Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2065692	10/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Pain Diagnostic & Solutions	729 Sunrise Ave, Ste 602, Roseville, CA	

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
D5467	CONTROL PROCEDURES CFR(s): 493.1256(d)(9)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's quality control material, calibrator, and interview with the laboratory testing person on October 23, 2023, at 12:00 pm, the laboratory failed to use different lot's control material from the calibrator. The findings include: 1. The laboratory used an LC-MS/MS method to detect various drugs in the patient urine sample. It generates a standard curve each time of testing. The laboratory used a calibrator to generate the standard curve, however, it used the calibrator material from the same lot as quality control material. Therefore, the validity of the test method cannot be assured and might have had harmed patient. 2. The laboratory testing person on October 23, 2023, at 12:00 pm, affirmed that the laboratory used the calibrator material from the same lot as quality control material. 3. The laboratory's testing declaration form, signed by the laboratory owner on 10/9 /2023, stated that the laboratory performed approximately 352,000 tests, annually.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's patient test records, quality control material, calibrator, and interview with the laboratory testing person on October 23, 2023, at 12:00 pm, the laboratory director failed to ensure that the laboratory is providing quality results for patient care. The findings include: See D5467.