

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2204301	(X3) Date Survey Completed 09/28/2023
Name of Provider or Supplier Lake Professionals, Llc	Street Address, City, State 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	A Recertification survey was performed on September 28, 2023 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.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 form (Laboratory Personnel Report), policy and procedure manual, and personnel records; as well as interview with laboratory personnel, the laboratory failed to establish a written policy to assess competency for the General Supervisor. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Testing Personnel 1 also serves as the General Supervisor. 2. Review of the laboratory's "Competency Assessment Policy" revealed the laboratory did not include performance of competency assessment for the General Supervisor to include tasks and responsibilities and frequency of performance. 3. Review of personnel records for Testing Personnel 1 revealed he did not have a competency assessment performed for his role as General Supervisor. 4. In interview on September 28, 2023 at 1 p.m., the Office Manager confirmed the laboratory's policy did not include competency assessment of the General Supervisor, and a competency assessment for the General Supervisor was not performed.</p>
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b)

The laboratory must document the date and time it receives a specimen.

This STANDARD is not met as evidenced by:

Based on review of patient records and interview with personnel, the laboratory failed to document the date and time specimens were received into the laboratory for two (2) of two (2) patients reviewed. Findings: 1. Review of a random selection of patient test records revealed the laboratory did not document the date and time the following patient specimens were received into the laboratory: - Accession 0100001529; collected January 15, 2023; test date January 20, 2023 - Accession 0100001741; collected January 24, 2023; test date January 31, 2023 2. In interview on September 28, 2023 at 12:45 p.m., Testing Personnel 1 stated the laboratory receives specimens from outside the laboratory. He confirmed the laboratory did not document the date and time the specimens identified above were received into the laboratory and stated the laboratory did not have a process for documenting the date and time specimens were received.

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 validation records as well as interview with laboratory personnel, the laboratory failed to ensure the policy and procedure manual contained complete policies for toxicology testing. Findings: 1. Review of the laboratory's policy and procedure manual revealed a policy "Cutoff Reporting Units" with the following analytes and cut-off values: 6-AM - 10 ng/mL Amphetamines - 500 ng/mL Barbiturates - 200 ng/mL Benzodiazepines - 200 ng/mL Buprenorphine - 20 ng/mL Cannabinoids (TCH) - 50 ng/mL Cocaine Metabolites - 300 ng/mL EDDP - 1000 ng/mL MDMA - 500 ng/mL Opiates - 300 ng/mL Oxycodone - 100 ng/mL PCP - 25 ng/mL Propoxyphene - 300 ng/mL Methamphetamine - 500 ng/mL Ethyl Glucuronide - 500 ng/mL 2. Review of the laboratory's validation records revealed the laboratory did not include Benzodiazepines, EDDP, MDMA, PCP, and Propoxyphene. 3. Further review of the

	<p>laboratory's validation records revealed the cutoff values in the validation records did not match the cutoff values in the "Cutoff Reporting Units" policy for the following analytes: Buprenorphine - 5 ng/mL Cocaine Metabolites - 150 ng/mL 4. In interview on September 28, 2023 at 1:15 p.m., the Office Manager confirmed the policy identified above contained analytes and cutoff values that were not validated. She also confirmed the cutoff values in the policy did not match the validation records for Buprenorphine and Cocaine Metabolites.</p>
<p>D5415</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with laboratory personnel, the laboratory failed to label laboratory prepared bleach solution with the preparation and expiration date. Findings: 1. Observation by surveyors during the laboratory tour on September 28, 2023 at 9:19 a.m. revealed a laboratory prepared 10% bleach solution in a bottle labeled as follows: P: 7/25/22 E: 10/25/22 2. In interview on September 28, 2023 at 9:35 a.m., Testing Personnel 1 stated he prepares the bleach solution monthly, but does not document the preparation and expiration date.</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with laboratory personnel, the laboratory failed to ensure laboratory supplies were not used beyond their expiration date. Findings: 1. Observation by surveyors during the laboratory tour on September 28, 2023 at 9:19 a.m. revealed the following expired items: a) Immunalysis cTHC Urine Calibrator 2; Reference 10012-5; Lot E46712; Expiration date: July, 31, 2023; Quantity: one (1) b) Hydrochloric Acid Solution; 1.00 normal; Lot 2001408; Expiration date: January 16, 2022; Quantity: one (1) 2. In interview on September 28, 2023 at 9:38 a.m., Testing Personnel 1 confirmed the items identified above were expired.</p>
<p>D5429</p>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
 Based on observation, review of the laboratory's policy and procedure manual and maintenance records, and interview with laboratory personnel, the laboratory failed to perform maintenance as required by the laboratory. Findings: 1. Observation by surveyors during the laboratory tour on September 28, 2023 at 9:19 a.m. revealed the laboratory utilized the Olympus AU640 for toxicology testing. 2. Review of the laboratory's policy and procedure manual revealed the following: a) Olympus AU640: Weekly Maintenance - The principle of this procedure is to properly perform Preventative Maintenance at a weekly interval on the Olympus including performing a W2, photocal, photometer checks and verifying photocal results according to CLIA and Manufacturer regulations. b) Olympus AU640: 3 Month Maintenance - The principle of this procedure is to properly perform Preventative Maintenance at a 3 month interval on the Olympus to replace the wash solution rolling tube and clean air filters according to CLIA and Manufacturer regulations. 3. Review of the laboratory's "AU640 Maintenance Log" revealed the following monthly maintenance tasks: a) Clean sample and reagent probe wash wells b) Clean mix bar wash wells c) Clean wash nozzle unit d) Clean DI water tank e) Clean DI water filter f) Clean sample probe filter 4. Further review of the laboratory's maintenance logs from January 2023 to August 2023 revealed the laboratory failed to perform weekly, monthly, and 3 month maintenance as follows: - Weekly maintenance not performed March 28, 2023 - Monthly maintenance not performed August 2023 - 3 month maintenance not performed January 2023 - August 2023 5. In interview on September 28, 2023 at 12: 50 p.m., Testing Personnel 1 confirmed the maintenance identified above was not performed.

D5793

ANALYTIC SYSTEMS QUALITY ASSESSMENT
 CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
 Based on observation, record review, and interview with personnel, laboratory failed to have Quality Assurance monitors in place to identify and correct quality issues in Analytic Systems. Findings: 1. The laboratory failed to ensure the policy and procedure manual contained complete policies for toxicology testing. Refer to D5403. 2. The laboratory failed to label laboratory prepared bleach solution with the preparation and expiration date. Refer to D5415. 3. The laboratory failed to ensure laboratory supplies were not used beyond their expiration date. Refer to D5417. 4. The laboratory failed to perform maintenance as required by the laboratory. Refer to D5429.

D6079

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory

director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Laboratory Director failed to provide overall direction and management to the laboratory. Findings: 1. The laboratory failed to establish a written policy to assess competency for the General Supervisor. Refer to D5209. 2. The laboratory failed to document the date and time specimens were received into the laboratory for two (2) of two (2) patients reviewed. Refer to D5313. 3. The laboratory failed to ensure the policy and procedure manual contained complete policies for toxicology testing. Refer to D5403. 4. The laboratory failed to label laboratory prepared bleach solution with the preparation and expiration date. Refer to D5415. 5. The laboratory failed to ensure laboratory supplies were not used beyond their expiration date. Refer to D5417.

D6080

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(c)

The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's CMS 209 form (Laboratory Personnel Report) and personnel records, as well as interview with personnel, the Laboratory Director failed to delegate, in writing, the responsibilities of the General Supervisor. Findings: 1. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed Testing Personnel 1 also serves as the General Supervisor. 2. Further review of personnel records revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities of General Supervisor to Testing Personnel 1. 3. In interview on September 30, 2023 at 1 p.m., the Office Manager and Testing Personnel 1 confirmed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities of General Supervisor to Testing Personnel 1.

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 record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided and to identify failures. Refer to D5793.

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, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Refer to D5429.

D6144

GENERAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1463

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the General Supervisor failed to provide day-to-day supervision to testing personnel to ensure accurate and reliable test performance of laboratory testing. Findings: 1. The laboratory failed to document the date and time specimens were received into the laboratory for two (2) of two (2) patients reviewed. Refer to D5313. 2. The laboratory failed to ensure the policy and procedure manual contained complete policies for toxicology testing. Refer to D5403. 3. The laboratory failed to label laboratory prepared bleach solution with the preparation and expiration date. Refer to D5415. 4. The laboratory failed to ensure laboratory supplies were not used beyond their expiration date. Refer to D5417. 5. The laboratory failed to perform maintenance as required by the laboratory. Refer to D5429.