

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2124201	(X3) Date Survey Completed 04/28/2025
Name of Provider or Supplier Louisiana Pain Specialists, Llc	Street Address, City, State 2706 Hessmer Ave, Suite A, Metairie, 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 Louisiana Pain Specialists, LLC, CLIA ID 19D2124201, on April 28, 2025. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, review of manufacturer's Certificate of Analysis documents, and interview with personnel, the laboratory failed to ensure two (2) of thirty-six (36) Cerilliant standards for Toxicology testing were stored per the manufacturer's requirements. Findings: 1. Observation by surveyor during the laboratory tour on April 28, 2025 at 9:38 am revealed the following Cerilliant standards stored in the "LC-MS" reagent freezer: a) Cerilliant Morphine-3-B-D-glucuronide: lot FE11142310, quantity: one (1) vial and lot FE07262109, quantity: one (1) vial. The manufacturer's label stated "Refrigerate (Do Not Freeze)." b) Cerilliant 6-Acetylmorphine: lot FE07082101, quantity: one (1) vial. The manufacturer's label stated "Refrigerate." 2. Review of the manufacturer's Certificate of Analysis sheets revealed the following storage requirements: a) Cerilliant Morphine-3-B-D-glucuronide: "Store unopened and upright in refrigerator (2 degrees</p>

Celsius (C) to 8 degrees C) b) Cerilliant 6-Acetylmorphine: "Store unopened and upright in refrigerator (2 degrees C to 8 degrees C) 3. In interview on April 28, 2025 at 9:50 am, the Technical Supervisor confirmed the two (2) identified Cerilliant standards were not stored in a refrigerator per the manufacturer's requirements.

D5805

TEST REPORT
CFR(s): 493.1291(c)

(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 review of the laboratory's CLIA certificate, patient final test reports, test menu, and interview with personnel, the laboratory failed to utilize the correct CLIA identification number of the testing laboratory for seven (7) of seven (7) patient Toxicology reports reviewed. Findings: 1. Review of the laboratory's CLIA certificate revealed the CLIA identification number as 19D2124201. 2. Review of random selection of patient final test reports for Toxicology revealed the laboratory provided the CLIA identification number, 19D2119690, of a closed laboratory for the following patients: Patient LA255134A Patient LA256069A Patient LA255147A Patient LA254041A Patient LA253063A Patient LD243131A Patient LH244203A 3. In interview on April 28, 2025 at 12:35 pm, the Technical Supervisor stated the CLIA listed on the patient final reports was incorrect. 4. Review of the laboratory's test menu revealed the laboratory performs 251,700 Toxicology tests annually.

D6087

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(iii)

(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

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 the laboratory personnel performed test methods as required. Refer to D5413.

D6098

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(8)

(e)(8) Ensure that reports of test results include pertinent information required for interpretation;

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed

to ensure patient final reports included required pertinent information. Refer to D5805.

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 observation by surveyor, 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 ensure two (2) of thirty-six (36) Cerilliant standards for Toxicology testing were stored per the manufacturer's requirements. Refer to D5413. 2. The laboratory failed to utilize the correct CLIA identification number of the testing laboratory for seven (7) of seven (7) patient Toxicology reports reviewed. Refer to D5805.