Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1100495	(X3) Date Survey Completed 01/31/2018
Name of Provider or Supplier Central Louisiana Anesthesia And Pain Management	**Street Address, City, State** 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Certification Survey was performed on January 31, 2018 at Central Louisiana Anesthesia and Pain - CLIA #19D1100495 and was found in compliance with 42 CFR 493, Requirements for Laboratories. However, standard level deficiencies were cited.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure manual, and interview with personnel, the laboratory failed to establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. Findings: 1. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to establish written policies and procedures that include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel involved in any phase of laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. Interview with personnel 2 on January 31, 2018 revealed she was unaware of all the policies and procedures that were required. Personnel 2 confirmed the laboratory failed to have a complete policy and procedure manual.

D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel the laboratory failed to establish their own means and ranges for twenty (20) of twenty (20) types of quality control material utilized in Chemistry, Toxicology and Hematology. Findings: 1. Observation by surveyor on January 31, 2018 revealed the laboratory maintained the following analyzers for patient testing for Immunology, Chemistry, Toxicology and Hematology: a) Abbott Architect Plus c4000 Chemistry Analyzer which tests for: Albumin (Alb), Alkaline phosphatase (ALP), Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Direct Bilirubin (DBil), Total Bilirubin (TBil), Calcium (CA), Chloride (CL), Carbon Dioxide (CO2), Creatinine (Creat), Glucose (Glu), Lactate Dehydrogenase (LDH), Potassium (K), Sodium (NA), Total Protein (TP), Blood Urea Nitrogen (BUN), Amphetamine (Amph), Barbiturates (Barb), Benzodiazepines (Benzo), Cocaine (COC), Methamphetamine (Methamph), Opiates (OPI), Phencyclidine (PCP), Cannabinoids (THC), and Tricyclic's (TCA). b) Abbott Cell-Dyn Emerald Hematology Analyzer which tests for Complete Blood Cell (CBC) testing which includes: White Blood Cell counts (WBC), Red Blood Cell counts (RBC), Hemoglobin (Hgb), Hematocrit (Hct), Platelet (Plt) and Auto Differential. 2. Review of Quality Control package inserts revealed the following: a) BIO-RAD Liquid Assayed Multiqual Control package insert stated "It is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." b) Abbott Architect DOA MC I, MC II, THC, PCP, AMP/OPI, Meth, Amph, Barb, Benzo and COC package inserts all stated "The result of the controls should be within the range established by the laboratory." c) Abbott Cell-Dyn 18 Plus Hematology Control package insert stated "The assigned values are presented as a mean and recovery range. The mean assay values are derived from repetitive testing on several instruments operated and maintained according to the manufacturer's instructions; they do not necessarily apply to a single instrument. The recovery ranges are intended to reflect inter-laboratory and inter-instrument variability; thus they are wider than the +/- 2 SD QC Range for one instrument." 3. Review of the laboratory policy and procedure manual revealed the laboratory had a procedure for establishing means and acceptable ranges for quality control material. 4. Review of Quality Control Records from February 2017 through January 31, 2018 revealed the laboratory utilized the following twenty (20) lot numbers of control material without establishing their own means and ranges as required by the manufacturer. a) BIO-RAD Liquid Assayed Multiqual Controls 1 and 3: Lot numbers: 45781, and 45783. Lot numbers: 45771, and 45773. Lot numbers: 45731, and 45733. b) Abbott Architect Controls: DOA MC I

	and MC III: Lot numbers 45770 THC: Lot number 87679FD01 and 03813FD01 PCP, Meth, Amph, Barb, Benzo and COC: Lot number 57832FD01 AMP/OPI: Lot number 90882FD01 c) Abbott Cell Dyn 18 Plus Controls: Lot numbers: L6326, N6326, and H6326 Lot numbers: L7044, N7044, and H7044 Lot numbers: L7128, N7128, and H7128 Lot numbers: L7212, N7212, and H7212 Lot numbers: L7296, N7296, and H7296 Note: The laboratory failed to document the dates when the lot numbers were put into use to ensure that expired items were not utilized beyond their expiration dates. 5. Interview with Personnel 3 on January 31, 2018 revealed that she had established quality control ranges; however the Technical Consultant maintained that data and calculations off site.
D5805	TEST REPORT CFR(s): 493.1291(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 observation and record review, the laboratory failed to include the disclaimer contained in the Beckman Coulter package inserts on the report for Urine Drug Screen testing. Findings: 1. Observation by the surveyors on January 31, 2018 revealed the laboratory utilized the Abbott Architect Plus c4000 Chemistry Analyzer for Urine Drug Screen (UDS) testing and reporting of Amphetamine (Amph), Barbiturates (Barb), Benzodiazepines (Benzo), Cocaine (COC), Methamphetamine (Methamph), Opiates (OPI), Phencyclidine (PCP), and Cannabinoids (THC) in patient urine samples. 2. Review of the Abbott Architect package inserts for Amph, Barb, Benzo, COC, Methamph, OPI, PCP, and THC revealed under the "Intended Use: This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary results are used." 3. Review of a random selection of patient records for Urine Drug Screen testing that utilized the Abbott Architect Plus c4000 Chemistry Analyzer from February 7, 2017 through January 23, 2018 revealed the laboratory failed to include the full disclaimer from the manufacturer for the following patients: On February 7, 2017 Patient 1. On April 4, 2017 Patient 2. On June 5, 2017 Patient 3. On August 9, 2017 Patient 4. On September 11, 2017 Patient 5. On October 17, 2017 Patient 6. On November 8, 2017 Patient 7 On December 13, 2017 Patient 8. On January 23, 2018 Patient 9. 4. Review of the Task 1 and 3 Form submitted to the surveyor on January 31, 2017 revealed the laboratory performs the following annual volumes for UDS testing: Amph - 4000, Barb - 4000, Benzo - 4000, COC - 4000, Methamph - 4000, OPI - 4000, PCP - 4000, and THC - 4000. 5. Interview with Personnel 3 on January 31, 2017 confirmed that patient urine drug screen test results did not include the disclaimer.

D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory established their own means and ranges for twenty (20) of twenty (20) types of quality control material utilized in Chemistry, Toxicology and Hematology. Refer to D5469.