Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2133848	02/23/2022
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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to maintain work records for Toxicology PT performed with the College of American Pathologists (CAP) from June 2020 until the date of survey. The GS confirmed on 2/23/22 at 9:45 am that PT work records were not maintained.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by:

	Based on surveyor review of the Competency Assessment (CA) records and interview with the General Supervisor (GS) the laboratory failed to follow its policies and procedures for assessing the competency of Testing Personnel (TP) who perform Toxicology testing at the date of survey. The findings include: 1. The CA was not performed on seventeen out nineteen TP in the calendar years, 2020, and 2021. 2. The GS confirmed on 2/23/22 at 10:20 am the laboratory did not follow the CA procedure.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisor (GS), the laboratory failed to review and evaluate coded PT results obtained with the College of American Pathologists (CAP) in the calendar year 2021. The findings include: 1. The laboratory did not evaluate Code 28 (response qualified with a greater or less than sign; unable to quantitative) for Toxicology Identification sample DMPM-01 in event A. 2. The laboratory did not evaluate Code 22 (result is outside the method/instrument reportable range) for for Toxicology Identification sample DMPM-06 in event B. 3. The GS confirmed on 2/23/22 at 1:30 pm that the laboratory failed to evaluate coded results for PT events.
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: 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 unacceptable scores in Toxicology tests performed with peer group evaluation ALT-PT-II. The findings include: 1. The laboratory received unacceptable scores as follows: a) Duloxetine, Sample ID UR21-7577 b) Acetaminophen, Phentermine Sample ID UR21-7578 c) Naloxone Sample UR21-7579 2. There was no documented evidence that the laboratory investigated the failures. 3. The GS confirmed on 2/23/22 at 2:45 pm that the laboratory did not review and document an evaluation of unacceptable PT results.
D5315	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(c) The laboratory must refer a specimen for testing only to a CLIA-certified laboratory or a laboratory meeting equivalent requirements as determined by CMS. This STANDARD is not met as evidenced by: Based on surveyor review of Toxicology Records, Final Reports and interview with the General Supervisor (GS) and Techincal Supervisor (TS), the laboratory referred the interpretation of chromatography for Urine Toxicology confirmation testing to a

	non-CLIA-certified laboratory from June 2020 to the date of survey. The GS & TC confirmed on 2/23/22 at 2:45 pm that toxicology tests were reviewed and resulted from a non-CLIA-certified laboratory.
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: a) Based on surveyor review of the Procedure Manual (PM) and interview with the General Supervisor (GS), the laboratory failed to follow their procedure for "Validation" on the Allegiant 6460 Triple Quad analyzer from June 2020 to the date of survey. The findings include: 1. The "Validation" procedure "5.3.13" states "Cite any applicable reference literature". a. No reference literature was cited in with the Validation Studies(VS). 2. The "validation" procedure "5.3.9" states "method comparison/Patient sample study: A minimum of 10 patient samples and 2 spiked blank matrixes at multiple concentrations spanning the reportable range should be run and compared with a reference method. a) No reference patient tests reports where included in the VS to corroborate the reference laboratories toxicology results. b) Out of 684 samples run and compared on each insrument, 13 specimens where recorded with an number, 671 where recorded as negative. i) There was no cutoff range defined for the comparison study. The study listed Limit Of Quantification (LOQ) and upper limit of quantification (ULOQ). 3. The GS confirmed on 2/23/22 at 2:00 am the policy "Validation" was not being followed. b) Based on surveyor review of the Procedure Manual (PM) and interview with the General Supervisor (GS), the laboratory failed to follow their procedure for "LOT-to-LOT VERIFICATION" on the Allegiant 6460 Triple Quad analyzer from June 2020 to the date of survey. The findings include: 1. The "LOT-to-LOT VERIFICATION" 5.2 "LCMS" 5.2.1 "Calibrators" procedure states "Each new lot of calibrator is verified by assaying as patient samples using the new lot of calibrators and current lot of calibrators. New Calibrator lots are verified for acceptable performance prior to depletion of the present lot. The calculated mean of all confirmation results should be within +20% of nominal (target) concentration. The target is accepted as the calibrator concentration." a) There was no evidence of the aforementioned procedure was followed. 2. The "LOT-to-LOT VERIFICATION" 5.2 "LCMS" 5.2.2 "Controls" Each new lot of control is verified by analysis using the current lot of calibrators and QC. results for the new QC lot must meet acceptance criteria for the new lot to be accepted. New control lots are verified for acceptable performance prior to depletion of the present lot". a) There was no evidence of the aforementioned procedure was followed. 3. The "LOT-to-LOT VERIFICATION" 5.1 "Analyzer" , 5.1.3 "Controls", states "each new lot of control is verified by analysis (5x) using the current lot of reagents. Results for both the old QC lot and the new QC lot must meet acceptable performance prior to depletion the present lot. Prior to the depletion of a current lot of control material, begin parallel studies with the new lot of controls." a) There was no evidence of the aforementioned procedure was followed. 4. The GS confirmed on 2/23/22 at 2:30 pm the aforementioned procedures were not being followed.
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, Manufacture Package Insert (MPI) and interview with the General Superviosr (GS), the laboratory failed to put open dates on QC material for Toxicology tests run on the Indiko Plus analyzer the time of survey. The findings include: 1. The MAS DOA TOTAL 5, MGC Select DAU high and low creatinine did not have open dates 2. The GS confirmed on 2 /23/22 at 11:45 am the laboratory failed to put open dates on the control material.
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 surveyor review of Performance Specification (PS) records and interview with the General Supervisor (GS), the laboratory failed to ensure that all PS procedures were adequate for all analytes run on the Indiko Plus analyzer from June 2020 to the date of survey. The finding includes: 1. Precision for all analytes was not completed on the Indiko Plus before starting patient testing. 2. There was no evidence a range study for Creatinine was performed before starting patient testing. 3. There was no documented evidence the Laboratory Director reviewed all PS. 4. The GS confirmed at 10:10 am on 2/23/22 the laboratory failed to ensure that all PS procedures were adequate before starting patient testing.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

	This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specifications (PS) and interview with the General Supervisor (GS), the laboratory failed to have complete PS for Toxicology tests performed on the Allegiant 6460 Triple Quad analyzer from June 2020 to the day of the survey. The findings include: 1. A review of the PS revealed the laboratory did not establish performance characteristics as follows: a. The validation of the hydrolysis control did not include validation of: i. Optimal Enzyme Concentration ii. Temperature of the Heat Block iii. Time on the Heat Block b. No source from Clinical Scientific Literature was available to support PS. c. Accuracy was not established for all parameters at 20% per Clinical Scientific Literature.d. No Specimen stability study. e. Method comparision was completed. f. Cutoff values were not defined or verified. 2. The GS confirmed on 2/23/22 at 1:00 pm that the Laboratory Director did not ensure that PS were completed.
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 records and interview with the General Supervisor (GS), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment of Toxicology and Chemistry QC used on the Indiko Plus and Allegiant 6460 Triple Quad analyzers from June 2020 to the date of survey. The findings include: 1. There was no documented evidence to show QC was verified. 2. The GS confirmed on 2/23/22 at 12:15 pm that all assayed QC material was not verified before putting in use.
D5803	TEST REPORT CFR(s): 493.1291(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. This STANDARD is not met as evidenced by: Based on the surveyor review of Test Reports (TR) and interview with the General Supervisor (GS), the laboratory failed to maintain information as part of patients charts from to the date of the survey. The findings include: 1) Ten out out of ten TR

	had information that may affect the interpretation of test results. a) Toxicology Screening test results were under the heading "Lab EIA". b) Toxicology Confirmatory test results were in the heading "LC/MS/MS Result". 2) The GS confirmed on 2/23/21 at 11:15 AM the TR had information that may affect the interpretation of test results.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on the surveyor review of the Final Reports (FR), Procedue Manual (PM) and interview with the General Supervisor (GS), the laboratory failed to have accurate Cutoff Ranges (CR) for Toxicolofgy tests run on the Indiko Plus analyzer from June 2020 to the date of the survey. The findings include: 1. A review of the FR revealed the CR for Amphetamine was 1000 ng/mL but the PM states 500 ng/mL. 2. A review of the FR revealed the CR for Bupenorphine was 5 ng/mL bu the PM states 20 ng/mL 3. A review of the FR revealed the CR for Cocaine was 300 ng/mL bu the PM states 150 ng/mL. 4. A review of the FR revealed the CR for Methadone Metabolite was 50 ng/mL bu the PM states 1000 ng/mL 5. A review of the FR revealed the CR for Phencyclidine was 20 ng/mL bu the PM states 25 ng/mL 6. The GS confirmed on 2/23 /21 at 11:00 am that these tests did not have accurate Cutoff Ranges on the FR.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisor (GS), the Laboratory Director (LD) failed to ensure that PT samples were tested for all analytes run on the Indiko Plus and Allegiant 6460 Triple Quad analyzers from June 2020 to the date of the survey. The findings include: 1. Not all analytes run on the Indiko Plus and Allegiant 6460 Triple Quad analyzers are offered for PT testing in each College of American Pathologists (CAP) survey events. 2. The GS confirmed on 2/23/22 at 2:35 pm that the LD did not ensure PT samples were tested for all tests performed in the laboratory.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with

	the General Supervisor (GS), the Laboratory Director (LD) failed to ensure that Toxicology results performed with the College of American Pathologists (CAP) and ALT PT were reviewed and evaluated by the appropriate staff from June 2020 until the date of survey. The findings include: 1. There was no documented evidence the laboratory reviewed any CAP or ALT PT events. 2. The GS confirmed on 2/23/22 at 1: 50 pm that the LD did not ensure all PT reports were reviewed.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on surveyor review of Personnel Records (PR) and interview with the General Supervisor (GS), the Laboratory Director failed to ensure that the education and training records were available on the date of the survey. The finding includes: 1. Education and training records were not available for seventeen out of 19 TP. 2. The TP confirmed on 1/25/22 at 1:30 pm that education records were not available.