Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D1105419	02/07/2018
Name of Provider or Supplier	**Street Address, City, State**	
Southern Idaho Pain Institute Pc	120 Rose St N, Twin Falls, ID	

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
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 an observation of laboratory refrigerator and freezer, a procedure manual review, and an interview with the laboratory testing personnel, the laboratory failed to define the storage requirements for the drug analysis standards and controls since the last survey on March 7, 2016. Findings: 1. An observation on February 7, 2018 at 12: 15 PM, of the laboratory Hot-Point freeze-thaw freezer where drug analysis standards and controls were stored, revealed the temperature of the freezer had not been monitored and the refrigerator failed to include acceptable temperature ranges. 2. An observation on February 7, 2018 at 12:15 PM, of the laboratory Hot-Point freeze-thaw freezer revealed the 72 Cerilliant reference drug standards stored in the freezer were not in a frozen state. 3. A review of the drug testing standard operating procedure revealed the operating procedure failed to include the temperature storage requirements for the standards stored in the freezer and the reagents and controls stored in the refrigerator. 4. An interview on February 7, 2018, at 12:14 PM, with the testing personnel, confirmed the laboratory failed to monitor the lab freezer temperature.
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2)

	The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on an observation of chemical storage and handling in the laboratory and an interview with the laboratory testing personnel, the laboratory director failed to provide and establish a safe environment that ensures adequate chemical storage and handling for methanol, isopropanol, and acetone since January 2017. Findings: 1. An observation on February 7, 2018 at 11:50 AM, of the laboratory space, revealed there were nine 4-liter bottles of methanol, six 4-liter bottles of isopropanol, and twelve 4-liter bottles of acetone stored on the floor and on an open shelf in the open laboratory space. 2. An interview on February 7, 2018, at 11:50 AM, with the testing personnel, confirmed the laboratory failed to establish safety procedures for the storage of chemicals.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review and an interview with the testing personnel, the laboratory director failed to specify, in writing, the responsibilities and duties of each consultant, supervisor, and testing person engaged in the preanalytical, analytic, and postanalytical phases of testing since March 7, 2016. Findings: 1. A record review revealed the laboratory director failed to specify, in writing, the responsibilities for the technical supervisor who is also the general supervisor and the testing personnel. 2. An interview on February 7, 2018 at 11:00 AM, with the testing personnel, confirmed there was no delegation of responsibilities identified in writing for the personnel listed on the CMS-209 form.