Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1049257	(X3) Date Survey Completed 06/02/2021
Name of Provider or Supplier Interventional Spine Specialists Of Florida Llc	**Street Address, City, State** 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 conducted on 06/02/2021 found that the ANESTHESIA PAIN CARE CONSULTANTS INC clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following condition was cited: -D5200 General Laboratory Systems.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory did not meet the condition for General Laboratory Systems. Findings include: -The laboratory failed to do at least twice a year accuracy verification for 10 out of 63 analytes tested in urine toxicology. Refer to D5217.
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 record review and staff interview, the laboratory failed to do competency evaluation for technical supervisor (TS) for 2 out of 3 years reviewed. Findings include: -Review of CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director (LD) on 05/12/2021 revealed that there was 1 TS. -Review of personnel records revealed that the laboratory failed to have documentation of competency assessment for TS for 2019 and 2020. During an interview on 06/02/2021 at 10:30 am, with TS, she confirmed that the laboratory failed to have competency assessment for her on 2019 and 2020.
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 technical supervisor (TS) interview, the laboratory failed to provide documentation to verify the accuracy for 10 out of 63 analytes tested in urine toxicology from 2019 to 2021, at least twice annually. This is a repeated deficiency. Findings include: -Review of College of American Pathologists (CAP) proficiency testing (PT) records showed that the analytes Ethyl Sulfate (EtS), Norhydrocodone, Ritalinic Acid, Tapentadol, Midazolam, Naloxone, Naltrexone, N Desmethyltapentadol, Mitragynine and Secobarbital were not included in the list of CAP urine toxicology analytes tested in their PT. -Review of PT policy signed by the laboratory director on 3/20/2020, revealed that the policy failed to list the requirement of at least twice a year accuracy verification for analytes evaluated with a split sample study. -The laboratory provided documentation of one split sample testing for 2019, 2020 and 2021. The laboratory failed to do twice a year verification for the analytes Ethyl Sulfate (EtS), Norhydrocodone, Ritalinic Acid, Tapentadol, Midazolam, Naloxone, Naltrexone, N Desmethyltapentadol, Mitragynine and Secobarbital. During an interview on 6/2/2021 at 12:00 pm with TS, she explained that she understood that the requirement for the verification of accuracy was to do one per year, she confirmed that the laboratory failed to do twice a year verification for the analytes listed above.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory Quality Assessment (QA) plan failed to ensure the laboratory performed at least twice a year accuracy verification for 10 out of 63 analytes for 2 out of 2 years reviewed. Findings include: -Review of Plan of Correction signed by the laboratory director (LD) on 8/16/2019 revealed that the laboratory will ensure that the deficiency of failing to perform twice a year accuracy verification for analytes not included by proficiency testing programs will not recur with the quarterly review using the Quarterly Audit Assessment (QAA) form. Review of the Quality Assurance (QA) plan revealed that in section D, for

	analytes not graded by proficiency testing (PT) agencies, the laboratory will do annual accuracy verification. Based on that statement the laboratory performed one split sample study per year for 2019 and 2020. During an interview on 06/2/2021 at 12:30 PM, with technical supervisor, she confirmed that the QA plan failed to ensure that the analytes that are not included in PT programs had at least twice a year accuracy verification.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director (LD) failed to ensure that the laboratory quality assurance plan appropiately monitored the laboratory processes. Findings include: -The review of the Quality Assurance records showed that the LD failed to ensure that the laboratory verified the accuracy of testing at least twice a year for: Ethyl Sulfate (EtS), Norhydrocodone, Ritalinic Acid, Tapentadol, Midazolam, Naloxone, Naltrexone, N Desmethyltapentadol, Mitragynine and Secobarbital analytes. Refer to D5217 and D5791.