Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2133848	05/14/2024
Name of Provider or Supplier	**Street Address, City, State**	
Revive Spine And Pain Center	1001 Lincoln Drive West, Marlton, 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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratories NJ State License, Proficiency Testing (PT) and interview with the State of New Jersey Proficiency Provider Program lead, the Laboratory Director (LD) failed to be in compliance with New Jersey Administrative code N.J.A.C. 8:44-2.5(b)3. The finding includes: 1. N.J.A.C. 8:44-2.5 (b)3. states Laboratories shall: iii. Maintain records of all proficiency testing results in surveys in which they participate and make such records, including results, interpretations and cumulative performance data routinely available to the Department of Health and Senior Services. 2. The LD failed to make PT Liquid chromatography-mass spectrometry Toxicology data routinely available to the Department of Health and Senior Services and Centers for Medicare & Medicaid Services.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: a) Based on surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisor (GS), the laboratory failed to review and evaluate results when they received an unacceptable score in Toxicology tests performed with the American Proficiency Institute (API) for the First and second events in 2023 and the second event 2022. The findings include: 1. The laboratory received an "Not Graded

	2" Grade for Specific Gravity samples UAD-01, and UAD-02 in event 1, 2023. 2. The laboratory received an "Not Graded 2" Grade for Specific Gravity samples UAD-04, and UAD-06 in event 2, 2022. 3. There was no documented evidence that the laboratory investigated the failures. 4. The GS confirmed on 5/14/24 at 10:45 am that the laboratory did not review and document an evaluation of unacceptable PT results. b) Based on surveyor review of the PT records and interview with the GS the laboratory failed to review coded results for Hematology Testing performed with the College of American Pathologists (CAP) in the calendar years 2022 and 2023. The findings include: 1. The laboratory received coded results (Code 27 - Lack of participant or referee consensus) for event DMPW-B 2022 Drug Monitoring for Pain Management. a) Clinical Study sample DMPM-08 was coded "see note 27". 2. The laboratory received coded results (Code 20 - no appropriate response/target could not be graded) for event DMPW-A 2023 Drug Monitoring for Pain Management. a) Cannabinoids sample DMPM-01 was coded "Code 20". 3. There was no documented evidence that aforementioned coded PT results were reviewed. 4. The GS confirmed on 5/14/23 at 1:15 pm that the laboratory did not review coded PT results.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) Records and interview with the Technical consultant (TC), the laboratory used expired QC material for Hematology testing from to 5/8/24 to the date of survey. The findings include: 1. QC material expiration date changes once opened. 2. MAS Total Drugs of abuse QC material was stable for 30 days after opening. 3. MAS Total Drugs of abuse level 4 lot # DAT206034A and 5 lot DAT26035A expired 5/8/24. 4. Approximately five patients were run per day. 5. The GS confirmed on 5/14/24 at 11:00 am that the laboratory used expired QC 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 General Supervisor (GS), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment of Toxicology QC used on the Indiko Plus analyzer from 4/8/24 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) MAS total control level 3 lot DAT26033A b) MAS total control level 2 lot DAT26032A c) MAS total control level 4 lot DAT26034A d) MAS total control level 5 lot DAT26035A 2. the GS confirmed on 5/14/24 at 11:20 am that all assayed QC material was not verified before putting in use.