Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1101214	03/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Coba Toxicology Llc	218 W Nasa Parkway Suite A, Webster, TX	

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 laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D5022 - 42 C.F.R. 493.1213 Condition: Toxicology D5300 - 42 C.F.R. 493.1240 Condition: Pre-Analytic Systems D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6076 - 42 C.F.R. 493.1441 Condition: Laboratory Director; high complexity Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 review of the laboratory's records, and staff interview, it was revealed the laboratory failed to meet the requirements for the subspecialty of toxicology. The findings were: 1. The laboratory failed to have documentation of monitoring the correct freezer, room temperature or humidity range. (refer to D5413). 2. The laboratory failed to have documentation of performing complete preanalytical establishment studies (refer to D5311). 3. The laboratory failed to have documentation

	of performing calibration verification (refer to D5439). 4. The laboratory failed to have documentation of monitoring quality control values for immediate error (refer to D5441). 6. The laboratory failed to have documentation of a quality assessment plan that could identify and correct problems (refer to D5391).
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 College of American Pathologists (CAP) laboratory proficiency testing records, laboratory policy, and confirmed in interview, the laboratory failed to document a self-evaluation for the proficiency testing not graded by the proficiency testing program. Findings were: 1. Review of the CAP Actions Laboratories Should Take when a PT result is Not graded (Rev 03/2011) revealed: "27 = lack of participant or referee consensus Action required Document that the laboratory performed a self-evaluation and compared its results to the intended responses when provided in the Participant Summary. If comparison is not available, perform and document alternative assessment (i.e., split samples) for the period that commercial PT reached non-consensus to the same level and extent that would have been tested." 2. Review of the laboratory policy Proficiency Testing effective August 2009 under Procedure for assessing Ungraded PT Performance revealed "Review the participant summary report and assess performance by evaluating the 'submitted result' to the intended result." 3. Review of the laboratory proficiency testing from 2016 and 2017 revealed 3 of 4 events for Pharmacogenetics (PGX) with no documentation of the self-evaluation for a grade of [27]. PGX-A 2017 Pharmacogenetics - reviewed 10/4/17 CYP2D6 Gene Duplication Specimen lab result Grade PGX-02 no [27] PGX-03 no [27] PGX-A 2016 Pharmacogenetics reviewed 8 /12/16 CYP2D6 specimen lab result grade PGX-02 CYP2D6*4 [27] CYP2D6*5 PGX-03 CYP2D6*2 [27] CYP2D6*5 PGX-B 2016 Pharmacogenetics no review date documented CYP2D6 specimen lab result grade PGX-05 CYP2D6*1 [27] CYP2D6*2 [27] 4. Review of the laboratory proficiency testing from 2016 and 2017 revealed 1 of 4 events for Urine Drug Adulterant with no documentation of the self-evaluation for a grade of [27]. DAI-A 2016 Urine Drug Adulterant reviewed 5/6/16 Oxidants specimen lab result Grade DAI-01 positive [27] 5. An interview with the lab director on 03/26/18 at 1030 hours in the laboratory confirmed the above findings.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Based on review of laboratory policy, manufacturer's instructions and random review of patient testing requisitions and results, the laboratory failed to meet the requirements for the preanalytical phase of testing as evidenced by: 1. The laboratory failed to have documentation of performing studies to support its pre-analytic samples stability claims (refer to D5311). 2. The laboratory failed to ensure a complete client services manual was provided to its clients. (refer to D5317) 3. The laboratory failed to have an effective QA (quality assessment) system in place to identify and correct problems for the toxicology testing (refer to D5391)
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: A. Based on observations, review of laboratory policies, laboratory records, and confirmed in interview, the laboratory failed to provide documentation to support the preanalytical requirements for the urine toxicology patient testing for the Water Aquity TQD UPLC/MS/MS (High-performance liquid chromatography mass spectrometry). Findings were: 1. A review of the laboratory records revealed the laboratory performed patient testing for the following analytes on the Water Aquity TQD UPLC/MS/MS: 38 drug panel urine: Morphine Oxymorphone Hydromorphone Naloxone Codeine Oxycodone Naltrexone Hydrocodone Methylone 6-acetyllmorphine Methampetamine Amphetamine MDA (3,4-Methylenedioxyamphetamine) O-Des-Tramadol MDMA (3,4-Methylenedioxymethamphetamine) MDEA(Methylenedioxyethylamphetamine) Benzolecgonine Ritalinic Acid Meperidine Tramadol Methylphenidate MDPV (Methylenedioxypyrovalerone) Tapentadol LSD (Lysergic acid diethylamide) EDDP (metabolite of Methadone) Mephedrone PCP (Phencyclidine) Meprobamate Fentanyl Tapentadol Buprenorphine Norbuprenorphine Alpha-hydrox Carisoprodol Methadone Lorazepam Oxazepam Temazepam Nordiazepam 2. Surveyor observations on 03/27 /18 at 0840 hours in the laboratory revealed testing person #1 processed frozen urine specimens under the laboratory biosafety hood. Several different sample cups (Discover Plus POCT cups, orange top sterile urine cups, white top sterile urine cups) were observed with various collection dates from 03/20/18, 03/21/18 and 03/24/18. An interview with the TP#1 on 03/27/18 at 0855 hours in the laboratory revealed the observed specimens were received in the laboratory on 03/26/18 and stored frozen in the original specimen containers overnight. Specimen Id Date of collection 52071 03 /20/18 52026 03/20/18 52070 03/20/18 52074 03/21/18 52072 03/20/18 52073 03/20 /18 52075 03/20/18 3. The laboratory was asked for preanalytical studies for the various sample cups at frozen, refrigerated, and room temperature for the above analytes. The laboratory was asked for preanalytical studies to include the shipping conditions the laboratory used for specimen handling. No documentation was provided. 4. An interview with the lab director on 03/26/18 at 1115 hours confirmed the above findings. He acknowledged that the laboratory should perform stability studies to include all the specimen cups, all temperature storage, and shipping

	conditions. B. Based on review of laboratory policies, laboratory records, patient final reports, and confirmed in interview, the laboratory failed to provide documentation to support the preanalytical requirements for the Applied Biosystems Quan Studio 7 Flex patient testing. Findings were: 1. Review of the laboratory policy High-throughput isolation of PCR-ready DNA from buccal cells using the MagMax DNA Mutli-sample Ultra Kit revealed under sample collection and storage (buccal cells) "samples can be stored: at room temperature or 4 C overnight in the doctor office or our facility. At -20 C for up to several weeks in our facility." 2. Review of the laboratory Applied Biosystem Quan Studio 7 Flex specimen stability records revealed the laboratory performed a 6-day stability study at room temperature in 2016. No documentation was provided for a refrigerator and/or freezer stability study. 3. Random review of patient test records from June 2017 - October 2017 revealed 19 of 24 specimens that were documented as performed past the 6-day stability. Patient IDdate collected received date testing performed 2034 09/19/2017 09/28/2017 10/16/2017 elapsed time in days 27 2043 09/25/2017 09/28/2017 10/16/2017 elapsed time in days 21 2044 09/25/2017 09/28/2017 10/16/2017 elapsed time in days 21 2045 09/25/2017 09/28/2017 10/16 /2017 elapsed time in days 21 2736 08/10/2017 not provided 10/16/2017 elapsed time in days 67 64 08/14/2017 not provided 10/16/2017 elapsed time in days 63 2080 09/06 /2017 09/08/2017 10/16/2017 elapsed time in days 40 2759 09/12/2017 09/15/2017 10 /16/2017 elapsed time in days 34 1883 08/09/2017 08/15/2017 10/02/2017 elapsed time in days 54 2732 08/09/2017 08/15/2017 10/02/2017 elapsed time in days 54 2734 08/09/2017 not provided 10/02/2017 elapsed time in days 54 2764 08/10/2017 not provided 10/02/2017 elapsed time in days 53 1168 06/20/2017 06/26/2017 07/03 /2017 elapsed time in days 13 1169 06/20/2017 06/26/2017 07/03/2017 elapsed time in days 13 1441 06/21/2017 06/26/2017 07/03/2017 elapsed time in days 12 723 06/16 /2017 06/26/2017 07/03/2017 elapsed time in days 17 2091 10/11/2017 10/13/2017 11 /20/2017 elapsed time in days 40 2326 10/17/2017 10/20/2017 11/20/2017 elapsed time in days 34 2340 10/19/2017 10/23/2017 11/20/2017 elapsed time in days 32 4. The laboratory was asked for a stability study for 67 days after the collection date. The laboratory was asked for a refrigerated and freezer specimen stability study. No documentation was provided. 5. An interview with the testing person #3 on 3/27/18 at 1110 hours confirmed that once she received the patient swabs, she stores them in the refrigerator until testing is performed. According to the CMS-116 signed by the laboratory director on 3/9/18, the facility performed 231000 tests in toxicology and 350 PGX annually key: CMS - Centers for Medicare and Medicaid Services
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 review of the laboratory's client service manual and confirmed in interview, the laboratory failed to provide the appropriate specimen handling for urine samples to their clients. (specimen handling) Findings were: 1. A review of the laboratory's policy Specimen collection and submission instructions Urine Collection Procedure revealed no documentation of information on specimen handling to include the storage temperature pior to shipment or during shipment and/or the testing stability for urine patient testing. (cross refer to D5311) 2. An interview with the lab director on 03/26/18 at 1045 hours in the laboratory confirmed the above findings. He

	acknowledged that the laboratory should have a client services manual should include instructions for specimen processing.
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 the laboratory's quality assessment plan, and staff interview, it was revealed the laboratory's quality assessment plan failed to identify and correct issues in pre-analytic systems. The findings were: 1. The laboratory's quality assessment plan failed to identify and correct that the laboratory failed to have documentions of performing pre-analytic studies to support its sample stability claims. Refer to D5311 2. The laboratory failed to provide the appropriate specimen handling for urine samples to their clients. Refer to D5317
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory policy, manufacturer's instructions and random review of patient testing requisitions and results, the laboratory failed to meet the requirements for the analytical phase of testing as evidenced by: 1. The laboratory failed to establish the correct room temperature and humidity for the Olympus AU400. (refer to D5413) 2. The laboratory the laboratory failed to document the identity, preparation and expiration dates for the reagents for the Water Aquity TQD UPLC/MS/MS. (refer to D5415) 3. The laboratory failed to document every 6-month calibration verifications on all required analytes on the Olympus AU400 chemistry analyzer. (refer to D5439) 4. The laboratory failed to follow its policy to establish its own expected ranges for quality control acceptability for the adulterant testing for Creatinine, Nitrites, Oxidants, pH and specific gravity on the Olympus AU400 chemistry analyzer. refer to D5441) 5. The laboratory failed to perform two control materials during the extraction phase every day of PGX (pharmacogenomics) patient testing on the Applied Biosystems Quan Studio 7 Flex. (refer to D5453) 6. The laboratory failed to follow its policy to establish the quality control acceptability testing for the Water Aquity TQD UPLC/MS/MS toxicology analyzer. (refer to D5469)
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 the manufacturer's instructions, review of the laboratory environmental logs, and confirmed in interview the laboratory failed to establish the correct room temperature and humidity for the Olympus AU400. Findings were: 1. Review of the AU400 User Guide (August, 2002) revealed the operating environment was 18 to 32 C and 40 - 80 % humidity. 2. Review of the laboratory environmental logs from January 2017 - February 2018 revealed no acceptable temperature and humidity range. 3. An interview with the testing person #1 on 03/27/18 at 1040 hours in the laboratory confiremd the above findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observations and confirmed in interview, the laboratory failed to document the identity, preparation and expiration dates for the reagents for the Water Aquity TQD UPLC/MS/MS (High-performance liquid chromatography mass spectrometry). Findings were: 1. Surveyor observations on 03/26/18 at 1400 hours reavealed bottles of reagents on top of the Water Aquity TQD UPLC/MS/MS with no documentation of: (1) Name of reagent and/or concentration of reagent (2) Storage temperature (3) Preparation and expiration dates 2. An interview with the testing person #2 on 03/26 /18 at 1410 hours confirmed the above findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the

	range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the Olympus AU400 chemistry analyzer records and interview of facility personnel, the laboratory failed to document every 6-month calibration verifications on all required analytes on the Olympus AU400 chemistry analyzer. (Oxidant, Creatinine, pH testing, specific gravity, barbiturate, THC) Findings were: 1. Review of the laboratory policy Calibration Verification (effective August 2009) revealed "linearity of the instrument/reagent system will be verified when put into and semiannually after (whenever applicable) or when calibration verification fails to meet acceptable limits." 2. Review of the laboratory records for the Olympus AU400 in 2016, 2017, and 2018 revealed 0 of 6 documentations of the 6-month calibration verification for Oxidant, Creatinine, pH testing, specific gravity, barbiturate, and THC. 3. The laboratory was asked to provide documentation of the 6-month calibration verification for the above analytes for the Olympus AU400 chemistry analyzer. No documentation was provided. 4. An interview with the lab director on 03 /26/18 at 1200 hours confirmed the above findings. He was unaware the calibration verification needed to be performed for qualitative tests.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the laboratory's quality control (QC) records from January 2018 to March 2018, and staff interview, it was revealed the laboratory failed to follow its policy to establish its own expected ranges for quality control acceptability for the adulterant testing for Creatinine, Nitrites, Oxidants, pH and specific gravity on the Olympus AU400 chemistry analyzer. The findings were: 1. Review of the laboratory policy Quality Control effective August 2009 revealed under Control Procedures "the laboratory must establish the number, type and frequency of testing calibration or control materials and establish criteria for acceptability used to monitor test performance during a run of patient specimens. 2. Review of the package insert for Validity Controls 1-5 Adulterant Toxicology Control

	(Rev 08/15) revealed "laboratories should establish their own values for mean and expected ranges." 3. The laboratory was asked for the data that established the laboratory mean and expected ranges for the adulterant testing for Creatinine, Nitrites, Oxidants, pH and specific gravity on the Olympus AU400. No documentation was provided. 4. An interview with the testing person #1 on 03/27/18 at 1040 hours in the laboratory revealed the laboratory used the the package insert target range. He was unaware the QC needed to be established prior to use. The laboratory performs approximately 31000 toxicology testing on the Olympus AU400.
D5453	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iv)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory extraction worksheets and confirmed in interview, the laboratory failed to perform two control materials during the extraction phase every day of PGX (pharmacogenomics) patient testing on the Applied Biosystems Quan Studio 7 Flex. Findings were: 1. A review of the DNAdavnced Buccal Swab Extraction worksheet from June 2017 to December 2017 revealed 2 of 12 days when there was documentation of one control that were run during the extraction phase of patient testing. 07/05/17 11/20/17 2. The laboratory was asked for documentation of the other control run for the above dates. No documentation was provided. 3. The laboratory was asked for documentation of the two control materials, including one that is capable of detecting errors in the extraction process for each of the runs for the following dates. 6/3/17 7/7/17 7/31/17 8/8/17 8/15/17 10/3/17 10/13/17 10/16/17 11/28 /17 12/18/17 4. An interview with the testing person #3 on 03/27/18 at 1010 hours confirmed the above findings. She was unaware she needed to perform controls every day of patient testing. According to the CMS-116 signed by the laboratory director on 3/9/18, the facility performed 350 PGX annually.
D5455	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(v)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory extraction worksheets and confirmed in interview, the laboratory failed to perform two control materials during the amplification phase every day of PGX (pharmacogenomics) patient testing on the Applied Biosystems

	Quan Studio 7 Flex. Findings were: 1. A review of the DNAdavnced Buccal Swab Extraction worksheet from June 2017 to December 2017 revealed 2 of 12 days when there was documentation of one control that were run during the amplification phase of patient testing. 07/05/17 11/20/17 2. The laboratory was asked for documentation of the other control run for the above dates. No documentation was provided. 3. The laboratory was asked for documentation of the two control materials, including one that is capable of detecting errors in the amplification process for each of the following dates. 6/3/17 7/7/17 7/31/17 8/8/17 8/15/17 10/3/17 10/13/17 10/16/17 11/28 /17 12/18/17 4. An interview with the testing person #3 on 03/27/18 at 1010 hours confirmed the above findings. She was unaware she needed to perform controls every day of patient testing. According to the CMS-116 signed by the laboratory director on 3/9/18, the facility performed 350 PGX annually.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the laboratory's quality control (QC) records from January 2018 to March 2018, and staff interview, it was revealed the laboratory failed to follow its policy to establish the quality control acceptability testing for the Water Aquity TQD UPLC/MS/MS toxicology analyzer. The findings were: 1. A review of the laboratory's establishment studies for the following tests revealed the facility made its own control material for establishing the parameters of its test systems: 38 drug panel urine: Morphine Oxymorphone Hydromorphone Naloxone Codeine Oxycodone Naltrexone Hydrocodone Methylone 6-acetyllmorphine Methampetamine Amphetamine MDA (3,4-Methylenedioxyamphetamine) O-Des-Tramadol MDMA (3,4-Methylenedioxymethamphetamine) MDEA(Methylenedioxyethylamphetamine) Benzolecgonine Ritalinic Acid Meperidine Tramadol Methylphenidate MDPV (Methylenedioxypyrovalerone) Tapentadol LSD (Lysergic acid diethylamide) EDDP (metabolite of Methadone) Mephedrone PCP (Phencyclidine) Meprobamate Fentanyl Tapentadol Buprenorphine Norbuprenorphine Alpha-hydrox Carisoprodol Methadone Lorazepam Oxazepam Temazepam Nordiazepam 2. Review of the laboratory policy Quality Control effective August 2009 revealed under Control Procedures "the laboratory must establish the number, type and frequency of testing calibration or control materials and establish criteria for acceptability used to monitor test performance during a run of patient specimens. 3. Review of the laboratory policy In-House QC preparation and Qualification revealed under Testing "Prepare all level QC in 10 sets and inject 3 times each after treatment like sample. Find out the

	concentration using calibration curve and outside referral QC that include all required components. Calculate Mean and SD for all." 4. The laboratory was asked for the 10 sets of data to calculate the mean and SD for the current QC stock solution made on 10 /04/17. No documentation was provided. 5. An interview with the testing person #1 on 03/27/18 at 1040 hours in the laboratory revealed the laboratory used the the analyte target value +/- 20 %. He was unaware the QC needed to be established prior to use. The laboratory performs approximately 200,000 toxicology testing on the Water Aquity TQD UPLC/MS/MS toxicology analyzer. key: SD - standard deviation
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 the laboratory's quality control records and staff interview, it was revealed the laboratory quality assessment failed to identify and correct problems in the analytic systems. The findings were: 1. The laboratory failed to follow its policy to establish its own expected ranges for quality control acceptability for the adulterant testing for Creatinine, Nitrites, Oxidants, pH and specific gravity on the Olympus AU400 chemistry analyzer. (refer to D5441) 2. The laboratory failed to perform two control materials during the extraction phase every day of PGX (pharmacogenomics) patient testing on the Applied Biosystems Quan Studio 7 Flex. (refer to D5453) 3. The laboratory failed to perform two control materials during the amplification phase every day of PGX (pharmacogenomics) patient testing on the Applied Biosystems Quan Studio 7 Flex. (refer to D5455) 4. The laboratory failed to follow its policy to establish the quality control acceptability testing for the Water Aquity TQD UPLC/MS /MS toxicology analyzer. (refer to D5469) 5. The laboratory failed to establish the correct room temperature and humidity for the Olympus AU400. (refer to D5413) 6. The laboratory failed to document every 6-month calibration verifications on all required analytes on the Olympus AU400 chemistry analyzer. (Oxidant, Creatinine, pH testing, specific gravity, barbiturate, THC (refer to D5439)
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of patient test reports and interview of facility personnel, it was revealed that the laboratory failed to include a disclaimer on test reports for tests not

	FDA- cleared. (Water Aquity TQD UPLC/MS/MS) Findings were: 1. Review of the "LISTING OF TESTS PERFORMED IN THE FACILITY" revealed the laboratory tested for the following 38 drug analytes on the Water Aquity TQD UPLC/MS/MS: 38 drug panel urine: Morphine Oxymorphone Hydromorphone Naloxone Codeine Oxycodone Naltrexone Hydrocodone Methylone 6-acetyllmorphine Methampetamine Amphetamine MDA (3,4-Methylenedioxyamphetamine) O-Des-Tramadol MDMA (3,4-Methylenedioxymethamphetamine) MDEA(Methylenedioxyethylamphetamine) Benzolecgonine Ritalinic Acid Meperidine Tramadol Methylphenidate MDPV (Methylenedioxypyrovalerone) Tapentadol LSD (Lysergic acid diethylamide) EDDP (metabolite of Methadone) Mephedrone PCP (Phencyclidine) Meprobamate Fentanyl Tapentadol Buprenorphine Norbuprenorphine Alpha-hydrox Carisoprodol Methadone Lorazepam Oxazepam Temazepam Nordiazepam 2. A random review of 7 patient report for the above drug analytes revealed 7 of 7 test reports did not include the statement "The performance characteristics of this test were determined by (Laboratory Name). It has not been cleared or approved by the U.S. Food and Drug Administration". Specimen Id Date of collection 52071 03/20/18 52026 03/20/18 52070 03/20/18 52074 03/21/18 52072 03/20/18 52073 03/20/18 52075 03/20/18 3. An interview with the lab director on 3/27/18 at 1340 hours in the laboratory confirmed the above findings. Key: CMS- Centers for Medicare & Medicaid Services
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 review of the laboratory records, manufacturer's instructions, and staff interview, it was revealed the laboratory director failed to provide overall management and direction of the laboratory. (refer to D6082, D6091, D6093)
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 review of the laboratory's procedures, records, and staff interview, it was revealed the laboratory director failed to ensure preanalytic requirements for sample storage, transport, and stability of samples were completely defined and provided to clients. (refer to D5311 and D5317)
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: A review of the laboratory's College of American Pathologists (CAP) proficiency testing records and staff interview, it was revealed the laboratory director failed to have documentation of evaluation for review of ungraded proficiency testing. (refer to D5291)
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 review of the laboratory's quality control records and staff interview, it was revealed the laboratory director failed to ensure a quality control plan was established and followed for toxicology and PGX testing. The findings were: 1. The laboratory director failed to ensure the laboratory followed its policy to establish its own expected ranges for quality control acceptability for the adulterant testing for Creatinine, Nitrites, Oxidants, pH and specific gravity on the Olympus AU400 chemistry analyzer. (refer to D5441) 2. The laboratory director failed to ensure the laboratory performed two control materials during the extraction phase every day of PGX (pharmacogenomics) patient testing on the Applied Biosystems Quan Studio 7 Flex. (refer to D5453) 3. The laboratory director failed to ensure the laboratory performed two control materials during the amplification phase every day of PGX (pharmacogenomics) patient testing on the Applied Biosystems Quan Studio 7 Flex. (refer to D5455) 4. The laboratory director failed to ensure the laboratory followed its policy to establish the quality control acceptability testing for the Water Aquity TQD UPLC/MS/MS toxicology analyzer. (refer to D5469)