Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D2005035	09/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
Interventional Pain Institute	500 Chesterfield Center Ste 250, Chesterfield, MO	

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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for the Eppendorf Centrifuge 5804, observation of laboratory centrifuge and interview with the technical supervisor (TS), the laboratory failed to follow the manufacturer's instructions for proper installation of the centrifuge. Findings: 1. Review of the Eppendorf Centrifuge 5804 manufacturer's instructions states, "Lift the device by the underside in the vicinity of the device feet and place it directly on a suitable lab bench." 2. Observation of the laboratory centrifuge showed the Eppendorf Centrifuge 5804 was installed directly on the floor. 3. Interview with the technical supervisor on September 12, 2023 at 1:30 PM confirmed the laboratory failed to follow the manufacturer's instructions for proper installation of the centrifuge.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on observation of the Sciex 4500 LCMS urine drug confirmation testing analyzer, review of laboratory procedures, and interview with the technical supervisor (TS), the laboratory failed to ensure solutions were labeled to indicate expiration dates. Findings: 1. Observation of the Sciex 4500 LCMS urine drug confirmation testing analyzer showed mobile phase A stored at room temperature with a preparation date of 08/17/2023 and no expiration date. 2. Observation of the Sciex 4500 LCMS urine drug confirmation testing analyzer showed mobile phase B stored at room temperature with a preparation date of 08/23/2023 and no expiration date. 3. Review of laboratory procedure "TOX001", states "Stored Mobile Phases can be kept at room temperature and should be discarded if stored more than a month's time." 4. Interview with the TS on September 12, 2023 at 2:00 PM confirmed, the laboratory failed to ensure solutions were labeled to indicate expiration dates.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, review of patient test reports for urine drug confirmation testing and interview with the technical supervisor (TS), the laboratory failed to ensure the procedure cut-off values matched the cut-off value on the patient test report for two of 42 analytes. Findings: 1. Review of the laboratory procedure "TOX001" states the cut-off value for "Nordiazepam as 25 ng/mL and Oxazepam as 50 ng/mL." 2. Review of the patient test reports for urine drug confirmation testing showed the cut-off value for Nordiazepam as 50 ng/mL and Oxazepam as 25 ng/mL. 3. Interview with the TS on September 12, 2023 at 2:00 PM confirmed that the laboratory's procedure cut-off value for Nordiazepam and Oxazepam did not match the cut-off value on the patient test report.