Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2149361	05/01/2024
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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director (LD) and Techinical Supervisor (TS), the LD failed to be present for a reasonable period of each working day in each laboratory for which he was director from 8/26/22 to the day of survey as required by PA state regulations. Findings include: 1.The PA State regulation 5.22 (g) states: "A director shall be present for a reasonable period of each working day in each laboratory for which he is director." 2.The laboratory's policy GEN 105.0 LD Communication states, "The Laboratory Director will be available for laboratory and laboratory personnel, as well as for clients (physicians), once a month or as needed by phone, email, and other communication means. In addition, many laboratory activities are completed through qualified Laboratory Director designees. Laboratory Director will document the director's site visits and communication(s) with the laboratory on the Director's Site Visit and Communication Log. " 3. According to the Laboratory Director Log the LD visited the laboratory 11 of 29 months from 01/2022 to the day of survey. 4. The LD confirmed the findings above on 05/01/2024 at 01:00 pm.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's

	instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of temperature records, observation of the laboratory, and interview with the laboratory director (LD) and technical supervisor (TS), the laboratory failed to monitor and document refrigerator temperatures to ensure operating conditions were met for the proper storage of reagents for chemistry testing from 8/11/2022 to the day of survey. Findings Include: 1. On the day of the survey, 05/01/2024 at 12:30 pm, review of 2 of 2 months of laboratory's temperature logs revealed the laboratory failed to monitor and document refrigerator temperature for weekends and holidays from 5/24/2022 to the day of survey. 2. During observation of the laboratory the following reagents were found to be stored in refrigerator in the laboratory. 7 of 7 IMCSzyme- acceptable storage temperature 2-8 degrees Celsius 8 of 8 Rapid Hydrolysis Buffer- acceptable storage temperature 2-30 degrees Celsius 3. The LD and TS confirmed the findings above on 05/01/2024 at 1:00 pm.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the laboratory director (LD) and technical supervisor (TS), the laboratory failed to evaluate twice a year the relationship between 2 of 2 AB Sciex Triple Quad 4500MD analyzers used for toxicology testing performed from 08/26/2022 to the date of survey. Findings include: 1. On the day of survey, 05/01/2024, the laboratory failed to provide documentation of the biannual comparison studies for the following instruments used for Toxicology testing performed from 08/26/2022 to 05/012024: - AB Sciex Triple Quad 4500 MD SN: CP20101710 v. AB Sciex Triple Quad 4500 SN: BJ23581405 2. The LD and TS confirmed the findings above on 05/01/2024 at 1:00 pm.