

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2204301	(X3) Date Survey Completed 02/26/2026
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	An Initial certification survey was performed at Lake Professionals, LLC, CLIA ID 19D2204301, on February 26, 2026. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard 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:</p> <p>I. Based on review of the laboratory's policies, CMS-209 (Laboratory Personnel Report) form, and personnel records; as well as interview with personnel, the laboratory failed to establish written policies and procedures to assess competency of the Technical Supervisor. Findings: 1. Review of the laboratory's policy "Training and Evaluation of Competency" revealed the laboratory did not include competency assessment of the Technical Supervisor. 2. Review of the laboratory's CMS-209 form revealed Personnel 2 served as Technical Supervisor. 3. In interview on February 26, 2026 at 9 a.m., the Technical Supervisor confirmed the laboratory did not have a policy for competency assessment of the Technical Supervisor. II. Based on review of the laboratory's policies, CMS-209 (Laboratory Personnel Report) form, and personnel records; and interview with personnel, the laboratory failed to ensure personnel competency assessments for one (1) of one (1) personnel serving as Technical Supervisor was performed. Findings: 1. Review of the laboratory's CMS-209 form revealed Personnel 2 served as Technical Supervisor. 2. Review of personnel records for Personnel 2 revealed the laboratory did not have documentation of the Laboratory Director performing competency assessments for the role of</p>

Technical Supervisor. 3. In interview on February 26, 2026 at 9 a.m., the Technical Supervisor confirmed the Laboratory Director did not perform a competency assessment for his role as Technical Supervisor.

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(a)

(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on review of patient records and the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to follow their policy for specimen rejection notification for seven (7) of seven (7) patients reviewed. Findings: 1. Review of the laboratory's "Specimen Rejection Log" revealed the following patient specimens were rejected due to "Lost in transit:" Specimen 0114688 Specimen 0114689 Specimen 0114684 Specimen 0114683 Specimen 0114682 Specimen 0114686 Specimen 0114687 2. Review of the laboratory's policy "Urine Specimen Rejection" revealed "For all rejected specimens, a 'Notification of Rejected Specimen' form will be sent to the office of the ordering physician (see Appendix B of the Client Resource Manual)." 3. In interview on February 26, 2026 at 10:30 a.m., Testing Personnel 1 stated the office manager notified the clinic of the rejection through a message portal. She further stated she rejected the samples in the Laboratory Information System (LIS) on February 24, 2026. She confirmed the laboratory did not have documentation of a specimen rejection form sent to the clinic for the specimens identified above.

D5317

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(d)

(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 policy and procedure manual and interview with personnel, the laboratory failed to establish detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing. Findings: 1. In interview on February 26, 2026 at 9:10 a.m., Testing Personnel 1 stated the laboratory receives samples from outside clinics via FedEx. 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not have detailed instructions for providers that included the following: (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. 3. In interview on February 26, 2026 at 10:02 a.m., the Technical Supervisor confirmed the laboratory did not provide written instructions to outside providers who submit samples.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

(b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 observation, review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to have a policy for calibration verification of the Olympus AU 640 analyzer. Findings: 1. Observation by surveyor during the laboratory tour on February 26, 2026 at 8:35 a.m. revealed the laboratory utilized the Olympus AU 640 analyzer for urine drug screen testing of the following analytes on urine specimens: 6-acetylmorphine, Amphetamine, Barbiturates, Buprenorphine, Cocaine, Ethyl Glucuronide, Marijuana (THC), Methamphetamine, Opiates, and Oxycodone. 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a policy for calibration verification of the analyzer. 3. In interview on February 26, 2026 at 9:38 a.m., the Technical Supervisor confirmed the laboratory did not have a policy as identified above.

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 reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

	<p>This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to provide overall management and direction to the laboratory. Findings: 1. The laboratory failed to follow their policy for specimen rejection notification for seven (7) of seven (7) patients reviewed. Refer to D5311. 2. The laboratory failed to establish detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317.</p>
<p>D6103</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>(e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Findings: 1. The laboratory failed to establish written policies and procedures to assess competency of the Technical Supervisor. Refer to D5209 I. 2. The laboratory failed to ensure personnel competency assessments for one (1) of one (1) personnel serving as Technical Supervisor was performed. Refer to D5209 II.</p>
<p>D6106</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>(e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5403.</p>
<p>D6107</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)</p> <p>(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of the laboratory's policies and personnel records and interview with personnel, the Laboratory Director failed to provide a written job description for the Technical Supervisor. Findings: 1. Review of the laboratory's policies and personnel records revealed the laboratory did not have a job description for the role and responsibilities of the Technical Supervisor. 2. In interview on February 26, 2026 at 9 a.m., the Technical Supervisor confirmed the laboratory did not have a job description for Technical Supervisor.

D6112

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451

The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Technical Supervisor failed to provide technical and scientific oversight for the laboratory. Findings: 1. The laboratory failed to follow their policy for specimen rejection notification for seven (7) of seven (7) patients reviewed. Refer to D5311. 2. The laboratory failed to establish detailed written instructions for providers to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. 3. The laboratory failed to have a policy for calibration verification of the Olympus AU 640 analyzer. Refer to D5403.