Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2124201	08/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
Louisiana Pain Specialists, Llc	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 Certification survey was performed at Louisiana Pain Specialists, LLC, CLIA ID # 19D2124201, on August 22, 2023. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard deficiencies were cited.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, records, test menu, and interview with personnel, the laboratory failed to verify the accuracy of Urine Drug Confirmation testing in 2023 at least one (1) out of two (2) times annually as required. Findings: 1. Review of the laboratory's "Proficiency Testing" policy revealed "For Alternative PT surveys: Must take place at least twice per year, approximately 6 months apart." 2. Review of the laboratory's test menu, proficiency testing and alternative proficiency testing records from April 2023 revealed the laboratory did not have documentation of alternative proficiency testing that covered the following drugs for the first half (January through June) of 2023: 6-MAM, 7-Aminoclonazepam, Alpha-hydroxyalprazolam, Alprazolam, Amphetamine, Benzoylecgonine, Carisoprodol, Clonazepam, Coedine, Diazepam, EDDP, Ketamine, MDMA, Meperidine, Meprobmate, Methamphetamine, Morphine, Nordiazepam, Normeperidine, Noroxycodone, Oxazepam, Oxycodone, Oxymorphone, PCP, Tapentadol, and Temazepam. 3. In interview on August 22, 2023 at 3:33 pm, the Technical Supervisor confirmed the laboratory did not verify the accuracy of Urine Drug Confirmation testing for the identified drugs for the first half of 2023.
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 policies, proficiency testing (PT) records, and interview with personnel, the laboratory failed to have documentation of the Laboratory Director's review of unacceptable results for Urine Drug Confirmation testing for one (1) of two (2) events in 2022. Findings: 1. Review of the laboratory's "Proficiency Testing" policy under the "Review of Corrective Actions" section revealed "The Technical Supervisor and Laboratory Director will review the Proficiency Testing Exception Investigation Form for accuracy and completeness and sign and date the form." 2. Review of the laboratory's College of American Pathologists (CAP) 2022 DMPM-A Drug Monitoring for Pain Management proficiency testing records revealed the laboratory had "unacceptable" results for the following samples: DMPM-01, DMPM-02, and DMPM-03. 3. Further review of the laboratory's CAP 2022 DMPM-A Drug Monitoring for Pain Management proficiency testing records revealed the laboratory completed a "Proficiency Testing Exception Investigation Form;" however, the Laboratory Director did not review/sign and date the form. 4. In interview on August 22, 2023 at 3:28 pm, the Technical Supervisor confirmed the Laboratory Director did not sign the identified investigation form for the unacceptable results for the CAP 2022 DMPM-A event.
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 policies and interview with personnel, the laboratory failed to update the hydrolysis quality control (HQC) preparation procedure for Urine Drug Confirmation testing to the laboratory's current practices. Findings: 1. Review of the laboratory's "Hydrolysis Quality Control" procedure revealed "Hydrolysis Quality Control (HQC) is prepared by using Morphine-3-beta-D-glucuronide, Oxazepam glucuronide and S-urine." 2. Review of the laboratory's HQC preparation worksheet for "Lot # HQC-010" revealed the laboratory used Temazepam

	glucuronide lithium salt, not Oxazepam glucuronide. 3. In interview on August 22, 2023 at 12:15 pm, the Technical Supervisor confirmed the laboratory did not update their HQC policy to include the change in cerilliant standard used for preparation.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5217.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were performed when proficiency results were unacceptable. Refer to D5221.
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 record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5403.
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. Refer to D5403.