Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1093125	07/07/2020
Name of Provider or Supplier	**Street Address, City, State**	
Doctors Pain Management Associates	825 E Oak St, Kissimmee, FL	

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	An initial certification survey was conducted on July 7, 2020. Doctors Pain Management Associates clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to perform function checks to validate the speed and time on their centrifuge from 3/2/20 to 7/7/20. Findings: Review of the maintenance logs showed there was no record of the laboratory's validation of the Southwest Science SC1024 centrifuge for speed and time. The laboratory used the centrifuge to spin patient samples at 10.5 G (Gauss) for 8 minutes . During an interview on 7/7/20 at 11:07 AM, the Technical Supervisor stated they had not performed validations on their centrifuge.
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 record review and interview, the laboratory's Lab Report failed to list all the required information from 3/2/20 to 7/7/20. Findings: 1. Review of the toxicology Lab Report showed address of the location where the testing was done and the units of measurement for the test results for 4 out of 4 patients (#1, 2, 3, 4) test results. The laboratory's quantitative test results were measured in ng/ml (nanograms per milliliter). The Clinical Laboratory Improvement Amendments (CLIA) Application for Certificate signed and dated by the laboratory director on 7/7/19 noted the total estimated annual test volume was 244,800. During an interview on 7/7/20 at 2:49 PM, the Technical Supervisor stated that the address of the laboratory and the units of measurements were not on the Lab Report. 2. Review of the toxicology Lab Report showed that for 3 (#1, 3, 4) out of 4 patients, the quantitative test results were above the laboratories reportable range. The reportable range for norfentanyl was 4 - 900 ng /ml and patient #1's norfentanyl tests results were reported as 2452.54. The reportable range for hydromorphone was 20 - 4500 ng/ml and patient #3's hydromorphone tests results were reported as 40,451.03. The reportable range for oxycodone was 20 - 4500 ng/ml and patient #4's oxycodone tests results were reported as 4534.54. Test results for patient #1 should have been reported as it was greater than 900 ng/ml. Test results for patient #3 and #4 should have been reported as they were greater than 4500 ng/ml. The Clinical Laboratory Improvement Amendments (CLIA) Application for Certificate signed and dated by the laboratory director on 7/7/19 noted the total estimated annual test volume was 244,800. During an interview on 7/7/20 at 2:36 PM, the Technical Supervisor stated that the laboratory was reporting quantitative results outside the range of the reportable ranges.