Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D2084932	04/04/2018
Name of Provider or Supplier	**Street Address, City, State**	
Central States Pain Clinic	1300 37th Street, Suite 6, West Des Moines, IA	

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
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of patient test reports, Thermofisher 3200 patient test records and confirmed with laboratory personnel identifier #5 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 4/4/2018, the laboratory failed to meet the post-analytical requirements for ensuring that test results are accurately sent to the final test report as specified in the standard D5801 and the test report included the correct date of testing performed as specified in the standard D5805.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

	This STANDARD is not met as evidenced by: Based on review of patient test reports, the Thermofisher 3200 analyzer patient and quality control records, and confirmed by laboratory personnel identifier #5 (refer to the Laboratory Personnel Report) at approximately 11:30 am on 4/4/2018 , the laboratory failed to have a electronic health record (EHR) system in place to accurately send patient test results from the Thermofisher 3200 analyzer to the EHR test report for four out of four patients (identifiers Patient A, B, C and D) who had drug confirmation testing performed in November 2017. The findings include: 1. Patients A and B had drug confirmation testing performed on 11/11/2017. The test report documented results for 48 analytes, including, Alpha-HydroxyAlprazolam. 2. Patients C and D had drug confirmation testing performed on 11/7/2017. The test report documented results for 48 analytes, including, Alpha-HydroxyAlprazolam. 3. Comparison of the November 2017 quality control records and the patient test reports revealed no quality control results for the analyte, Alpha-HydroxyAlprazolam. 4. The patient test records from the Thermofisher 3200 analyzer confirmed that the laboratory did not test for the analyte, Alpha-HydroxyAlprazolam. 5. The test reports for Patients A, B, C and D all stated the patient test results as "Not Detected" for the analyte, Alpha-HydroxyAlprazolam. 6. Laboratory personnel identifier #5 confirmed that the laboratory did not test for the analyte, Alpha-HydroxyAlprazolam. The EHR reported out a result for an analyte not performed by the laboratory.
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 review of patient test reports, the Thermofisher 3200 analyzer records and confirmed by laboratory personnel identifier #5 (refer to the Laboratory Personnel Report) at approximately 11:00 am on 4/4/2018 , the laboratory failed to include the correct test report date for two out of four patients (patient identifiers A and B) who had drug confirmation testing performed in November 2017. The findings include: 1. Patient A had drug confirmation testing performed on 11/11/2017. 2. Patient B had drug confirmation testing performed on 11/11/2017. 3. The patient test reports for Patient A and Patient B had the testing date as 11/10/2017.