Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D1106349	08/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Central California Pain Management	3550 Q Street, #304, Bakersfield, CA	

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
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, random review of ten (10) patient records from 01/14/2017 to 07/23/2018, and an interview, it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the preanalytic Toxicology quality assessment systems for 2017 and 2018 to the date of the survey. The Findings include: a. The surveyor requested on 08/02/108 (survey date) documentation of ongoing assessing practices/issues related to test requests, specimen submission, handing and referral, and the frequency of monitoring; the laboratory failed to provide written documentation (records) of any preanalytic quality assessment activities or problems. b. The testing personnel affirmed 08/02/108 12:25 AM that the laboratory did not follow the written policy and procedure to assess, monitor and correct problem in the preanalytical systems (refer to laboratory General QA Policy, Effective Date 01.01.2012, pgs.1-8).
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

	This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, random review of ten (10) patient records from 01/14/2017 to 07/23/2018, and an interview, it was determined that the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the postanalytic Toxicology quality assessment systems for 2017 and 2018 to the date of the survey. The Findings include: a. The surveyor requested on 08/02/108 (survey date) documentation of ongoing quality assessment (QA) for the postanalytic system includes assessing practices/issues related to test report monitoring and evaluating the accuracy and completeness of the laboratory's test reports and the laboratory's turn-around times and procedures for notification of test results. b. The testing personnel affirmed 08/02/108 12:25 AM that the laboratory did not follow the written policy and procedure to assess, monitor and correct problem in the postanalytical systems (refer to laboratory General QA Policy, Effective Date 01.01.2012, pgs.1-8).
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on lack of documentation for competency assessments, review of quality control records, and interview with the laboratory director and a testing person, it was determined that the technical consultant (laboratory director) failed to perform and document the performance of all testing personnel and assuring that the staff maintained their competency to perform test procedures promptly, accurately, and proficiently. The findings included: a. There was no documentation to show that the testing personnel were evaluated during the years 2017 and /2018, which is considered the following minimum requirements. 1. The procedures for evaluation of the competency of the staff must include, but are not limited to: 2. Direct observation of the testing performed (including sample handling, processing and testing). 3. Monitoring the recording and reporting of results. 4. Direct observation of instrument maintenance. 5. Review of intermediate worksheets, quality controls. 6. Assessment of testing previously analyzed specimens (external QC and proficiency testing). 7. Assessment of problem solving skills. c. On 068/02/2018 12:45 AM (Survey date) the laboratory testing person affirmed that no competency assessments were performed and documented during the above period.