Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2204301	10/27/2021
Name of Provider or Supplier	**Street Address, City, State**	
Lake Professionals, Llc	501 W St Mary Blvd, Ste 308, Lafayette, LA	

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	An Initial survey was performed on October 27, 2021 at Lake Professionals, L.L.C., CLIA ID # 19D2204301. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to ensure the policy manual contained complete policies and procedures. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include detailed written instructions for the

	following: a) Specimen rejection to include but not limited to: rejection of turbid urines received for patient testing 2. In interview on October 27, 2021 at 12:13 pm, the General Supervisor stated the laboratory currently does not have a centrifuge in place to handle turbid urines received for testing. The General Supervisor further stated the laboratory needed to update the above identified procedure.
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 observation by surveyor, review of laboratory's maintenance records and interview with personnel, the laboratory failed to ensure monthly maintenance for the Olympus AU640 Chemistry analyzer was performed per manufacturer instructions for one (1) of ten (10) months reviewed. Findings: 1. Observation by surveyor during the laboratory tour on October 27, 2021 at 9:30 am revealed the laboratory utilizes the Olympus AU640 Chemistry analyzer for Toxicology testing. 2. Review of the laboratory's "AU640 Maintenance Log" revealed the following monthly maintenance tasks: a) Clean probe wash wells b) Clean mix bar wash well c) Clean wash nozzles d) Clean water tank e) Clean water filter f) Clean sample probe filter 3. Further review of the laboratory's "AU640 Maintenance Log" from January 2021 through October 2021 revealed the laboratory did not have documentation of performing the monthly maintenance for the following one (1) of ten (10) months reviewed: a) August 2021 4. In interview on October 27, 2021 at 12:13 pm, the General Supervisor stated the monthly maintenance was due during the last week of August; however, the laboratory was closed due to Hurricane Ida and was performed upon laboratory reopening. The General Supervisor confirmed the laboratory did not perform the above identified maintenance as required.
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 observation by surveyor, review of manufacturer's package inserts and patient test reports as well as interview with personnel, the laboratory failed to report Urine Drug Screen (UDS) results as required by the manufacturer. Findings: 1. Observation by surveyor during the laboratory tour on October 27, 2021 at 9:30 am revealed the laboratory utilizes the Olympus AU640 Chemistry analyzer for Urine Drug Screen (UDS) testing to include the following tests: Buprenorphine (BUP),

	Amphetamine (AMP), Methamphetamine (METH), Opiates (OPI), Oxycodone (OXY), 6-Acetylmorphine (Heroin Metabolite), Cocaine Metabolite (COC), Barbituates (BARB), Ethyl Glucuronide (ETG), Benzoylecgonine (BENZO), Synthetic Cannabinoids (K2-Spice), and Cannabinoids 2. Review of the Olympus AU640 Chemistry analyzer package inserts under "Intended Use" revealed "The Immunlysis Urine Enzyme Immunoassay Kit provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC-MS) or Liquid Chromatography-tandem Mass Spectrometry (LC-MS/MS) is the preferred confirmatory method. Clinical Consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are used". 3. Review of the laboratory's patient test reports revealed the laboratory did not include the disclaimer for intended use on patient reports to state the entire confirmatory process. 4. In interview on October 27, 2021 at 12:13 pm, the General Supervisor stated she was unaware the disclaimer on patient reports did not include all the pertinent information required. 5. Review of the Task 1&3 form provided to surveyor revealed the laboratory performs 127,607 UDS tests annually.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of maintenance logs, and interview with personnel, the Laboratory Director failed to ensure maintenance procedures were maintained to ensure acceptable levels of test performance. Refer to D5429.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on observation by surveyors, record review, and interview with personnel, the Laboratory Director failed to ensure final reports included required pertinent information. Refer to D5805.
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 review of the laboratory's policies and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D5403.