Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1049257	08/01/2019
Name of Provider or Supplier	**Street Address, City, State**	
Interventional Spine Specialists Of Florida Llc	7171 N University Dr Ste 300, Tamarac, 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	A recertification survey was conducted on August 1, 2019. Anesthesia Pain Care Consultants Inc was found not in compliance with 42 CFR 493, requirements for clinical laboratories.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not have the required signatures on all of the documentation, and failed to maintain all of the proficiency testing records. Findings: The laboratory uses the College of American Pathologist (CAP) to verify the accuracy of urine toxicology analytes. Review of the laboratory's proficiency testing records with CAP showed that the laboratory director or designee failed to sign the performance evaluation for the 2017; 2nd and 3rd events. CAP records also showed that the laboratory director or designee and the testing personnel also failed to sign the attestation for the 2017 3rd event. The laboratory also was unable to provide documentation showing the instrument test results for 2017; 3rd

	event, and 2018 ; 2nd and 3rd events. During an interview on 8/1/19 at 10:28 AM, the Technical Consultant acknowledged that the forms were not signed and that she was unable to located the instrument test results.
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 record review and interview, the laboratory failed to provide documentation to verify the accuracy of the testing methods for 6 out of 49 analytes tested in urine toxicology from 8/1/17 to 12/31/18; at least twice annually. Findings: Review of the College of American Pathologist (CAP) records showed that the analytes ETS (Ethyl Sulfate), Norhydrocodone, Secobarbital, and Tapentadol were not include in the list of CAP urine toxicology analytes tested in their proficiency testing (PT). CAP list of analytes also did not include Gabapentin and Pregabalin before the 2018 3rd PT event. The laboratory was unable to provide documentation that showed the PT was performed at least twice annually for the above mentioned analytes from 8/1/17 to 12 /31/18. During an interview on 8/1/19 at 1:44 PM, the Technical Consultant acknowledged she did not know where the PT for ETS, Norhydrocodone, Secobarbital, Tapentadol, Gabapentin and Pregabalin where located.
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 record review and interview, the laboratory failed to provide documentation of quality control lot to lot comparison from 8/1/17 to 3/6/19 for toxicology. Findings: Review of the quality control logs showed that there were no lot to lot comparisons from 8/1/17 to 3/6/19 for the Shimadzu AB Sciex Triple Quad 4500MD toxicology analyzer. During an interview on 8/1/19 at 1:00 PM, the Testing Personnel acknowledged that she didn't know where the documentation of the toxicology lot to lot comparisons where located.