Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2111958	10/26/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pain Relief Solutions, Llc	1500 N University, Ste 101, Coral Springs, FL	

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
D0000	An initial certification survey conducted at PAIN RELIEF SOLUTIONS, LLC on 10/26/2022 found the clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 record review and staff interview, the laboratory failed to have attestation signed by the Laboratory Director (LD) or its designee for 1 out of 1 event reviewed for the specialty of Chemistry in 2022. Findings include: Review of Proficiency American Institute (API) proficiency testing (PT) records revealed that for second event of 2022 the LD failed to sign the attestation for the Chemistry specialty. During an interview on 10/26/2022 at 05:45 PM, the Office Manager confirmed that the laboratory failed to have a signed attestation by the LD for the event of reference.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to document the weekly,

	monthly and bimonthly maintenance on the Horiba PentraC400 Analyzer as per manufacturer instructions and procedure manual since June 2022. Findings include: - Review of the policy for the operation of the Horiba PentraC400 signed by the Laboratory Director on 06/20/2022, revealed the requirement for the following maintenance actions. Daily: ISE module activation and ISE module etching. Weekly: Needle deproteinization and ISE module cleaning. Monthly: Wash tower cleaning, Syringe plunger tips replacement, Qualitest and Cooling Unit Filter cleaning. Bimonthly (every two months): Filter replacement and Glycol level checking. Review of the "PC400 Instrument Maintenance Log" since June 2022, revealed that the laboratory failed to document the following maintenance actions: Weekly: fourth week of June, third and fourth week of July, third and fourth week of August, second, third and fourth week of September and third and fourth week of October. Monthly: No documentation in July and October. Bimonthly: No documentation during this period. During an interview on 10/26/2022 at 04:00 PM, the TP # A confirmed that the laboratory failed to document all weekly, monthly and bimonthly maintenance actions for the period of reference.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on lack of records and interview, the laboratory failed to validate their laboratory information management system (LIMS) before use to ensure it was properly exporting the testing results since 06/20/2022. Findings include: -Review of LIMS records revealed that the laboratory used LABTRACK LIMS software. The laboratory had no records of the LABTRACK LIMS validation. Review of the procedure manual revealed was signed by the Laboratory Director on 06/20/2022. During an interview over the phone with Laboratory Director on 10/26/2022 at 5:50 pm, he explained that the laboratory performed a validation of the LABTRACK LIMS before patients testing and they were going to contact the providers of the system, no documentation of the validation of the LIMS was provided till 10/28/2022.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that 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 record review and staff interview, the Laboratory Director (LD) failed to sign and date the test performance verification for the confirmation test panel for

	analysis of pain management drugs and metabolites in human urine using liquid chromatography with tandem mass spectrometry (LC-MS/MS) before patient testing on 06/20/2022. Findings include: -Review of the performance verification study for the confirmation panel for drugs and metabolites in human urine using LC-MS/MS revealed that it was not signed and dated by the LD before patient testing on 06/20 /2022. During an interview on 10/26/2022 at 05/55 PM the LD confirmed that he failed to sign and date the complete validation of the confirmation panel in human urine for pain management drugs and its metabolites before patients testing on 06/20 /2022.