Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2149361	09/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Center For Interventional Pain & Spine Llc	300 Welsh Road, Building 2, Suite 104, Horsham, PA	

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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on the review of the Chemical Inventory Communication Policy, observation of the laboratory and interview with the laboratory Director (LD), Technical Supervisor (TS) and General Supervisor, the Laboratory failed to have adequate Personnel Protective Equipment (PPE) procedures for handling quality controls and calibrators prepared in the laboratory. Findings include: 1. The Chemical Inventory Communication Policy, SAF 104.0, under PPE sections states "It is the responsibility of management to provide a safe working environment and to provide equipment to ensure the personal safety to all employees. While this statement holds true, it is the responsibility of staff to ensure PPE equipment is maintained in sufficient quantities, obtained if needed, and located in an area accessible to all employees in time of need." 2. On the day of survey, 09/12/2018, the SAF 104.0 Chemical Inventory Communication Policy lacked specifics in PPE needed to be used in the laboratory when working with specimen and during preparation of quality material produced in the laboratory. 3. The LD and TS confirmed the findings above on 09/12/2018 around 12:24 pm.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it

	can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on Sciex LCMS/MS record review and interview with the Laboratory Director (LD) and the Technical Supervisor (TS), the laboratory failed to verify the performance specification of the Lower Limit of Quantification (LLOQ) and Upper Limit of Quantification (ULOQ) cutoff values for the Sciex LCMS/MS used for confirmatory toxicology tests before reporting patient results from 7/23/2018 to 9/12/2018. Findings include: 1. On the day of survey, 09/12/2018, the Laboratory could not provide the surveyor with validation documentation for the LLOQ and ULOQ cutoff values used for the Sciex LCMS/MS confirmation toxicology tests. 2. From 7/23/2018 to 09/12/2018, 1475 patient Toxicology Confirmatory tests were analyzed. 3. The LD and TS confirmed the findings above on 09/12/2018 around 10:30 am. * LCMS/MS = Liquid Chromatography Mass Spectrometry
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 upon Sciex LCMS/MS record review and interview with the Laboratory Director (LD) and the Technical Supervisor (TS), the laboratory failed to establish, verify and document the acceptability of all control materials (3 of 3) prepared in house for the Sciex LCMS/MS from July 23, 2018 to September 12, 2018. Findings include: 1. On the day of survey, 09/12/2018, the laboratory could not provide documentation of documented criteria for acceptability and show statistical parameters performed on 3 of 3 unassayed quality control materials prepared in the laboratory. 2. From 7/23/2018 to 09/12/2018, 1475 patient Toxicology Confirmation tests were analyzed. 3. The LD and TS confirmed the findings above on 09/12/2018 around 12:00 pm.