Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1093125	12/16/2019
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	Unannounced Complaint Investigation #2019017812 was conducted on 12/16/19. Doctors Pain Management Associates was not in compliance with 42 CFR 493, requirements for clinical laboratories.
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 personnel files and interview with the Laboratory Director, the laboratory failed to perform competency evaluations on the Technical Supervisor or the Testing Person since high complexity Toxicology testing began on 5/21/18. Findings: The competency policy, not signed by the Laboratory Director, read, "New personnel are assessed initially during training, at 6 months, and at least annually thereafter by the Laboratory Director or designee....Personnel who have not been assessed to perform a specific test or to operate a specific instrument are not allowed to use the test/instrument to report clinical results." The personnel files did not reveal any competency evaluations performed on the Technical Supervisor or Testing person since high complexity testing began on 05/21/18. Interview with the Laboratory Director on 12/16/19 at 6:27 PM confirmed that there competencies were not performed.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on review of the College of American Pathologist (CAP) proficiency testing (PT) and interview, the laboratory failed to perform and provide documentation to verify the accuracy of the testing methods for 10 out of 62 analytes tested in urine toxicology from 5/21/18 to 12/13/19, at least twice annually. Findings: Review of the College of American Pathologist (CAP) proficiency testing (PT) showed that 10 analytes were not included in CAP's test menu. The following 10 analytes were not included in CAP's test menu: Ethyl Sulfate, Midazolam, Mitragynine, Naloxone, Naltrexone, N-desmethyl Tapentadol, Norhydrocodone, Ritalinic Acid, Secobarbital, and Tapentado. The laboratory performed Split Testing on 4/19/19 that included the following 4 analytes: Ethyl Sulfate, Norhydrocodone, Secobarbital, and Tapentado. No Split Testing could be located on the following 6 analytes: Midazolam, Mitragynine, Naloxone, Naltrexone, N-desmethyl Tapentadol, and Ritalinic Acid. The laboratory started high complexity testing of toxicology analytes on 5/21/19 and stopped testing on 12/13/19. Split Testing was performed only once between 5/21/18 and 12/13/19. During an interview on 12/16/19 at 4:44 PM, the Testing Personnel confirmed that the Split Testing was performed only once.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on Medical Laboratory Evaluation (MLE) proficiency testing (PT) record review and the College of American Pathologists (CAP) proficiency testing (PT) records and interview, the laboratory failed to document proficiency evaluation for the 3rd event in 2017, and verification activities for the 2nd and 3rd events in 2018, and the 1st, 2nd, and 3rd events in 2019. Findings: 1. Review of the Medical Laboratory Evaluation (MLE) proficiency testing (PT) records for the 2017 3rd event showed that there was no documentation of the evaluation of the PT results. During an interview on 12/16/19 at 7:39 PM, the Laboratory Director acknowledged he did not know where the proficiency testing review form was located. 2. Review of for showed that the Laboratory Director failed to verify that PT samples were run in the same manner as patients by signing the attestation statement. Attestation statements were not signed by the Laboratory Director for 2nd, and 3rd events in 2018, and the 1st, 2nd and 3rd events in 2019. During an interview on 12/16/19 at 11:45 AM, the Testing Personnel acknowledged that the attestation forms were not signed by the laboratory director.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the moderate complex testing procedures review, the moderate complex testing procedures and the high complexity testing procedure, and interview with the Laboratory Director, the Laboratory Director did not sign any policies or

	procedures since he became Laboratory Director in 2016. Findings: Review of policies and procedures revealed that the Laboratory Director will approve all new policies and review them every 2 years. Review of the moderate complex testing procedures revealed a signature from the former Laboratory Director in 2015, but no signature of the current Laboratory Director when he took over in 2016. Review of the high complexity testing procedure (began 05/21/18) revealed no signature of the Laboratory Director as reviewed. Interview on 12/16/19 at 6:31 PM the Laboratory Director revealed that he started as Laboratory Director in 2016 (he could not recall specific date) and confirmed that he did not sign the policies as reviewed.