Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2016617	06/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Spine And Pain, Llc	2 8th Street, Hammonton, NJ	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Techincal Supervisor (TS), the laboratory failed to have a procedure for six month method comparison between two Carolina CL800 analyzers performing Toxicology testing from 2/15/22 to the date of survey. The TS confirmed on 6/25/24 that the laboratory did not have the above mentioned procedure.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation of Quality Control (QC) material in use, review of Manufacture Package Inserts (MPI) and interview with the Techincal Supervisor (TS), the laboratory failed to put open and expiration dates on QC material for Toxicology tests run on the Carolina CLC800 analyzer at the time of survey. The findings include:

	1. The expiration date of the QC material shortens once opened. 2. The laboratory did not put open or expiration dates on controls in use run on the Carolina CLC800 analyzer . 3. The TS confirmed on 6/25/24 at 11:45 am the laboratory failed to put open and expiration dates on the control material.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of Quality Control (QC) records and interview with Techincal Supervisor (TS), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment of Toxicology QC used on the Carolina CLC800 analyzer from 12/15/to the date of survey. The findings include: 1. There was no documented evidence that QC material was verified for the following Lot numbers: a) UDT- Multi Drug Lot H2341 A&B b) Lin-ZHI Methadone Lots 2310037 & 2310039 2. The TS confirmed on 6/25/24 at 11:20 am that all assayed QC material was not verified before putting in use.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), and interview with the Techincal Supervisor (TS) the laboratory failed to have available Corrective Action (CA) procedures to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports on the date of survey. The TS confirmed on 6/25/2024 at 1:00 pm that the laboratory failed to have available CA procedures.