

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D1100495	<b>(X3) Date Survey Completed</b>  12/17/2019
<b>Name of Provider or Supplier</b>  Central Louisiana Anesthesia And Pain Management	<b>Street Address, City, State</b>  3311 Prescott Road Suite 415, Alexandria, LA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Certification Survey was performed on December 17, 2019 at Central Louisiana Anesthesia and Pain, CLIA ID # 19D1100495. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish a policy and procedure manual. Findings: 1. Review of the laboratory's policy manual revealed the laboratory did not have a policy to include the following:</p>

	<p>a) Course of action if test system becomes inoperable 2. In interview on December 17, 2019 at 12:20 pm, Personnel 2 confirmed the laboratory did not have a the above policy.</p>
<p><b>D5421</b></p>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to have complete performance studies for Oxycodone. Findings: 1. Observation by surveyor during the laboratory tour on December 17, 2019 revealed the laboratory performs Oxycodone testing on the Abbott Architect Plus c4000. 2. Review of the laboratory's performance specification studies for Oxycodone revealed the laboratory started patient testing in May 2019 on the Abbott Architect Plus c4000 chemistry analyzer. 3. Further review of the laboratory's performance specification studies revealed the laboratory did not include the following: a) Complete precision: day-to-day studies and the raw data to support the studies 4. In interview on December 17, 2019 at 01:00 pm, Personnel 2 stated the day to day studies were completed during the installation week by performing quality control daily for 5 days but the laboratory did not include these studies in the installation records. 5. In further interview on December 17, 2019, Personnel 2 confirmed the laboratory performed complete precision but did not include the day-to-day studies and the raw data to support testing. 6. Review of the laboratory's Task 1 and 3 form revealed the laboratory performs 5,060 Oxycodone tests annually.</p>
<p><b>D6013</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(3)(ii)</p> <p>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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.</p>
<p><b>D6031</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(13)</p>

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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) 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 responsible for any aspect of the testing process. Refer to D5403.

**D6036**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:  
Based on observation, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory.  
Findings: 1. The laboratory failed to have a complete policy and procedure manual. Refer to D5403. 2. The laboratory failed to have complete performance studies for Oxycodone. Refer to D5421.