Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2002690	04/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Powell Recovery Center Inc	14 S Broadway, Baltimore, MD	

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 review of the Maryland State licensing database, the laboratory failed to have a current Maryland State Permit for Medical laboratory testing as required in the Code of Maryland Regulations Title 10, subtitle 10 for toxicology testing. Findings: 1. Review of the Maryland state licensing database showed that the laboratory's Maryland State license expired on 12/31/2017. The Office of Health Care Quality for the Maryland Department of Health and Mental Hygiene did not have a current application to renew the laboratory's medical laboratory permit. 2. The laboratory is not in compliance with the applicable Maryland State laboratory requirements.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) results and interview with the technical consultant, the laboratory did not ensure that all laboratory analytes that were not included in subpart I of this part were verified for accuracy at least twice annually. Findings: 1. The laboratory records show that the laboratory was not enrolled in a PT program for urine creatinine and urine heroin testing. 2. The technical consultant stated that the PT agency confirmed that the program that they were

	enrolled in would include all the required analytes tested in the lab. The PT results submitted to the PT agency did not include urine creatinine and urine heroin. 3. The laboratory's policies and procedures did not include a written procedure for verifying the accuracy of urine creatinine and urine heroin at least twice a year as required. 4. During the survey on 03/29/18 at 12:30 PM the technical consultant confirmed that the first set of PT results did not include urine creatinine and urine heroin.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to have written policies and procedures for retention of laboratory records and entering and reporting patient test results (D5403); and failed to ensure that the verification of the toxicology analyzer was completed prior to testing and reporting patient test results (D5421).
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 review of the procedure manual and interview with the testing person, the laboratory did not have written policies and procedures for entering and reporting patient test results. Findings: 1. According to the testing person the toxicology analyzer is not interfaced with the electronic medical records (EMR). The toxicology results are manually entered into the EMR and the original printouts from the analyzer are stored. 2. During the exit interview on 03/29/18 at 12:30 PM the testing person

	confirmed that the procedure manual did not have written policies and procedures for manually entering patient test results from the EMR. The testing person confirmed that there were no detailed instructions for transferring the patient test results from one system to another and where to store the original printouts for the next two years.
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 review of the "Establishment and Verification of the Method Performance" procedure and interview with the technical consultant and laboratory supervisor, the laboratory failed to ensure that the verification of the toxicology analyzer was completed prior to testing and reporting patient test results. Findings: 1. The "Establishment and Verification of the Method Performance" procedure requires that the laboratory perform accuracy, precision, analytical sensitivity and reference range testing to verify the accuracy of the toxicology analyzer. 2. The "Establishment and Verification of the Method Performance" procedure states: "Run 2-3 levels of controls in duplicate per run over the entire period of evaluation. Collect approximately 20 data points. This data can be used to calculate accuracy, between and within run precision." The laboratory records were reviewed and there was no data to show that accuracy and precision had been performed, evaluated and found to be acceptable. 3. The "Establishment and Verification of the Method Performance" procedure states: "Split approximately 25 samples. Send on set of patient samples to a referral laboratory and run the second set of samples simultaneously in your laboratory. CALCULATE AND GRAPH the data obtained. The same data may be used to verify the reference range established by the manufacturer." The laboratory records were reviewed and there was no data to show that 25 split samples had been performed, evaluated and found to be acceptable. There was no graph showing that the data had been calculated and found to be acceptable. 4. The "Establishment and Verification of the Method Performance" procedure states: "Run at least three levels of calibrator in triplicate as patients. You must include a zero, medium and a high level. GRAPH the data obtained... Record the data on the form provided. Calculate the correlation coefficient and the slope. Graph the data." The laboratory records were reviewed and there was no data to show that the calibrator had been run in triplicate; the data was not documented on the form provided; there was no calculation of the correlation coefficient and the slope; and none of the data was graphed per the instructions listed in the procedure. 5. The toxicology analyzer was installed on 06/07/18 and 06/13/18. At the time of the survey the testing person contacted the company to get copies of the installation and verification documents. The data that was sent did not reflect the verification procedures listed above. 6. During the survey on 03/29/18 at 12:30 PM the technical consultant confirmed that the "Establishment and Verification of the Method Performance" procedure had not been performed as required and the data had not been reviewed and found to be acceptable prior to testing and reporting patient test results. 7. On 04/05/18 the laboratory supervisor e-mailed documentation provided by

	the technical support personnel who performed the installation of the toxicology analyzer. The data was labeled "Quality Control Table" and was dated 06/08/17. The name of the test that was listed was Valproic L and Valproic R. The control name was labeled Val 100, Val 50 and Val 25. 8. A phone conversation with the laboratory supervisor on 04/05/18 at 2:20 PM confirmed that the laboratory was not performing Valproic testing. The laboratory supervisor was not sure what the data was suppose to represent in relationship to the validation. 9. The laboratory's procedure titled "Establishment and Verification of the Method Performance" was not followed by the personnel who performed the validation and the documentation that was provided did not ensure that the toxicology analyzer had been validated and found to be acceptable prior to performing and releasing patient test results.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: I. Based on review of the communication log and interview with the testing personnel, the laboratory director did not ensure that the established quality control (QC) procedures to monitor the overall operation of the laboratory were maintained. Findings: 1. The procedure labeled "Quality Control Responsibilities for the Laboratory Personnel of Powell Recovery Center Clinical Laboratory" requires the testing personnel to document the remedial actions taken on the QC printout. 2. On 01 /23/18 the communication log noted that the alcohol had been retested on multiple samples on 01/19/28. The testing person pulled the original reports, the retested reports and QC printouts for the original testing date of 01/19/18 and retested date of 01/23/18. The testing person explained how the QC results were acceptable but there were about 30 specimens that were positive at the end of the test run. The testing person stated that it is unusual for that many specimens to have positive results. Technical support for the analyzer was contacted and told the lab to repeat the specimens. The reports were held and the specimens were retested on 01/23/18 and found to be negative at which point the results were reported. 3. During the survey on 03/29/18 at 11:00 AM the testing person confirmed that the communication log and QC printouts did not include details of the findings and corrective actions taken. II. Based on review of the procedure for "Establishment and Verification of the Method Performance" procedure and interview with the testing personnel, the laboratory director did not ensure that the quality assurance (QA) program included validation of the toxicology analyzer prior to testing and reporting patient test results. The laboratory director failed to ensure that the "Establishment and Verification of the Method Performance" procedure had been completed and found to be acceptable prior to testing and reporting patient test results. Cross refer to Tag D5421 for details.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of

	the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review and interview with the technical consultant (TC), the laboratory director (LD) did not specify in writing the duties and responsibilities of each person involved in the performance of preanalytic, analytic, and postanalytic phases of testing. Findings: 1. A review of the standard operating procedure manual (SOPM) showed that there was no description of duties and responsibilities for the LD, clinical consultant, and testing personnel. 2. During an interview on 3/29/18 at 12: 30 PM, the TC confirmed that there was no list of duties and responsibilities for the LD, clinical consultant, and testing personnel in the SOPM.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of the "Establishment and Verification of the Method Performance" procedure and interview with the technical consultant, the technical consultant did not ensure that the verification of the toxicology analyzer was completed prior to testing and reporting patient test results. Cross refer to Tag D5421 for details.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records and interview with the technical consultant, the technical consultant did not ensure that the laboratory was enrolled in PT for all tests performed in the laboratory. Cross refer to Tag D5217 for details.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not

	limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of the laboratory consultant's duties procedure and interview with the technical consultant (TC), the TC was not documenting weekly visits or reviews via the phone of the laboratory as required by the written procedure. Findings: 1. The laboratory started testing on 01/02/18. The communication log documenting the review of the laboratory records for January through March 29, 2018 were reviewed. The records did not include documentation of weekly on-site visits or phone reviews performed by the TC for the month of January 2018. The months of February and March included only 2 visits per month. 2. During the survey on 03/29/18 at 12:30 PM the TC stated that the methods for documenting the visits had changed several times and confirmed that all the visits were not documented in the communication log.