Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D2040899	06/04/2018
Name of Provider or Supplier	**Street Address, City, State**	
Revived Soul Medical Pc	1329 East 17th Street, Brooklyn, NY	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on surveyor's observation, review of the RSM Agilent 6460 reagent log sheets and confirmed in an interview with the technical supervisor and consultant, the laboratory failed to ensure that the information on the RSM Agilent 6460 reagent log sheets used to record the reagent, control & calibration materials were properly recorded. FINDINGS: The technical supervisor and consultant confirmed on June 4, 2018 at approximately 4:00 PM, that the current RSM LC/MS/MS worksheet in use did not include the following information: strength and concentration, storage requirements, preparation and expiration dates.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's Quality Assessment (QA) polices

	/procedures and confirmed in an interview with the technical supervisor and technical consultant, the laboratory failed to follow it's QA policy and perform the monthly QA review for the urine drug testing for the calendar year 2017 through survey date.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on surveyor's review of test requisitions and confirmed in an interview with the technical supervisor and consultant, the laboratory failed to include the following information: The test(s) to be performed (screening or confirmatory); the source of the specimen and the date and time of specimen collection.
D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on surveyor's review of test requisitions, test reports and confirmed in an interview with the laboratory technical supervisor and consultant, the laboratory failed to have a system in place to ensure that the individual(s) entering the patient data into the laboratory's information system (LIS) and/or Electronic Medical Record (EMR) is transcribing it correctly.
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: Based on a surveyor's review of the laboratory's procedure manual and confirmed in an interview with technical supervisor and consultant, the laboratory failed to establish written procedures to include: patient preparation, specimen collection, specimen labeling, including patient name or unique patient identifier, specimen storage and preservation and specimen acceptability and rejection. FINDINGS: The technical supervisor and consultant confirmed on June 4, 2018 at approximately 2:30 PM, that the laboratory failed to have written preanalytic procedures for patient preparation, specimen collection, specimen labeling, including patient name or unique patient identifier, specimen storage and preservation and specimen acceptability and rejection.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on surveyor's review test requisition and confirmed in an interview with the technical supervisor and consultant, the laboratory failed to document the date and time of receipt of the urine specimens, used for drug testing, from all four locations. FINDINGS: The technical supervisor and consultant confirmed on June 4, 2018 at approximately 3:30 PM, the laboratory failed to document the date and time of receipt for the urine specimens, used for drug testing, from all four locations.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory procedure manual and an interview with the technical supervisor and consultant, the laboratory failed to have description of the course of action to take if a test system for the LC/MS/MS becomes inoperable and a

	procedure for twice yearly verification of the non-regulated test analytes for both urine drug screening and confirmatory testing.
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's review of QC records and confirmed in an interview with the technical supervisor and consultant, the laboratory failed to perform and document the controls for lot to lot change for the Carolina CLC 800 chemistry analyzer used for drug screening testing. FINDINGS: The technical supervisor and consultant confirmed on June 4, 2018 at approximately 5:00 PM that the laboratory failed perform and document the controls for lot to lot change for the Carolina CLC 800 chemistry analyzer used for drug screening testing from 01/01/2017 through survey date.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a surveyor's review of five random patient test reports for LC/MS/MS and confirmed in an interview with the technical supervisor and consultant at 5:00 PM on the day of survey, the laboratory failed to include the report date on the final test reports for five of five patient test reports.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.

	1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor's review of laboratory records and findings and an interview with the technical consultant, the laboratory director failed to fulfill his responsibilities and provide overall management of the laboratory. Refer to D6093, D6094 and D6107.
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's review of QC records and confirmed in an interview with the technical supervisor and consultant, the laboratory director failed to ensure that the QC program for Carolina CLC 800 chemistry analyzer used for drug screening testing was maintained to assure quality laboratory services. Refer to D5469.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 a surveyor review of the quality assessment (QA) program and confirmed in an interview with the technical supervisor and consultant, the laboratory director failed to ensure that the laboratory's QA program was maintained as part of the laboratory's overall quality systems program. Refer to D5291.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on surveyor's review of the personnel records and an interview with technical

	supervisor and consultant, the laboratory director failed to specify, in writing, the duties/responsibilities for the technical supervisor and consultant for the high complexity toxicology testing.