Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2111958	08/12/2024
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	A recertification survey conducted on 08/12/2024 found the PAIN RELIEF SOLUTIONS, LLC clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: 1-Based on record review and interview, the laboratory failed to test three out of three samples reviewed within the acceptable timeframe for urine drug testing. Findings included: -Review of the form CMS-116 CLINICAL LABORATORY IMPROVEMENT AMENDEMENTS (CLIA) APPLICATION FOR CERTIFICATION, signed by the Laboratory Director (LD) on 07/19/2024 revealed that the laboratory performed the following tests in urine: in the Horiba Pentra C-400 analyzer they performed screening for the following drugs Amphetamines, Barbiturates, Benzodiazepines, Cocaine Metabolites, Opiates, pH and Creatinine. For the confirmation test, the laboratory used the Liquid Chromatography Tandem Mass Spectrometry (LC/MS) for the following drugs: Alpha-Hydroxyalprazolam, Lorazepam, Nordiazepam, Temazepam, Benzoylecgonine (Cocaine metabolite), Fentanyl, Methadone, Norbuprenorphine, Tapentadol, Tramadol, 6-MAM (6-Monoacetylmorphine), Hydromorphone, Morphine, Oxycodone, Amphetamine, Carisoprodol, Gabapentin, Methamphetamine and Pregabalin. The laboratory has an estimated testing volume of 35,00 tests performed annually. -Review of procedure

	signed by the LD on 05/28/2024 revealed that the policy "Specimen Rejection" stated that: "Specimen rejection is used to ensure quality laboratory testing and the integrity of the samples. Specimen rejection protocol establishes criteria for rejection and occurs during specimen accessioning and processing. Our laboratory reserves the right to reject any sample that may be inadequate due to any one of the following reasons: 1. Specimen received containing insufficient volume. 2. Specimen that is not labeled with the full name of the patient. 3. Specimen has not completed requisition form. 4. Specimen for which the identifying information on the container does not match the requisition form. 5. If more that two validation parameters are not met, the ordering physician will be alerted. 6. Specimens that do not adhere to our laboratory stability standards Urine stability: i. Frozen: 30 days ii. Refrigerated: 10 days iii. Ambient temperature: 7 days" -Review of three patients reports revealed the following: Patient #1 (collected on 07/24/2024), screening test performed on 08/06/2024 (the 10 days timeframe was due on 08/03/2024) and the confirmation test on 08/07/2024. The two tests were done outside of the acceptable storage stability. Patient #2 and #3 (collected on 07/31/2024), screening test performed on 08/10/2024 and confirmation on 08/11 /2024 (outside of the 10 days) During an interview on 08/12/2024 at 01:30 PM, the laboratory testing person confirmed that the patients listed above were tested outside of the acceptability stability criteria for refrigerated samples.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on lack of records and interview, the laboratory failed to perform the verification of the analyzer Horiba Pentra C-400 after the analyzer was moved to the new location before patient testing on 07/17/2023. Findings included: -Review of the form CMS-116 CLINICAL LABORATORY IMPROVEMENT AMENDEMENTS (CLIA) APPLICATION FOR CERTIFICATION, signed by the Laboratory Director (LD) on 07/19/2024 revealed that the laboratory performed the screening in urine in the Pentra C-400 analyzer for the following drugs: Amphetamines, Barbiturates, Benzodiazepines, Cocaine Metabolites, Opiates and the measurement of pH and Creatinine. -Review of procedure signed by the LD on 05/28/2024 revealed that the policy; "Validation of Test Methods" stated the following: "Before introducing a new instrument or test method into the laboratory, evaluation studies must be performed prior to initiating patient testing in order to: " Examine its performance under laboratory conditions " Develop lab-specific performance claims " Compare the new method with a similar method presently in use in another laboratory " Determine acceptable precision and accuracy and reportable range for each analyte to be tested. This requirement applies when: " An instrument is RELOCATED*. *If the relocated instrument produces comparable results on previously tested patient samples and the control results are in range, the laboratory may determine that performance specifications are not affected. In this case, a full performance verification study would not be required." -the laboratory had no records that performed the comparison

	study for the Pentra C-400 analyzer after the relocation and before patient testing on 07/17/2023. -The laboratory tested 4423 samples from 07/17/2023 to 08/12/2024. During an interview on 08/12/2024 at 01:35 PM, with the testing person, he confirmed that the laboratory failed to perform the Horiba Pentra C-400 verification before patient testing.