

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2204301	(X3) Date Survey Completed 03/18/2025
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 at Lake Professionals, LLC, CLIA ID 19D2204301, on March 18, 2025. Lake Professionals, LLC was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1441 CONDITION: Laboratories performing high complexity testing; Laboratory Director 42 CFR 493.1447 CONDITION: Laboratories performing high complexity testing; Technical Supervisor 42 CFR 493.1453 CONDITION: Laboratories performing high complexity testing; Clinical Consultant 42 CFR 493.1459 CONDITION: Laboratories performing high complexity testing; General Supervisor
D2014	<p>TESTING OF PROFICIENCY TESTING SAMPLES</p> <p>(b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with personnel, the laboratory failed to ensure the proficiency testing attestation statements were signed by testing personnel and/or the Laboratory Director for three (3) of four (4) events reviewed. Findings: 1. Review of the laboratory's proficiency testing records revealed the laboratory enrolled in the American Proficiency Institute (API) proficiency testing program to verify the accuracy of Toxicology testing twice a year. 2. Review of the 2023 and 2024 API Chemistry Miscellaneous proficiency testing records revealed the following documentation was not completed: 2023 1st Event: Testing Personnel did not sign the attestation form 2024: 1st Event and 2nd Event:</p>

Laboratory Director and Testing Personnel did not sign the attestation form 3. In interview on March 18, 2025 at 12:25 pm, the Office Manager stated not aware the identified attestation statements were not signed.

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's proficiency testing (PT) records and interview with personnel, the laboratory failed to ensure the evaluation of the PT results for Chemistry in 2024 for one (1) of two (2) events reviewed was performed by the Laboratory Director or designee. Findings: 1. Review of the laboratory's American Proficiency Institute's (API) PT records for 2024 revealed there was no documentation of the Laboratory Director's review of the results for the Chemistry Miscellaneous 2nd event. 2. In interview on March 18, 2025 at 1225 pm, the Office Manager stated she was unaware that the evaluation form for the identified event was not included and Laboratory Director's review not performed.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of the laboratory's quality control (QC) policies, quality control records, and interview with personnel, the laboratory failed to follow their established QC verification policy for new lots of Toxicology controls. Findings: 1. Observation by surveyor during the laboratory tour on March 18, 2025 at 10:27 am revealed the laboratory utilized the Olympus AU640 instrument for Toxicology testing with the following lot numbers of controls (current lot numbers in-use): Immunalysis Multi-Drug Control: Low: lot E53041 and High: lot E53042 Immunalysis Buprenorphine Urine Control: Low: lot E53108 and High: lot E53109 Immunalysis 6-Acetylmorphine Urine Control: Low: lot E53984 and High: lot E53985 Immunalysis Oxycodone Urine Control: Low: lot E53075 and High: lot E53076 Immunalysis cTHC Urine Control: Low: E52984 and High: lot E52985 Immunalysis Amphetamine Urine Control: Low: lot E53439 and High: lot E53440 Immunalysis Ethyl Glucuronide Control: Low: lot E52661 and High: lot E52662 2. Review of the laboratory's "Quality Control New Lot Verification and Range Establishment" policy revealed "it is laboratory policy to validate every new lot of QC materials to ensure the expected test performance matches the values obtained by the lab. For qualitative controls on the AU, the current lot of QC material must be run with the new lot to ensure quality control acceptability for each day prior to patient testing. In qualitative testing the value generated is a relative number representing the change in absorbance for that specimen which is then compared to the value obtained for the cutoff calibrator, and that value is used to discriminate negative from positive but is not a representation of the actual amount of drug present in the sample. For

quantitative mean establishment, the new lot of QC should be run a minimum of 20 times over several days and this data can be averaged to establish an acceptable range." 3. Review of the laboratory's quality control records revealed the laboratory did not have documentation of QC verification for the identified current lot numbers of Toxicology controls. 4. In interview on March 18, 2025 at 1:00 pm, the Office Manager did not have an answer as to if the laboratory performed a new lot QC verification for the controls currently in use. The Office Manager stated she reached out to the testing personnel; however, did not receive a response.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Repeat Deficiency from recertification survey performed on September 28, 2023
Based on observation by surveyor, review of the laboratory's maintenance records, and interview with personnel, the laboratory failed to perform maintenance as required by the manufacturer. Findings: 1. Observation by surveyor during the laboratory tour on March 18, 2025 at 10:27 am revealed the laboratory utilized the Olympus AU640 instrument for Toxicology testing. 2. Review of the "AU640e Maintenance Log" revealed the following required maintenance: a) Weekly: perform a W2, perform a photocal, perform a photometer check, and wash pre-solution bottle b) Monthly: clean sample and reagent probe wash wells, clean mix bar wash wells, clean wash nozzle unit, clean DI water tank, clean DI water filter, and clean sample probe filter c) 3 Months: replace was solution rolling tube and clean air filters 3. Review of the laboratory's Olympus AU640 maintenance logs from July 2024 through February 2025 revealed the laboratory did not perform the following maintenance as required: a) Weekly: not performed the week of January 13, 2025, January 27, 2025, February 3, 2025, and February 18, 2025 b) Monthly: not performed September 2024, October 2024, and November 2024 c) 3 Months: not performed July 2024 through February 2025 4. Further review of the laboratory's Olympus AU640 maintenance logs revealed a signature line for a monthly review of the logs. There was no documentation of a monthly review of the logs from July 2024 through February 2025. 5. In interview on March 18, 2025 at 12:25 pm, the Office Manager was unaware the identified maintenance tasks were not completed.

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.

This STANDARD is not met as evidenced by:
Based on observation by surveyor, record review, and interview with personnel, the laboratory failed to follow procedures to monitor, assess, and correct problems, identified with the analytic system. Findings: 1. Review of the laboratory's "Quality Management Plan" policy revealed "The Laboratory Director is responsible for overall QA. The Laboratory Director with assistance from the Laboratory Manager is

responsible for QA activities with the laboratory as described herein." 2. Review of the laboratory's "Monthly QM" reports from July 2024 through February 2025 revealed the Laboratory Director did not review the reports. 3. Observation by surveyor, review of records, and interview with personnel revealed the laboratory did not identify the following issues within the analytic system: a) The laboratory failed to follow their established QC verification policy for new lots of Toxicology controls. Refer to D5401. b) The laboratory failed to perform maintenance as required by the manufacturer. Refer to D5429.

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:
I. Based on review of the laboratory's CMS 116 application, CMS 209 form, laboratory records, and interview with personnel, the laboratory failed to have the Laboratory Director position filled. Findings: 1. Review of the laboratory's CMS 116 application and CMS 209 (Laboratory Personnel Report), received on March 18, 2025 at 9:45 am, revealed a Laboratory Director was not listed. 2. In interview on March 18, 2025 at 9:45 am, the Office Manager stated the laboratory did not currently have a Laboratory Director as they were in the process of hiring one. The Office Manager stated the laboratory stopped patient testing on Friday, March 14, 2025. 3. In interview on March 18, 2025 at 10:04 am., the Office Manager stated she did not know the date the previous Laboratory Director left and stated she would ask the owner. 4. Review of the laboratory's records, including maintenance, quality control, proficiency testing, and quality assessment, revealed there was no documentation of the previous Laboratory Director's review of records since June 2024. 5. In further interviews on March 18, 2025 at 12:25 pm, 1:00 pm, and 2:14 pm (time of the exit conference) the Office Manager stated she did not have an answer regarding the previous Laboratory Director's last day of employment.. II. Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure proficiency testing records were maintained. Refer to D6091. 2. The Laboratory Director failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Refer to D6093. 3. The Laboratory Director failed to ensure maintenance procedures were followed to ensure acceptable levels of test performance. Refer to D6095. 4. The Laboratory Director failed to ensure the positions of Clinical Consultant, Technical Supervisor, and General Supervisor were filled. Refer to D6101. 5. The Laboratory Director failed to ensure the current Testing Personnel had the appropriate training prior to patient testing. Refer to D6102.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iii)

(e)(4)(iii) 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; and

	<p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency testing records were maintained. Findings: 1. The laboratory failed to ensure the proficiency testing attestation statements were signed by testing personnel and/or the Laboratory Director for three (3) of four (4) events reviewed. Refer to D2014. 2. The laboratory failed to ensure the evaluation of the PT results for Chemistry in 2024 for one (1) of two (2) events reviewed was performed by the Laboratory Director or designee. Refer to D5221.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Refer to D5401.</p>
D6095	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6)</p> <p>(e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;</p> <p>This STANDARD is not met as evidenced by: **Repeat Deficiency from recertification survey performed on September 28, 2023** Based on observation by surveyor, review of maintenance records, and interview with personnel, the Laboratory Director failed to ensure maintenance procedures were followed to ensure acceptable levels of test performance. Refer to D5429.</p>
D6101	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11)</p> <p>(e)(11) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS 209 form, personnel records, and interview with personnel, the Laboratory Director failed to ensure the positions of Clinical Consultant, Technical Supervisor, and General Supervisor were filled. Findings: 1. The laboratory failed to have the Technical Supervisor position filled. Refer to D6108. 2. The laboratory failed to have the Clinical Consultant position filled. Refer to D6134. 3. The laboratory failed to have the General Supervisor position filled. Refer to D6141.</p>

D6102

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(12)

(e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies, CMS 209 form, personnel records, and interview with personnel, the Laboratory Director failed to ensure the current Testing Personnel had the appropriate training prior to patient testing. Findings: 1. Review of the laboratory's "Laboratory Director Roles and Responsibilities" policy revealed "The Laboratory Director ensures that, prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results." 2. Review of the laboratory's CMS 209 form (Laboratory Personnel Report), received on March 18, 2025 at 9:45 am, revealed the laboratory had one (1) Testing Personnel. 3. In interview on March 18, 2025 at 9:45 am, the Office Manager stated the laboratory did not have a Laboratory Director as they were in the process of hiring one. The Office Manager stated the laboratory stopped patient testing on Friday, March 14, 2025. 4. Review of the laboratory's personnel records revealed the current Testing Personnel was hired in March 2025. The current Testing Personnel's training document was dated March 3, 2025. 5. Further review of the current Testing Personnel's "Competency Assessment New Hire/Test System" records revealed the Office Manager performed her training. There was no documentation of the Laboratory Director approving the Testing Personnel prior to patient testing. 6. In interview on March 18, 2025 at 12:25 pm, the Office Manager stated she did not have a clinical laboratory testing background, only served as the office practice manager. The Office Manager confirmed the Laboratory Director did not approve/sign off on the Testing Personnel's training.

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 review of the laboratory's CMS 209 forms and interview with personnel, the laboratory failed to have the Technical Supervisor position filled. Findings: 1. Review of the laboratory's CMS 209 (Laboratory Personnel Report), received on March 18, 2025 at 9:45 am, revealed a Technical Supervisor was not listed. Review of the laboratory's previous CMS 209 form from 2023 revealed the previous Laboratory Director served as Technical Supervisor. 2. In interview on March 18, 2025 at 9:45 am, the Office Manager stated the laboratory did not have a Technical Supervisor. The Office Manager stated the laboratory stopped patient testing on Friday, March 14, 2025.

D6134

CLINICAL CONSULTANT

CFR(s): 493.1453

The laboratory must have a clinical consultant who meets the requirements of 493.1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of the laboratory's CMS 116 application, CMS 209 forms, laboratory records, and interview with personnel, the laboratory failed to have the Clinical Consultant position filled. Findings: 1. Review of the laboratory's CMS 209 (Laboratory Personnel Report), received on March 18, 2025 at 9:45 am, revealed a Clinical Consultant was not listed. 2. Review of the laboratory's previous CMS 209 form from 2023 revealed the previous Laboratory Director served as Clinical Consultant. 3. In interview on March 18, 2025 at 9:45 am, the Office Manager stated the laboratory did not have a Clinical Consultant. The Office Manager stated the laboratory stopped patient testing on Friday, March 14, 2025.

D6141

GENERAL SUPERVISOR

CFR(s): 493.1459

The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of the laboratory's CMS 209 form, personnel records, and interview with personnel, the laboratory failed to have the General Supervisor position filled. Findings: 1. Review of the laboratory's CMS 209 (Laboratory Personnel Report), received on March 18, 2025 at 9:45 am, revealed a General Supervisor was not listed. 2. Review of the laboratory's previous CMS 209 form from 2023 revealed previous Testing Personnel 1, who was no longer employed as of May 26, 2024, served as General Supervisor. 3. Review of personnel records revealed a different previous Testing Personnel 2 served as General Supervisor; however, was no longer employed as of February 28, 2025. 4. In interview on March 18, 2025 at 9:45 am, the Office Manager stated the laboratory did not have a General Supervisor. The Office Manager stated the laboratory stopped patient testing on Friday, March 14, 2025.