Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1101214	01/05/2022
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	A recertification survey was performed on 01/05/2022. The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D5300 - 42 C. F.R. 493.1240 Condition: Preanalytic systems; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director; The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
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 the manufacturer's instructions, review of the laboratory's policy and patient test records, and confirmed in interview, the laboratory failed to meet the requirements for preanalytic systems. Refer to D5311 and D5317
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 review of laboratory policies, laboratory and patient test records from 2020 to 2021, and confirmed in interview, the laboratory failed to establish and follow a procedure for specimen storage and preservation, transport conditions; specimen acceptability and rejection requirements for 38 of 38 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. Review of the laboratory policy INCA Toxicology, LLC Production Method-MIX Confirmation of 38 analytes by LC /MS/MS revealed no documentation of the specimen processing; specimen storage and preservation; and specimen acceptability and rejection for the above analytes. 3. Random review of patient test logs from 2020 to 2021 revealed the laboratory received the following 10 specimens from outside clients with no documentation of the specimen integrity. Date: 07/01/20: Accn # 59737, 59743 Date: 10/15/20: Accn # 49921, 49924 Date: 10/22/20: Accn # 60219 Date: 07/06/21: Accn # 63332, 64062 Date: 12/22/21: Accn # 65509, 55032, 65883 4. An interview with the primary testing person on 1/5/22 at 1030 hours in the laboratory revealed the laboratory used to receive specimens with temperature tags but they discontinued that practice. 5. Review of the patient final reports from the above dates revealed the laboratory analyzed and reported the above patients. 6. An interview with the laboratory director on 1/5/22 at 1120 hours in the laboratory confirmed the above findings. This is a repeat deficiency from the 3/27/18 survey.
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 a client service manual to include specimen acceptability and rejection requirements to their clients. 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 acceptability and rejection for urine patient testing. (cross refer to D5311) 2. An interview with the lab director on 1/5/22 at 1045 hours in the laboratory confirmed the above findings. This is a repeat deficiency from the 3/27/18 survey.

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 manufacturer's instructions, laboratory policy, surveyor observations, and confirmed in interview, the laboratory failed to document the revised expiration dates for five of five levels of calibrators and controls stored in the laboratory refrigerator for urine toxicology testing on the Olympus AU400 chemistry analyzer . Findings were: 1. Review of the package insert for the Siemens Syva Emit Calibrators/Controls (10871245-E, 2017-10) under Stability revealed "once opened, the Emit Calibrators /Controls are stable for 5 weeks when recapped and stored at 2-8 C when not in use. 2. Surveyor observations on 1/5/21 at 1040 hours revealed the Siemens Syva Emit Calibrators/Controls level 1-5 stored in secondary tubes in the Olympus sample racks with no documentation of the revised expiration date. 3. Review of the laboratory records revealed the laboratory performed 231,000 toxicology testing annually. 4. An interview with the primary testing person on 1/5/22 at 1115 hours in the laboratory confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, maintenance records for the Olympus AU400 chemistry analyzer from 2020 and 2021, and confirmed in interview, the laboratory failed to ensure maintenance was performed with at least the frequency as specified by the manufacturer for five of twenty days reviewed. Findings included: 1. Review of the Olympus AU400 Chemistry analyzer User's Guide (January 28, 2005) under Chapter F-Maintenance revealed "to obtain accurate results and optimum system performance, be sure to perform the following daily maintenance procedures." The following required daily maintenance included: Inspect Sample and Reagent Syringes for Leaks Check the Wash Solution Rolling Pump for Leaks Inspect the concentrated wash Solution Level Inspect and Clean Sample Probe, Reagent Probe, and Mix Bars Inspect the Printer and Paper Prepare for a Sample Probe Wash Change DI water in the Pre-Dilution Bottle 2. Random review of the Maintenance logs from the Olympus AU400 from 2020 revealed no documentation of the daily maintenance for five of twenty days reviewed. 2/28/20 4/02/20 4/24/20 8/07/21 9/09/21 3. Review of the above dates revealed the laboratory performed patient testing. 2/28/20: Patient ID 61460, 61762 4/02/20: Patient ID 53888, 45428 4/24/20: Patient ID 59598, 59594 8 /07/21: Patient ID 59869, 60026 9/09/21: Patient ID 60083, 60075 4. An interview with the laboratory director on 1/5/22 at 1151 hours in the laboratory confirmed the above findings.

D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory and patient test records from July 2020 to December 2021, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions when performing calibration procedures for two of two analytes (Barbiturate Assay and Cannabinoid Assay) reviewed on the urine toxicology testing on the Olympus AU400 chemistry analyzer. Findings included: 1. Review of the package insert for the Siemens Syva Emit II Plus Barbiturate Assay (10871369_J, 2018-11) under Calibration revealed "Required Calibrators/Controls for Qualitative Analysis: Level 0; Level 3; Level 5." 2. Review of the package insert for the Siemens Syva Emit II Plus Cannabinoid Assay (10871686_F, 2015-04) under Calibration revealed "Required Calibrators/Controls for Qualitative Analysis: Level 0; Level 3; Level 5." 3. Review of the calibration records from July 2020 to December 2021 revealed the laboratory used Emit Calibrator level 3, 4, and 5 for Cannabinoid; and Emit Calibrator Level 2,3,4, and 5 for Barbiturate. 4. Random review of patient test logs from July 2020 to December 2021 revealed the laboratory performed Cannabinoid and Barbiturate for the following 10 patients. Date: 07/01/20: Accn # 59737, 59743 Date: 10/15/20: Accn # 49921, 49924 Date: 10/22/20: Accn # 60219 Date: 07/06/21: Accn # 63332, 64062 Date: 12/22/21: Accn # 65509, 55032, 65883 5. An interview with the laboratory manager on 1/5/22 at 1120 hours in the laboratory confirmed the above findings.
D5467	CONTROL PROCEDURES CFR(s): 493.1256(d)(9)(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-- When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory and patient test records from July to December 2021, and confirmed in interview, the laboratory failed to use quality control material from a different lot number than was used to calibrate the system for two of two analytes (Barbiturate Assay and Cannabinoid Assay) reviewed on the urine toxicology testing on the Olympus AU400 chemistry analyzer. Findings included: 1. Review of the calibration records from July to December 2021 revealed

	the laboratory used Emit Calibrator level 3, 4, and 5 for Cannabinoid; and Emit Calibrator Level 2,3,4, and 5 for Barbiturate. 2. Review of the quality control records from July to December 2021 revealed the laboratory performed Emit Calibrator /Control level 2 and 5 for controls, the same lot number as the calibrators used. Emit Level 2, lot 9A548UL-PI exp 12/29/21; lot 9A548UL-P2, exp 3/17/22 Emit Level 5, lot 9A608uL-P2, exp 1/30/22 3. Random review of patient test logs from July to December 2021 revealed the laboratory performed Cannabinoid and Barbiturate for the following five patients. Date: 07/06/21: Accn # 63332, 64062 Date: 12/22/21: Accn # 65509, 55032, 65883 4. An interview with the laboratory director on 1/5/22 at 1120 hours confirmed the above findings.
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: I. Based on review of laboratory quality control and patient test records from 2020 to 2021 and confirmed in interview, the laboratory failed to establish a policy for the acceptability of two of two levels of quality control for two of two toxicology tests (Cannabinoid, Barbiturate) on the Olympus AU400 chemistry analyzer. Findings included: 1. Review of the laboratory quality control records from 2021 revealed the laboratory used the following acceptable ranges for the following two levels of quality controls for Cannabinoid and Barbiturate. Emil Level 2 Calibrator/Control, lot 9A548UL-P2, exp 3/17/22 Cannabinoid: 9.6 - 22.4 Barbiturate: 70 - 130 Emit Level 5 Calibrator/Control, lot 9A608UL-P2, exp 1/30/22 Cannabinoid: 640 - 960 Barbiturate: 153.6 - 230 2. Review of the laboratory records available revealed no documentation of a policy to establish the acceptability criteria of the above controls nor how the laboratory established the ranges above. 3. Review of the laboratory records revealed the laboratory performed 231,000 chemistry tests annually. 4. An interview with the laboratory director on 1/5/22 at 1120 hours confirmed the above findings. II. Based on review of the laboratory's quality control (QC) and patient test records from 2020 and 2021, and confirmed in interview, the laboratory failed to establish the quality control acceptability testing for three of three levels of quality control for 38 of 38 analytes performed on 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 three levels of material (low, mid, high) 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 Production Method-Mis Confirmation of 38 analytes by LC-MS/MS revealed no documentation of the acceptability criteria for the above in house controls. 3. The laboratory performs approximately 231,000 chemistry testing annually. 4. An interview with the laboratory director on 1/5/22 at 1120 hours confirmed the above findings This is a repeat deficiency from the 3/27/18 survey.
D6067	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Each individual performing moderate complexity testing must have training to ensure that the individual has-- (A) the skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (B) the skills required for implementing all standard laboratory procedures; (C) the skills required for performing each test method and for proper instrument use; (D) the skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed; (E) a working knowledge of reagent stability and storage; (F) the skills required to implement the quality control policies and procedures of the laboratory; (G) an awareness of the factors that influence test results; and (H) the skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel and training records for the Olympus AU400 chemistry analyzer from 2019 to 2021, and confirmed in interview, it was revealed the laboratory failed to have documentation of ensuring one of three testing personnel received training to cover each of the skills required. The findings were: 1. A review of the laboratory's CMS209 revealed three testing personnel (TP #1, 2, 3) 2. Review of the laboratory training records revealed no documentation of the following skills for one of three testing person (TP#3, hired December 2019) for testing on the Olympus AU400 chemistry analyzer. - implementing procedures - perfoming each test and proper use of the instrument - performing maintenance, calibration - knowledge of reagent stability and storage - control policies/procedures - factors which could influence test results, and - how to assess the validity of test results. 3. An interview with the laboratory director on 1/5/22 at 1005 hours in the laboratory confirmed the findings.
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's records and staff interview, it was revealed the laboratory director failed to provide overall management for the laboratory. (Refer to D6082)
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 records, patient records, and confirmed in interview, the laboratory director failed to ensure the laboratory provided quality laboratory services for all aspectes of test performance. Refer to D5311, D5467