Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2073260	08/06/2024
Name of Provider or Supplier	**Street Address, City, State**	
Pain & Rehabilitation Consultants	101 Red Hill Way, Madison, AL	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with Testing Personnel #1, the laboratory failed to ensure the Laboratory Director signed the attestation statement for one of one event reviewed in 2024. The findings include: 1. A review of the API PT records revealed no signature by the Laboratory Director (or designee) on the attestation statement for 2024 Chemistry Miscellaneous 1st Event. 2. During an interview on 8/6/24, at 11:31 PM, Testing Personnel #1 confirmed the above findings.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of the validation records for the Thermo Scientific Indiko Plus

	Toxicology analyzer and an interview with the Laboratory Director, the Laboratory Director failed to document review and approval of the validation procedures prior to instrument use for patient testing on 9/14/2022. The findings include: 1. A review of Thermo Scientific Indiko Plus validation records revealed no evidence of the Laboratory Director's review and approval (as evidenced by signature and date) before the instrument was utilized for patient testing on 4/9/2024. 2. During an interview on 8 /6/2024 at 11:07 AM, the Laboratory Director confirmed the above findings.