been written for specimen submission, handling and processing. Refer to D5311; (2) The laboratory director failed to ensure procedures had been written for the analytical phase of testing. Refer to D5403.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, procedure manuals, manufacturer's instructions, and interview with the general supervisor, technical supervisor and testing person #1, the technical supervisor failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical supervisor failed to ensure that verification procedures were adequate to determine the performance characteristics. Refer to D6115; (2) The technical supervisor failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Refer to D6117; (3) The technical supervisor failed to ensure persons were evaluated at least semiannually during the first year of performing high complexity testing. Refer to D6127.
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 a review of records and interview with the technical supervisor and testing person #1, the technical supervisor failed to ensure that verification procedures were adequate to determine the performance characteristics. Findings include: (1) The technical supervisor failed to ensure the acceptable performance of the laboratory

	computer system was verified. Refer to D5421; (2) The technical supervisor failed to ensure analytical specificity and specimen integrity were validated for urine and saliva drug testing. Refer to D5423.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on a review of records, policy and procedure manuals, manufacturer's instructions, and interview with the general supervisor, technical supervisor and testing person #1, the technical supervisor failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Findings include: (1) The technical supervisor failed to ensure the accuracy of testing was verified at least twice annually. Refer to D5217; (2) The technical supervisor failed to ensure a procedure had been written for specimen submission, handling and processing had been written. Refer to D5311; (3) The technical supervisor failed to ensure written instructions were provided to clients collecting and referring urine drug specimens. Refer to D5317; (4) The technical supervisor failed to ensure procedures had been written for the analytical phase of testing. Refer to D5403; (5) The technical supervisor failed to ensure an analyzer was stored as required by the manufacturer. Refer to D5413; (6) The technical supervisor failed to define a function check protocol to ensure the centrifuge was functioning properly. Refer to D5435.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical supervisor and testing person #1, the technical supervisor failed to ensure persons were evaluated at least semiannually during the first year of performing high complexity testing. Findings include: (1) On the first day of the survey, surveyor #2 reviewed personnel records. The following was identified for 2 of 2 testing persons: (a) Testing Person #1 - This person completed initial training 06/29/16 and annual training 12/21/17. There was no evidence that a semiannual evaluation had been performed. (b) Testing Person #2 - This person completed initial training 06/29/16 and annual training 12/29/17. There was no evidence that a semiannual evaluation had been performed. (2) Surveyor #2 reviewed the findings with the technical supervisor and testing person #1 who stated semiannual evaluations had not been performed.