

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D2040899	<b>(X3) Date Survey Completed</b>  03/05/2021
<b>Name of Provider or Supplier</b>  Revived Soul Medical Pc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3029</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(2)</p> <p>Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of the laboratory's current standard operating procedure (SOP) and an interview with the current technical supervisor, the laboratory failed to retain a copy for each test procedure on the Agilent 6460 LC/MS/MS analyzer, Carolina CLC 800 chemistry analyzer and the discontinued laboratory SOP manual to include all phases of laboratory testing, for at least 2 years. FINDINGS: The current technical supervisor confirmed on March 5, 2021, at approximately 11:00 AM, the surveyor's finding that the laboratory failed to retain a copy for each test procedure on the Agilent 6460 LC/MS/MS analyzer, Carolina CLC 800 chemistry analyzer and the discontinued laboratory SOP manual for the time period from 7/1/2018 though 8/20/19. a. the laboratory relocated to this current location 1329 East 17th Brooklyn, NY 11229 from 1901 Avenue P Suite 1A Brooklyn NY 11229 on August 20, 2019. However, the laboratory did not move all the laboratory records, documents and procedure manuals to this location on August 20, 2019. b. the current technical supervisor searched the basement for these records, documents and procedures but could not locate them, therefore, they were not available for review at this survey.</p>
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>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.</p>

This STANDARD is not met as evidenced by:  
 Based on the lack of 2018 and 2019 Quality (QC) records, calibration records, assay sheets for the stock reagents and control/calibrators for the LC/MS/MS Agilent 6460 Mass spectrum analyzer used for confirmatory testing and the discontinued Carolina CLC 800 chemistry analyzer used for urine drug screening and an interview with the current technical supervisor, the laboratory failed to retain QC records, calibration records, assay sheets for the stock reagents and control/calibrators for at least 2 years. FINDINGS: 1. The current technical supervisor confirmed on March 5, 2021, at approximately 11:30 AM, the surveyor's finding that the laboratory failed to retain QC records, calibration records, assay sheets for the stock reagents and control/calibrators for at least 2 years for the LC/MS/MS Agilent 6460 Mass spectrum analyzer from 7/1/2018 through 11/30/2019. 2. The following Records and Documents were not available for review at this survey: Agilent 6460 LC/MS/MS- confirmatory testing a. Inventory of stock reagents, reagent log sheets used to record the reagents, QC & calibration material b. Log sheet for reagents, to include strength, concentration, date of preparation, expiration dates and storage requirements c. Maintenance for the Agilent 6460 (e.g. tuning, column changes) and auxiliary equipment and instruments d. Preventative maintenance and service records e. Acceptable criteria for limit of detection, limit of quantitation, upper limit detection for all analytes f. Low and high control acceptable ranges g. List of positive cutoffs for all analytes h. Corrective action for manual integration for poor chromatography or misidentified peaks. Discontinued Carolina CLC 800 -urine screening a. QC and calibration records and assay sheets for this material b. Maintenance and function checks, preventative and service records c. Criteria for storage of urine specimens for urine drug monitoring testing d. Calibration verification chemistry analyzer from 7/1/18 through 8/20/19 e. Corrective and/or remedial action for unacceptable controls and calibrator results.

**D3033**

**RETENTION REQUIREMENTS**

CFR(s): 493.1105(a)(3)(i)

In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years.

This STANDARD is not met as evidenced by:  
 Based on the lack of records and documentation for the validation studies on the Agilent 6460 LC/MS/MS analyzer and an interview with the current technical supervisor, the laboratory failed to retain the records and documentation for the validation studies on the Agilent 6460 when the laboratory relocated to the current address. FINDINGS: 1. The current technical supervisor confirmed on March 5, 2021, at approximately 10:30 AM, the surveyor's finding that the laboratory failed to retain the records and documentation for the validation studies on the Agilent 6460 when the laboratory relocated to the current address on August 20, 2019. a. the original validation documents and records were retained for the the Agilent 6460 LC/MS/MS analyzer b. the Carolina CLC 800 chemistry analyzer was discontinued on August 20, 2019 no records were available for review at the time of this survey.

**D3039**

**RETENTION REQUIREMENTS**

CFR(s): 493.1105(a)(5)

	<p>Quality system assessment records. Retain all laboratory quality system assessment records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of Quality Assessment (QA) records for 2018 and 2019 and confirmed in an interview with the current technical supervisor, at the time of this survey, the laboratory failed to retain the QA records and documentation for the calendar years 2018 and 2019.</p>
<b>D6076</b>	<p><b>LABORATORY DIRECTOR</b> CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of current laboratory policies and procedures, lack of laboratory records and an interview with the current technical supervisor, the laboratory director failed to provide overall management and fulfill the responsibility for the overall operation of the laboratory and failed to ensure compliance with applicable regulations. Refer to D6093 and D6094</p>
<b>D6093</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of current laboratory policies and procedures, lack of laboratory records and an interview with the current technical supervisor, the laboratory director failed to ensure that all components of quality control for toxicology testing were maintained to provide quality laboratory services. Refer to: D 3031 and D3033</p>
<b>D6094</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of current laboratory policies and procedures, lack of laboratory records and an interview with the current technical supervisor, the laboratory director failed to ensure that quality assessment programs were maintained to assure the quality of laboratory services and identify failures in quality as they occur for toxicology testing. Refer to: D3029 and D3039</p>